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, 2014

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.)
1616 Eastlake Ave. East, Suite 510 Seattle, WA (Address of principal executive offices)	**98102** (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 ☑ 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 ☑ 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 ☑

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

The number of shares of the registrant's common stock, $0.001 par value per share, outstanding at November 12, 2014 was 24,564,058.

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, 2014 (Unaudited)	December 31, 2013 (Audited)
Assets		
Current assets		
Cash and cash equivalents	$ 11,374,251	$ 6,342,161
Accounts receivable, net	29,151	139,072
Prepaid expense	266,726	280,627
Inventory, net	45,867	-
Total current assets	11,715,995	6,761,860
Furniture and equipment, net	185,000	163,147
Intangible assets, net	4,365,312	4,395,633
Deferred financing costs	426,961	651,961
Security deposit	78,958	36,446
Total assets	$ 16,772,226	$ 12,009,047
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 439,248	$ 248,142
Accrued expenses	393,704	399,478
Deferred rent	8,549	48,157
Payroll liabilities	682,356	476,477
Product recall liabilities	3,385	211,493
Other current liabilities	12,375	23,649
Total current liabilities	1,539,617	1,407,396
Stockholders' Equity		
Preferred stock - $.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	-	-
Common stock - $.001 par value; 75,000,000 shares authorized, 24,564,058 and 18,574,334 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	24,564	18,574
Additional paid-in capital	44,569,561	31,099,691
Accumulated deficit	(29,361,516)	(20,516,614)
Total stockholders' equity	15,232,609	10,601,651
Total liabilities and stockholders' equity	$ 16,772,226	$ 12,009,047

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,	
	2014	**2013**	**2014**	**2013**
Revenue				
Diagnostic testing service	$ 3,426	$ 72,187	$ 37,425	$ 361,905
Product sales	-	4,410	-	223,440
Total Revenue	3,426	76,597	37,425	585,345
Cost of Revenue				
Diagnostic testing service	-	25,938	-	75,893
Product sales	-	-	-	238,669
Total Cost of Revenue	-	25,938	-	314,562
Gross Profit	3,426	50,659	37,425	270,783
Selling expenses	282,374	373,418	743,597	965,383
Research and development expenses	923,169	321,111	1,856,439	731,258
General and administrative expenses	2,043,138	2,858,027	6,280,102	6,600,819
Total operating expenses	3,248,681	3,552,556	8,880,138	8,297,460
Operating Loss	(3,245,255)	(3,501,897)	(8,842,713)	(8,026,677)
Interest income	11	53	154	53
Interest expense	151	1	2,343	360
Loss before Income Taxes	(3,245,395)	(3,501,845)	(8,844,902)	(8,026,984)
Income Taxes	-	-	-	-
Net Loss	$ (3,245,395)	$ (3,501,845)	$ (8,844,902)	$ (8,026,984)
Loss per common share - basic and diluted	$ (0.13)	$ (0.22)	$ (0.37)	$ (0.55)
Weighted average shares outstanding, basic & diluted	24,537,379	15,830,033	23,860,843	14,697,221

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

ATOSSA GENETICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock				
	Shares	**Amount**	**Additional Paid-in Capital**	**Accumulated Deficit**	**Total Stockholders' Equity**
Balance at December 31, 2013	18,574,334	$ 18,574	$ 31,099,691	$ (20,516,614)	$ 10,601,651
Issuance of common shares for cash	5,834,234	5,834	13,996,328	-	14,002,162
Issuance of common shares for services	22,731	23	(23)	-	-
Financing fees from 2014 Public Offering	-	-	(1,078,417)	-	(1,078,417)
Amortization of deferred financing costs	-	-	(225,000)	-	(225,000)
Issuance of Common shares upon exercise of warrants	20,000	20	31,980	-	32,000
Employees option exercise and cancellation of restricted stock grants	112,759	113	199,887	-	200,000
Compensation cost for stock options granted to executives and employees	-	-	545,115	-	545,115
Net loss for the nine months ended September 30, 2014	-	-	-	(8,844,902)	(8,844,902)
Balance at September 30, 2014	**24,564,058**	**$ 24,564**	**$ 44,569,561**	**$ (29,361,516)**	**$ 15,232,609**

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,	
	2014	**2013**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (8,844,902)	$ (8,026,984)
Adjustments to reconcile net loss to net cash used in operating activities:		
Common shares issued for services	-	144,391
Compensation cost for stock options granted	545,115	1,187,717
Depreciation and amortization	380,977	350,536
Bad debt expense	80,870	228,841
Changes in operating assets and liabilities:		
Accounts receivable	29,051	(386,514)
Inventory	(45,867)	-
Prepaid expenses	(71,099)	71,439
Security deposits	(42,512)	(43,160)
Accounts payable	191,106	(37,086)
Payroll liabilities	205,879	149,493
Deferred rent	(39,608)	60,753
Accrued expenses	(5,774)	(304,626)
Product recall liabilities	(208,108)	402,840
Other current liabilities	(11,274)	20,300
Net cash used in operating activities	(7,836,146)	(6,182,060)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture and fixtures	(102,530)	(346,007)
Purchase of software	(184,979)	(54,667)
Net cash used in investing activities	(287,509)	(400,674)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock and warrants	13,155,745	12,551,098
Net cash provided by financing activities	13,155,745	12,551,098
NET INCREASE IN CASH & CASH EQUIVALENTS	5,032,090	5,968,364
CASH & CASH EQUIVALENTS, BEGINNING BALANCE	6,342,161	1,725,197
CASH & CASH EQUIVALENTS, ENDING BALANCE	$ 11,374,251	$ 7,693,561
SUPPLEMENTAL DISCLOSURES:		
Interest paid	$ 2,343	$ 359
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Reclassification of furniture and equipment to prepaid expenses	$ 15,000	$ -
Common stock issued as commitment fee under stock purchase agreement	$ -	$ 2,387,250

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

ATOSSA GENETICS INC.
NOTES TO CONDENSED 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 initially formed to develop and market medical devices that collect specimens for further testing. The Company's fiscal year ends on December 31st.

In December 2011, the Company established The National Reference Laboratory for Breast Health, Inc., or the NRLBH, as a wholly-owned subsidiary. The NRLBH is a CLIA-certified laboratory which performs tests including nipple aspirate fluid ("NAF") cytology testing and pharmacogenetics testing. The NRLBH is also developing other tests such as the NextCYTE test.

In September 2012, the Company acquired the assets of Acueity Healthcare, Inc. ("Acueity"). The purchased assets included intellectual property rights related to the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000. No liabilities were assumed by Atossa and Atossa assumed no future financial obligations. In consideration for the assets, Atossa provided the following consideration to the shareholders of Acueity: 862,500 shares of common stock, valued at $5.00 per share, and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, valued at $2.3457 per warrant, using a Black-Scholes-Merton Valuation Technique. The acquired patents relate to intraductal diagnostic and therapeutic devices and methods of use. The Company did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools. The Company cannot provide any assurance that it will be successful commercializing these tools.

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 condensed consolidated financial statements are prepared using generally accepted accounting principles in the United States of America 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 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. If the Company is unable to obtain adequate capital, it could be forced to cease operations. These matters raise substantial doubt about the Company's ability to continue as a going concern for the foreseeable future. The accompanying condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is 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 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 its medical devices including the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, (3) laboratory services, and (4) short-term or long-term borrowings from banks, stockholders or other party(ies) when 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, consisting 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, 2013, which contain information useful to understanding the Company's business and financial statement presentations. The Condensed Consolidated Balance Sheet as of December 31, 2013 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 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 in the United States of America.

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.

Recently Issued Accounting Pronouncements:

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company.

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 U.S. 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 condensed consolidated financial statements.

In June 2014, FASB issued ASU 2014-10, *Elimination of Development Stage Entity Requirements*. This ASU eliminates the concept of Development Stage Entities (DSE's) from U.S. GAAP and is intended to result in cost-savings for certain entities, such as start-ups or research and development entities. As a result of these changes; the financial statements of developing entities no longer need to meet the inception-to-date income cash flow and equity information; developing companies do not have to label their financial statements as "development stage"; and certain disclosures related to the nature of the entity's development stage activities are no longer required. The Company adopted the provisions of this ASU beginning with the quarter ended June 30, 2014.

In August 29, 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* This ASU requires the 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.

Reclassifications:

The prior period deferred financing costs have been reclassified to conform to the current year presentation. The reclassification had no impact on previously reported net loss or accumulated deficit.

Certain prior period accrued expenses have been reclassified as accounts payable to conform to the current year presentation. The reclassification had no impact on previously reported net loss or accumulated deficit.

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2014	December 31, 2013
Tradeshow and other marketing events	$ 150,000	$ -
Prepaid hardware and software	42,426	131,204
Prepaid insurance	36,800	112,517
Retainer and security deposits	29,500	36,906
Other	8,000	-
	$ 266,726	$ 280,627

NOTE 5: FURNITURE AND EQUIPMENT

Property, plant furniture and equipment consisted of the following:

	September 30, 2014	December 31, 2013
Machinery and equipment	$ 429,355	$ 326,824
Leasehold improvements	93,665	93,665
Capitalized new product development costs	-	15,000
Less: Accumulated depreciation	(179,728)	(114,050)
Less: Allowance for loss on impairment	(158,292)	(158,292)
Furniture and equipment, net	$ 185,000	$ 163,147

Depreciation expense for the three months ended September 30, 2014 and 2013 were $24,643 and $27,165, respectively, and $65,678 and $62,849 for the nine month periods then ended.

NOTE 6: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	September 30, 2014	December 31, 2013
Patents	$ 4,794,853	$ 4,794,853
Capitalized license costs	200,000	-
Software	190,817	105,839
Less: Accumulated amortization	(820,358)	(505,059)
	$ 4,365,312	$ 4,395,633

Intangible assets amounted to $4,365,312 and $4,395,633 as of September 30, 2014 and December 31, 2013, respectively, and consisted of patents, capitalized license costs and software acquired. The acquired software mainly consisted of $58,000 in laboratory software, $31,500 in the newly developed Company website and $70,400 in internal use SAP Business One ERP system which is under development. The amortization period for the purchased software is three years. Amortization expense related to software for the three months ended September 30, 2014 and 2013 was $4,913 and $5,730, respectively, and $22,436 and $15,322 for the nine month periods then ended.

Patents amounted to $4,794,853 as of both September 30, 2014 and December 31, 2013 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 is from 9 to 14 years. Amortization expense related to patents was $93,497 and $281,196 for the three months and nine months ended September 30, 2014. Amortization expense for patents was $90,977 and $272,992 for the three months and nine months ended September 30, 2013.

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 were $5,000 and $11,667 for the three and nine months ended September 30, 2014, respectively.

Future estimated amortization expenses as of September 30, 2014 for the five succeeding years is as follows:

For the Year Ending December 31,	Amounts
2014 (includes the remainder of the year)	$ 110,215
2015	440,539
2016	433,277
2017	414,957
2018	393,990
Thereafter	2,572,334
	$ 4,365,312

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	September 30, 2014	December 31, 2013
Accrued bonus payable	$ 566,185	$ 408,362
Accrued payroll liabilities	102,892	48,232
Accrued payroll tax liabilities	13,279	19,883
	$ 682,356	$ 476,477

NOTE 8: 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 certificate of designation with the Delaware Secretary of State.

On May 19, 2014, the Company adopted a stockholder rights agreement which provides 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 (the "2014 Public Offering"). 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 if our stock trades above $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 a warrant to purchase 175,027 shares of common stock, 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"). The 2014 Placement Agent Warrant entitles the Placement Agent to purchase 175,027 shares of the Company's common stock at $3.00 per share. The cash payment of $980,151 for 2014 Placement Agent Fee and the $121,707 aggregated initial fair value of the 2014 Placement Agent Warrants (see *Fair Value Considerations* below) 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 (the "Initial Exercise Date"). Subject to the call right described above, the 2014 Warrants shall expire and no longer be exercisable on the fifth anniversary of the Initial Exercise Date (the "Expiration Date"). 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 for equity classification.

Fair Value Consideration

The Company's accounting for the issuance of the 2014 Warrants required the estimation of fair values of the financial instruments. The development of fair values of financial instruments requires the selection of appropriate methodologies and the estimation of often subjective assumptions. The Company selected the valuation techniques based upon consideration of the types of assumptions that market participants would likely consider in exchanging the financial instruments in market transactions. The 2014 Warrants were valued using a Black-Scholes-Merton Valuation Technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary to assess the fair value of these instruments.

The 2014 Investor Warrants and the 2014 Placement Agent Warrants were valued at $834,986 or $0.72 per warrant, and $121,707 or $0.70 per warrant, respectively. The following tables reflect assumptions used to determine the fair value of the 2014 Warrants:

	Fair Value Hierarchy Level	January 29, 2014	
		2014 Investor Warrants	Placement Agent Warrants
Indexed shares		1,166,849	175,027
Exercise price		$ 3.00	$ 3.00
Significant assumptions:			
Stock price	1	$ 2.50	$ 2.47
Remaining term	3	5 years	5 years
Risk free rate	2	1.45%	1.42%
Expected volatility	3	37.96%	37.95%

Outstanding Warrants

As of September 30, 2014, warrants to purchase 6,033,426 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
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

NOTE 9: NET LOSS PER SHARE

The Company accounts for and discloses net loss per common share in accordance with FASB 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-month and nine-month periods ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Options to purchase common stock	3,464,232	2,246,651	3,464,232	2,246,651
Warrants to purchase common stock	6,033,426	4,775,550	6,033,426	4,775,550
Restricted stock units	-	-	-	-
	9,497,658	7,022,201	9,497,658	9,497,658

NOTE 10: 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, 2014 and December 31, 2013, the Company had $11,124,251 and $6,092,161 in excess of the FDIC insured limit, respectively.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Commitments

The future minimum lease payments due subsequent to September 30, 2014 under all non-cancelable operating leases are as follows:

Year Ending December 31,	**Amount**
2014 (remainder of the year)	$ 105,723
2015	480,007
2016	464,771
2017	105,894
Total minimum lease payments	**$ 1,156,395**

Affymetrix Purchase Commitment

In September 2013, in connection with the development of the NextCYTE test by the NRLBH, the NRLBH entered into an "OwnerChip Program Agreement" with Affymetrix, Inc, 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. 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. The NRLBH obligated to purchase 20 additional arrays during the next two year contract term

A5 Software Development Commitment

On June 10, 2013, the Company entered into an irrevocable license and service agreement with A5 Genetics KFT, Corporation, pursuant to which the Company received the world-wide (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 commercial launch of NextCYTE test and receiving FDA approval.. The Company must also pay a royalty of $50 for each NextCYTE Test performed and $65 as a service fee for each NextCYTE Test performed. The agreement terminates on the later of the ten year anniversary of the agreement or the expiration of the latest to expire patent covering the software.

Luminex Reagent Rental Agreement and Assay License Agreement

On September 2, 2014, in connection with the development of a pharmacogenetics test by the NRLBH, the NRLBH entered into a three year 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 rental agreement.

BioVentive Laboratory Marketing Service Agreement

On August 28, 2014, NRLBH entered into a three year Laboratory Marketing Services Agreement with BioVentive, Inc. ("BioVentive"), which provides that BioVentive market and promote the NRLBH laboratory tests to licensed physicians practicing medicine for a fixed fee. BioVentive's rights are exclusive for pharmacogenomics tests, so long as BioVentive meets certain minimums, and non-exclusive for all other tests. The agreement may be terminated prior to the end of the three year term by either party for material breach that is not cured and the NRLBH may terminate if BioVentive fails to meet certain minimums or if the NRLBH undergoes a change of control. If the agreement is terminated by the NRLBH for any reason other than for cause (which includes a material un-cured breach by BioVentive or if BioVentive fails to meet certain minimums), the NRLBH is required to pay BioVentive a termination fee equal to approximately three months of fees otherwise payable to BioVentive.

Targeted Medical Education (TME) Master Service Agreement

On September 1, 2014, the NRLBH entered into a Master Service Agreement with Targeted Medical Education (TME), where TME provides matched sets of de-identified tissue samples and clinically annotated retrospective data on 100 cancer patients for testing and evaluation of the NextCYTE test for a total cost of $162,600. As of September 30, 2014, the Company has paid $100,000 in set-up fees as R&D expenses.

Contingencies

On June 30, 2011, Robert Kelly, the Company's former President, filed a counterclaim against the Company in an arbitration proceeding, alleging breach of contract in connection with the termination of a consulting agreement between Mr. Kelly (dba Pitslayer LLC) and the Company that was entered into in July 2010 in connection with his resignation from the Company as President and a director. The consulting agreement was terminated by the Company in September 2010.

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director

On November 3, 2014, the matters with Messrs. Kelly and Cononi were settled through mutual agreement of the parties. The parties agreed to mutual releases and to dismiss the arbitration and federal actions. The amount paid by the Company to settle this matter was not significant.

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 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 our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our 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. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition brief on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. 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.

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, 2014. 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.

FDA Warning Letter

On February 21, 2013, the Company received a Warning Letter ("Warning Letter") from the FDA regarding its Mammary Aspirate Specimen Cytology Test (MASCT) System and MASCT System Collection Test (currently called the "ForeCYTE Breast Aspirator," and together, the "System"). The Warning Letter arises from certain FDA findings during a July 2012 inspection, to which the Company responded in August 2012. In that response, the Company explained why the Company believed it was in compliance with applicable regulations and/or was implementing changes responsive to the findings of the FDA inspection. The FDA alleges in the Warning Letter that following 510(k) clearance of the MASCT System, the Company changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA stated that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" while the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made the Company determined and documented that the change could not significantly affect the safety or effectiveness of the MASCT System, and thus, that a new 510(k) was not required in accordance with the FDA's guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device." The Warning Letter also identified certain issues with respect to the Company's marketing of the System and the Company's compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. The Company responded to the Warning Letter on March 13, 2013, and identified the corrective actions that had been made, or were otherwise underway. The Company also filed a new 510(k) application for the MASCT System which was withdrawn in August 2013 after receiving feedback from the FDA.

On October 4, 2013, the Company initiated a voluntary recall of the system to address FDA's concerns regarding the modifications identified in the Warning Letter. As a result of this recall, this product is currently not being marketed or distributed in the United States. The Company submitted a new premarket notification, or 510(k) application, with the FDA on December 23, 2013 that covered the collection, preparation, and processing of NAF specimens and includes the spray method of fixing specimens to the collection membrane and in September 2014 the FDA rendered a decision that the ForeCYTE Breast Aspirator is not "substantially equivalent" to its predicate device. The ForeCYTE Breast Aspirator is therefore not cleared by the FDA for marketing in the United States. We cannot market or distribute the ForeCYTE Breast Aspirator within the United States until we receive clearance for this device from the FDA.

On March 14, 2014, the FDA completed a follow up inspection at the Company's Seattle facility. A Form 483 was provided to the Company at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified regarding the Company's quality management system. The FDA investigator also orally identified five additional discussion points related to the Company's product labeling prior to the recall of the MASCT System; sufficiency of the content of the Company's pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, the Company submitted a response to the FDA, which included its proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept the Company's response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with the Company's proposed corrective actions, or accepts them but finds that the Company has not implemented them adequately, or if the Company otherwise is found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate additional warning letters, or initiate without further notice an enforcement action, fines and penalties. The FDA also may not clear a 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

NOTE 12: STOCK BASED COMPENSATION

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 $147,399 and $545,115 for the three months and nine months ended September 30, 2014, respectively. The stock based compensation for the three months and nine months ended September 30, 2013 was $188,763 and $1,187,717, respectively.

The following table presents information concerning stock option grants for the nine months ended September 30, 2014:

	Employees	**Executives & Officers**	**Directors**
Date of Grant	January – September 2014	January – September 2014	January - September 2014
Fair value of common stock on date of grant	$ 1.66 - 2.20	$ 1.22 - 2.20	$ 1.22 - 2.20
Exercise price of the options	$ 1.66 - 2.20	$ 1.22- 2.20	$ 1.22-2.20
Expected life of the options (years)	6.06	6.06 - 6.11	5.09 – 5.31
Dividend yield	0.00%	0.00%	0.00%
Expected volatility	40.28- 41.72%	40.69 - 41.70%	38.64 - 38.68%
Risk-free interest rate	1.91 - 2.11%	1.85 - 2.11%	1.53 – 1.75%
Expected forfeiture per year (%)	10.00%	10.00%	10.00%
Weighted average fair value of the options per unit	$ 0.87	$ 0.53	$ 0.70

Options issued and outstanding as of September 30, 2014 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, 2014	2,282,719	$ 4.43		$ 282,063
Granted	2,081,669	1.53		
Forfeited	(740,156)	4.36		21,540
Exercised	(160,000)	1.20		69,388
Outstanding as of September 30, 2014	3,464,232	3.10	8.21	117,267
Exercisable as of September 30, 2014	1,347,215	4.49	6.47	15,856
Vested and expected to vest (1)	3,190,856	$ 3.17	8.11	$ 108,485

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

At September 30, 2014, there were 2,117,017 unvested options outstanding that will vest over a weighted-average period of 2.98 years. The total estimated compensation expense to be recognized in connection with these options is $1,596,602.

Issuance of Restricted Common Stock and Stock Options for Directors' and Executives' Compensation

On October 10, 2013, the Company issued 24,510 shares of restricted stock with a grant date value of $50,000 or $2.04 per share to a new board member. On March 1, 2014, the Company agreed to issue 22,728 shares of restricted stock with a grant date value of $50,000 or $2.20 per share to a new board member. These share issuances were canceled in May 2014 in connection with a new compensation plan adopted by the Board of Directors for independent members of the Board and the grants were each replaced with $35,000 in cash payment.

On May 6, 2014, options to purchase a total of 15,000 shares of common stock, with exercise prices of $1.22 per share which was the fair market value on the date of grant, were also granted under the 2010 Plan to each of our four non-employee directors for service on the Board during the year following our 2014 annual meeting of stockholders. On that date, options to purchase 665,000 shares of stock, exercisable at $1.22 per share, which was the fair market value on the date of grant, were granted to senior officers under the 2010 Plan. The options granted to non- employee directors vest quarterly over one year and options granted to the senior officers vest quarterly over four years.

In May 2014, 200,000 stock options were granted outside the 2010 Plan to the Vice President of Clinical Research and Development. The options have an exercise price of $1.25, which was the fair market value on the date of grant, and vest 25% at the end of the first year and vest quarterly thereafter over the following three years.

In June 2014, 200,000 stock options were granted outside the 2010 Plan to the Senior Vice President of Global Regulatory Affairs and Quality Assurance. The options have an exercise price of $1.41, which is the fair market value on the date of grant, and vest 25% at the end of the first year and vest quarterly thereafter over the following three years.

In September 2014, 200,000 stock options were granted outside the 2010 Plan to the Senior Vice president of Operations as an inducement grant material to hiring a new employee in this position. The options have an exercise price of $1.86, which was the fair market value on the date of grant, and vest 25% at the end of the first year and vest quarterly thereafter over the following three years.

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. On January 1, 2012, 450,275 shares were added to the 2010 Plan and on January 1, 2013, 516,774 shares were added to the 2010 Plan, and on January 1, 2014, 742,973 shares were added to the 2010 plan as provided under the terms of the 2010 Plan.

The Company granted options to purchase 2,081,669 shares of common stock to employees and directors and issued 160,000 shares of common stock in connection with the exercise of directors stock options during the nine months ended September 30, 2014. There are 329,426 options available for grant under the 2010 Plan as of September 30, 2014.

NOTE 13: SUBSEQUENT EVENTS

Management has evaluated subsequent events through November 12, 2014, the date which the condensed consolidated financial statements were available to be issued. All subsequent events requiring recognition as of September 30, 2014 have been incorporated into these condensed consolidated financial statements, 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," "plan," "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 will obtain in a timely manner, and maintain once obtained, clearance from the Food and Drug Administration and foreign regulatory bodies, including our CE Mark, to sell, market and distribute our medical devices;
- our ability to successfully launch the FullCYTE Breast Aspirator in the United States and our ForeCYTE Breast Aspirator outside the United States;
- the estimated costs associated with our product recall;

- 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 new tests, devices and treatments currently in development, including the FullCYTE Breast Aspirator, and in the time frames currently expected;
- our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we seek launch the FullCYTE Breast Aspirator and while we seek additional regulatory clearance in the United States and overseas to market, sell and distribute our ForeCYTE Breast Aspirator and laboratory tests;
- 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 requirements for manufacturing, distributing, and promoting the FullCYTE Breast Aspirator, NAF cytology test and FullCYTE Microcatheter and to obtain regulatory approvals and/or clearances for our other products and services in development, including our ability to timely and adequately respond to and ultimately close-out the Warning Letter we received from the FDA on February 21, 2013, and the inspectional observations and discussion points we received March 14, 2014 and any issues resulting therefrom;
- 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 test;
- 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 products and services that we may develop, both regionally and nationally;
- 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; and
- our ability to sell additional shares of our common stock to Aspire Capital under the terms of our purchase agreement with them.

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 “RISK FACTORS,” that we believe could cause actual results or events to differ materially from 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 improving breast health through the development of a suite of laboratory services, medical devices and therapeutics. Our laboratory services are being developed by our subsidiary, The National Reference Laboratory for Breast Health, Inc. (the NRLBH), and are intended to address each of the four stages of the breast health care path: the cytological analysis of nipple aspirate fluid (NAF); the cytological analysis of ductal lavage fluid collected from each individual breast duct with our proprietary microcatheters; the profiling of newly diagnosed breast cancers through the determination of gene expression profiles in breast cancer biopsy tissue; and the monitoring of breast cancer survivors for pre-clinical recurrence through a blood test for circulating tumor cells. The NRLBH has developed and is currently marketing NAF cytology tests and pharmacogenomics tests.

Our medical devices under development 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. Other devices under development include intra ductal microcatheters for the collection of ductal lavage fluid and for the potential administration of a targeted therapeutic, and various tools for potential use by breast surgeons. Our ForeCYTE Breast Aspirator (previously called the MASCT System) was launched nationally in early 2013 and was recalled in October 2013. It will not be re-launched in the United States unless and until we receive additional regulatory clearance from the FDA.

We plan to develop certain of our medical devices and laboratory tests so that they can be used in clinical settings, including potentially as companion diagnostics to pharmaceutical therapies. For example, we plan to develop our patented intra ductal microcatheters for the potential delivery of a pharmaceutical targeted to a condition called ductal carcinoma in-situ (DCIS). We also plan to develop our medical devices and laboratory tests as companion diagnostics to pharmaceutical therapies to treat women at high risk of breast cancer and for the treatment of proliferative epithelial disease (PED). These programs are in the early pre-clinical stage and will require testing and are likely to require approval and/or clearance from the FDA prior to commercialization in the United States.

Our strategy consists of the following:

(1) Launch the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator Outside the U.S.: We intend to launch our FullCYTE Breast Aspirator in the United States through distributors. We also intend to introduce the ForeCYTE Breast Aspirator into one or more foreign markets. In October 2014, we received a CE Mark for the ForeCYTE Breast Aspirator.

(2) Continue to Promote and Commercialize the NRLBH's Laboratory Tests and our other Medical Devices: We plan to promote the tests currently being offered by the NRLBH, including NAF cytology tests and pharmacogenetics tests, and to continue the development and commercialization of our other tests and devices under development.

(3) Develop Pharmaceutical Therapies supported by our Devices and Laboratory Services: We plan to develop our patented microcatheters to deliver pharmaceuticals to initially treat DCIS. We also plan to develop our devices and laboratory services for use as companion diagnostics. For example, we intend to use our devices to collect specimens of NAF, test the NAF specimens in our laboratory, provide pharmaceutical treatment options for the breast health conditions detected by our tests and then use our medical devices to monitor treatment response. We expect that these companion diagnostic systems will initially target PED and/or high risk women and will require lengthy and costly clinical trials that we will undertake only with input and direction from the FDA.

(4) Advance Partnering Opportunities: We plan to work with third parties and partners to develop our business. For example, we plan to work with Fisher Healthcare and PSS McKesson to distribute the FullCYTE Breast Aspirator and we may partner with one or more laboratories to act as NAF collection sites using our FullCYTE Breast Aspirator in the United States and our ForeCYTE Breast Aspirator outside the United States. We plan to retain clinical research organizations (CROs) for clinical development of potential therapeutic programs and we intend to partner with pharmaceutical companies to develop companion diagnostic systems, which may include therapeutics to treat PED, DCIS and/or high risk women.

(5) Promote Physician and Patient Awareness: Our products and services are highly innovative and gaining adoption will require that physicians change the way they practice medicine. To facilitate adoption, we will continue to educate physicians and patients by engaging key opinion leaders, publishing in peer reviewed journals, and working with patient advocacy groups.

Many of our medical devices and the NRLBH's laboratory services, as well as the breast health companion diagnostic systems, are currently under development and, if required by FDA, we must receive additional regulatory clearances and/or approvals prior to marketing and commercialization.

The MASCT System (which we currently refer to as the ForeCYTE Breast Aspirator) was launched in a "field experience" trial in 2012 and nationally in the beginning of 2013. In October 2013, we voluntarily recalled the MASCT System to address concerns raised by the FDA in a Warning Letter we received in February 2013. In December 2013, we submitted a pre-market notification to the FDA for a 510(k) clearance for the ForeCYTE Breast Aspirator, and in September 2014 the FDA determined that the ForeCYTE Breast Aspirator is not substantially equivalent to its predicate device which means that as of the date of this report the device is not cleared by the FDA for marketing in the United States. We are currently evaluating the feedback we received from the FDA and the U.S. regulatory pathway for the ForeCYTE device.

The NRLBH has been certified pursuant to the Clinical Laboratory Improvement Amendments, or CLIA. CLIA certification is legally required to receive reimbursement from federal or state medical benefit programs, like Medicare and Medicaid, and is a practical requirement for most third-party insurance benefit programs. Our CLIA-certified laboratory, which is permitted to accept NAF samples from all 50 states under its CLIA certification, its state licenses, or, in New York under recognized exemption provisions while its license application is pending, examines the NAF specimens by cytological analysis. In mid-October 2014, the NRLBH began providing pharmacogenetics testing, which are marketed by the NRLBH's sales and marketing partner, BioVentive, Inc., and through the date of this report the NRLBH has processed approximately 238 tests.

Prior to the recall of the ForeCYTE Breast Aspirator, we entered into the following agreements for the distribution of the ForeCYTE Breast Aspirator in the U.S. market: On April 30, 2013, we entered into a Distribution and Marketing Services Agreement with Millennium Medical Devices LLC, covering New York City and Northern New Jersey; in May 2013, we entered into a distribution agreement with Fisher Healthcare, a division of Fisher Scientific Company, LLC, and in September 2013, we entered into a distribution agreement with McKesson Medical Surgical. On August 26, 2014, the NRLBH entered into an agreement with BioVentive, Inc. for the sales and marketing of our laboratory services.

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by: selling our equity securities; selling the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States; generating laboratory service revenue from our services performed by the NRLBH; and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

Our Voluntary Product Recall

On October 4, 2013, we initiated a voluntary recall to remove the MASCT device (which was also called the "ForeCYTE Test" prior to the recall) from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The recall has now been completed.

The purpose of this voluntary recall was to address concerns raised by the FDA in a Warning Letter received by Atossa in February 2013. In that Warning Letter, the FDA raised concerns about (1) the instructions for use (IFU) for the MASCT device; (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the NAF specimen collection process identified in the then-current IFU.

As of September 30, 2014, we have incurred cumulative actual recall expenses of $429,829 including the estimated costs of pursuing the additional 510(k) clearance.

Prior to the commencement of the recall in October 2013, substantially all of our revenue was from sales of the MASCT System and patient collection kits and from testing services performed by our laboratory. As a result of the recall of the MASCT System and patient collection kits, we have ceased generating product revenue. Our laboratory services revenue has also virtually ceased as of October 2013.

We will incur additional sales and marketing expenses as we commercialize the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States. We will need to revise our sales and marketing tools, continue hiring direct sales employees and engage new distributors. We also expect to continue to hire clinical consultants to assist in the sale of our NAF cytology tests. The FullCYTE Breast Aspirator may not gain adoption as quickly as the ForeCYTE Breast Aspirator and it may sell at lower margins. If so, our potential sales and revenues will be negatively impacted.

Follow-up FDA Inspection

On March 14, 2014, the FDA completed a follow up inspection at our Seattle facility. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified. The FDA inspector also verbally identified five additional discussion points related to our product labeling prior to the recall of the MASCT System; sufficiency of the content of our then-pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, we submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, or if we otherwise are found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate additional warning letter, or initiate without further notice an enforcement action, fines and penalties. The FDA also may not clear our devices and services under development. Any of the foregoing would have a material adverse effect on our business.

Revenue Sources

Our business provides us with two potential revenue sources: (i) sales-based revenue from the sale of our medical devices, such as our ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator and patient kits to distributors, physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from laboratory services performed by the NRLBH, such as preparation and interpretation of the NAF samples sent to our laboratory for analysis, pharmacogenetic tests and other tests that may be developed and commercialized by the NRLBH. We do not anticipate generating revenue until and unless we develop and launch new laboratory tests and/or until we launch the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States. We plan to initially sell the breast aspirators and our laboratory services through regional and national specialty product distributors, with independent sales representatives specializing in women’s health, and through our own direct sale force.

Commercial Lease Agreements

On March 4, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease terminated on March 31, 2014 and provides for monthly rent of $1,100 and a security deposit of $1,500. On March 20, 2014, the Company entered into a new agreement with Sanders properties which extends the terms of the lease through March 31, 2015 with a monthly rent of $1,150.

On December 9, 2011, the Company entered into another commercial lease agreement with Fred Hutchinson Research Center for lab and office space located in Seattle, WA. The lease provides for monthly rent of $16,395 for the period from February 24, 2012 to August 31, 2012, $19,923 for the period from September 1, 2012 to August 31, 2013, and $20,548 for the period from September 1, 2013 to November 29, 2014. The security deposit of $32,789 was paid in March 2012 and recorded as Security Deposit on the consolidated balance sheet. In July 2013, the Company entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces in our existing building under a separate lease agreement. The lease is from August 2013 through November 2014, and the gross rent is $ 4,800 per month. For the nine months ended September 30, 2014, the Company incurred $197,744 of rent expense for the lease, which included leasing office management expenses and the new agreement with ARE LLC.

On March 24, 2014, the Company entered into another commercial lease agreement with ARE LLC (Alexandria) for the Company's laboratory space which extends the term of the existing lease with Fred Hutchison Research Center which expires in November 2014 through November 30, 2016. The lease provides for monthly rent payments of $22,736 from December 2014 through November 2015 and $23,258 from December 2015 through November 2016. As of September 30, 2014, the Company incurred and recorded security deposits of $25,000.

On August 8, 2014, the Company entered into a new commercial lease agreement with the Legacy Group Inc., to lease office space in Seattle, WA in conjunction with expiration of the current office space lease with Fred Hutchinson Research Center on November 29, 2014. The lease provides for monthly rent payments of $16,695 from December 1, 2014 through June 30, 2015, $17,172 from July 1, 2015 through June 30, 2016 and $17,649 from July 1, 2016 through June 30, 2017.

We expect that these laboratory facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional laboratory space for at least the next 24 months. We may need to secure additional office space as we grow our sales and marketing force and add to our administrative staff. Additional office space is readily available in our local market and we believe we can rent when necessary additional office space on acceptable terms.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the year ended December 31, 2013, we disclosed our critical accounting policies and estimates upon which our financial statements are derived. There have been no changes to these policies since December 31, 2013. Readers are encouraged to review these disclosures in conjunction with the review of this report.

Results of Operations

Three Months and Nine Months Ended September 30, 2014 and 2013

Revenue and Cost of Goods Sold. For the three months and nine months ended September 30, 2014, revenue totaled $3,426 and $37,425, consisting of additional cash collected in excess of the amounts we accrued previously at the Medicare rates. Total revenue for the three and nine months ended September 30, 2013 was $76,597 and $585,345. Cost of revenue was $ 0 for the three months and nine months ended September 30, 2014, compared to $25,938 and $314,562 in the same periods in 2013.

For the three months and nine months ended September 30, 2014, gross profit totaled $3,426 and $37,425, compared to $50,659 and $270,783 in the same period in 2013. The Company has recognized virtually no revenue or cost of revenue since the voluntary recall in October 2013.

Operating Expenses. For the three months ended September 30, 2014, total operating expenses were $3,248,681 consisting of general and administrative (G&A) expenses of $2,043,138, research and development (R&D) expenses of $923,169, and selling expenses of $282,374, representing an decrease of $303,875, or 9% from $3,552,556 in the same period in 2013, consisting of G&A expenses of $2,858,027, R&D expenses of $321,111, and selling expenses of $373,418. Operating expenses for the nine months ended September 30, 2014 were $8,880,138 consisting of G&A expenses of $6,280,102, R&D expenses of $1,856,439, and selling expenses of $743,597. Operating expenses increased $582,678, or 7% from $8,297,460 for the same period in 2013 consisting of $6,600,819 in G&A expenses, $731,258 in R&D expenses, and $965,383 in selling expenses.

The change in operating expenses form last year is due to lower selling and G&A expenses as a result of the recall offset by higher R&D expenses as we develop new products and services. 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, FullCyte Breast Aspirator and our laboratory service offerings, we would also begin to incur additional sales and marketing expenses as we continue building a regional, and ultimately national, sales force.

Selling Expenses. Selling expenses for the three months ended September 30, 2014 were $282,374, a decrease of $91,044, or 24%, from $373,418 for the three months ended September 30, 2013. Selling expenses for the three months ended September 30, 2014 consisted primarily of $54,077 in selling and marketing professional fees, $108,329 in compensation expenses, $99,319 in advertisement, and $20,649 in travel. Selling expenses for the nine months ended September 30, 2014 were $743,597, a decrease of $221,786, or 23% from $965,383 for the same period in 2013. Selling expenses for the nine months ended September 30, 2014 consisted of $301,317 in compensation expenses, $116,180 in selling and marketing professional fees, and $305,450 in advertising.

Selling expenses decreased as a result of the voluntary recall in October 2013. We expect selling expenses will increase when we prepare for and execute the relaunch of ForeCYTE Breast Aspirator outside the United States and to launch the FullCYTE Breast Aspirator. Selling expenses may also increase as we market and sell the services offered by the NRLBH, including NAF cytology tests and potentially other tests.

R&D Expenses. R&D expenses for the three months ended September 30, 2014 were $923,169, an increase of $602,058, or 187%, from $321,111 for the three months ended September 30, 2013. R&D expenses for the nine months ended September 30, 2014 were $1,856,439, an increase of $1,125,181, or 154% 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. G&A expenses for the three months ended September 30, 2014 were $2,043,138, a decrease of $814,889, or 29%, from $2,858,027 in the same period in 2013. The decrease in 2014 G&A expenses over 2013 was primarily attributable to $275,519 lower capital raising expenses, $396,262 lower recall expenses, $54,510 lower consulting fees, $325,715 lower advertising and marketing fees and $212,279 lower bad debt expenses. This decrease is offset by $358,688 higher legal and regulatory fees in 2014 as a result of the recall, and $88,994 increase in salaries and employees benefits as we grew headcount in our manufacturing and regulatory departments to fulfill the demands of new product development and regulatory requirements.

G&A expenses for the nine months ended September 30, 2014 were $6,280,102, a decrease of $320,717, or 5% from $6,600,819 for the same period in 2013. The decrease in 2014 G&A expenses over 2013 was primarily attributable to the $428,872 lower capital raising costs, $230,062 lower consulting fees, $396,225 lower recall expenses, $327,959 lower advertising and marketing fees, and $147,971 lower bad debt expenses. This decrease is offset by $786,074 in higher legal and regulatory fees as a result of the recall and $402,204 increase in employees and directors compensation as we grew headcount in our manufacturing and regulatory departments to fulfill the demands of new product development and regulatory requirements.

We expect our G&A expenses to grow as we hire additional administrative and manufacturing personnel to prepare for and execute on the launch of the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, and our other products and services under development and as we incur additional costs associated with being a publicly traded company.

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building the MASCT System. The report of our independent auditors issued on our consolidated financial statements as of and for the years ended December 31, 2013 and 2012 expresses substantial doubt about our ability to continue as a going concern.

On March 27, 2013, we entered into a stock purchase agreement with Aspire Capital Fund, LLC, and pursuant to that agreement we sold common stock to Aspire from March 2013 through October 2013 for a total aggregate purchase price of $11,303,745. On November 8, 2013, we terminated this stock purchase agreement and entered into a new agreement with Aspire which provides that we may sell common stock to Aspire under the terms and subject to the conditions and limitations set forth therein. Under the new agreement, Aspire is committed to purchase up to an aggregate of $25 million of shares of our common stock over the 30 month term of the new agreement, subject to certain conditions set forth therein. On December 23, 2013, we sold $1 million of common stock to Aspire under this new agreement so that up to a total of $24 million remains available for sale to them as of the date of this report.

On January 29, 2014, we closed a public offering of 5,834,234 units at the price of $2.40 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.20 a share of common stock, for gross proceeds of approximately $14.0 million. The warrants are exercisable at $3.00 per share and are callable by us if and when the trading price of our common stock is $6.00 per share over a defined period and subject to a daily volume minimum.

Substantial doubt of our ability to continue as a going concern continues and is dependent on our obtaining additional adequate capital to fund additional operating losses until we become profitable. If we are unable to obtain adequate capital, we could be forced to cease operations.

Cash Flows

As of September 30, 2014, we had cash and cash equivalents of $11,374,251.

Net Cash Flow from Operating Activities

Net cash used in operating activities was approximately $7,836,146 for the nine months ended September 30, 2014, compared with $6,182,060 for the nine months ended September 30, 2013. The increase in cash used in operating activities of $1,654,086 resulted primarily from an increase in R&D activities related to our new product developments, additional salaries to support the operations, and legal expenses related to the recall and ongoing litigation.

Net Cash Flow from Investing Activities

Net cash used in investing activities was $287,509 for the nine months ended September 30, 2014, compared with $400,674 for the nine months ended September 30, 2013. The decrease was due to the additional capitalized fixed assets inventory equipment purchased in 2013.

Net Cash Flow from Financing Activities

Net cash provided by financing activities was $13,155,745 for the nine months ended September 30, 2014, compared with $12,551,098 for the nine months ended September 30, 2013. The increase was primarily due to net proceeds of the public offering in January 2014.

Funding Requirements

We expect to incur substantial expenses and generate ongoing operating losses for the foreseeable future as we prepare for the scale-up manufacturing and launch of the ForeCYTE Breast Aspirator outside the United States and FullCYTE Breast Aspirator in the United States, complete the development of and launch the NextCYTE tests, and other devices and laboratory services in the pipeline and start the development of our planned therapeutic programs. We expect our existing capital resources as of the date of this report to be sufficient to fund our planned operations through at least the first quarter of 2015. If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following:

- the time and expense needed to launch our medical devices including the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator;
- the expense associated with building a network of sales representatives to market the our medical devices, laboratory services and our planned therapeutic programs; and
- the degree and speed of patient and physician acceptance of our products and services and the degree to which third-party payors approve the tests for reimbursement.

We do not expect to generate revenue until we launch our aspirator devices or launch our laboratory services. We expect our continuing operating losses to result in increases in cash used in operations over at least the next year. Although we expect our existing resources as of the date of this report, to be sufficient to fund our planned operations through the first quarter of 2015, we may require additional funds earlier than we currently expect to successfully commercialize the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator. Because of the numerous risks and uncertainties associated with the development and commercialization of the aspirators and our other devices, tests and therapeutics in the pipeline, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated research and development activities and commercialization efforts.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders would result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. Further, we may elect to raise additional funds even before we need them if we believe the conditions for raising capital are favorable.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Recent Accounting Pronouncements

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company.

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 U.S. 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 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. We are currently evaluating the impact of its pending adoption of ASU 2014-09 on our condensed consolidated financial statements.

In June 2014, FASB issued ASU 2014-10, *Elimination of Development Stage Entity Requirements.* This ASU eliminates the concept of Development Stage Entities (DSE's) from U.S. GAAP and is intended to result in cost-savings for certain entities, such as start-ups or research and development entities. As a result of these changes, the financial statements of developing entities no longer need to meet the inception-to-date income, cash flow and equity information; the requirement to label financial statements as those of a developing company was eliminated; and certain disclosures related to the nature of the entities development stage activities were eliminated. We adopted ASU 2014-10 for the reporting period ended June 30, 2014.

In August 29, 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This ASU requires the 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 issues". 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.

ITEM 3. QUANTATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, our principal executive officer and principal financial officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On June 30, 2011, Robert Kelly, the Company's former President, filed a counterclaim against the Company in an arbitration proceeding, alleging breach of contract in connection with the termination of a consulting agreement between Mr. Kelly (dba Pitslayer LLC) and the Company that was entered into in July 2010 in connection with his resignation from the Company as President and a director. The consulting agreement was terminated by the Company in September 2010.

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director.

On November 3, 2014, the matters with Messrs. Kelly and Cononi were settled through mutual agreement of the parties. The parties agreed to mutual releases and to dismiss the arbitration and federal actions. The amount paid by the Company to settle this matter was not significant.

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 our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our 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 our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our 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. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. 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.

We believe this complaint is without merit and plan to defend ourselves vigorously. Failure by us to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on our 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, 2014. The costs associated with defending and resolving the complaint 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 our business, will depend upon many unknown factors and management's view of these may change in the future.

ITEM 1A. RISK FACTORS

RISK FACTORS

A purchase of our shares of Common Stock is an investment in our securities and involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information contained in this report, before purchasing our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the Common Stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

There has been no material changes to the risk factors described in the Company's Annual Report on Form 10-K, as filed with the SEC on March 27, 2014, and which are incorporated into this report by this reference, except for the following items which have been updated.

Anticipated liquidity issues beginning in 2015.

For the nine months ended September 30, 2014, we generated no revenue and we incurred a net loss of $8,848,265. We expect that our existing resources will be sufficient to fund our planned operations through at least the first quarter of 2015. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We may not receive or maintain regulatory clearance for our medical devices and laboratory service, including the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, and other sources of capital may not be available when we need them or on acceptable terms. For example, we may not be able to raise capital by selling Common Stock to Aspire because the Aspire registration statement may not remain effective. If we are unable to raise in a timely fashion the amount of capital we anticipate needing, from Aspire or otherwise, we would be forced to curtail or cease operations.

Potential Changes in FDA policies regarding FDA regulation of laboratory developed tests or "home brew" tests could adversely affect our business and results of operations.

The FDA has asserted that laboratory diagnostic tests developed and validated by a laboratory for its own use, also known as LDTs or "home brew" tests, are subject to regulation under the Federal Food, Drug and Cosmetic Act, or FDCA. In addition, manufacturers and suppliers of analyte specific reagents, or ASRs, which we may utilize in our LDTs, are required to register with the FDA, conform manufacturing operations to the FDA's Quality System Regulation, or QSR, and comply with certain reporting and other record keeping requirements.

The FDA has not historically asserted authority with respect to most LDTs performed by high complexity laboratories certified under CLIA, which is the type of laboratory that we have established. However, on July 31, 2014, the FDA announced plans to formally regulate most LDTs. The announcement came in the form of letters to Congress attaching the preliminary drafts of guidance documents describing the FDA's proposed framework for regulatory oversight of LDTs. The documents were provided to Congress in order to satisfy Section 1143 of the Food and Drug Administration Safety and Innovation Act, which required the FDA to notify Congress at least 60 days prior to issuance of draft or final guidances on the regulation of LDTs. The FDA is expected to wait at least 60 days before issuing the regulatory framework in official draft form for public comment. The FDA expects to have a 90-day comment period for interested stakeholders prior to implementation of the proposed regulatory plan.

The documents were provided to Congress in order to satisfy Section 1143 of the Food and Drug Administration Safety and Innovation Act, which required the FDA to notify Congress at least 60 days prior to issuance of draft or final guidances on the regulation of LDTs. The FDA is expected to wait at least 60 days before issuing the regulatory framework in official draft form for public comment. The FDA expects to have a 90-day comment period for interested stakeholders prior to implementation of the proposed regulatory plan. Although we have not studied the potential impact of the proposed new regulations, we believe that if they become effective, the new FDA guidelines may require premarket notification or approval for LDTs that we are currently developing, potentially including our NAF test, as well as tests that we may develop and perform in the future; however, the proposed new regulations do provide that the FDA will continue to exercise regulatory discretion for LDTs for "unmet needs" when no FDA cleared or approved alternative exists. Additionally, the FDA has indicated to us that the manner in which our laboratory previously processed NAF samples combined with the manner in which they were marketed prior to our October 2013 recall constitutes an in-vitro diagnostic test service that is subject to their regulatory authority and we may therefore be required to obtain a 510(k) clearance covering our laboratory processing. The FDA may also choose to exercise regulatory authority over our laboratory because it is wholly-owned by us and as a medical device manufacturer we are subject to FDA regulation.

Any additional premarket notification or approval requirements could restrict or delay our ability to provide specialized diagnostic services and may adversely affect our business. FDA regulation of LDTs, or increased regulation of the various medical devices used in laboratory-developed testing, could increase the regulatory burden and generate additional costs and delays in introducing new tests.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits

10.1[(a)]	BioVentive Laboratory Marketing Service Agreement dated August 28, 2014 between BioVentive, Inc. and NRLBH.
10.2	TME Master Service Agreement dated September 1, 2014 between Targeted Medical Education (TME) and NRLBH.
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Kyle Guse
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T

(a) Confidential treatment requested for portions of this Exhibit.

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 thereunto duly authorized.

Date: November 12, 2014

/s/ Steven C. Quay

President and Chief Executive Officer
(On behalf of the Registrant)

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(As Principal Financial and Accounting Officer)

Exhibit 10.1

CONFIDENTIAL TREATMENT REQUESTED BY ATOSSA GENETICS INC.

THE USE OF THE FOLLOWING NOTATION IN THIS EXHIBIT INDICATES THAT A CONFIDENTIAL PORTION HAS BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION: [***]

LABORATORY MARKETING SERVICES AGREEMENT

THIS LABORATORY MARKETING SERVICES AGREEMENT ("Agreement") is entered into August 26, 2014, by and between BioVentive, Inc., a California corporation ("Contractor"), and The National Reference Laboratory for Breast Health, Inc. a Delaware corporation ("NRLBH"). Contractor and NRLBH are referred to as a "Party" or the "Parties."

RECITALS

WHEREAS, NRLBH is a CLIA-certified laboratory that performs various tests, including nipple aspirate fluid cytology tests (the "NAF Tests") and that is in the process of becoming qualified to perform pharmacogenomics tests (the "Pharmacogenomic Tests");

WHEREAS, Contractor markets laboratory tests to licensed physicians practicing medicine (the "Contractor Customers") throughout the United States (the Territory"); and

WHEREAS, NRLBH wishes to engage Contractor to market the NAF Tests and Pharmacogenomic Tests and any other tests that the parties mutually agree in writing to be marketed by Contractor (collectively, the "Marketed Tests"), performing such service as more fully described in Section 1 and Exhibit A hereto (the "Services"), and Contractor is willing to provide those Services in accordance with the terms set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereto, intending to be legally bound, agree as follows:

I. ENGAGEMENT OF THE SERVICES.

A. Engagement of Contractor. NRLBH hereby appoints Contractor as an authorized representative to use its reasonable commercial efforts to market and promote the Marketed Tests to Contractor Customers in the Territory and the Contractor hereby accepts such appointment.

B. Exclusivity. Contractor shall be a non-exclusive marketing contractor for the NAF Tests and NRLBH shall be free to contract others to market and promote the NAF Tests. Contractor shall be the exclusive marketing contractor for the Pharmacogenomic Tests so long as the Contractor meets or exceeds the Pharmacogenomic Test Minimums identified in Section ill.0 and during such exclusive period NRLBH shall not contract with another party, directly or indirectly to market and promote the Pharmacogenomic Test; however, if such minimums are not met NRLBH shall provide written notice to the Contractor and the Contractor shall automatically become non-exclusive with respect to the Pharmacogenomic Tests and NRLBH shall then be free to contract with others to market and promote the Pharmacogenomic Tests. However, nothing in this Agreement shall limit or restrict NRLBH from utilizing its employees to market and promote the Marketed Tests.

C. Scope of Services. Contractor shall render the Services identified in the attached Exhibit A on behalf of NRLBH to the current and future Contractor Customers. Contractor shall use reasonable commercial efforts to market and promote the Marketed Tests to Contractor Customers in the Territory and (a) exercise the highest degree of professionalism in the furnishing of the Services, (b) be responsible to provide the infrastructure and personnel through which it shall furnish the Services at its sole expense, and (c) perform the Services in a timely and professional manner consistent with similarly situated contractors and marketing consultants. Except as provided in Section III.E, Contractor shall not sub-contract or otherwise delegate its obligations under this Agreement, without NRLBH's prior written consent. Contractor shall not, directly or through others, distribute, market or promote products and services, including the Marketed Tests, that are competitive, directly or indirectly, with services and products provided by NRLBH or its parent company, Atossa Genetics, Inc. ("Atossa") and all Marketed Tests shall be marketed and promoted only for, and provided only to, the NRLBH.

D. Legal Compliance. The manner and means by which Contractor performs its Services for NRLBH shall be in Contractor's sole discretion and control, subject to this Agreement, applicable law and in compliance with all related Federal and state regulations, ethical business practices and NRLBH's regulatory compliance policies, including those set forth in the attached Exhibit R.

II. COMPENSATION FOR SERVICES.

A. Fixed Monthly Service Fee. In consideration for the provision by Contractor of the Services hereunder, NRLBH shall pay Contractor a fixed fee as set forth in the attached Exhibit D (each, a "Monthly Service Fee"), which shall be paid by NRLBH within 15 days of the end of the month for which the Monthly Service Fee applies. NRLBH shall not be obligated to pay the Monthly Service Fee if Contractor is in breach of this Agreement. If this Agreement is terminated for any reason, NRLBH shall pay Contractor the Monthly Service Fee owing for all Services performed by Contractor prior to and including the effective date of termination.

B. Termination Fee. Contractor shall be entitled to, and the NRLBH shall pay, if and when due, the Termination Fee set out in Section VI.C.

C. Compliance with Law. It is the intention of the Parties that the Monthly Service Fee shall at all times be in compliance with all applicable laws, rules, regulations, policies and interpretations and shall not exceed the Fair market value for the Services provided by Contractor hereunder, and shall not be determined in a manner that violates the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), or other applicable Federal Health Care Program laws, rules, regulations, policies or interpretations. The term "Federal Health Care Program" is used herein as it is defined in 42 U.S.C. 1320a-7b(f), and includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (e.g., Medicare, Medicaid, TRICARE). If either Party determines at any time or is reliably informed by governmental authorities that the compensation arrangements or other terms set forth herein violate or are likely to be determined by a governmental authority to violate such laws, rules, regulations, policies or interpretations, the Parties agree to meet immediately and in good faith to amend this Agreement so as to eliminate such concern or violation and to bring this Agreement into compliance with the foregoing. Any such amendment shall, to the extent permitted by law, have the same aggregate economic effect upon the Parties. Such determination, information or amendment shall not allow either Party to claim that this Agreement is void or voidable.

III. ORDERING.

A. Purchase Terms. Marketed Tests shall be ordered directly by the Contractor Customers and/or their healthcare providers. Contractor shall provide Contractor Customers with test requisition forms which shall be supplied by NRLBH. The test requisition forms shall have a unique identifier indicating that the test was ordered by a physician who is -a Contractor Customer.

B. Pricing; Billing. NRLBH shall provide Contractor from time to time with price sheets for the Marketed Tests and Contractor shall use the prices indicated on such price sheets, and no others, in marketing the Marketed Tests. NRLBH shall be responsible for all billing to Contractor Customers.

C. Minimums. Exhibit C sets forth the minimum quantity of Pharmacogenomic Tests that must be ordered by the Contractor Customers on or before the dates and at the minimum prices set forth in Exhibit C (the "Pharmacogenomic Test Minimums").

D. Sales Materials. NRLBH shall make available to the Contractor a copy of brochures, literature, training materials and labeling which may be copied, but not altered in anyway, by Contractor at its sole expense and utilized to distribute, market and promote the Marketed Tests. The Contractor shall use only such sales materials as are provided by NRLBH or those materials that are otherwise approved in writing in advance by NRLBH. All use by the Contractor of the name "NRLBH," "National Reference Laboratory for Breast Health" or any other name or mark that is copyrighted, trademarked or service-marked by NRLBH shall be subject to The prior written approval of NRLBH. Upon any termination of this Agreement, the Contractor shall immediately cease the use of all such names and marks and shall return to NRLBH any supplies, samples, brochures, product literature, training materials and other materials bearing such names or marks.

E. Authorized Sub-contractors and Sub-Contractors. Contractor may delegate or assign some or all of its duties envisioned by this Agreement hereunder to its qualified employees and independent representatives and other personnel engaged and/or employed by Contractor ("Contractor Representatives"), provided that:

1. Such representatives shall not be health care professionals or persons in a similar position who might be capable of exerting undue influence on a Contractor Customer or its patients.

2. NRLBH retains the right, at its sole discretion, to revoke permission for Contractor to allow any of Contractor's independent contractors or employees to take actions in furtherance of the Contractor's duties under this Agreement.

3. Contractor must require its contractors, sub-Contractors and/or employees to be bound by the terms and conditions of this Agreement or substantially similar terms relating to Contractor, all in a document reasonably satisfactory to NRLBH. NRLBH retains the right to inspect and/or require modifications to Contractor's agreements with its independent, contractors and sub-Contractors and/or employees at any time.

4. Contractor shall remain liable as a principal and not as surety for all of its obligations hereunder.

5. Contractor shall indemnify, defend and hold harmless NRLBH and its employees, shareholders, officers, directors, agents and other affiliates, to the fullest extent permitted by law, against any and all claims, actions, demands, losses, costs, expenses, damages and claims of any kind whatsoever which NRLBH may sustain or incur, including reasonable legal fees and costs, as a result of or arising from Contractor's failure to fulfill its obligations or perform its duties with respect to its employees, contactors, shareholders, officers, directors, agents, sub-contractors, and other affiliates of Contractor. Said indemnification by Contractor shall include its negligent, willful or intentional action, and/or omission.

F. NRLBH Discretion in Acceptance. NRLBH shall have ultimate discretion regarding the acceptance by NRLBH of requests for the Marketed Tests. In exercising such discretion, NRLBH shall take into consideration such factors as it deems relevant, including but not limited to whether it has the necessary licenses to deliver the Marketed Tests in the location of the Contractor Customer, and the necessary billing or provider numbers to bill and be paid for such services by third party payors, and other relevant factors such as the number and mix of Marketed Tests requested by or at a given location. NRLBH may require Contractor Customers to execute such typical and customary forms of agreement as applicable to NRLBH's customers generally, including forms and formats for ordering testing and for submitting billing information.

G. Training. During the first 30 days of the term of this Agreement and from time to time thereafter as determined by NRLBH, NRLBH will provide Contractor's sales personnel with training geared toward reasonably preparing such personnel to market and sell the Marketed Tests in a manner generally accepted for similar products in the industry.

H. Specimen Collection.

1. **Atossa Devices.** Contractor shall not market, promote or distribute the medical devices offered by Atossa. If a Contractor Customer inquires about an Atossa medical device, Contractor shall refer the Contractor Customer to Atossa or one of Atossa's medical device distributors. Contractor shall not receive any compensation for such referral.

2. **Other Specimen Collection Materials.** Subject to Section III.H.1., the parties may mutually agree that Contractor shall provide other specimen collection materials to Contractor Customers, such as shipping containers, and other materials reasonably necessary for the collection and transport of specimens to NRLBH. However, Contractor shall be responsible for procuring and providing, at its sole cost, the patient specimen collection kits for the Pharmacogenomic Tests and such collection kits shall comply with all regulatory requirements and be reasonably acceptable to NRLBH.

IV. INDEPENDENT CONTRACTOR RELATIONSHIP.

Contractor's relationship with NRLBH will be that of an independent contractor and nothing in this Agreement should be construed to create a partnership, joint venture, franchise, or employer-employee relationship. Contractor is not authorized to make any representation, contract, or commitment on behalf of NRLBH not expressly authorized by NRLBH. Contractor will not be entitled to any of the benefits that NRLBH may make available to its employees, such as group insurance, profit sharing or retirement benefits. Contractor will be solely responsible for all lax returns and payments required to be filed with or made to any federal, state or local tax authority with respect to Contractor's performance of services and receipt of fees under this Agreement. NRLBH will regularly report amounts paid to Contractor by filing Form 1099-M1SC with the Internal Revenue Service as required by law. NRLBH will not withhold or make payments for social security; make unemployment insurance or disability insurance contributions; or obtain worker's compensation insurance on Contractor's behalf. Contractor agrees to accept exclusive liability for complying with all applicable state and federal laws governing self-employed individuals, including obligations such as payment of taxes, social security, disability and other contributions based on fees paid to Contractor, its agents or employees under this Agreement. Contractor hereby agrees to indemnify and defend NRLBH against any and all such taxes or contributions, including penalties and interest.

V. CONFIDENTIALITY.

A. Confidentiality. The Parties acknowledge that the terms of this Agreement are confidential and will not be disclosed without the prior written consent of the non-disclosing Party except as may otherwise be required by law. Further, during the Term of this Agreement, and at all times following termination thereof, each Party shall keep strictly confidential all information which they obtain from the other Party during the Term, including, in particular, "Proprietary Information" and "Third Party Information," as each of such terms is defined below. Neither Party shall use or disclose to any person, firm, or other entity or permit any person to examine, copy or duplicate any such confidential information furnished by one Party to the other, except as otherwise required by law. Upon the termination of this Agreement (irrespective of the reason or circumstances), unless otherwise agreed to in writing by the Parties, each Party will return to the other Party all such confidential information in its possession, as well as any copies or information derived therefrom. Without limiting any other provision herein, the provisions of this Section shall survive any termination or expiration of this Agreement. Furthermore, upon termination of this Agreement, unless otherwise agreed to in writing by the Parties, NRLBH and Contractor shall immediately discontinue their use (if any) of the name or trademarks .of the other (or developed for NRLBH by Contractor) and shall immediately discontinue all representations or statements from which it might be inferred that any relationship exists between NRLBH and Contractor.

B. Defined Terms. For purposes of this Agreement:

"Proprietary Information" includes, without limitation: (a) trade secrets, inventions, ideas, processes, formulas, source and object codes, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques; (b) information regarding plans for research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers, customers and prospective customers; and (c) information regarding the skills and compensation of employees and contractors. Notwithstanding the other provisions of this Agreement, Proprietary Information does not include (x) information that has been published or is otherwise readily available to the public other than by a breach of this Agreement; (y) information independently developed by personnel or agents of one Party having no access to the other Party's Proprietary Information; or (z) information known to the receiving Party prior to its receipt from the disclosing Party.

"Third Party Information" means Proprietary Information received from a third party (i.e. a person or entity other than a Party to this Agreement). The Parties each understand that shall maintain the confidentiality of Third Party Information in accordance with the foregoing terms of this Section V.

C. HIPAA Compliance. In connection with the provision of the Services provided hereunder. Contractor may have access to certain protected health information as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended. Contractor agrees to execute and comply with the HIPAA Business Associate Agreement attached Exhibit E, which is hereby incorporated by reference. This Section V.C. shall survive the termination of this Agreement.

D. Ownership of Proprietary Information. Each Party acknowledges that all data, documents (whether in draft or final form), databases, storage media, files, electronic or otherwise, computers, equipment and accessories, pagers, personal digital assistants, telephones and other property containing or referring to Proprietary Information shall at all times be the exclusive property of the disclosing Party.

E. Remedies. NRLBH and Contractor acknowledge and agree that the agreements, covenants and undertakings contained in this Section V relate to matters which are of a special unique and extraordinary character and that a violation of the terms of this Article will cause irreparable injury to the other Party, the amount of which may be extremely difficult, if not impossible, to estimate or determine and may not be adequately compensated by monetary damages. Therefore, NRLBH and Contractor agree that either Party shall be entitled to an injunction, restraining order or other equitable relief from any court of competent jurisdiction, restraining any violation or threatened violation of any such terms by the other Party or such other persons, as the court will order. The rights and remedies provided by this Section V are cumulative and will be in addition to any other rights and remedies which either Party may have at law or equity.

VI. TERMINATION.

A. Term. Unless terminated by either Party in accordance with the terms of this Section VI, the initial term of this Agreement shall be three years (the "Initial Term"). Further, this Agreement will automatically renew for an additional two year terms (each, a "Renewal Term"), unless terminated by either Party upon ninety (90) days' prior written notice prior to the expiration of the Initial Term or the then-applicable Renewal Term. The Initial Term and the Renewal Term are sometimes referred to in this Agreement together as the "Term."

B. **Termination.** This Agreement may be terminated as follows:

1. Either Party may terminate this agreement after the Initial Term upon thirty (30) days' prior written notice to other Party.

2. Either Party may terminate this Agreement at any time upon a material breach of this Agreement by the other Party if such breach is not cured within 60 days after written notice of said breach by the non-breaching Party to the Party in breach (the "Cure Period") or if the Agreement is alleged by a federal or state regulator, or based on advice of counsel to either Party, to violate a Health Care Law.

3. NRLBH may terminate this Agreement if Contractor fails to meet or exceed the Pharmacogenomic Test Minimums.

4. NRLBH may terminate this Agreement upon a change in control of NRLBH or Atossa, through merger, share transfer, completed tender offer, or otherwise, or upon the sale or license of all or substantially all the assets of NRLBH or Atossa.

A termination pursuant to clause (2) or (3) shall be considered a "Termination for Cause".

C. **Termination Fee.** In the event the Agreement is terminated by NRLBH for any reason other than a Termination for Cause, then NRLBH shall pay to Contractor within 30 days of such termination a fee equal to (the "Termination Fee"): the actual cash received by NRLBH for the sale of Pharmacogenomic Tests to Contractor Customers during the three month period preceding the effective date of termination multiplied by 30%.

D. **Return of Property.** Upon termination of this Agreement or earlier if requested by the other Party, any and all notes, memoranda, specifications, devices, formulas, and documents, together with all copies thereof in any form, and any other material containing or disclosing any Third Party Information or Proprietary Information shall be returned to the Party that provided such information to the other Party under this Agreement.

VII. REPRESENTATIONS AND WARRANTIES; INSURANCE; INDEMNITY

A. No Debarment/Exclusion. Each Party certifies to the other that neither it nor any of its employees, agents or contractors performing services under this Agreement is excluded under 42 U.S.C. §1320(a)-7 from participation under any Federal Health Care Program; and (ii) no action has occurred or is pending or threatened against it or to its knowledge against any employee, Contractor or agent engaged to provide items or services that could result in such exclusion (collectively, "Exclusions/Adverse Actions"). During the term of this Agreement, Each Party agrees to notify the other Party in writing of any Exclusions/Adverse Actions within five (5) days of learning of any such Exclusions/Adverse Actions and provide the basis of the Exclusions/Adverse Actions. Each Party acknowledges that the exclusion of any of its personnel from participation in the Medicare or Medicaid programs shall result in his or her immediate removal from work under this Agreement, Each Party acknowledges and agrees that any unresolved Exclusions/Adverse Actions of or against it or any employee, agent or contractor utilized, directly or indirectly, in .the performance of this Agreement may serve as the basis for the immediate termination of this Agreement by the other Party.

B. Insurance; Expenses. Each Party shall carry general liability and professional liability (if applicable) insurance covering liability for claims, causes of actions, actions, losses, liabilities, damages, and expenses arising out of, caused by or otherwise resulting from the negligence or otherwise wrongful acts or omissions of its employees and/or agents occurring while each is engaged in activities related to this Agreement. Said policies shall contain minimum limits of liability of one million dollars ($1,000,000) per occurrence and three million dollars ($3,000,000) in the aggregate, or as the Parties may otherwise mutually agree. All expenses incurred by either Party, including for marketing, training and promotional purposes, shall be the sole responsibility of the Party incurring such expenses.

C. NRLBH Indemnity. NRLBH shall indemnify and hold Contractor harmless from any claims arising out of the Marketed Tests from any third party, including government entities (including any fees, costs, including, without limitation, attorneys' fees, expert witness fees and costs of court, and expenses associated with the defense against Same), except to the extent such claims arise from the negligence or willful misconduct of Contractor, including any breach of this Agreement.

D. Authority. NRLBH represents that it is a corporation duly organized under the laws of the State of Delaware and Contractor represents that it is corporation duly organized under the laws of the State of California. Each party represents that (i) it has all necessary corporate power to enter into this Agreement, (ii) the execution and delivery of this Agreement has been duly authorized by all necessary corporate action, and (iii) this Agreement, once executed and delivered, shall be a legal, valid and binding obligation of the respective Party enforceable in accordance with their respective terms.

E. Contractor Indemnity. Contractor shall indemnify and hold NRLBH harmless from any claims arising out of the Services provided by Contractor from any third party, including government entities (including any fees, costs, including, without limitation, attorneys' fees, expert witness fees and costs of court, and expenses associated with the defense against same), except to the extent such claims arise from the negligence or willful misconduct of NRLBH, including any breach of this agreement.

F. Goodwill. Each Party agrees that the goodwill and reputation of the other Party are essential and should not be impaired at any time. Neither Party nor its agents shall communicate or cause or encourage others to communicate with any person in a manner which: (i) disparages the other Party or its respective affiliates, directors, officers, employees, representatives, agents, business partners, sub-contractors, contractors, suppliers, or the products or services of any of the foregoing; or (ii) adversely affects, disrupts or interferes with the other Party's reputation, goodwill, business relationships, business plans, litigation, claims, business arrangements or agreements; or (iii) causes economic harm to the other Party.

VIII. MISCELLANEOUS.

A. Severability. If one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceable shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. Notwithstanding the foregoing, a court of competent jurisdiction may reform any provision found invalid, illegal, or unenforceable in a manner consistent with the intent of the Parties so as render such provision fully enforceable to the extent permitted by law.

B. Counterparts; Electronic Transmission. This Agreement may be executed in counterparts, with all counterparts constituting one and the same original. Signatures may be transmitted or delivered by electronic means, including facsimile and digital image (e.g., .PDF, ..JPG) and such electronic version shall constitute an original for all purposes.

C. No Assignment. This Agreement may not be assigned by either Party without the other Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Subject to the foregoing, this Agreement shall be binding upon the heirs, successors, and permitted assigns of the Parties hereto.

D. Governing Law. This Agreement shall be governed by and construed under the laws of the State of Washington without regard to the principles of conflicts of laws thereof. Any judicial proceeding brought to enforce this Agreement, or any matter related thereto, shall be brought in the appropriate court for King County, State of Washington or the appropriate United States District Court for the Western District of Washington. By execution of this Agreement, each Party accepts and agrees to the exclusive jurisdiction and venue of the aforesaid courts and irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement, subject to a Party's appeal rights.

E. Injunctive Relief. A breach of certain promises or agreements contained in this Agreement may result in irreparable and continuing damage to the non-breaching Party for which there may be no adequate remedy at law, and the non-breaching Party is therefore entitled to seek injunctive relief as well as such other and further relief as may be appropriate. For purposes of this Section WILE., if a non-breaching Party seeks injunctive relief, the breaching Party shall waive any requirement of a bond or other security and shall be liable for reasonable attorney fees and costs incurred in enforcing the terms of this Agreement.

F. Survival. The following provisions shall survive termination of this Agreement Sections V, Section V.C, VI.C, Section VII.D, Section VII.F, and Section VIII.

G. Waiver. No waiver by a Party to this Agreement of any breach of this Agreement shall be a waiver any preceding or succeeding breach. No waiver by a Party to this Agreement of any right under this Agreement shall be construed as a waiver of any other right. Neither Party shall be required to give notice to enforce strict adherence to all terms of this Agreement.

H. Entire Agreement. This Agreement and the exhibits attached hereto, constitute the final, complete and exclusive agreement of the Parties with respect to the subject matter hereof and supersede and merge all prior discussions between the Parties. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by the Party to be charged.

I. Notices. All notices, requests and other communications under this Agreement must be in writing, and must be mailed by registered or certified mail, postage prepaid and return receipt requested, or delivered by hand to the Party to whom such notice is required or permitted to be given. If mailed, any such notice will be considered to have been given five (5) business days after it was mailed postage prepaid to the address provided below or updated by delivery of written notice in accordance with the provisions of this Section VIII.I. If delivered by hand, any such notice will be considered to have been given when received by the Party to whom notice is given.

NRLBH

National Reference Laboratory for
Breast Health, Inc.
1616 Eastlake Ave., East, No. 300
Seattle, Washington 98102
Attention: President
Tel.: (800) 351-3902
Fax: (206) 430-1288

CONTRACTOR

BIOVENTIVE, INC.
26895 Aliso Creek Road, B-793
Aliso Viejo, CA 92656
Attention: President
Tel.: (858) 856-2870
Fax: (949) 618-8850

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representative as of the date first set forth above.

NATIONAL REFERENCE LABORATORY FOR BREAST HEALTH, INC.

By: /s/ Kyle Guse
Kyle Guse
Chief of Financial Officer and General Counsel

BIOVENTIVE, INC.

By: /s/ Brett R. Nauta
Brett R. Nauta
Chief Executive Officer

EXHIBIT A

CONTRACTOR SERVICES

Contractor shall promote and market the Marketed Tests, by providing promotional and marketing services, including without limitation, the services more fully described below (the "Services") through qualified employees and independent representatives and other personnel engaged and/or employed by Contractor ("Contractor Representatives") in accordance with the Agreement to which this Exhibit A forms a part

1. **Customer Liaison Services.** Contractor shall provide customer service liaison support to Contractor Customers, in person and by phone, regarding issues such as specimen collection, complaints, missed tests, logistical questions with Marketed Tests, specimen requirements and labeling, specimen transport and tracking. Contractor shall ensure the ongoing in-person and phone customer service required to maintain Contractor Customers; however, NRLBH shall also maintain customer service support during West coast and East coast business hours. Contractor shall report to NRLBH any customer service problems upon occurrence. Contractor shall maximize sales of Marketed Tests.

2. **Insurance Coordination.** Contractor will assist NRLBH in obtaining information necessary to yen insurance eligibility of patients.

3. **Training.** Contractor will provide ongoing training to its Contractor Representatives and all necessary sales support, and will compensate its employees and representatives as may be appropriate and in compliance with applicable Federal, State and local laws and regulations.

4. **Authorized Materials.** Contractor shall use only materials supplied by or approved by the NRLBH, including without limitation test requisitions and order forms and sales and marketing materials. Contractor is not authorized to extend any representation, warranty, guaranty, obligation or responsibility (express or implied) with respect to the Marketed Tests without express written authorization from NRLBH.

5. **No Impermissible Services.** In no case shall Contractor or its Contractor Representatives perform any tasks that are normally the responsibility of the Contractor Customer or its office staff, including without limitation, performing nursing functions, or performing clerical services for the Contractor Customer. Upon request by NRLBH, Contractor shall provide to NRLBH a signed certification from each Contractor Representative assigned to perform Services hereunder that the Contractor Representative shall comply fully with the Agreement and this Exhibit.

EXHIBIT B

ADDITIONAL COMPLIANCE OBLIGATIONS OF CONTRACTOR

1. **Chief Compliance Officer.** Contractor shall designate a Chief Compliance Officer who shall make it a key point of his or her efforts to assure that all Contractor Representatives continue to gain additional knowledge on compliance-related issues. Contractor's Chief Compliance Officer shall timely inform NRLBH's Compliance Officer of any compliance-related issues (within not later than 5 business days following the initial discovery of issues that may raise a compliance concern, with periodic updates as required by NRLBH until the issue is resolved).

2. **HIPAA Privacy Standards.** In accordance with HIPAA, Contractor will adopt and maintain HIPAA compliance plan, as well as HIPAA-compliant privacy standards. Contractor will appoint a privacy officer.

3. **Background Checks on Employees and Contractors.** Contractor will ensure that none of its employees, owners or contractors have been excluded or debarred from Medicare or Medicaid or any other Federal Health Care Program.

4. **No Kickbacks.** Contractor will maintain policies and procedures reasonably calculated to assure that all individuals providing services to NRLBH and the Contractor Customers:

    a. Are prohibited from engaging in any act or omission that promotes, encourages or results in the overutilization of the Marketed Tests.

    b. Are required to comply with the Anti-Kickback Statute and other applicable state and federal statutes, policies and regulations.

    c. May not engage in any illegal activities related to the furnishing of the Marketed Tests (such illegal activities include – but are not limited to – paying kickbacks, incentives and/or gratuities to Contractor Customers or to individuals who might influence a customer's decision to order lab testing from NRLBH, or to provide such person with gifts, bribes, services, or any other form of remuneration in exchange for – or to induce – referrals):

    d. Act in accord with applicable guidance issued by the Inspector General of the Department of Health and Human Services (as updated from time to time).

    e. They may not be a health care professional or person in a similar position who might be capable of exerting undue influence on a Contractor Customer or their patients.

EXHIBIT C

MINIMUM PHARMACOGENOMIC TESTS

	Minimum Annual Test Quantity Processed by NRLBH	Minimum Average Cash Receipts Per Test Measured Monthly
First year of Agreement	[***]	$[***]
Second year of Agreement	[***]	$[***]
Third year of Agreement	[***]	$[***]
Annually after Initial Three Year Term	[***]	$[***]

CONFIDENTIAL TREATMENT REQUESTED BY ATOSSA GENETICS INC.

EXHIBIT D

FIXED MONTHLY FEE FOR CONTRACTOR SERVICES

Fixed Monthly Service Fee payable to Contractor shall be an amount equal to actual cash received by the NRLBH during the month from Marketed Tests performed for patients of Contractor Customers multiplied by [***].

EXHIBIT E

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("BA Agreement") dated August 26, 2014 (the "Effective Date") is entered into by and between The National Reference Laboratory for Breast Health, Inc. ("NRLBH"), and BioVentive, Inc. ("Contractor"), each a "Party" and collectively, the "Parties."

WHEREAS, NRLBH and Contractor have entered into, or are entering into, or may subsequently enter into, agreements or other documented arrangements (collectively, the "Business Arrangements") pursuant to which Contractor may provide products and/or services for NRLBH that require Contractor to access, create and use health information that is protected by state and/or federal law; and

WHEREAS, pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the U.S. Department of Health & Human Services ("HHS") promulgated the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Standards"), at 45 C.F.R. Parts 160 and 164, requiring certain individuals and entities subject to the Privacy Standards (each a "Covered Entity", or collectively, "Covered Entities") to protect the privacy of certain individually identifiable health information ("Protected Health Information", or "PHI"); and

WHEREAS, pursuant to HIPAA, FIRS has issued the Security Standards (the "Security Standards"), at 45 C.F.R. Parts 160, 162 and 164, for the protection of electronic protected health information ("EPHI"); and

WHEREAS, in order to protect the privacy and security of PHI, including EPHI, created or maintained by or on behalf of NRLBH, the Privacy Standards and Security Standards require NRLBH to enter into a "Business Associate Agreement" with certain individuals and entities providing, services for or on behalf of NRLBH if such services require the use or disclosure of PHI or EPH1; and

WHEREAS, on February 17, 2009, the federal Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), was signed into law and the HITECH Act imposes certain privacy and security obligations on NRLBH in addition to the obligations created by the Privacy Standards and Security Standards; and

WHEREAS, the HITECH Act revises many of the requirements of the Privacy Standards and Security Standards concerning the confidentiality of PHI and EPHI, including extending certain HIPAA and HITECH Act requirements directly to business associates; and

WHEREAS, the HITECH Act requires that certain of its provisions be included in business associate agreements, and that certain requirements of the Privacy Standards be imposed contractually upon NRLBH as well as business associates; and

WHEREAS, Contractor and NRLBH desire to enter into this Business Associate Agreement;

NOW THEREFORE, in consideration of the mutual promises set forth in this Agreement and the Business Arrangements, and other good and valuable consideration, the sufficiency and receipt of which are hereby severally acknowledged, the Parties agree as follows:

1. Contractor Obligations. Contractor may receive from NRLBH, or create or receive on behalf of NRLBH, health information that is protected under applicable state and/or federal law, including without limitation, PHI and EPHI. All capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in the Privacy Standards, Security Standards or the HITECH Act, as applicable (collectively referred to hereinafter as the "Confidentiality Requirements"). All references to PHI herein shall be construed to include EPHI. Contractor agrees not to use or disclose (or permit the use or disclosure of) PHI in a manner that would violate the Confidentiality Requirements if the PHI were used or disclosed by NRLBH in the same manner.

2. Use of PHI. Except as otherwise required by law, Contractor shall use PHI in compliance with 45 C.F.R. § 164.504(e). Furthermore, Contractor shall use PHI (i) solely for NRLBH's benefit arid only for the purpose of performing services for NRLBH as such services are defined in Business Arrangements, and (ii) as necessary for the proper management and administration of the Contractor or to carry out its legal responsibilities, provided that such uses are permitted under federal and state law. NRLBH shall retain all rights in the PHI not granted herein. Use, creation and disclosure of de-identified health information by Contractor are not permitted unless expressly authorized in writing by NRLBH.

3. Disclosure of PHI. Subject to any limitations in this BA Agreement, Contractor may disclose PHI to any third party persons or entities as necessary to perform its obligations under the Business Arrangement and as permitted or required by applicable federal or state law. Further, Contractor may disclose PHI for the proper management and administration of the Contractor, provided that (i) such disclosures are required by law, or (ii) Contractor: (a) obtains reasonable assurances from any third party to whom the information is disclosed that it will be held confidential and further used and disclosed only as required by law or for the purpose for which it was disclosed to the third party; (b) requires the third party to agree to immediately notify Contractor of any instances of which it is aware that PHI is being used or disclosed for a purpose that is not otherwise provided for in this Agreement or for a purpose not expressly permitted by the Confidentiality Requirements. Additionally, Contractor shall ensure that all disclosures of PHI by Contractor and the third party comply with the principle of "minimum necessary use and disclosure," i.e., only the minimum PHI that is necessary to accomplish the intended purpose may be disclosed; provided further, Contractor shall comply with Section 13405(b) of the HITECH Act, and any regulations or guidance issued by HHS concerning such provision, regarding the minimum necessary standard and the use and disclosure (if applicable) of Limited Data Sets. If Contractor discloses PHI received from NRLBH, or created or received by Contractor on behalf of NRLBH, to agents, including a sub-Contractor (collectively, "Recipients"), Contractor shall require Recipients to agree in writing to the same restrictions and conditions that apply to the Contractor under this Agreement. Contractor shall report to NRLBH any use or disclosure of PHI not permitted by this Agreement, of which it becomes aware, such report to be made within two (2) business days of the Contractor becoming aware of such use or disclosure. In addition to Contractor's obligations under **Section 9**, Contractor agrees to mitigate, to the extent practical and unless otherwise requested by NRLBH in writing, any harmful effect that is known to Contractor and is the result of a use or disclosure of PHI by Contractor or Recipients in violation of this Agreement.

4. Accounting of Disclosures. Contractor shall make available to NRLBH in response to a request from an individual, information required for an accounting of disclosures of PHI with respect to the individual in accordance with 45 CFR § 164.528, as amended by Section 13405(c) of the HITECH Act and any related regulations or guidance issued by HHS in accordance with such provision. Contractor shall provide to NRLBH such information necessary to provide an accounting within thirty (30) days of NRLBH's request or such shorter time as may be required by state or federal law. Such accounting must be provided without cost to the individual or to NRLBH if it is the first accounting requested by an individual within any twelve (12) month period. For subsequent accountings within a twelve (12) month period, Contractor may charge a reasonable fee based upon the Business's labor costs in responding to a request for electronic information (or a cost-based fee for the production of non-electronic media copies) so long as Contractor informs NRLBH and NRLBH informs the individual in advance of the fee, and the individual is afforded an opportunity to withdraw or modify the request. Such accounting obligations shall survive termination of this Agreement and shall continue as long as Contractor maintains PHI.

5. Withdrawal of Authorization. If the use or disclosure of PHI in this Agreement is based upon an individual's specific authorization for the use of his or her PHI, and (i) the individual revokes such authorization in writing, (ii) the effective date of such authorization has expired, or (iii) the consent or authorization is found to be defective in any manner that renders it invalid, Contractor agrees, if it has notice of such revocation or invalidity, to cease the use and disclosure of any such individual's PHI except to the extent it has relied on such use or disclosure, or where an exception under the Confidentiality Requirements expressly applies.

6. Records and Audit. Contractor shall make available to the United States Department of Health and Human Services or its agents, its internal practices, books, and records relating to the use and disclosure of PHI received from, created, or received by Contractor on behalf of NRLBH for the purpose of determining NRLBH's compliance with the Confidentiality Requirements or any other health oversight agency, in a time and manner designated by the Secretary. Except to the extent prohibited by law, Contractor agrees to notify NRLBH immediately upon receipt by Contractor of any and all requests by or on behalf of any and all federal, state and local government authorities served upon Contractor for PHI.

7. Implementation of Security Standards; Notice of Security Incidents. Contractor will use appropriate safeguards to prevent the use or disclosure of PHI other than as expressly permitted under this Agreement. Contractor will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the PHI that it creates, receives, maintains or transmits on behalf of NRLBH. Contractor acknowledges that the HITECH Act requires Contractor to comply with 45 C.F.R. §§ 164.308, 164.310, 164.312 and 164.316 as if Contractor were a Covered Entity, and Contractor agrees to comply with these provisions of the Security Standards and all additional security provisions of the HITECH Act. Furthermore, to the extent feasible, Contractor will use commercially reasonable efforts to ensure that the technology safeguards used by Contractor to secure PHI will render such Pill unusable, unreadable and indecipherable to individuals unauthorized to acquire or otherwise have access to such PHI in accordance with HHS Guidance published at 74 Federal Register 19006 (April 17, 2009), or such later regulations or guidance promulgated by HHS including the National Institute for Standards and Technology ("NIST") standards adopted by HHS concerning the protection of identifiable data such as PHI. Lastly, Contractor will promptly report to NRLBH any successful Security Incident of which it becomes aware. At the request of NRLBH, Contractor shall identify: the date of the Security Incident, the scope of the Security Incident, the Contractor's response to the Security Incident and the identification of the party responsible for causing the Security Incident, if known.

8. Data Breach Notification and Mitigation.

8.1 HIPAA Data Breach Notification and Mitigation. Contractor agrees to implement reasonable systems for the discovery and prompt reporting of any "breach" of "unsecured PHI" as those terms are defined by 45 C.F.R. § 164.402 (hereinafter a "HIPAA Breach"). The Parties acknowledge and agree that 45 C.F.R. § 164.404, as described below in this Section, governs the determination of the date of a HIPAA Breach. In the event of any conflict between this Section and the Confidentiality Requirements, the more stringent requirements shall govern. Contractor will, following the discovery of a HIPAA Breach, notify NRLBH immediately within fifteen (15) Contractor discovers such HIPAA Breach, unless Contractor is prevented from doing so by 45 C.F.R. § 164.412 concerning law enforcement investigations. For purposes of reporting a HIPAA Breach to NRLBH, the discovery of a HIPAA Breach shall occur as of the first day on which such HIPAA Breach is known to the Contractor or, by exercising reasonable diligence, would have been known to the Contractor. Contractor will be considered to have had knowledge of a HIPAA Breach if the HIPAA Breach is known, or by exercising reasonable diligence would have been known, to any person (other than the person committing the HIPAA Breach) who is an employee, officer or other agent of the Contractor. No later than three (3) business days following a HIPAA Breach, Contractor shall provide NRLBH with sufficient information to permit NRLBH to comply with the HIPAA Breach notification requirements set forth at 45 C.F.R. § 164.400 *et seq.* Specifically, if following information is known to (or can be reasonably obtained by) the Contractor, Contractor will provide NRLBH with: (i) contact information for individuals who were or who may have been impacted by the HIPAA Breach (e.g., first and last name, mailing address, street address, phone number, email address); (ii) a brief description of the circumstances of the HIPAA Breach, including the date of the HIPAA Breach and date of discovery; (iii) a description of the types of unsecured PHI involved in the HIPAA Breach (e.g., names, social security number, date of birth, address(es), account numbers of any type, disability codes, diagnostic and/or billing codes and similar information); (iv) a brief description of what the Contractor has done or is doing to investigate the HIPAA Breach, mitigate harm to the individual impacted by the HIPAA Breach, and protect against future HIPAA Breaches; and (v) appoint a liaison and provide contact information for same so that NRLBH may ask questions or learn additional information concerning the HIPAA Breach. Following a HIPAA Breach, Contractor will have a continuing duty to inform NRLBH of new information learned by Contractor regarding the HIPAA Breach, including but not limited to the information described in items (i) through (v), above.

8.2 Data Breach Notification and Mitigation under Other Laws. In addition to the requirements of the foregoing Section, Contractor agrees that in the event any Individually Identifiable Information is lost, stolen, used or disclosed in violation of one or more State data breach notification laws, Contractor shall promptly: (1) cooperate and assist NRLBH with any investigation into any State Breach or alleged State Breach; (ii) cooperate and assist NRLBH with any investigation into any State Breach or alleged State Breach conducted by any State Attorney General or State Consumer Affairs Department (or their respective agents); (iii) comply with NRLBH's determinations regarding NRI.BH's and Contractor's obligations to mitigate to the extent practicable any potential harm to the individuals impacted by the State Breach; and (iv) assist with the implementation of any decision by NRLBH or any State agency, including any State Attorney General or State Consumer Affairs Department (or their respective agents), to notify individuals impacted or potentially impacted by a State Breach.

9. Term and Termination.

9.1 This BA Agreement shall commence on the Effective Date and shall remain in effect until terminated in accordance with the terms of this Section, provided, however, that termination shall not affect the respective obligations or rights of the Parties arising under the Business Arrangements prior to the effective date of termination, all of which shall continue in accordance with their terms.

9.2 NRLBH shall have the right to terminate this BA Agreement if the Contractor fails to observe or perform any material covenant or obligation contained in this BA Agreement for ten (10) days after written notice thereof has been given to the Contractor.

9.3 Termination of this BA Agreement pursuant to **Section 9.2** above shall be cause for NRLBH to immediately terminate for cause any Business Arrangement pursuant to which Contractor is entitled to receive PHI from NRLBH.

9.4 Upon termination of this BA Agreement for any reason, Contractor agrees either to return to NRLBH or to destroy all PHI received from NRLBH or otherwise through the performance of services for NRLBH, that is in the possession or control of Contractor or its agents. In the case of PHI which is not feasible to "return or destroy," Contractor shall extend the protections of this BA Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Contractor maintains such PHI. Contractor further agrees to comply with other applicable state or federal law, which may require a specific period of retention, redaction, or other treatment of such PHI.

10. No Warranty. PHI IS PROVIDED TO Contractor SOLELY ON AN "AS IS" BASIS. COMPANY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.

11. Miscellaneous.

11.1 Notice. All notices, requests, demands and other communications required or permitted to be given or made under this BA Agreement shall be in writing, shall be effective upon receipt or attempted delivery, and shall be sent by (1) personal delivery; (ii) certified or registered United States mail, return receipt requested; or (iii) overnight delivery service with proof of delivery. Neither Party shall refuse delivery of any notice hereunder.

To NRLBH: National Reference Laboratory for Breast Health, Inc. 1616 Eastlake Ave., East, No. 300 Seattle, Washington 98102 Attention: President Tel.: (800) 351-3902 Fax: (206) 430-1288
To Contractor: BIOVENTIVE, INC. 26895 Aliso Creek Road, B-793 Aliso Viejo, CA 92656 Attention: President Tel.: (858) 856-2870 Fax: (949) 618-8850

11.2 Waiver. No provision of this BA Agreement or any breach thereof shall be deemed waived unless such waiver is in writing and signed by the Party claimed to have waived such provision or breach. No waiver of a breach shall constitute a waiver of or excuse any different or subsequent breach.

11.3 Severability. Any provision of this BA Agreement that is determined to be invalid or unenforceable will be ineffective to the extent of such determination without invalidating the remaining provisions of this BA Agreement or affecting the validity or enforceability of such remaining provisions.

11.4 Entire Agreement. This BA Agreement constitutes the complete agreement between Contractor and NRLBH relating to the matters specified in this Agreement, and supersedes all prior representations or agreements, whether oral or written, with respect to such matters. In the event of any conflict between the terms of this BA Agreement and the terms of the Business Arrangements or any such later agreement(s), the terms of this BA Agreement shall control unless the terms of such Business Arrangements are more strict with respect to PHI and comply with the Confidentiality Requirements, or the Parties specifically otherwise agree in writing. No oral modification or waiver of any of the provisions of this BA Agreement shall be binding on either Party; provided, however, that upon the enactment of any law, regulation, court decision or relevant government publication and/or interpretive guidance or policy that NRLBH believes in good faith will adversely impact the use or disclosure of PHI under this BA Agreement, NRLBH may amend the BA Agreement to comply with such law, regulation, court decision or government publication, guidance or policy by delivering a written amendment to Contractor which shall be effective thirty (30) days after receipt. No obligation on either Party to enter into any transaction is to be implied from the execution or delivery of this BA Agreement. This BA Agreement is for the benefit of, and shall be binding upon the Parties, their affiliates and respective successors and assigns. No third party shall be considered a third-party beneficiary under this BA Agreement, nor shall any third party have any rights as a result of this BA Agreement.

11.5 Governing Law. This BA Agreement shall be governed by and interpreted in accordance with the laws of the state of Washington, excluding its conflicts of laws provisions. Jurisdiction and venue for any dispute relating to this BA Agreement shall exclusively rest with the state and federal courts in the county in which NRLBH is located.

11.6 Equitable Relief. Contractor understands and acknowledges that any disclosure or misappropriation of any PHI in violation of this BA Agreement will cause NRLBH irreparable harm, the amount of which may be difficult to ascertain, and therefore agrees that NRLBH shall have the right to apply to a court of competent jurisdiction for specific performance and/or an order restraining and enjoining any such further disclosure or breach and for such other relief as NRLBH shall deem appropriate. Such right of NRLBH is to be in addition to the remedies otherwise available to NRLBH at law or in equity. Contractor expressly waives the defense that a remedy in damages will be adequate and further waives any requirement in an action for specific performance or injunction for the posting of a bond by NRLBH.

11.7 Nature of Agreement; Independent Contractor. Nothing in this BA Agreement shall be construed to create (i) a partnership, joint: venture or other joint business relationship between the Parties or any of their affiliates, or (ii) a relationship of employer and employee between the Parties. Contractor is an independent Contractor, and not an agent of NRLBH. This BA Agreement does not express or imply any commitment to purchase or sell goods or services.

11.8 Counterparts. This BA Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document. In making proof of this BA Agreement, it shall not be necessary to produce or account for more than one such counterpart executed by the Party against whom enforcement of this Agreement is sought.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

NATIONAL REFERENCE LABORATORY FOR BREAST HEALTH, INC.

By: /s/ Kyle Guse
Printed Name: Kyle Guse
Title: Chief of Financial Officer and General Counsel

BIOVENTIVE, INC.

By: /s/ Brett R. Nauta
Printed Name: Brett R. Nauta
Title: Chief Executive Officer

MASTER SERVICES AGREEMENT
By and Between

TME RESEARCH
And
The National Reference Laboratory for Breast Health, Inc.

This Master Services Agreement **("Agreement")** is effective as of September 1, 2014 and is by and between TME Research LLC **("TME RESEARCH"),** with a principal place of business at 250 Cetronia Road, Suite 302, Allentown, PA 18104**,** and The National Reference Laboratory for Breast Health, Inc. ("COMPANY"), with a principal place of business at 1616 Eastlake Ave. East, Suite 360, Seattle, WA 98102.

WHEREAS, TME RESEARCH is engaged in the business of providing Breast Cancer Study and Research Services such as access to tissue and patient registries, study concept and design; IRB interface services, on-line database development, study implementation including study set-up, launch, investigator recruitment, and oversight, data monitoring; and associated work including but not limited to data analysis, summary, and preparation for publication and/ or public release, as well as access to the TME Scientific Advisory Board; and

WHEREAS, COMPANY is in the business of developing innovative breast health products and services designed to provide critical information that empowers women and their healthcare providers to take charge of and protect their breast health today and in the future and;

Whereas COMPANY desires to acquire and analyze matched sets of patient tissue with clinically annotated data with its NextCYTE microarray test and

Whereas TME RESEARCH desires to provide such specific services to COMPANY as specifically defined in an attachment to this Agreement and under the restrictions set out in agreed upon terms and conditions;

Now therefore, for and in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, the parties agree as set forth herein.

1. DEFINITIONS

1.1 **"TME RESEARCH Data"** means any TME RESEARCH data and information provided to COMPANY by TME RESEARCH for use under this Agreement or applicable Statement(s) of Work, including all patient electronic medical data of which such data shall be de-identified and provided in accordance with Data Specifications set forth in this Agreement. For the purpose of this Agreement, TME RESEARCH Data shall not include any patient tissue samples or the like provided by TME Research to COMPANY. For the purpose of this Agreement, TME RESEARCH Data shall not include any data subject to any applicable law, legal, contractual, or other restriction against such provision of data by any source of such data.

1.2 **"Applicable Law"** means any international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, or ordinance that applies to either party or to the services or this Agreement, and includes without limitation, rules of HIPAA.

1.3 **"Confidential Information"** means information in the possession or under control of either TME RESEARCH or COMPANY including without limitation the terms and content of this Agreement, the TME RESEARCH Data, and protocols, the analytical algorithms and techniques used by TME RESEARCH and/or COMPANY. Confidential Information does not include information which was known to the receiving party or was in the public domain before disclosure, which becomes part of the public domain after disclosure by publication or other means except by a breach of this Agreement by the receiving party, was received from a third party under no duty or obligation of confidentiality to the disclosing party, or was independently developed by the receiving party without reference to the Confidential Information.

1.4 **"Data Specifications"** means the method, format, structure, organization, and content of the data that TME RESEARCH will provide to COMPANY as further specified in the applicable SOW and which Data Specifications may be modified from time to time in accordance with this Agreement.

1.5 **"COMPANY Data"** means data in the possession of COMPANY that was not provided by TME RESEARCH. In the event that COMPANY obtains data from other sources and that data is part of the TME RESEARCH Data at the time that duplicate data is obtained from another source by COMPANY, then the TME RESEARCH Data shall continue to be considered to be TME RESEARCH Data.

1.6 **"HIPAA"** means the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §1302d et seq., as amended by the Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, and implementing regulations promulgated thereunder, including the Privacy Standards, 45 C.F.R. Parts 160 and 164, and the omnibus rule changes to the Privacy and Security Rules, as may be amended from time to time.

1.7 **"Intellectual Property"** means all: (i) copyrights (including, without limitation, the right to reproduce, distribute copies of, display and perform the copyrighted work and to prepare derivative works), copyright registrations and applications, trademark ("TM") rights, trademark registrations and applications, patent rights, patent applications and patent issuances, trade names, mask-work rights, Trade Secrets, moral rights, author's rights, privacy rights, publicity rights, algorithms, rights in packaging, goodwill and other proprietary rights and all renewals and extensions thereof; (ii) intangible legal rights or interests evidenced by or embodied in any idea, design, concept, technique, invention, discovery, enhancement or improvement, whether or not patentable, copyrightable or trademarkable; and (iii) all derivatives of any of the foregoing.

2. SERVICES

2.1 TME RESEARCH will provide to COMPANY the services set forth in Exhibit A, a Statement of Work ("SOW"), which sets out with specificity the services and deliverables to be provided and the fees to be paid. Additional SOWs may be executed by the parties and will be incorporated into and governed by this Agreement for any other projects agreed to by the parties that will be governed under this Agreement. If any term in a SOW conflicts with this Agreement, the SOW will control. All tissue samples provided to COMPANY under this Agreement or any SOW shall become and remain the exclusive and sole property of the COMPANY; however, use of such tissue samples shall remain as restricted in the related SOW under which they are provided.

2.2 Either party may request changes to any services or deliverables set forth in an SOW by submitting a written request detailing the proposed changes to the other party. The parties agree to negotiate and execute an amendment reflecting agreed-upon changes and any related terms.

3. LICENSE GRANT

Subject to the terms and conditions of this Agreement, TME RESEARCH hereby grants COMPANY a limited, non-exclusive, nontransferable, except as provided herein, right and license to the TME RESEARCH Data and tissue samples for use exclusively as set forth within any SOW under this Agreement. Nothing herein shall restrict TME RESEARCH from using TME RESEARCH Data for any and all purposes anywhere in the world.

4. PAYMENTS

4.1 COMPANY will pay to TME RESEARCH the fees specified in the applicable SOW. TME RESEARCH shall deliver all deliverables under an SOW provided that COMPANY has fulfilled all of its payment obligations to date and subject to IRB approval(s). All invoiced amounts for services performed in accordance with the terms and conditions of this Agreement and any SOW are due net thirty (30) days from the date of invoice. If COMPANY identifies items in an invoice which are disputed, COMPANY will notify TME RESEARCH in writing, noting its objection to the disputed item(s) with specificity, within ten (10) working days of the date of the invoice.

4.2 In addition to all of the payments otherwise required under this Agreement, exclusive of any taxes imposed upon TME RESEARCH' net income, COMPANY shall pay any and all taxes, duties, or excises imposed upon any payments made to TME RESEARCH hereunder by any governmental authority, including without limitation any sales, use, service, value-added, withholding or similar taxes.

5. TERM AND TERMINATION

5.1 This Agreement will commence on the Effective Date and will terminate on the third (3rd) anniversary of the Effective Date unless earlier terminated in accordance with this Agreement, or unless extended by a written amendment and signed by both parties. Any SOW, the duration of which extends beyond the expiration or termination of this Agreement, will continue to be performed for the term of such SOW, and will continue to be governed by the terms of this Agreement, which terms shall remain in effect beyond the expiration or termination of this Agreement solely with respect to such SOW, unless such SOW is also terminated in accordance with the terms and conditions of this Agreement.

5.2 Either party may immediately terminate this Agreement or any individual Statement(s) of Work, or TME RESEARCH may suspend performance of Services, for a material breach of this Agreement or the applicable Statement(s) of Work by the other party (the "**Breaching Party**"), provided that the Breaching Party fails to cure such material breach within forty-five (45) days (or thirty (30) days for payment breaches) after receipt of written notice specifying such material breach.

5.3 Either party may immediately terminate this Agreement or any SOW upon written notice to the other party upon the happening of any of the following events: (i) if any certificate, authorization, approval or exemption from a regulatory authority required for the conduct of the services is revoked, suspended, or expires without renewal; (ii) if the continuation of the services would be rendered illegal or in violation of Applicable Law; or (iii) upon the other party's becoming insolvent or unable to pay all material debts when due, including without limitation if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent, prompt Notice of such event to be provided to the other party to the extent permissible under any Applicable Law.

5.4 Either party may terminate this Agreement or any SOW without cause upon sixty (60) days prior written notice to the other party, or as may be otherwise provided in a SOW.

5.5 Upon receipt of notice of termination of this Agreement or any Statement(s) of Work by either party: (i) the parties will, as soon as reasonably practicable and in accordance with Applicable Laws, discontinue providing the applicable services, and no payments from COMPANY to TME RESEARCH will be refundable unless otherwise defined in a SOW.

5.6 Termination of this Agreement or of a SOW for any reason shall not affect the rights of the parties that have accrued on or before termination.

6. CONFIDENTIALITY AND PRIVACY COMPLIANCE

6.1 In the event the receiving party (i) is required by Applicable Law to disclose the disclosing party's Confidential Information, or (ii) receives a subpoena, other validly issued administrative or judicial order, or a request pursuant to regulatory audit, requesting Confidential Information of the disclosing party, then in any such case the receiving party may, to the limited extent necessary to comply with the requirements of 6. l(i) or (ii), disclose the other party's Confidential Information. In such event, to the extent practicable and permitted by Applicable Law or the requesting government agency, the receiving party shall promptly notify the disclosing party in writing of such request and provide reasonable assistance to the disclosing party, at the disclosing party's expense, if the disclosing party wishes to seek a protective order or similar relief.

6.2 Each party may use the other party's Confidential Information only in connection with its rights and obligations under this Agreement. Except as expressly permitted herein, each party will maintain in confidence and will not disclose the other party's Confidential Information, using the same degree of care, but no less than reasonable care, as it uses to protect its own confidential information of a similar nature. The receiving party may disclose the disclosing party's Confidential Information only to the receiving party's respective employees, independent contractors, outside consultants (including its legal counsel, its insurance carriers and agents, and its financial and accounting advisers) and actual and potential investors, lenders, acquirers and collaborators who (i) have a need to know such Confidential Information; (ii) are made aware of the Confidential Information's confidential or proprietary nature; and (iii) are under a written obligation to protect confidential or proprietary information (including the Confidential Information) no less restrictive than the obligations set forth herein. To the extent necessary to discharge a party's obligations under this Agreement, that party may disclose the other party's Confidential Information to regulatory authorities, ethics committees, and institutional review boards. To the extent that Confidential Information contains the disclosing party's standard operating procedures, confidential product specifications, proprietary data, trade secrets, or proprietary methods, no portion thereof may be photocopied or replicated in any way.

6.3 TME RESEARCH and COMPANY will comply with all Applicable Law relating to protection of personal information contained in the TME RESEARCH Data and COMPANY databases, respectively. Notwithstanding anything to the contrary herein, all individually identifiable information shall only be used and disclosed in accordance with HIPAA and Applicable Law. Any TME RESEARCH Data provided by TME RESEARCH to COMPANY will be provided in accordance with the Data Specifications as set forth in the applicable SOW, and any COMPANY Data and/or TME RESEARCH Data provided to a third party as intended under this Agreement or any SOW will be provided in accordance to HIPAA, specifically in a manner consistent with 45 C.F.R. Section 164.514(b). Should COMPANY discover any TME RESEARCH Data that it reasonably should know should be de-identified as described above which is not de-identified, COMPANY will use its best efforts to promptly notify TME RESEARCH of such occurrence.

6.4 Disposal of Confidential Information. Each Party agrees that, upon the disclosing party's written request, the receiving party will return to the disclosing party or destroy, as reasonably directed by the disclosing party. The foregoing notwithstanding, each receiving party may retain one (1) archival copy of the disclosing party's Confidential Information in a limited access file for purposes of monitoring its ongoing obligations hereunder and to comply with any applicable regulatory requirements.

6.5 No License Granted. Except as provided herein or specifically in a SOW hereunder, disclosure of Confidential Information under this Agreement shall not be construed to create in or grant to the receiving party any license, right, title, interest, or ownership in or to any of the disclosing party's Confidential Information.

6.6 Injunctive Relief. Each party agrees that a breach of this Agreement by the receiving party may result in irreparable harm to the disclosing party for which money damages would be inadequate. Consequently, in the event of a breach or threatened breach by the receiving party of this Agreement, the disclosing party shall be entitled, without the requirement of posting a bond or other security, to seek equitable relief, including injunctive relief and specific performance in addition to other remedies available to the disclosing party at law or in equity.

7. OWNERSHIP

7.1 No right or license, or assignment of either party's patent, copyright, trademark, trade secret is granted under this Agreement.

7.2 As between the parties, each party will retain full and exclusive ownership of all right, title, and interest in and to all of its Intellectual Property, including materials, documents, Data, methodologies, systems and inventions provided by either party to the other hereunder, except to the extent stated otherwise herein this Section 7.

7.3 Any and all materials, documents, data, methodologies, systems, inventions, discoveries, derivatives, enhancements and improvements that are deliverables or developed under a SOW, whether or not patentable, which are conceived, and prepared and/or developed, by TME RESEARCH in the course of performing the services shall be the sole and exclusive property of TME RESEARCH, **except to the extent any COMPANY Intellectual Property is contained therein and except to the extent any reports or data analysis are developed or derived from the services provided to COMPANY by TME RESEARCH under the terms of this Agreement which are deliverables under this Agreement, in which case such derivative or newly developed data deliverables shall be owned by each party without the need to account to the other party. Either party shall have the right to use such derivative or newly developed data deliverables for its own business purposes without the need for authorization or consent from the other party.**

7.4 Any and all materials, documents, data, methodologies, systems, inventions, discoveries, derivatives, enhancements and improvements that are deliverables or developed under a SOW, whether or not patentable, which are conceived, and prepared and/or developed, by COMPANY shall be the sole and exclusive property of COMPANY (“COMPANY DERIVED IP”), **except to the extent any TME RESEARCH Intellectual Property is contained therein and except to the extent developed or derived by TME RESEARCH and provided to COMPANY under the terms of this Agreement, or to the extent Data is provided as a Deliverable to TME Research by COMPANY under the terms of this Agreement, in which case such derivative or newly developed data shall be owned by each party without the need to account to the other party. Either party shall have the right to use such derivative or newly developed data for its own business purposes without the need for authorization from the other party.** For clarity, notwithstanding anything in this Agreement or SOW to the contrary, the parties agree that COMPANY DERIVED IP, shall at all times remain the sole and exclusive property of the COMPANY and shall include all materials, documents, data, methodologies, systems, inventions, discoveries, derivatives, enhancements and improvements, whether or not patentable, that are derived from the NextCYTE micro array test, including any such derivations using the TME RESEARCH Intellectual Property that is licensed or otherwise provided to COMPANY under this Agreement or any SOW. By way of example and without limitation, if a SOW requires that COMPANY provide any data, test, results or analysis of the NextCYTE micor array tests to TME then such data, test, result or analysis shall remain the sole and exclusive property of COMPANY.

7.5 For purposes of clarity, such business purposes mentioned in Sections 7.3 and 7.4 above shall include, but shall not be limited to, the right of publication under its own name and in accordance with Section 10. Notwithstanding anything to the contrary contained herein, the parties agree that if the other party’s name or products or reference to the project that is the subject of any particular SOW is made in writing, the other party shall have the right to review and comment on any such publication prior to release of such publication.

8. LIMITATION OF LIABILITY AND INDEMNIFICATION

8.1 EXCEPT AS PROVIDED BELOW, NEITHER PARTY OR ANY THIRD PARTY LICENSOR OF A PARTY SHALL BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL, OR INDIRECT DAMAGES, OR ANY DAMAGES FOR LOST DATA, BUSINESS INTERRUPTION, LOST PROFITS, LOST REVENUE, OR LOST BUSINESS, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND BASED ON ANY THEORY OF LIABILITY, ARISING OUT OF THIS AGREEMENT, WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE, AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. IN NO EVENT WILL THE AGGREGATE LIABILITY OF ANY PARTY UNDER THIS AGREEMENT EXCEED THE TOTAL FEES PAID UNDER THIS AGREEMENT OR THE APPLICABLE SOW DURING THE TWELVE MONTHS IMMEDIATELY PRECEDING THE EVENT GIVING RISE TO THE CAUSE OF ACTION.

8.2 Indemnification. **Subject to Section 8.1 above, including without limitation the aggregate liability of each Party,** each Party (the "Indemnifying Party") shall indemnify and hold harmless the other Party, and their respective directors, employees, consultants and agents (the "Indemnified Parties") from and against any and all liabilities, losses, damages, costs, and other expenses (including reasonable attorneys' fees) ("Losses") incurred by the Indemnified Parties as a result of any claim, demand, action or proceeding by any third party against such Indemnified Parties (each, a "Claim") to the extent arising from or relating to any material breach of any representation, warranty, covenant, or obligation of the Indemnifying Party under this Agreement, or any gross negligence or willful misconduct by the Indemnifying Party or any of its employees, agents, or subcontractors, provided the Indemnifying Party is found liable for such expenses as adjudicated in a final court of competent jurisdiction, if the Indemnifying Party so chooses to go to a court of last resort, otherwise the initial court of competent jurisdiction.

8.3 Settlement. No settlement or compromise of a Claim subject to the indemnification provision will be binding on either Party without prior written consent. Such consent of settlement or compromise will not be unreasonably withheld, conditioned or delayed. Neither party will admit fault on behalf of the other Party without the prior written approval of that party.

9. WARRANTIES AND DISCLAIMER

9.1 Each Party represents and warrants to the other that: (i) it has the full corporate or limited liability power, as applicable, to enter into this Agreement and to perform its obligations hereunder; (ii) this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; and (iii) this Agreement does not contravene, violate or conflict with any other agreement of such Party.

9.2 EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT, ALL MATERIALS, PRODUCTS AND SERVICES, IF ANY, ARE PROVIDED "AS IS," "WHERE IS" AND WITHOUT WARRANTY OF ANY KIND. EXCEPT AS SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY REPRESENTATIONS OR WARRANTIES IN CONNECTION WITH ANY AND ALL MATERIALS, PRODUCTS AND SERVICES PROVIDED PURSUANT TO THIS AGREEMENT, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY RIGHTS, TITLE, ANY WARRANTIES ARISING OUT OF A COURSE OF PERFORMANCE, DEALING OR TRADE USAGE, AND THEIR EQUIVALENTS UNDER THE LAWS OF ANY JURISDICTION.

10. PUBLICITY

Except as necessary to perform the services and except as limited below in this Section, the parties agree they shall not disclose the existence or the terms and conditions of this Agreement or any associated Statements of Work to any third party, except as may be required (i) to implement or enforce the terms of this Agreement; (ii) by legal procedure or by law; or (iii) by an existing or potential investor, acquiring company, bank or other financial institution, under appropriate non-disclosure terms in connection with a merger, acquisition, financing, loan agreement or similar corporate transaction; and the parties agree they shall not, except as required by legal procedure or by law, without first obtaining the prior written consent of the other party, (i) announce this Agreement in a press release or promotional material, (ii) disclose TME RESEARCH as the source of any data provided to COMPANY to any third party without the written consent of TME RESEARCH; or (iii) use each other's name, symbols or marks in any form of publicity without the prior written consent of the other party.

11. INDEPENDENT CONTRACTOR

The relationship of the parties to each other under this Agreement is that of independent contractors, and nothing contained herein will be construed to constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind. Except as expressly provided for in this Agreement, under no circumstances will the employees or agents of one party be considered employees or agents of the other party. Neither party may act in a manner which expresses or implies a relationship other than that of independent contractor, nor bind the other party.

12. ASSIGNMENT

Either party may assign this Agreement without the other party's prior written consent to a successor in interest by reason of merger, acquisition, partnership, license agreement or otherwise; provided that no assignment to a direct competitor of the other party will be permitted without such other party's prior written consent. Except as expressly provided in this Section, neither party will have the right to assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other party, which consent will not be unreasonably withheld, conditioned or delayed. Any attempt at assignment in violation of this Section shall be null and void.

13. DISPUTE RESOLUTION

If a dispute arises between the parties relating to this Agreement, the parties will meet and attempt to resolve the dispute in good faith. In the event the dispute is not resolved through negotiation within ten business days after said meeting, the parties will submit to confidential, non-binding mediation before a mutually acceptable mediator. Each party will designate at least one corporate officer with full authority to resolve the dispute who will attend and participate in the mediation. If the dispute remains unresolved after mediation, then each party will be free to pursue any available remedy at law or in equity. Each party will bear its own legal fees and any costs incurred under this Section.

14. GENERAL

14.1 **Notice.** Any notice or communication required or permitted hereunder shall be in writing and shall be deemed received (i) on the date received if delivered by a reputable overnight delivery service, or (ii) three days after the date postmarked if sent by first class, registered or certified mail, with return receipt requested. Notice given under this Section 15.1 shall be sent to the parties at the addresses first cited above (or such other address as the applicable party may provide by written notice):

14.2 **Insurance.** Each party will maintain in full force and effect throughout the performance of this Agreement worker's compensation, general liability, automobile liability, and professional general or product liability insurance coverage in amounts appropriate to conduct its business and sufficient to cover its indemnification obligations hereunder, at its sole cost and expense.

14.3 **Severability.** If any term of this Agreement is declared unenforceable, then the unenforceability thereof will not affect the remaining terms of this Agreement, provided the commercial goals of the Agreement or relevant SOW may be reasonably met.

14.4 **Waiver.** Failure to enforce any of the terms or conditions of this Agreement will not constitute a waiver of any such terms or conditions, then or in the future, or of any other terms or conditions.

14.5 **Governing Law and Forum; Compliance with Law.** This Agreement will be governed by and construed in accordance with the laws of the State of Pennsylvania, without regard to its conflict of laws provisions. The parties hereby consent to the exclusive jurisdiction of the state and federal courts located in the State of Pennsylvania.

14.6 **Compliance with Law.** Each party is responsible for compliance with all Applicable Laws pertaining to the performance of its obligations under this Agreement, including without limitation HIPAA or any other applicable law relating to security or privacy of information or the exchange of health information.

14.7 **Entire Agreement.** This Agreement, including any Statement(s) of Work, amendments and attachments hereto, constitutes the entire understanding of the parties hereto with respect to the subject matter hereof and supersedes and replaces all prior contracts, agreements, and understandings relating to the same subject matter, whether written or oral. No waiver, consent, change or modification to this Agreement will be binding, unless in writing and signed by duly authorized representatives of TME RESEARCH and COMPANY. The Attachments and any amendments attached hereto and referenced herein shall constitute an integral part of this Agreement. Section titles and headings contained in this Agreement are intended for convenience only and are not intended to effect the interpretation or construction of any term or provision hereof. This Agreement may be executed in counterparts. Those provisions of this Agreement which, by their nature are meant to survive any termination of this Agreement will so survive.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement through their duly authorized representatives as of the Effective Date.

TME Research		The National Reference Laboratory for Breast Health, Inc.	
By:	*/s/ Mark Gittleman*	*By:*	*/s/ Kyle Guse*
Name:	*Mark Gittleman*	*Name:*	*Kyle Guse*
Title:	*President*	*Title:*	*CFO*
Date:	*9/1/14*	*Date:*	*9/15/14*

EXHIBIT A
Statement of Work

TME Research, LLC
and
The National Reference Laboratory for Breast Health, Inc.

Project: NextCyte Full Transcriptome Data Analysis of Patients with Invasive Breast Cancer

Terms and Conditions

This Statement of Work, effective as of September 1, 2014, (the "Effective Date of the Statement of Work"), is entered into pursuant to and under the terms and conditions of the TME Research Master Services Agreement between TME Research and The National Reference Laboratory for Breast Health, Inc. effective as of August 29, 2014. The terms of the TME Research Master Services Agreement ("Master Agreement") and the terms of this Statement of Work shall apply to this project. Should there be any inconsistencies between the terms, the terms of this Statement of Work shall take precedence.

Overall Obiectives/Scope of Work

In accordance with the terms and conditions in the Master Agreement and the terms of this SOW and any of its Exhibits or other agreed to documents duly signed by representatives of the parties, the major objectives are as defined below:

Objective: To provide matched sets of de—identified tissue samples and clinically annotated retrospective data on 100 breast cancer patients for testing and evaluation of the NextCyte gene test

Tasks include:

- TME will provide to NRLBH tissue sample slides from formalin fixed paraffin embedded (FFPE) blocks and matched de—identified clinically annotated data (de—identified in accordance with HIPAA regulations) such as patient age, tumor characteristics, nodal status, staging, recurrence and death, as defined by NRLBH requirements and agreed to in writing by both parties
- NRLBH to use its NextCyte gene chip microarray test on the tissue samples provided by TME and provide per sample results back to TME
- NRLBH shall perform own data analysis and provide the results of such testing and analysis to TME
- TME will provide Consultant Services, at the rates stated below, including interpretation of these data clinical value, and recommendations for next steps, if desired by NRLBH

If mutually desirable and agreed upon by NRLBH and TME for the fees outlined below for Consulting Services, TME principle investigators may co—author publication/s of the results

TME Tissue Samples with Clinical Annotations will be provided per the description below:

- 100 FFPE de—identified (no patient identifiers) breast tissue samples with clinically relevant annotations specific to the NRLBH testing objective/s for NextCyte gene chip microarray test to include:
  - 50 from patients diagnosed with node positive disease with five year minimum follow up
  - 50 from patients diagnosed with node negative disease with five year minimum follow up
  - Samples from up to 4 diverse breast specialist practices

Clinical annotations will include traditional pathologic parameters and the 5year + follow up data, such parameters as requested by NRLBH and agreed to in writing by TME.

Tissue Sample/Data Use

All of the data/samples/reports provided by TME to NRLBH, as documented within this SOW, will be used for the sole purpose of establishing that NextCyte gene chip microarray test alone and/or in conjunction with the clinical and pathology report results can analyze breast cancer from FFPE tissues samples in a retrospective cohort and predict:

1) Lymph node status
2) Five year recurrence
3) Systemic treatment impact

The tissue samples, or any parts thereof, and/or annotated clinical data provided by TME shall not be used for any other purpose(s) unless agreed to in writing by TME prior to such use(s). The parties agree that the tissue samples or any data provided by TME to NRLBH will not be used for subject identification. The parties agree that certain other uses may require a separate agreement, including separate costs, for such usage, that is agreed upon by the parties.

Deliverables and Timelines

Deliverable	Timeline
TME provide a total of 100 patient tissue samples plus matched clinical data	As soon as practically feasible after Master Agreement and SOW signing and upon receipt of clinical data requirements from NRLBH
TME provide additional tissue samples plus clinical data to complete the project (as needed and determined by NRLBH)	As soon as practically feasible after receipt of request
NRLBH to provide sample test results to TME	Upon completion of testing
NRLBH provide to TME analysis and review of aggregate and analyzed data	TBD
TME provide Consulting services	TBD

Compensation

Based on the scope of the project outlined in this Statement of Work, the total cost of this project will be $162,600, plus any additional fees for Consulting Services billed at the hourly Consultant rate provided herein.

Payment Schedule

The parties agree to the payment amounts and due dates for such payments as provided below. Payments shall be made by NRLBH by check to TME:

TME Research
Suite 302
250 Cetronia Road
Allentown, Pa. 18104

Description of Services Provided	Due Date	Amount
Start—Up Costs: · Study Concept development including review of data requirements and objectives, create data collection strategy, development of research protocol and clinically annotated data collection tool and IRB submission for PI and Sub—investigators · Licensing of/Access to/utilization of TME database for study purposes · Investigator site start up and training costs · PI site admin/closing costs/document storage, etc. · Investigator path lab start up and training costs	At Master Agreement and SOW Signing, receipt of data requirements from NRLBH	$99,600
Slide Preparation & Delivery — Initial Delivery: · Study Supervision—Clinical Coordinator/project manager · Screening and enrollment of patients for inclusion · Pathology slide prep, shipping · Data extraction and organization from TME database	At time of Initial Delivery of first 25 samples plus data sets	$31,500

Slide Preparation & Delivery — Final Delivery & Payment for any Additional Slide Delivery: · Study Supervision—Clinical Coordinator/project manager · Screening and enrollment of patients for inclusion · Pathology slide prep, shipping, · Data extraction and delivery from TME database	At time of final Delivery	$31,500
Additional patient screening, data extraction, preparation slide and shipping to meet stated objective of 100 evaluable patients	Upon Delivery	$450 per slide set with annotated data (slide set defined as set of FFPE slides provided for each patient)
Consulting Services: • Analysis • Interpretation/recommendations • Publications	TBD (as agreed to in writing by the parties)	$500/hour/consultant

Additional Terms

In addition to the terms and conditions of the Master Agreement, the parties agree:

(1) that TME shall have the right to audit the processes/procedures used by NRLBH to conduct the testing and to audit the results of the tests reported by NRLBH. Such audit(s) will be conducted at a reasonable time and place agreed to by the parties after such request for audit is made by TME. All TME costs associated with such audit shall be borne by TME; and

Administrative Detail

- All state and federal laws regarding privacy, including HIPAA, will be followed in this engagement.
- This Statement of Work is consistent with meeting the protections stipulated by the Department of Health and Human Services' regulations related to the payment for personal and/or management services set forth at 42 C.F.R. §1001.952(d). No health care providers will receive any payments, or other remuneration, for the purpose of inducing them to utilize any TME product or service.
- TME represents and warrants that the fees charged to NRLBH are standard and are at or below the rates charged to other TME customers for the same or similar services. These rates are Fair Market Value (FMV) for the expertise offered by TME.

IN WITNESS WHEREOF, the parties have accepted and agreed to this Statement of Work:

TME Research, LLC		**The National Reference Laboratory for Breast Health, Inc.**	
By:	/s/ Mark Gittleman	By:	/s/ Kyle Guse
Name:	Mark Gittleman	Name:	Kyle Guse
Title:	President	Title:	CFO
Date:	9/1/14	Date:	9/14/14

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven C. Quay, certify that:

1. I have reviewed this Report of Atossa Genetics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2014

/s/ Steven C. Quay
Steven C. Quay
Chief Executive Officer and President
(Principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kyle Guse, certify that:

1. I have reviewed this Report of Atossa Genetics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2014

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Atossa Genetics Inc. (the "Company") on Form 10-Q for the period ending September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven C. Quay, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12 , 2014

/s/ Steven C. Quay
Steven C. Quay
Chief Executive Officer and President
(Principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Atossa Genetics Inc. (the "Company") on Form 10-Q for the period ending September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kyle Guse, Chief Financial Officer, General Counsel and Secretary of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2014

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)