ATOSSA GENETICS INC
Form 10-Q
December 21, 2012

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, 2012

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.)

4105 E. Madison Street, Suite 320	98112
Seattle, WA	(Zip Code)
(Address of principal executive offices)	

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 þ

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 þ

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

The number of shares of the registrant's common stock, $0.001 par value per share, outstanding at December 19, 2012 was 12,919,367.

ATOSSA GENETICS INC.

FORM 10-Q

QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. Consolidated FINANCIAL STATEMENTS - UNAUDITED

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (Unaudited)	December 31, 2011 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 418,570	$ 1,910,821
Restricted cash	250,000	1,000,000
Accounts receivable	175,408	1,224
Prepaid expense	39,975	31,184
Rental deposits	1,500	2,200
Total Current Assets	885,453	2,945,429
Fixed Assets		
Furniture and Equipment, net	67,497	80,467
Total Fixed Assets	67,497	80,467
Other Assets		
Security deposit	36,446	5,157
Intangible assets, net	4,703,078	40,841
Total Other Assets	4,739,524	45,998
Total Assets	$ 5,692,474	$ 3,071,894
Liabilities and Stockholders' Equity		
Current Liabilities		
Line of Credit	$ 250,000	$ 1,000,000
Accounts payable	72,100	64,766
Accrued expenses	1,888,344	442,329
Note payable - related party	80,453	5,078
Total Current Liabilities	2,290,897	1,512,173

Stockholders' Equity		
Preferred stock - $.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock - $.001 par value; 75,000,000 shares authorized, 12,119,367 shares issued and outstanding	12,119	11,257
Additional paid-in capital	11,415,761	6,200,520
Accumulated deficit	(8,026,303)	(4,652,056)
Total Stockholders' Equity (Deficit)	3,401,577	1,559,721
Total Liabilities and Stockholders' Equity	$ 5,692,474	$ 3,071,894

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

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For The Three Months Ended September 30,		For The Nine Months Ended September 30,		From April 30, 2009 (Inception) Through September 30, 2012
	2012	2011	2012	2011	
Revenue					
Diagnostic Testing Service	$ 104,011	$ -	$ 376,696	$ -	$ 376,696
Product Sales	1,565	-	6,690	-	8,190
Total Revenue	105,576	-	383,386	-	384,886
Cost of Revenue					
Diagnostic Testing Service	(9,000)	-	(29,985)	-	(29,985)
Product Sales	-	-	-	-	(5,164)
Total Cost of Revenue	(9,000)	-	(29,985)	-	(35,149)
Loss on Reduction of Inventory to LCM	(6,077)	-	(29,884)	-	(121,910)
Gross Profit	90,499	-	323,517	-	227,827
Selling expenses	(87,704)	-	(281,971)	-	(455,026)
General and Administrative expenses	(1,138,467)	(1,274,189)	(3,405,198)	(2,231,906)	(7,766,497)
Total operating expenses	(1,226,171)	(1,274,189)	(3,687,169)	(2,231,906)	(8,221,523)
Operating Loss	(1,135,672)	(1,274,189)	(3,363,652)	(2,231,906)	(7,993,694)
Interest Income	46	2,267	1,219	3,428	6,588
Interest Expense	(7,756)	(758)	(11,816)	(8,388)	(38,947)
Net Loss before Income Taxes	(1,143,382)	(1,272,680)	(3,374,249)	(2,236,866)	(8,026,053)
Income Taxes	-	-	-	-	250
Net Loss	$ (1,143,382)	$ (1,272,680)	$ (3,374,249)	$ (2,236,866)	$ (8,026,303)
Loss per common share - basic and diluted	$ (0.10)	$ (0.11)	$ (0.30)	$ (0.27)	$ (1.05)
	11,256,867	11,256,867	11,256,867	8,394,219	7,657,400

Weighted average shares outstanding, basic & diluted	

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

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For The Nine Months Ended September 30, 2012	For The Nine Months Ended September 30, 2011	For The Period From April 30, 2009 (Inception) to September 30, 2012
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (3,374,249)	$ (2,236,866)	$ (8,026,303)
Common shares issued for services	-	-	71,000
Compensation cost for stock options granted	96,251	111,288	266,703
Loss on reduction of inventory to LCM	29,884	-	121,910
Loan initiation fee accrued for notes payable	-	-	2,000
Depreciation and amortization	25,586	6,420	41,208
Adjustments to reconcile net loss to net cash provided by operating activities:			
Increase in accounts receivable	(174,183)	-	(175,407)
Increase in inventory	(29,884)	-	(121,910)
Increase in prepaid expenses	(8,791)	(41,946)	(39,975)
Increase in security deposits	(30,589)	(2,200)	(37,946)
Increase (decrease) in accounts payable	7,335	(1,500)	72,101
Decrease in accrued payroll	-	(278,571)	-
Increase (decrease) in accrued expenses	1,491,014	(10,392)	1,933,342
Net cash used in operating activities	(1,967,626)	(2,453,767)	(5,893,277)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of furniture & fixtures	-	(35,776)	(86,465)
Purchase of software	-	(49,500)	(50,466)
Net cash used in investing activities	-	(85,276)	(136,931)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net proceeds from issuance of common stocks and warrants	400,000	5,713,785	6,370,325
(Repayments of) Proceeds from bank line of credit	(750,000)	1,000,000	250,000
Proceeds from (repayments of) loans from related parties	75,375	(179,000)	78,453
Cash released from (restricted for) commercial line of credit	750,000	(1,000,000)	(250,000)
Net cash provided by financing activities	475,375	5,534,785	6,448,778
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS	(1,492,251)	2,995,742	418,570
CASH & CASH EQUIVALENTS, BEGINNING BALANCE	1,910,821	10,253	-
CASH & CASH EQUIVALENTS, ENDING BALANCE	$ 418,570	$ 3,005,994	$ 418,570

SUPPLEMENTAL DISCLOSURES:			
Interest paid	$ 13,892	$ 5,389	$ 19,281
Income taxes paid	$ -	$ -	$ 250
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Common stock and warrants issued for assets purchase	$ 4,674,853	$ -	$ -
Options issued for previously accrued director compensation	$ 45,000	$ -	$ -

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

ATOSSA GENETICS INC.

Notes to Consolidated Financial Statements

(Unaudited)

September 30, 2012

NOTE 1: NATURE OF OPERATIONS

The Company's operations began in December 2008 with the negotiations for the acquisition of the Mammary Aspirate Specimen Cytology Test System, or the MASCT System, patent rights and assignments and the FDA clearance for marketing, which acquisition was completed in January 2009. Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was formed to develop and market the MASCT System, a cellular and molecular diagnostic risk assessment product for the detection of pre-cancerous changes that could lead to breast cancer. The Company's fiscal year ends on December 31st.

In December 2011 the Company established the National Reference Laboratory for Breast Health, or NRLBH, as a wholly-owned subsidiary. NRLBH is the Company's CLIA-certified laboratory where the ForeCYTE and ArgusCYTE test specimens are examined for the presence of normal, pre-malignant, or malignant changes as determined by cytopathology and biomarkers that distinguish "usual" ductal hyperplasia, a benign condition, from atypical ductal hyperplasia, which may lead to cancer. These cytopathological results provide patients and physicians with information about the care path that should be followed, depending on the individual risk of future cancer as determined by the results.

In September 2012 the Company acquired the assets of Acueity Healthcare, Inc. ("Acueity"). The assets included six 510(k)-cleared medical devices, 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries). The FDA-cleared, patented medical devices consist of microendoscopes, light sources, and biopsy tools. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the duct system via fiberoptic video images. Abnormalities that are visualized can then be biopsied from inside the duct with the biopsy tools that are inserted adjacent to the microendoscope. The 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.

Development Stage Risk

From April 30, 2009 (inception) through September 30, 2012, the Company earned $384,886 in revenue from the sale of its MASCT System and laboratory services. The Company's activities have been accounted for as those of a "Development Stage Enterprise" as set forth in Accounting Standards Codification ("ASC") 915 "Development Stage Entities", which was previously Statement of Financial Accounting Standards No. 7 ("SFAS 7"). Among the disclosures required by ASC 915 are that the Company's financial statements be identified as those of a development stage company, and that the statements of operations, stockholders' equity and cash flows disclose activity since the date of the Company's inception.

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 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. The accompanying 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, among other things, additional capital resources. Management's plans to obtain such resources for the Company include (1) obtaining capital from the sale of its equity securities, (2) sales of the MASCT System and laboratory service revenue, and (3) short-term borrowings from banks, stockholders or other related 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

The unaudited consolidated financial statements of Atossa Genetics Inc. have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. However, the information included in these interim consolidated financial statements reflects all adjustments (consisting solely of normal recurring adjustments) which are, in the opinion of management, necessary for the fair presentation of the consolidated financial position and the results of operations. Results shown for interim periods are not necessarily indicative of the results to be obtained for a full year. The consolidated balance sheet information as of December 31, 2011 was derived from the Company's audited consolidated financial statements. These interim consolidated financial statements should be read in conjunction with that report. Certain comparative amounts have been reclassified to conform to the current period's presentation.

Basis of Presentation:

The accompanying 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

Recently Issued Accounting Pronouncements:

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company. The adoption of these accounting pronouncements, including those not yet effective, is not anticipated to have a material effect on the financial position or results of operations of the Company.

Revenue Recognition:

Overview

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

Product Revenue

The Company recognizes revenue for sales of the MASCT kits and devices upon receipt of cash as the Company has an insufficient sales history on which to determine the collectability. Shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery. The Company will assess whether a price is fixed or determinable based upon the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. Once a history of sales and collectability has been established, the company will recognize revenue on an accrual basis with an offsetting reserve for doubtful accounts based on the history during the initial sales period.

Service Revenue

The Company records revenue for diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount. Amounts invoiced above the Medicare amount, namely non-Medicare, are not recognized on an accrual basis and instead are recognized on a cash basis as received. Diagnostic testing revenue at the Medicare rate is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Customer purchase orders and/or contracts will generally be used to determine the existence of an arrangement. Once the Company has historical sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare and non-Medicare billing on an accrual basis, with an offsetting allowance for doubtful accounts recorded based on history. The Company estimates it will utilize the diagnostic testing revenue history once it reaches 12 months of collection data to determine a proper allowance for doubtful accounts.

Cash and Cash Equivalents:

Cash and cash equivalents include cash and all highly liquid instruments with original maturities of three months or less.

As of September 30, 2012 and December 31, 2011, $250,000 and $1,000,000 of cash was restricted as collateral for a commercial line of credit obtained from JPMorgan Chase Bank in September 2011 (see Note 8). These amounts were designated as restricted cash under current assets on our consolidated balance sheets.

Use of Estimates:

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Accounts Receivable:

Accounts receivable are recorded at net realizable value consisting of the carrying amount less allowance for doubtful accounts, as needed. We assess the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer’s payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer credit worthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of these reserves.

Inventories:

The Company's inventories are stated at lower of cost or market. Cost is determined on a moving-average basis. Costs of inventories include purchase and related costs incurred in delivering the products to their present location and condition. Market value is determined by reference to selling prices after the balance sheet date or to management's estimates based on prevailing market conditions. Inherent in the lower of cost or market calculation are several significant judgments based on a review of the aging of the inventory, inventory movement of products, economic conditions, and replacement costs. Because the sales price of the MASCT System was substantially lower than its cost for the nine months ended September 30, 2012 and for the year ended December 31, 2011, resulting in the net realizable value of the MASCT System being determined at zero as of the balance sheet dates through taking the average sales price subtracted by selling expenses per unit, a $29,884 and $92,026 loss on reduction of inventory to the lower of cost or market was assessed and recorded as of and for the period and for the year then ended, respectively. Additionally, management periodically evaluates the composition of its inventories at least quarterly to identify slow-moving and obsolete inventories to determine if any valuation allowance is required. As of September 30, 2012 and December 31, 2011, management had identified no slow moving or obsolete inventory.

The Company provides ForeCYTE testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the Company for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System, and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits. For the nine months ended September 30, 2012 and for the year ended December 31, 2011, selling expense of $36,741 and $0 was recorded related to the ForeCYTE kits, respectively.

Property, plant, and equipment:

Property, plant and equipment are stated at cost less accumulated depreciation. Expenditures for maintenance and repairs are charged to earnings as incurred; additions, renewals and betterments are capitalized. When property, plant and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation are removed from the respective accounts, and any gain or loss is included in operations.

Depreciation is computed using the straight-line method over the estimated useful lives of the assets as follows:

	Useful Life (in years)
Machinery and equipment	5

Intangible assets:

For intangible assets subject to amortization, an impairment loss is recognized if the carrying amount of the intangible asset is not recoverable and exceeds fair value. The carrying amount of the intangible asset is considered not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use of the asset. Intangible assets as of September 30, 2012 and December 31, 2011 were mainly software acquired for the purpose of managing laboratory results and patents acquired (see Note 7).

Research and Development Expenses:

Research and development costs are generally expensed as incurred. The Company's research and development expenses consist of costs incurred for internal and external research and development.

Share Based Payments:

In December 2004, the Financial Accounting Standards Board, or the FASB, issued the Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share-Based Payment", which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in the FASB's ASC Topic 718, "Compensation – Stock Compensation." Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees or independent contractors are required to provide services. Share-based compensation arrangements include stock options and warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or SAB 107, which expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for SFAS No. 123(R). Companies may elect to apply this statement either prospectively, or on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123.

The Company has fully adopted the provisions of FASB ASC 718 and related interpretations as provided by SAB 107. As such, compensation cost is measured on the date of grant as the fair value of the share-based payments. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2012	December 31, 2011
Prepaid payroll taxes	$ 36,083	$ -
Prepaid insurances	2,472	14,146
Prepaid hardware/software maintenance and support service fee	1,420	12,850
Prepaid rent	-	4,188
	$ 39,975	$ 31,184

NOTE 5: RENTAL DEPOSITS

Rental deposits amounted to $1,500 and $2,200 as of September 30, 2012 and December 31, 2011, respectively, mainly consisted of the security deposits for office leases. The rental deposit in the amount of $1,500 as of September 30, 2012 consisted of one office lease with the lease term from April 1, 2011 to March 31, 2013 (see Note 13). The rental deposits of $2,200 as of December 31, 2012 consisted of two office leases separate from the one as of September 30, 2012, and the lease terms were from July 11, 2011 to July 31, 2012 and from October 1, 2011 to March 31, 2012 (see Note 13). Both were terminated on July 31, 2012 and March 31, 2012, respectively and were not renewed, and the security deposits have been received in full amount as of September 30, 2012.

NOTE 6: PROPERTY, PLANT, AND EQUIPMENT

Property, plant and equipment consisted of the following:

	September 30, 2012	December 31, 2011
Machinery and equipment	$ 86,465	$ 86,465
Less: Accumulated depreciation	(18,968)	(5,998)
Property, plant, and equipment, net	$ 67,497	$ 80,467

Depreciation expense for the nine months ended September 30, 2012 and 2011 was $12,970 and $3,920, respectively.

NOTE 7: INTANGIBLE ASSET

Intangible assets consisted of the following:

	September 30, 2012	December 31, 2011
Software	$ 50,466	$ 50,466
Patents	4,674,853	-
Less: Accumulated amortization	(22,241)	(9,625)
	$ 4,703,078	$ 40,841

Intangible asset amounted to $4,703,078 and $40,841 as of September 30, 2012 and December 31, 2011, respectively, and mainly consisted of patents acquired from Acueity in September 2012 in an asset purchase transaction and software previously acquired for the purpose of managing laboratory results. The acquired software in the amount of $50,466 for the purpose of managing laboratory results pursuant to a software installation agreement was entered into on June 8, 2011. The amortization period for the purchased software is 3 years. Amortization expense for the nine months ended September 30, 2012 and 2011 was $12,616 and $5,500, respectively.

Patents

Patents amounted to $4,674,853 and $0 as of September 30, 2012 and December 31, 2011, respectively, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction (see Note 15).

Patents will be 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 $0 for the nine months ended September 30, 2012 and 2011, respectively.

Future estimated amortization expenses as of September 30, 2012 for the five succeeding years is as follows:

As of September 30,	Amounts
2013	$376,841
2014	371,341
2015	360,100
2016	360,019
2017	360,019
Thereafter	2,874,758
	$4,703,078

NOTE 8: LINE OF CREDIT

In June 2011, the Company entered into a commercial line of credit agreement with JPMorgan Chase Bank. The term of the loan started from June 28, 2011 with maturity date on June 28, 2012. On July 23, 2012, the Company entered into a business loan extension agreement with JPMorgan Chase Bank to extend the loan for three months from the original maturity date. The line of credit agreement provides for borrowings up to $1,000,000. The adjustable interest rate is a rate per annum equal to the sum of an index, which is the LIBOR Rate plus 1.914 percentage point(s). The outstanding balance of the line of credit was $250,000 and $1,000,000 as of September 30, 2012 and December 31, 2011, respectively. The adjustable annual interest rate for the line of credit was 2.9138% and 2.2070% as of September 30, 2012 and December 31, 2011, respectively. On October 22, 2012, the Company paid off the line of credit in full amount.

As of September 30, 2012 and December 31, 2011, $250,000 and $1,000,000 of cash was restricted as collateral for the commercial line of credit, respectively.

NOTE 9: ACCRUED EXPENSES

Accrued expenses consisted of the following:

	September 30, 2012	December 31, 2011
Accrued expenses	$ 1,744,555	$ 201,113
Accrued bonus payable	135,239	153,830
Accrued payroll tax liabilities	7,951	87,386

Accrued interest	599	-
	$ 1,888,344	$ 442,329

NOTE 10: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of Common Stock, par value $0.001 per share, and 10,000,000 shares of Preferred Stock, par value $0.001 per share.

Reverse Stock-Split

On September 28, 2010, the Board of Directors approved a 1-for-2.26332 reverse share split for all issued and outstanding shares of Common Stock, with no change to the par value of the Common Stock.

Prior Issuances of Common Stock

On April 30, 2009 (inception), the Company issued 1,767,316 shares (or 4,000,000 shares prior to the reverse stock-split on September 28, 2010) to Ensisheim Partners LLC, a related party to the Company through common ownership, for cash in the amount of $24,000, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010); 1,325,487 shares (or 3,000,000 shares prior to the reverse stock-split on September 28, 2010) to Manistee Ventures LLC, a related party to the Company through common ownership, for cash in the amount of $18,000, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010); and 883,662 shares (or 2,000,000 shares prior to the reverse stock-split on September 28, 2010) to the Chairman, CEO and President of the Company at that time for cash in the amount of $12,000, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010).

On July 28, 2009, the Company issued 39,765 shares (or 90,000 shares prior to the reverse stock-split on September 28, 2010) to a director of the Company for cash in the amount of $540, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010).

On December 28, 2009, the Company issued 883,658 shares (or 2,000,000 shares prior to the reverse stock-split on September 28, 2010) to Ensisheim Partners LLC for cash in the amount of $100,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010).

On January 21, 2010, the Company issued 866,007 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) to forty-four (44) investors for cash in the amount of $98,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010).

On January 21, 2010, the Company issued 132,549 shares (or 300,000 shares prior to the reverse stock-split on September 28, 2010) to a servicer for effecting transactions intended to cause the Company to become a public company and to have its securities traded in the United States. The shares were issued at a value of $15,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010), the same price as the issuance of the 866,007 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date.

On January 21, 2010, the Company issued an additional 53,020 shares (or 120,000 shares prior to the reverse stock-split on September 28, 2010) to a shareholder who acquired 13,255 shares (or 30,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date as one of the forty-four (44) investors. Those shares were issued to the shareholder for services to be performed, including investor relations, media relations, and corporate communications. Those shares were issued at a value of $6,000, or $0.11 per share (or $0.05 per share prior

to the reverse stock-split on September 28, 2010), the same price as the issuance of the 866,007 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date.

On January 23, 2010, the Company issued 35,346 shares (or 80,000 shares prior to the reverse stock-split on September 28, 2010) to an investor for cash in the amount of $4,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010).

On April 27, 2010, the Company issued 13,256 shares (or 30,000 shares prior to the reverse stock-split on September 28, 2010) to a service provider for website development services pursuant to an original agreement between the Company and the web site developer executed on December 14, 2009 (the “measurement date”), where it was agreed at that time that, at the Company’s option, $50,000 would be paid or 13,256 shares (or 30,000 shares of common stock prior to the reverse stock-split on September 28, 2010) would be issued to the developer in exchange for his services.

On September 30, 2012, the Company issued 862,500 shares to the shareholders of Acueity as part of the consideration for the asset purchase (see Note 15). The shares were valued at $5.00 per share, the offering price of the then contemplated initial public offering, for which the registration statement on Form S-1 (File No. 333-179500) was subsequently declared effective by the Securities and Exchange Commission on November 7, 2012, and a prospectus was subsequently filed pursuant to Rule 424(b)(4) on November 9, 2012 (see Note 16), or $4,312,500 in total.

Private Placements and Warrants

On April 28, May 31, June 10, and June 23, 2011, pursuant to Securities Purchase Agreements with various investors (the "Investors"), the Company issued 5,256,800 shares of the Company's common stock and 5,256,800 warrants (the "Investor Warrants"), each of which entitles the investors to purchase the Company's common stock at $1.25 per share, for aggregate gross proceeds of $6,571,000 (the "Private Placement").

Placement Agent Fees

In connection with the Private Placement, the Company paid Dawson James Securities, Inc. (the "Placement Agent"), a cash fee equal to 10% of the gross proceeds from sale of the common stocks and warrants, plus 3% non-accountable expense allowance, an aggregate of $857,230 (the "Placement Agent Fee"). In addition, the Company entered into Warrant Agreements with the placement agent pursuant to which the Placement Agent received 788,520 warrants (the "Placement Agent Warrants"), each of which entitles the Placement Agent to purchase one share of the Company's common stock at $1.60 per share, plus an additional 788,520 warrants (the "Placement Agent Warrants"), each of which entitles the placement agent to purchase the Company's common stock at $1.25 per share. The cash payment of $857,230 Placement Agent Fee and the $495,876 aggregated initial fair value of the 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 Warrants, including the Investor Warrants and the Placement Agent Warrants, are exercisable at any time commencing after the earliest of the following to occur (the "Initial Exercise Date"):

(a) Six (6) months from the closing of the Company Initial Public Offering (initial public offering of the Company's Common Stock registered under the Securities Act),

(b) The closing of a "fundamental transaction" (in case of any reclassification, capital reorganization, exchange of shares, liquidation, recapitalization or change of the Common Stock, or in case of any consolidation or merger of the Company with or into another corporation or entity, or in case of any sale, lease or conveyance to another corporation or entity of all or substantially all of the assets of the Company), or

(c) Closing of a "significant private financing" (sale of the Company's securities primarily for capital raising purposes in a transaction or series of related transactions that is exempt from registration under the Securities Act and in which the Company issues securities representing at least 20% of the then outstanding capital stock of the Company, calculated assuming the conversion or exercise of all outstanding options, warrants and other securities convertible into or exercisable for capital stock of the Company).

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The Warrants shall expire and no longer be exercisable on the fifth anniversary of the Initial Exercise Date (the "Expiration Date"). The Company may at any time during the term of this Warrant reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the Board of Directors of the Company. The Warrants may be exercised for cash or, at the option of the Investor, may be exercised on a cashless basis. There are no redemption features embodied in the Warrants and they have met the conditions provided in current accounting standards for equity classification.

As a result of the amount of money raised in the Private Placement, the Private Placement constituted a "significant private financing" and the warrants became exercisable on June 30, 2011.

Fair Value Considerations

The Company's accounting for the issuance of warrants to the Investors and the Placement Agent 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 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 fair value these instruments.

The Investor Warrants and the Placement Agent Warrants were initially valued at $1,808,025 or $0.344 per warrant, $228,712 or $0.290 per warrant, and $267,164 or $0.339 per warrant, respectively. The following tables reflect assumptions used to determine the fair value of the Warrants:

		April-June2011	December 2011	
	Fair Value Hierarchy Level	Investor Warrants	Placement Agent Warrants	Placement Agent Warrants
Indexed shares		5,256,800	788,520	788,520
Exercise price		$ 1.60	$1.60	$1.25
Significant assumptions:				
Stock price	3	$ 0.906	$0.906	$0.906
Remaining term	3	6 years	6 years	6 years
Risk free rate	2	2.49 %	1.12 %	1.12 %
Expected volatility	3	53.55 %	54.21 %	54.21 %

Fair value hierarchy of the above assumptions can be categorized as follows:

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

- Risk-free rate- The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the warrants.

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(3) Level 3 inputs include:

- Stock price- The Company's common stock was not publicly traded at the time the Warrants were issued. Therefore, the stock price was determined implicitly from an iterative process in order for the combined fair value of the common stock and the warrants to equal the amount of proceeds received in the Private Placement, based upon the assumption that the Private Placement was the result of an arm's length transaction.

- Remaining term- The Company does not have a history to develop the expected term for its warrants. Accordingly, the Company expected that the Initial Exercise Date to occur within one year from the date of issuance plus the contractual term in the calculations.

- Expected volatility- We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by ASC 718-10-30, the Company has accounted for the warrants using the calculated value method. The Company identified seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

Asset Purchase and Warrants

On September 30, 2012, pursuant to the asset purchase agreement with Acueity, the Company issued 862,500 shares of common stock and 325,000 warrants ("Acueity Warrants") to the shareholders of Acueity, each of which entitles the recipients to subscribe for and purchase from the Company one share of the Company's common stock at $5.00 per share (the "Exercise Price"), subject to a six-month lock up agreement.

Warrants

The Acueity Warrants are exercisable at any time commencing after September 30, 2012 (the "Issuance Date") and shall expire and no longer be exercisable on the fifth anniversary of the Issuance Date (the "Expiration Date"). The Company may at any time during the term of the Acueity Warrants reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the Board of Directors of the Company. The Acueity Warrants do not have a cashless exercise provision. There are no redemption features embodied in the Acueity Warrants and they have met the conditions provided in current accounting standards for equity classification.

Fair Value Considerations

The Company’s accounting for the issuance of the Acueity 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 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 fair value these instruments.

The Acueity Warrants were valued at $762,353 or $2.3457 per warrant. The following tables reflect assumptions used to determine the fair value of the Warrants:

	Fair Value Hierarchy Level	September 2012 Acueity Warrants	
Indexed shares		325,000	
Exercise price		$ 5.00	
Significant assumptions:			
Stock price	3	$ 5.00	
Remaining term	3	5 years	
Risk free rate	2	0.62	%
Expected volatility	3	56.54	%

Fair value hierarchy of the above assumptions can be categorized as follows:

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

- Risk-free rate- The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the warrants.

(3) Level 3 inputs include:

- Stock price- The Company’s common stock was not publicly traded at the time the Acueity Warrants were issued. Therefore, the stock price was determined at the offering price of the then contemplated initial public offering, for which the registration statement on Form S-1 (File No. 333-179500) was subsequently declared effective by the Securities and Exchange Commission on November 7, 2012, and a prospectus was subsequently filed pursuant to Rule 424(b)(4) on November 9, 2012 (see Note 16).

- Remaining term- The Company does not have a history to develop the expected term for its warrants. Accordingly, the Company expected that the Initial Exercise Date to occur within one year from the date of issuance plus the contractual term in the calculations.

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Expected volatility- We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by ASC 718-10-30, the Company has accounted for the warrants using the calculated value method. The Company identified seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

Stock Option 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, subject to stockholder approval, 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 (or 2,263,320 shares prior to the reverse stock-split on September 28, 2010) are 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 April 4, 2011, 45,000 non-qualified stock options were granted under the Plan to Dr. Tim Hunkapiller for being a member of the Company's Scientific Advisory Board and consulting services to be provided to the Company.

On September 1, 2011, 219,000 incentive stock options were granted under the Plan to employees and officers and 200,000 non-qualified stock options were granted under the Plan to non-employee directors, respectively, for their employment with and services to be provided to the Company (see Note 14).

On April 30, 2012, 19,757 non-qualified stock options were granted under the Plan to members of the Board of Directors for their services provided to the Company.

NOTE 11: INCOME TAXES

The Company accounts for income taxes as outlined in ASC 740, “Income Taxes”, which was previously Statement of Financial Accounting Standards No. 109, “Accounting for Income Taxes” (“SFAS 109”). Under the asset and liability method of SFAS 109, deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company’s cumulative losses, management has concluded that a full valuation allowance against the Company’s net deferred tax assets is appropriate. No income tax liabilities existed as of September 30, 2012 and December 31, 2011 due to the Company’s continuing operating losses.

NOTE 12: 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, 2012 and December 31, 2011, the Company had $418,570 and $2,660,821 in excess of the FDIC insured limit, respectively.

NOTE 13: COMMITMENTS AND CONTINGENCIES

Lease Commitments

On September 29, 2010, the Company entered into a commercial lease agreement with CompleGen, Inc. for laboratory space located in Seattle, WA. The lease provides for monthly rent of $3,658 and a security deposit of $3,658. The lease terms are from September 29, 2010 through March 31, 2011, at which time the lease has converted to month to month unless two months' prior written notice of the intent to terminate the agreement is given. The monthly rent for the lease increased to $4,267 commencing January 2012. For the nine months ended September 30, 2012, the Company incurred $38,403 of rent expense for the lease.

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 provides for monthly rent of $1,100 and a security deposit of $1,500. The lease terms are from April 1, 2011 through March 31, 2013. For the nine months ended September 30, 2012, the Company incurred $9,900 of rent expense for the lease.

On July 9, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $600 and a security deposit of $1,200. The lease terms are from July 11, 2011 through July 31, 2012. For the nine months ended September 30, 2012, the Company incurred $4,200 of rent expense for the lease. This lease terminated on July 31, 2012 and was not renewed.

On September 27, 2011, the Company entered into another commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $1,400 and a security deposit of $1,000. The lease terms are from October 1, 2011 to March 31, 2012. For the period of October 1, 2011 through March 31, 2012, the Company incurred $8,400 of rent expense for the lease. This lease terminated on March 31, 2012 and was not renewed.

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 as of September 30, 2012. For the nine months ended September 30, 2012, the Company incurred $161,424 of rent expense for the lease, which included leasing office management expenses.

The future minimum lease payments due subsequent to September 30, 2012 under all non-cancelable operating leases for the next five years are as follows:

As of September 30,	Amount
2013	$246,296
2014	246,575
2015	41,096
2016	-
2017	-
Thereafter	-
Total minimum lease payments	$533,967

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) and the Company. The consulting agreement was terminated by the Company in September 2010. Mr. Kelly seeks $450,000 in compensatory damages, which is the amount he claims would have been earned had the consulting agreement been fulfilled to completion. A hearing in the arbitration is currently set for March 2013 but may be delayed to accommodate other third party civil and criminal proceedings that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

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. The specific amount of damages sought is to be proven at trial and not specified.

The Company is reasonably confident in its defenses to Mr. Kelly's claims. Consequently, no provision or liability has been recorded for Mr. Kelly's claims as of September 30, 2012. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

NOTE 14: RELATED PARTY TRANSACTIONS

Loans from Officer

On May 26, 2009, the Company borrowed $5,000 from its Chairman of the Board and Chief Executive Officer as a short-term, unsecured loan via verbal agreement and did not bear any interest. Commencing June 30, 2010, the loan was converted into a written Promissory Note bearing an annual interest rate of 10%, with a maturity date of December 31, 2010. This note was repaid in full on May 16, 2011 including approximately $439 of accrued interest.

On June 30, 2010, the Company borrowed an additional $100,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The loan under the note was funded to the Company on July 12, 2010. The note bears a 10% interest rate per annum and carries a $4,000 loan origination fee which is accreted to the loan balance throughout the life of the loan. The $4,000 loan origination fee was fully accreted to the loan balance as of March 31, 2011 and December 31, 2010, and recorded as interest expense for the year ended December 31, 2010. This note (including the $4,000 origination fee) was repaid in full on May 19, 2011 including approximately $8,959 in accrued interest.

On November 3, 2010, the Company entered into a line of credit agreement for borrowing up to $500,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The note bears a 10% interest rate per annum. An aggregate of $140,000 was funded to the Company under the line of credit as of March 31, 2011 which was repaid on May 31, 2011, including approximately $6,093 in accrued interest. As of December 31, 2011, the unpaid principal balance drawn from the line of credit was $5,078, which was fully repaid on March 31, 2012.

On July 30, 2012, the Company entered into a line of credit agreement for borrowing up to $500,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The note bears a 12% interest rate per annum. An aggregate of $79,300 was funded to the Company under the line of credit as of September 30, 2012, and the accrued interest was $1,153 as of September 30, 2012. The principal balance of $79,300 was fully repaid on October 11, 2012.

Exclusive License Agreement

On July 27, 2009, the Company entered into an exclusive license agreement with Ensisheim Partners LLC (“Ensisheim”), an entity solely owned by the Chairman and Chief Executive Officer of the Company and the Chief Technology Officer of the Company, who is also the Company’s Chairman and CEO’s wife. Pursuant to that

agreement, Ensisheim granted the Company an exclusive, worldwide, perpetual, irrevocable, royalty-bearing, license to the MASCT System, with the right to grant and authorize sublicenses. The license agreement provided that the Company would pay Ensisheim a royalty equal to 2% of net sales revenue, with a minimum royalty of $12,500 per fiscal quarter during the term of the agreement, which would have increased to a minimum royalty of $25,000 per fiscal quarter beginning in the quarter in which the first commercial sale of a licensed product would have taken place. From inception through December 31, 2010, the Company had incurred $16,250 in patent-related expenses under the license agreement with Ensisheim.

On June 17, 2010, the Company and Ensisheim entered into an Assignment Agreement, whereby Ensisheim assigned to the Company all rights to the patents and patent applications underlying the MASCT System. Pursuant to the assignment, the Company will have all responsibility for prosecution, maintenance, and enforcement and will indemnify Ensisheim from any and all claims against the patent estate. Ensisheim retained no residual rights with respect to the patents and patent applications. In conjunction with the assignment, the Company terminated the exclusive license agreement between the Company and Ensisheim dated July 27, 2009. As a result of the termination, the Company has no further obligations with respect to royalty payments to Ensisheim due under the old licensing agreement. As a result, the $12,500 of patent royalty payable to Ensisheim recorded as accrued royalty payable at December 31, 2009 has been reversed through royalty expense during the second quarter of 2010.

Commercial Lease Agreement

On December 24, 2009, the Company entered into a commercial lease agreement with Ensisheim for office space located in Seattle, Washington. The lease provided for annual rent of $13,200, plus applicable sales tax. From inception through December 31, 2009, the Company incurred $248 of rent expense for the lease with security deposit of $1,100. For the period of January 1, 2010 through June 30, 2010, the Company incurred $6,600 of rent expense for the lease. On July 15, 2010 the Company and Ensisheim terminated the lease, effective July 1, 2010 and the Company commenced use of the facility rent free until April 1, 2011 when the commercial lease agreement the Company entered into with Sanders Properties, LLC became effective (see Note 13). The $1,100 security deposit paid to Ensisheim was received as of September 30, 2012.

Executive Compensation

On May 19, 2010, the Company entered into employment agreements with three executives, including its Chief Executive Officer, its former President, and its Chief Technology Officer. The annual base salaries under each agreement were calculated based on combined consideration of the success of capital raise and the operating results of the Company, and capped at $360,000, $350,000, and $250,000, respectively for the three executives.

On July 22, 2010, in connection with the resignation and departure of Robert L. Kelly, the President and a director, the Company entered into a consulting agreement with a limited liability company controlled by Mr. Kelly. Under the agreement, the Company was to receive consulting services relating to capital raising and investor relations. The agreement was terminated by the Company in September 2010, through which time a total of $30,000 consulting expense had been paid.

On July 22, 2010, the Company restated and amended the employment agreements with its CEO and CTO. The agreements modified the base annual salary amounts to $250,000 and $200,000, respectively, effective retroactively to May 19, 2010. For the year ended December 31, 2011, the total amount of salaries and bonuses of the CEO and CTO was $693,048, of which $492,095 was recorded to research and development expense. For the nine months ended September 30, 2012, salaries and bonuses of CEO and CTO amounted to $269,438 and $200,550, of which $134,719 and $200,550 were recorded to research and development expense, respectively.

Share-Based Compensation

The amended employment agreement with the CEO, entered into on July 22, 2010, granted options to purchase 250,000 shares (or 565,830 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share, in consideration of his service to the Company. Of these options, 25% (or 62,500 shares) vested on December 31, 2010 with the remaining 75% (or 187,500 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

The amended employment agreement with the CTO, entered into on July 22, 2010, granted options to purchase 100,000 shares (or 226,332 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share in consideration of her service to the Company. Of these options, 25% (or 25,000 shares) vested on December 31, 2010 with the remaining 75% (or 75,000 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

On April 4, 2011, 45,000 non-qualified stock options were granted under the 2010 Stock Option and Incentive Plan to Dr. Tim Hunkapiller for being a member of the Company’s Scientific Advisory Board and consulting services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest as follows:

(i) 11,250 option shares shall vest ninety (90) days after the date of grant;
(ii) 11,000 option shares shall vest one hundred and eighty (180) days after the date of grant;
(iii) 11,500 option shares shall vest two hundred and seventy (270) days after the date of grant;
(iv) 11,250 option shares shall vest three hundred and sixty (360) days after the date of grant.

On September 1, 2011, 219,000 incentive stock options were granted under the 2010 Stock Option and Incentive Plan to employees and officers as part of their employment agreements, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) twenty-five percent (25%) of the underlying shares on the first anniversary of the date of grant; and
(ii) one-forty eighth (1/48) of the underlying shares monthly thereafter.

On September 1, 2011, 200,000 non-qualified stock options were granted under the 2010 Stock Option and Incentive Plan to non-employee directors for services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) 80,000 option shares shall vest on September 1, 2011;
(ii) 30,000 options shares shall vest on December 1, 2011;
(iii) 30,000 options shares shall vest on March 1, 2012;
(iv) 30,000 options shares shall vest on June 1, 2012;
(v) 30,000 options shares shall vest on September 1, 2012.

On April 30, 2012, 19,757 non-qualified stock options were granted under the 2010 Stock Option and Incentive Plan to non-employee directors for serving as directors of the Company, at an exercise price of $6.00 per share. These options have a ten-year contractual term and shall vest and become exercisable in full immediately as of the grant date.

In accordance with the guidance provided in ASC Topic 718, Stock Compensation (formerly SFAS 123R), the compensation costs associated with these 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 a compensation expense of $96,251 for the nine months ended September 30, 2012.

The Company estimated the fair value of these options using the Black-Scholes-Merton option pricing model based on the following weighted-average assumptions:

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	CEO & CTO		Dr. Hunkapiller		Employees & Officers		Non-employee Directors		Non-employee Directors	
Date of grant	22-Jul-10		4-Apr-11		1-Sep-11		1-Sep-11		30-Apr-12	
Fair value of common stock on date of grant	$ 2.756	(B)	$ 0.906	(C)	$ 0.906	(C)	$ 0.906	(C)	$ 6.00	(D)
Exercise price of the options	$ 5.00		$ 1.25		$ 1.25		$ 1.25		$ 6.00	
Expected life of the options (years)	3.33		5.31		5.65		5.65		5.00	
Dividend yield	0.00	%	0.00	%	0.00	%	0.00	%	0.00	%
Expected volatility	58.59	%	54.12	%	53.90	%	53.90	%	62.46	%
Risk-free interest rate	1.03	%	2.26	%	1.08	%	1.08	%	0.89	%
Expected forfeiture per year (%)	0.00	%	0.00	%		(A)	0.00	%	0.00	%
Weighted-average fair value of the options (per unit)	$ 0.6744		$ 0.3729		$ 0.3579		$ 0.3579		$ 3.0367	

(A) 0.00% for the first year after the grant date, and 2.50% for every three months thereafter.

(B) The fair value of the Company’s common stock was derived implicitly from the public offering filed in March 2010 at $3.00 per share and from the terms of an underwritten offering contemplated in July 2010 at $6.00 per Unit that was filed in October 2010, with $2.756 per share being allocated to common stock using an iterative approach in order for the combined fair value of the common stock and warrants to equal the amount of consideration to be received in the offering.

(C) The fair value of the Company’s common stock was derived implicitly from the Private Placement during April through June 2011 at $1.25 per Unit, wherein one Unit was comprised of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $1.60 per share.

(D) The fair value of the Company’s common stock was derived implicitly from the public offering filed in February 2012 at $6.00 per share.

In October 2010, the Company filed a Registration Statement on Form S-1 with the SEC. However, the market for early stage investments in medical technology transactions had deteriorated between mid-2010 and early 2011. In addition, the Company’s ability to negotiate with potential investors was limited. The Company’s cash position had also diminished since the summer of 2010 and the founders of the Company were unable to finance the Company at the level needed for growth. The withdrawal of the Registration Statement in February 2011 further weakened the impression of the Company in the market. The fair value of the Company’s common stock decreased from $2.756 in 2010 to $0.906 in 2011 primarily because the grants in 2011 relied on the arm’s-length negotiation of the private placement financing (for illiquid stock) as opposed to relying on an anticipated initial public offering (of publicly-traded stock), as was the case in 2010. The private placement transactions were between the company and over 200 accredited investors and ascribed a value of $0.906 to the Company’s common stock.

Fair value hierarchy of the above assumptions can be categorized as follows:

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

- Risk-free rate- The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the options.

(3) Level 3 inputs include:

- Expected lives- The expected lives of options granted were derived from the output of the option valuation model and represented the period of time that options granted are expected to be outstanding.

- Expected forfeitures per year- The expected forfeitures are estimated at the dates of grant and will be revised in subsequent periods pursuant to actual forfeitures, if significantly different from the previous estimates.

- Expected volatility- We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by ASC 718-10-30, the Company has accounted for the options using the calculated value method. The Company identified seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

The estimates of fair value from the model are theoretical values of stock options and changes in the assumptions used in the model could result in materially different fair value estimates. The actual value of the stock options will depend on the market value of the Company's common stock when the stock options are exercised.

Notwithstanding that the fair market value of the Company's common stock in September 2011 was $0.906 per share, the Company filed a Registration Statement on Form S-1 in February 2012 to offer shares of its common stock at $5.00 to $7.00 per share. This increase in share value is justified by the accomplishments achieved by the Company between September 2011 and February 2012. Specifically, the MASCT System manufacturing had been completed, supplies for the Field Experience Trial were completed and the Company had established an FDA-compliant inventory and warehousing facility. Further, the National Reference Laboratory for Breast Health, the Company's wholly-owned subsidiary, was established as a Delaware corporation, was equipped and staffed, and the protocols and procedures needed to be a CLIA-registered facility were put in place. Moreover, the ForeCYTE test, which involves cytopathology and five biomarkers of hyperplasia and one biomarker of sample integrity, was completed, tested, and validated to CLIA standards. Computer hardware and software was acquired, set up, made operational, and the ForeCYTE report template, with unique reporting information for the requesting physician and a patient letter template, were created. The company explored and identified a technology for the ArgusCYTE test, negotiated a supply agreement with the supplier, and tested and validated the test. An ArgusCYTE report template was also established and a new reporting scheme invented and a patent application filed.

Further, the Company negotiated the acquisition of the FullCYTE Microcatheter System from Hologics, reestablished the supply chain and began preparing for a commercial launch later in 2012 or early 2013. In doing so, the Company increased its U.S. patent portfolio from 5 to 31 and its total portfolio of patents and applications to over 120. The Hologic patent estate also contains the key patents that permit microcatheter-based intraductal treatment of cancer and pre-cancer. The Company also prepared marketing documents for the launch of the ForeCYTE and ArgusCYTE tests, which occurred in December 2011. The Company launched a clinical trial of the FullCYTE microcatheter to establish the feasibility of performing Next Generation Sequencing on the samples obtained with the microcatheter, negotiated the acquisition of the NextCYTE technology, and is conducting a study of the utility of the technology in providing superior information in the setting of cancer diagnosis and treatment selection.

The Company also established third-party relationships to perform the reimbursement billing in anticipation of the commercial launch and to permit electronic remittance of testing revenue. The Company launched a Field Test Experience limited launch of both the ForeCYTE and ArgusCYTE tests on schedule in December 2011 and has seen significant market acceptance of both tests from the doctors and clinics using the tests. The Company passed a CLIA inspection and became CLIA-certified, has obtained several state licenses and has pending applications in all remaining states where licensure is required. Finally, the Board of Directors and scientific advisory board were each strengthened with the addition of key new executives and scientists.

The Board of Directors considered each of the foregoing achievements, and considered input from the Company's investment bankers, in determining that the value of the Company supports a valuation of $5.00 to $7.00 per share of the Company's common stock when the Company filed its initial Registration Statement on Form S-1 in February

2012.

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Options issued and outstanding as of September 30, 2012 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
Outstanding as of January 1, 2012	608,000	$ 3.41	
Granted	19,757	6.00	
Expired	-	-	
Forfeited	-	-	
Outstanding as of September 30, 2012	627,757	3.49	5.51
Exercisable as of September 30, 2012	508,632	3.21	6.02
Vested and expected to vest [(1)]	624,049	3.50	5.49

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

As of September 30, 2012 and December 31, 2011, the aggregate intrinsic value of options outstanding, exercisable, and vested and expected to vest was $389,053 and $329,053, respectively.

A summary of the status of the Company’s unvested shares as of September 30, 2012 and changes during the period then ended is presented below:

Unvested Shares	Shares	Weighted-Average Grant-Date Fair Value
Unvested as of January 1, 2012	289,250	$ 159,013
Granted	19,757	60,000
Vested	(189,882)	(141,761)
Forfeited	-	-
Unvested as of September 30, 2012	119,125	$ 77,252

NOTE 15: ASSET PURCHASE

On September 30, 2012, the Company entered into an asset purchase agreement with Acueity Healthcare, Inc ("Acueity") to acquire substantially all of the assets of Acueity. Through the asset purchase, the Company acquired six 510(k) FDA cleared patents, 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), and cash in the amount of $400,000; no liabilities were assumed in the transaction. In consideration for the assets, the Company issued 862,500 shares of common stock, valued at $5.00 per share, the offering price listed on the prospectus filed pursuant to Rule 424(b)(4) on November 9, 2012 (see Note 16), and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, to the shareholders of Acueity, subject to a six-month lock up agreement. The warrants, which have a five-year term, do not have a cashless exercise provision. The warrants were valued at $2.3457 per warrant, 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 determine the fair value of the warrants (see Note 10). There are no future financial obligations from the Company to Acueity from the commercialization of the acquired assets.

NOTE 16: SUBSEQUENT EVENTS

On November 7, 2012, the Company's registration statement on Form S-1 (File No. 333-179500) was declared effective by the Securities and Exchange Commission for the Company's initial public offering. On November 9, 2012, pursuant to Rule 424(b)(4), the Company filed a prospectus for the initial public offering of 800,000 shares of its common stock with the offering price of $5.00 per share. As a result of the initial public offering, the Company received net proceeds of $3,455,000 after deducting underwriting discounts and commissions of approximately $545,000.

Management has evaluated subsequent events through December 14, 2012, the date which the consolidated financial statements were available to be issued. All subsequent events requiring recognition as of September 30, 2012 have been incorporated into these consolidated financial statements and there are no subsequent events that require disclosure in accordance with FASB ASC Topic 855, "Subsequent Events".

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

The following discussion of the financial condition and results of operations should be read in conjunction with the "Summary Financial Data" and the financial statements and the related notes included elsewhere in this prospectus. 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 elsewhere in this prospectus for additional information regarding forward-looking statements used in this prospectus.

Company Overview

We are a healthcare company focused on the prevention of breast cancer through the commercialization of diagnostic tests that can detect precursors to invasive breast cancer, and through the research, development, and ultimate commercialization of treatments for pre-cancerous lesions.

Our diagnostic tests consist of FDA-cleared and patented medical devices that can collect fluid and tissue samples from the breast milk ducts, where, according to the National Cancer Institute, over 95% of breast cancers arise. These samples are processed at our CLIA-certified laboratory, the National Reference Laboratory for Breast Health, which examines the specimens by microscopy for the presence of normal, pre-malignant, or malignant changes as determined by cytopathology and biomarkers that distinguish "usual" ductal hyperplasia, a benign condition, from atypical ductal hyperplasia, which may lead to cancer. These cytopathological results provide patients and physicians with information about the care path that should be followed, depending on the individual risk of future cancer as determined by the results.

Additionally, we are conducting research on the treatment of these pre-cancerous cells by using our patented and FDA-cleared microcatheters to deliver, directly into the milk ducts, pharmaceutical formulations that can be used to treat these pre-cancerous lesions. By using this localized delivery method, patients are expected to receive high local concentrations of these drugs at the site of the pre-cancerous lesions, potentially promoting efficacy of the treatment while limiting systemic exposure, which has the potential to lower the overall toxicity of these treatments.

Finally, the acquisition of the Acueity assets may become a complement to our current business at some point in the future. We are not currently allocating human or financial resources to these assets, with the exception of approximately $50,000 for patent maintenance fees and application prosecution expenses related to the Acueity asset purchase. Following the launch of our four diagnostic tests in the U.S., we will then begin to allocate human and financial resources to further develop and ultimately commercialize these medical devices. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishment of the supply chain of component

parts, securing manufacturers, performing test builds and commercial scale manufacturing, in late 2013. This asset purchase is not expected to have an impact on the development and commercialization timetables of our existing product lines. We cannot, however, provide any assurances that delays related to the launch of our four diagnostic tests, independent of this asset purchase, would not delay the expected development of these diagnostic tools or that we will ultimately be successful selling these tools.

Current Operations

We launched our commercial operations in late 2011 and, as of September 30, 2012, have enrolled and sold MASCT System kits or provided ArgusCYTE collection kits to 37 doctors and clinics as providers of the ForeCYTE and/or ArgusCYTE tests and have received, processed, and reported the results to physicians from 638 ForeCYTE samples and 41 ArgusCYTE samples. From inception (April 30, 2009) through September 30, 2012, we have generated $384,886 in revenue from the sale of our MASCT System and providing laboratory services. We incurred net operating losses of $3,374,249 and $2,236,866 for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, we had an accumulated deficit of approximately $8.0 million. 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 MASCT System and generating laboratory service revenue from our tests, and making short-term borrowings from stockholders or other related parties 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.

Revenue Sources

The commercialization of the ForeCYTE Test provides us with two revenue sources: (i) sales-based revenue from the sale of the MASCT System device and patient kits to physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from the preparation and interpretation of the NAF samples sent to our laboratory for analysis. The commercialization of the ArgusCYTE test provides only laboratory service revenue.

Commencing in December 2011, we began to market the ForeCYTE Test to physicians, primarily obstetric-gynecologists, as well as breast health and mammography clinics, for use in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. We are establishing relationships with breast cancer centers to provide the ArgusCYTE Test to their patients. We plan to initially use regional specialty product distributors, with independent sale representatives specializing in Women’s Health, to commercialize the ForeCYTE and ArgusCYTE Tests. As of September 30, 2012, we have entered an agreement with Diagnostic Test Group LLC (DTG); however, we cannot be certain that we will be able to build distributor relationships, including our relationship with DTG, adequately to address the national market. In addition to Dr. Quay, in April 2012 we hired a board-certified pathologist part-time to assist in the interpretation of the NAF samples.

Commercial Lease Agreements

On September 29, 2010, the Company entered into a commercial lease agreement with CompleGen, Inc. for laboratory space located in Seattle, WA. The lease provides for monthly rent of $3,658 and a security deposit of $3,658. The lease terms are from September 29, 2010 through March 31, 2011, at which time the lease has converted to month to month unless two months' prior written notice of the intent to terminate the agreement is given. The monthly rent for the lease increased to $4,267 commencing January 2012. For the nine months ended September 30, 2012, the Company incurred $38,403 of rent expense for the lease.

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 provides for monthly rent of $1,100 and a security deposit of $1,500. The lease terms are from April 1, 2011 through March 31, 2013. For the nine months ended September 30, 2012, the Company incurred $9,900 of rent expense for the lease.

On July 9, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $600 and a security deposit of $1,200. The lease terms are from July 11, 2011 through July 31, 2012. For the nine months ended September 30, 2012, the Company incurred $4,200 of rent expense for the lease. This lease terminated on July 31, 2012 and was not renewed.

On September 27, 2011, the Company entered into another commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $1,400 and a security deposit of $1,000. The lease terms are from October 1, 2011 to March 31, 2012. For the period of October 1, 2011 through March 31, 2012, the Company incurred $8,400 of rent expense for the lease. This lease terminated on March 31, 2012 and was not renewed.

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 as of September 30, 2012. For the nine months ended September 30, 2012, the Company incurred $161,424 of rent expense for the lease, which included leasing office management expenses.

We expect that these new facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional office and laboratory space for at least the next 24 months.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 3 to our financial statements included at the end of this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Revenue Recognition

Overview

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

Product Revenue

We recognize revenue for sales of the MASCT kits and devices upon the occurrence of all of the following: (i) receipt of cash, (ii) confirmation of product delivery (shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery), and (iii) assessment of whether a price is fixed or determinable based upon the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. Once a history of sales and collectability has been established, we expect to recognize revenue upon delivery of goods from the supplier's or our warehouse or upon arrival of goods at the customer's designated location, depending on the shipping terms, with an offsetting reserve for doubtful accounts estimated based on the relevant collections history.

Service Revenue

We recognize revenue for our diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount and upon satisfaction of the above four fundamental criteria. Amounts invoiced above the Medicare allowed reimbursement amount are recognized upon receipt of cash during the initial three- to six-month period as we have insufficient individual customer history on which to determine the collectability of amounts that are invoiced above the Medicare amount. Diagnostic testing revenue at the Medicare rate is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Customer purchase orders and/or contracts will generally be used to determine whether persuasive evidence of an arrangement exists. Once the Company has an appropriate history of sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare allowed and non-Medicare billing, when all criteria of revenue recognition are met, with an offsetting allowance for doubtful accounts estimated based on collections history. We estimate it will take between three to six months of sales and collection history to establish reasonable assurance of collection and estimate of doubtful accounts, which is subject to change based on the sufficiency of the actual number of sales transactions for the period.

Cash and Cash Equivalents

Cash and cash equivalents include cash and all highly liquid instruments with original maturities of three months or less.

Inventory

The Company's inventories are stated at lower of cost or market. Cost is determined on a moving-average basis. Costs of inventories include purchase and related costs incurred in delivering the products to their present location and condition. Market value is determined by reference to selling prices after the balance sheet date or to management's estimates based on prevailing market conditions. Inherent in the lower of cost or market calculation are several significant judgments based on a review of the aging of the inventory, inventory movement of products, economic conditions, and replacement costs. Because the sales price of the MASCT System was substantially lower than its cost for the nine months ended September 30, 2012 and for the year ended December 31, 2011, resulting in the net realizable value of the MASCT System being determined at zero as of the balance sheet dates through taking the average sales price subtracted by selling expenses per unit, $29,884 and $92,026 of loss on reduction of inventory to the lower of cost or market was assessed and recorded as of and for the period and for the year then ended, respectively. Additionally, management periodically evaluates the composition of its inventories at least quarterly to identify slow-moving and obsolete inventories to determine if valuation allowance is required. As of September 30, 2012 and December 31, 2011, management had identified no slow moving or obsolete inventory.

The Company provides ForeCYTE testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the Company for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System, and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits. For the nine months ended September 30, 2012 and for the year ended December 31, 2011, selling expense of $36,741 and $0 was recorded related to the ForeCYTE kits, respectively.

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 revenue and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Research and Development Expenses

Research and development costs are generally expensed as incurred. Our research and development expenses consist of costs incurred for internal and external research and development.

Share-Based Payments

In December 2004, the Financial Accounting Standards Board, or the FASB, issued the Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share-Based Payment," which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in the FASB's ASC Topic 718, "Compensation — Stock Compensation." Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees or independent contractors are required to provide services. Share-based compensation arrangements include stock options and warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or SAB 107, which expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for SFAS No. 123(R). Companies may elect to apply this statement either prospectively, or on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123.

We have fully adopted the provisions of FASB ASC 718 and related interpretations as provided by SAB 107. As such, compensation cost is measured on the date of grant as the fair value of the share-based payments. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

The amended employment agreement with the CEO, entered into on July 22, 2010, granted options to purchase 250,000 shares (or 565,830 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share, in consideration of his service to the Company. Of these options, 25% (or 62,500 shares) vested on December 31, 2010 with the remaining 75% (or 187,500 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

The amended employment agreement with the CTO, entered into on July 22, 2010, granted options to purchase 100,000 shares (or 226,332 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share in consideration of her service to the Company. Of these options, 25% (or 25,000 shares) vested on December 31, 2010 with the remaining 75% (or 75,000 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

On April 4, 2011, 45,000 non-qualified stock options were granted under the 2010 Stock Option and Incentive Plan to Dr. Tim Hunkapiller for being a member of the Company’s Scientific Advisory Board and consulting services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest as follows:

(i) 11,250 option shares shall vest ninety (90) days after the date of grant;
(ii) 11,000 option shares shall vest one hundred and eighty (180) days after the date of grant;
(iii) 11,500 option shares shall vest two hundred and seventy (270) days after the date of grant;
(iv) 11,250 option shares shall vest three hundred and sixty (360) days after the date of grant.

On September 1, 2011, 219,000 incentive stock options were granted under the 2010 Stock Option and Incentive Plan to employees and officers as part of their employment agreements, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) twenty-five percent (25%) of the underlying shares on the first anniversary of the date of grant; and
(ii) one-forty eighth (1/48) of the underlying shares monthly thereafter.

On September 1, 2011, 200,000 non-qualified stock options were granted under the 2010 Stock Option and Incentive Plan to non-employee directors for services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) 80,000 option shares shall vest on September 1, 2011;
(ii) 30,000 options shares shall vest on December 1, 2011;
(iii) 30,000 options shares shall vest on March 1, 2012;
(iv) 30,000 options shares shall vest on June 1, 2012;
(v) 30,000 options shares shall vest on September 1, 2012.

On April 30, 2012, 19,757 non-qualified stock options were granted under the 2010 Stock Option and Incentive Plan to non-employee directors for serving as directors of the Company, at an exercise price of $6.00 per share. These options have a ten-year contractual term and shall vest and become exercisable in full immediately as of the grant date.

In accordance with the guidance provided in ASC Topic 718, Stock Compensation (formerly SFAS 123R), the compensation costs associated with these 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 a compensation expense of $96,251 for the nine months ended September 30, 2012.

The Company estimated the fair value of these options using the Black-Scholes-Merton option pricing model based on the following weighted-average assumptions:

	CEO & CTO		Dr. Hunkapiller		Employees & Officers		Non-employee Directors		Non-employee Directors	
Date of grant	22-Jul-10		4-Apr-11		1-Sep-11		1-Sep-11		30-Apr-12	
Fair value of common stock on date of grant	$ 2.756	(B)	$ 0.906	(C)	$ 0.906	(C)	$ 0.906	(C)	$ 6.00	(D)
Exercise price of the options	$ 5.00		$ 1.25		$ 1.25		$ 1.25		$ 6.00	
Expected life of the options (years)	3.33		5.31		5.65		5.65		5.00	
Dividend yield	0.00	%	0.00	%	0.00	%	0.00	%	0.00	%
Expected volatility	58.59	%	54.12	%	53.90	%	53.90	%	62.46	%
Risk-free interest rate	1.03	%	2.26	%	1.08	%	1.08	%	0.89	%
Expected forfeiture per year (%)	0.00	%	0.00	%		(A)	0.00	%	0.00	%
Weighted-average fair value of the options (per unit)	$ 0.6744		$ 0.3729		$ 0.3579		$ 0.3579		$ 3.0367	

(A) 0.00% for the first year after the grant date, and 2.50% for every three months thereafter.

(B) The fair value of the Company's common stock was derived implicitly from the public offering filed in March 2010 at $3.00 per share and from the terms of an underwritten offering contemplated in July 2010 at $6.00 per Unit that was filed in October 2010, with $2.756 per share being allocated to common stock using an iterative approach in order for the combined fair value of the common stock and warrants to equal the amount of consideration to be received in the initial public offering.

(C) The fair value of the Company's common stock was derived implicitly from the Private Placement during April through June 2011 at $1.25 per Unit, wherein one Unit was comprised of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $1.60 per share.

(D) The fair value of the Company's common stock was derived implicitly from the public offering filed in February 2012 at $6.00 per share.

In October 2010, the Company filed a Registration Statement on Form S-1 with the SEC. However, the market for early stage investments in medical technology transactions had deteriorated between mid-2010 and early 2011. In addition, the Company's ability to negotiate with potential investors was limited. The Company's cash position had also diminished since the summer of 2010 and the founders of the Company were unable to finance the Company at the level needed for growth. The withdrawal of the Registration Statement in February 2011 further weakened the impression of the Company in the market. The fair value of the Company's common stock decreased from $2.756 in 2010 to $0.906 in 2011 primarily because the grants in 2011 relied on the arm's-length negotiation of the private placement financing (for illiquid stock) as opposed to relying on an anticipated initial public offering (of publicly-traded stock), as was the case in 2010. The private placement transactions were between the company and over 200 accredited investors and ascribed a value of $0.906 to the Company's common stock.

Fair value hierarchy of the above assumptions can be categorized as follows:

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

- Risk-free rate — The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the options.

(3) Level 3 inputs include:

- Expected lives — The expected lives of options granted were derived from the output of the option valuation model and represented the period of time that options granted are expected to be outstanding.

- Expected forfeitures per year — The expected forfeitures are estimated at the dates of grant and will be revised in subsequent periods pursuant to actual forfeitures, if significantly different from the previous estimates.

- Expected volatility — We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by ASC 718-10-30, the Company has accounted for the options using the calculated value method. The Company identified seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

The estimates of fair value from the model are theoretical values of stock options and changes in the assumptions used in the model could result in materially different fair value estimates. The actual value of the stock options will depend on the market value of the Company's common stock when the stock options are exercised.

Notwithstanding that the fair market value of the Company's common stock in September 2011 was $0.906 per share, the Company filed a Registration Statement on Form S-1 in February 2012 to offer shares of its common stock at $5.00 to $7.00 per share. This increase in share value is justified by the accomplishments achieved by the Company between September 2011 and February 2012, the end results of which are described elsewhere in this prospectus in the summary of the Company's business and operations. However, the specific actions that took place between September 2011 and February 2012 that supported this increase in value were as follows. The MASCT System manufacturing had been completed, supplies for the field experience trial were completed and the Company had established an FDA-compliant inventory and warehousing facility. Further, the National Reference Laboratory for Breast Health, the Company's wholly-owned subsidiary, was established as a Delaware corporation, was equipped and staffed, and the protocols and procedures needed to be a CLIA-registered facility were put in place. Moreover, the ForeCYTE test, which involves cytopathology and five biomarkers of hyperplasia and one biomarker of sample integrity, was completed, tested, and validated to CLIA standards. Computer hardware and software was acquired, set up, made operational, and the ForeCYTE report template, with unique reporting information for the requesting physician and a patient letter template, were created. The company explored and identified a technology for the ArgusCYTE test (which is the technology that the Company is currently using for the ArgusCYTE test), negotiated a supply agreement with the supplier, and tested and validated the test. An ArgusCYTE report template was also established and a new reporting scheme invented and a patent application filed.

Further, the Company acquired the FullCYTE Microcatheter System from Hologics, reestablished the supply chain and began preparing for a commercial launch later in 2012 or early 2013. In doing so, the Company increased its U.S. patent portfolio from 5 to 31 and its total portfolio of patents and applications to over 120. The Hologic patent estate also contains the key patents that permit microcatheter-based intractuctal treatment of cancer and pre-cancer. The Company also prepared marketing documents for the launch of the ForeCYTE and ArgusCYTE tests, which occurred in December 2011. The Company studied the use of the FullCYTE microcatheter in six patients to establish the

feasibility of performing next-generation tests on samples taken with the microcatheters. Additionally, the Company's scientists invented and filed a patent application to the NextCYTE technology and the Company has negotiated a one-year option to acquire commercial rights to additional NextCYTE-related technology to augment its existing position and has started researching the utility of the technology in providing superior information in the setting of cancer diagnosis and treatment selection.

The Company also established third-party relationships to perform the reimbursement billing in anticipation of the commercial launch and to permit electronic remittance of testing revenue. The Company launched a Field Test Experience limited launch of both the ForeCYTE and ArgusCYTE tests on schedule in December 2011 and has seen significant market acceptance of both tests from the doctors and clinics using the tests. The Company passed a CLIA inspection and became CLIA-certified, has obtained five state licenses and has a pending application in New York State, the only remaining state where licensure is required. Finally, the Board of Directors and scientific advisory board were each strengthened with the addition of key new executives and scientists.

The Board of Directors considered each of the foregoing achievements, and considered input from the Company's investment bankers, in determining that the value of the Company supported a valuation of $5.00 to $7.00 per share of the Company's common stock when the Company filed its initial Registration Statement on Form S-1 in February 2012.

Options issued and outstanding as of September 30, 2012 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
Outstanding as of January 1, 2011	608,000	$ 3.41	
Granted	19,757	6.00	
Expired	—	—	
Forfeited	—	—	
Outstanding as of September 30, 2012	627,757	3.49	5.51
Exercisable as of September 30, 2012	508,632	3.21	6.02
Vested and expected to vest[(1)]	624,049	3.50	5.49

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

As of September 30, 2012 and December 31, 2011, the aggregate intrinsic value of options outstanding, exercisable, and vested and expected to vest was $389,053 and $329,053, respectively.

A summary of the status of the Company's unvested shares as of September 30, 2012 and changes during the period then ended is presented below:

Unvested Shares	**Shares**	Weighted-Average Grant-Date Fair Value
Unvested as of January 1, 2012	289,250	$ 159,013
Granted	19,757	60,000
Vested	(189,882)	(141,761)
Forfeited	—	—
Unvested as of September 30, 2012	119,125	$ 77,252

Results of Operations

Discussion of Three Months Ended September 30, 2012

For the three months ended September 30, 2012, we had total revenue of $105,576, consisting of $1,565 product revenue from sales of MASCT Systems and $104,011 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. Total cost of revenue was $9,000, primarily attributable to cost of diagnostic testing services performed, which consisted of $9,000 in payments to doctors for their time administering the ForeCYTE testing service and $0 in shipping and packaging costs related to the delivery of test specimens from doctors to the Company. Since the inventory of MASCT System was recorded at zero net realizable value as a result of the lower of cost or market analysis performed at December 31, 2011, no corresponding cost of goods sold was recorded for the sales of MASCT System for the three months ended September 30, 2012. Gross profit was $95,011 for the diagnostic testing service and $1,565 for the product sales of MASCT System with no corresponding cost of goods sold. Loss on reduction of inventory to lower of cost or market was $6,077 for the three months ended September 30, 2012, primarily due to write-off of parts purchased during the three months for the assembly of MASCT System, which was determined at zero net realizable value as a result of lower of cost or market analysis performed at December 31, 2011 and September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. Total operating expenses were $1,226,171, consisting of G&A expenses of $1,138,467 and selling expenses of $87,704, which included $19,863 of cost of ForeCYTE and ArgusCYTE testing specimen collection kits that were immediately expensed upon purchase during the quarter. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. The selling expenses also included $67,493 in salaries and $0 in advertising.

The G&A expenses consisted primarily of $23,358 in salaries and bonus expense, $310,302 in legal expense, $49,579 in consulting expense, $34,475 in accounting expense, $5,133 in travel expense, $16,091 in professional fees, $26,774 in health insurance expense and $19,494 in business insurance. Also included in G&A expense is $548,108 in research and development expense, consisting primarily of $170,083 in salaries and bonus expense, $97,643 in rent expense, $1,684 in laboratory supplies, $20,882 in MASCT System development, $32,268 in MASCT Service development, $183,351 in ductal lavage product development, and $7,024 in circulating tumor cells service development.

Comparison of the Three Months Ended September 30, 2012 and 2011

Revenue and Cost of Goods Sold. For the three months ended September 30, 2012, we had total revenue of $105,576, consisting of $1,565 product revenue from sales of MASCT Systems and $104,011 diagnostic testing service revenue

from our ForeCYTE and ArgusCYTE testing services performed. This compares to total revenue of $0 for the three months ended September 30, 2011. Total cost of revenue for the three months ended September 30, 2012 was $9,000 primarily attributable to cost of diagnostic testing services performed, which consisted of $9,000 in payments to doctors for their time administering the ForeCYTE testing service and $0 in shipping and packaging costs related to the delivery of test specimens from doctors to the Company. Since the inventory of MASCT System was recorded at zero net realizable value as a result of the lower of cost or market analysis performed at December 31, 2011, no corresponding cost of goods sold was recorded for the sales of MASCT System for the three months ended September 30, 2012. For the three months ended September 30, 2011, total cost of revenue was $0. Gross profit for the three months ended September 30, 2012 was $95,011 for the diagnostic testing service and $1,565 for the product sales of MASCT System with no corresponding cost of goods sold. This compares to gross profit of $0 for the three months ended September 30, 2011. Loss on reduction of inventory to lower of cost or market was $6,077 for the three months ended September 30, 2012, primarily due to write-off of parts purchased during the quarter for the assembly of MASCT System which was determined at zero net realizable value as a result of lower of cost or market analysis at December 31, 2011 and September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. No loss on reduction of inventory to lower of cost or market was recorded for the three months ended September 30, 2011 due to no primary operating activities.

As discussed below, we expect that our R&D and G&A expenses will continue to increase in the foreseeable future, and that if we successfully launch the MASCT System and our related laboratory service offerings, we would also begin to incur sales and marketing expenses as we build a regional, and ultimately national, sales force. We may limit our fixed sales and marketing costs initially by employing temporary workers or those who are compensated on a commission basis. However, we expect our expenditures to increase significantly in future periods.

Operating Expenses. Total operating expenses were $1,226,171 for the three months ended September 30, 2012, consisting of G&A expenses of $1,138,467 and selling expenses of $87,704, which included $19,863 of cost of ForeCYTE and ArgusCYTE testing specimen collection kits that were immediately expensed upon purchase during the quarter. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. The selling expenses also included $70,361 in salaries and $0 in advertising. This compares to total operating expenses of $1,274,189 for the three months ended September 30, 2011, consisting of G&A expenses of $1,274,189 and selling expenses of $0. Total operating expenses decreased by $48,018 or 4% from $1,274,189 for the three months ended September 30, 2011 to $1,226,171 for the three months ended September 30, 2012 as the Company focused its efforts on our Initial Public Offering and delayed any growth plans until post funding.

General and Administrative Expenses. G&A expenses for the three months ended September 30, 2012 were $1,138,467, a decrease of $135,722 or 11% from $1,274,189 for the three months ended September 30, 2011. G&A expenses for the three months ended September 30, 2012 primarily consisted of $23,358 in salaries and bonus expense, $310,302 in legal expense, $49,579 in consulting expense, $34,475 in accounting expense, $5,133 in travel expense, $16,091 in professional fees, $26,774 in health insurance expense and $19,494 in business insurance. Also included in G&A expense is $548,108 in research and development expense, consisting primarily of $170,083 in salaries and bonus expense, $97,643 in rent expense, $1,684 in laboratory supplies, $20,882 in MASCT System development, $32,268 in MASCT Service development, $183,351 in ductal lavage product development, and $7,024 in circulating tumor cells service development.

G&A expenses for the three months ended September 30, 2011 were $1,274,189, and mainly consisted of $334,451 in legal, $193,807 in compensation expenses, $31,112 in consulting expenses, $24,110 in travel expense, $20,934 accounting expense, and $9,724 in other professional fees. Also included in G&A expense is $575,446 of R&D expense, consisting primarily of $149,708 in salaries and bonus expense, $11,392 in rent expense, $78,480 in MASCT System development, $0 in Ductal Lavage service development, $102,338 in Ductal Lavage product development, $101,735 in circulating tumor cells service development, and $50,237 in Laboratory supplies.

The increase in expenses is attributed to the launch of the Company's MASCT System, ForeCYTE service and ArgusCYTE service and the related growth in expenses to hire additional staff, expand our operations, and invest additional funds in Research and Development. We expect that our G&A expenses will continue to increase as we add additional full time and incur additional costs as a publicly traded company. Additionally, G&A costs are expected to rise as we increase headcount to coordinate the production and manufacture of the MASCT System, and the expected increase in service revenues.

Discussion of Nine Months Ended September 30, 2012

For the nine months ended September 30, 2012, we had total revenue of $383,386, consisting of $6,690 product revenue from sales of MASCT Systems and $376,696 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. Total cost of revenue was $29,985, primarily attributable to cost of diagnostic testing services performed, which consisted of $27,470 in payments to doctors for their time administering the ForeCYTE testing service and $2,515 in shipping and packaging costs related to the delivery of test specimens from doctors to the Company. Since the inventory of MASCT System was recorded at zero net realizable value as a result of the lower of cost or market analysis performed at December 31, 2011, no corresponding cost of goods sold was recorded for the sales of MASCT System for the nine months ended September 30, 2012. Gross profit was $346,711 for the diagnostic testing service and $6,690 for the product sales of MASCT System with no corresponding cost of goods sold. Loss on reduction of inventory to lower of cost or market was $29,884 for the nine months ended September 30, 2012, primarily due to write-off of parts purchased during the nine months for the assembly of MASCT System, which was determined at zero net realizable value as a result of lower of cost or market analysis performed at December 31, 2011 and September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. Total operating expenses were $3,687,169, consisting of G&A expenses of $3,405,198 and selling expenses of $281,971, which included $36,741 of cost of ForeCYTE and ArgusCYTE testing specimen collection kits that were immediately expensed upon purchase during the quarter. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. The selling expenses also included $196,326 in salaries and $48,557 in advertising.

The G&A expenses consisted primarily of $225,055 in salaries and bonus expense, $883,400 in legal expense, $151,245 in consulting expense, $102,640 in accounting expense, $25,541 in travel expense, $57,775 in payroll taxes, $64,118 in professional fees, $56,987 in health insurance expense and $53,584 in business insurance. Also included in G&A expense is $1,509,643 in research and development expense, consisting primarily of $488,536 in salaries and bonus expense, $198,058 in rent expense, $25,971 in laboratory supplies, $120,106 in MASCT System development, $489,778 in ductal lavage product development, $39,789 in ductal lavage service development and $30,797 in circulating tumor cells service development.

Comparison of the Nine Months Ended September 30, 2012 and 2011

Revenue and Cost of Goods Sold. For the nine months ended September 30, 2012, we had total revenue of $383,386, consisting of $6,690 product revenue from sales of MASCT Systems and $376,696 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. This compares to total revenue of $0 for the nine months ended September 30, 2011. Total cost of revenue for the nine months ended September 30, 2012 was $29,985 primarily attributable to cost of diagnostic testing services performed, which consisted of $27,470 in payments to doctors for their time administering the ForeCYTE testing service and $2,515 in shipping and packaging costs related to the delivery of test specimens from doctors to the Company. Since the inventory of MASCT System was recorded at zero net realizable value as a result of the lower of cost or market analysis performed at December 31, 2011, no corresponding cost of goods sold was recorded for the sales of MASCT System for the nine months ended September 30, 2012. For the nine months ended September 30, 2011, total cost of revenue was $0. Gross profit for the nine months ended September 30, 2012 was $346,711 for the diagnostic testing service and $6,690 for the product sales of MASCT System with no corresponding cost of goods sold. This compares to gross profit of $0 for the nine months ended September 30, 2011. Loss on reduction of inventory to lower of cost or market was $29,884 for the nine months ended September 30, 2012, primarily due to write-off of parts purchased during the quarter for the assembly of MASCT System which was determined at zero net realizable value as a result of lower of cost or market analysis at December 31, 2011 and September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. No loss on reduction of inventory to lower of cost or market was recorded for the nine months ended September 30, 2011 due to no primary operating activities.

As discussed below, we expect that our R&D and G&A expenses will continue to increase in the foreseeable future, and that if we successfully launch the MASCT System and our related laboratory service offerings, we would also begin to incur sales and marketing expenses as we build a regional, and ultimately national, sales force. We may limit our fixed sales and marketing costs initially by employing temporary workers or those who are compensated on a commission basis. However, we expect our expenditures to increase significantly in future periods.

Operating Expenses. Total operating expenses were $3,687,169 for the nine months ended September 30, 2012, consisting of G&A expenses of $3,405,198 and selling expenses of $281,971, which included $36,741 of cost of ForeCYTE and ArgusCYTE testing specimen collection kits that were immediately expensed upon purchase during the quarter. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. The selling expenses also included $196,326 in salaries and $48,557 in advertising. This compares to total operating expenses of $2,231,906 for the nine months ended September 30, 2011, consisting of G&A expenses of $2,231,906 and selling expenses of $0. Total operating expenses increased by $1,455,263 or 65% from $2,231,906 for the nine months ended September 30, 2011 to $3,687,169 for the nine months ended September 30, 2012.

General and Administrative Expenses. G&A expenses for the nine months ended September 30, 2012 were $3,405,198, an increase of $1,173,292 or 53% from $2,231,906 for the nine months ended September 30, 2011. G&A expenses for the nine months ended September 30, 2012 primarily consisted of $225,055 in salaries and bonus expense, $883,400 in legal expense, $151,245 in consulting expense, $102,640 in accounting expense, $25,541 in travel expense, $57,775 in payroll taxes, $64,118 in professional fees, $56,987 in health insurance expense and $53,584 in business insurance. Also included in G&A expense is $1,509,643 in research and development expense, consisting primarily of $488,536 in salaries and bonus expense, $198,058 in rent expense, $25,971 in laboratory supplies, $120,106 in MASCT System development, $489,778 in ductal lavage product development, $39,789 in ductal lavage service development and $30,797 in circulating tumor cells service development.

G&A expenses for the nine months ended September 30, 2011 were $2,231,906, and mainly consisted of $343,907 in legal expenses, $368,203 in compensation expenses, $79,232 in consulting expenses, $39,231 in travel expenses, $43,479 accounting expense, and $30,933 in other professional fees. Also included in G&A expense is $1,065,133 of R&D expense, consisting primarily of $437,178 in salaries and bonus expense, $37,573 in rent expense, $136,562 in MASCT System development, $38,810 in Ductal Lavage service development, $102,338 in Ductal Lavage product development and $84,055 in patent license acquisition.

The increase in expenses is attributed to the launch of the Company's MASCT System, ForeCYTE service and ArgusCYTE service and the related growth in expenses to hire additional staff, expand our operations, and invest additional funds in Research and Development. We expect that our G&A expenses will continue to increase as we add additional full time and incur additional costs as a publicly traded company. Additionally, G&A costs are expected to rise as we increase headcount to coordinate the production and manufacture of the MASCT System, and the expected increase in service revenues.

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 financial statements as of and for the year ended December 31, 2011 expresses substantial doubt about our ability to continue as a going concern. In 2011, we were successful in raising net proceeds of $5.7 million through a private placement in order to fund the growth of our operations and product development. In November 2012 we were successful in our initial public offering and raising net proceeds of $3.5 million. Our ability to continue as a going concern 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

For the nine months ended September 30, 2012, we incurred a net loss of $3,374,249. Net cash used in operating activities was $1,967,626 and net cash provided by financing activities was $475,375. During the nine months ended September 30, 2012 we repaid $750,000 that we previously drew on our bank line of credit. For the nine months ended September 30, 2011, we incurred a net loss of $2,236,866, net cash used in operating activities was $2,453,767, net cash used in investing activies was $85,276 and net cash provided by financing activities was $5,534,785.

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 ongoing launch of the MASCT System, complete the development of and launch the FullCYTE and NextCYTE Tests, and build and operate our planned diagnostics laboratory in the Fred Hutchinson Cancer Research Center. To fund our operations for at least the next 12 months under our current business plan, we estimate that we would need between $4 million and $6 million of additional capital. We expect that the proceeds from our initial public offering, together with our existing resources as of the date of this report, to be sufficient to fund our planned operations for at least the next 6 months. If we are unable to raise this amount of capital, 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 complete the manufacturing of the MASCT and Microcatheter Systems;
- the expense associated with building a network of independent sales representatives to market the MASCT System, ForeCYTE Test and ArgusCYTE Test; and
- the degree of patient and physician acceptance of our products and the degree to which third-party payors approve the ForeCYTE and ArgusCYTE Tests for reimbursement.

As of September 30, 2012, we have generated $384,886 in revenue. We do not expect to generate significant revenue until we are able to manufacture and launch the MASCT System more broadly. We expect our continuing operating losses to result in increases in cash used in operations over at least the next year. Although we expect the proceeds of our initial public offering, together with our existing resources as of the date of this report, to be sufficient to fund our planned operations for at least the next 6 months, we may require additional funds earlier than we currently expect to successfully commercialize the MASCT System. Because of the numerous risks and uncertainties associated with the development and commercialization of the MASCT System and our services, 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. The adoption of these accounting pronouncements, including those not yet effective, is not anticipated to have a material effect on the financial position or results of operations of the Company.

Jumpstart Our Business Startups Act of 2012

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. Our decision to opt out of the extended transition period under the JOBS Act is irrevocable.

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, 2012. 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, 2012, 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, 2012 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) and the Company. The consulting agreement was terminated by the Company in September 2010. Mr. Kelly seeks $450,000 in compensatory damages, which is the amount he claims would have been earned had the consulting agreement been fulfilled to completion. A hearing in the arbitration is currently set for March 2013 but may be delayed to accommodate other third party civil and criminal proceedings that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

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. The specific amount of damages sought is to be proven at trial and not specified.

The Company is reasonably confident in its defenses to Mr. Kelly's claims. Consequently, no provision or liability has been recorded for Mr. Kelly's claims as of September 30, 2012. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Unregistered Sales of Equity Securities

The Company has sold the following securities within the past three years which were not registered under the Securities Act of 1933:

Pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering as founder shares in connection with the formation of the Company, the Company issued 4,899,888 shares of its common stock as follows:

	Shares	Date	Consideration	
Steven Quay	883,662	April 30, 2009	$ 12,000	
Ensisheim Partners LLC	1,767,316	April 30, 2009		(1)
Ensisheim Partners LLC	883,658	December 28, 2009	$ 100,000	
Manistee Ventures, Inc.	1,325,487	April 30, 2009	$ 18,000	
John Barnhart	39,765	July 28, 2009	$ 540	

(1) The 1,767,316 shares of common stock issued to Ensisheim Partners LLC at the Company's inception were issued in consideration for $24,000 in cash and this entity's contribution to the Company of intellectual property rights and FDA marketing authorization for the MASCT System.

In January 2010, pursuant to an exemption from registration under Rule 504 pursuant to the Securities Act of 1933 (the "Securities Act"), the Company issued an aggregate of 901,354 shares of its common stock to 45 investors for aggregate cash proceeds of $102,000. Of these 45 investors, 13 are accredited investors and 4 are citizens and residents of Taiwan, Republic of China.

In January 2010, the Company issued 185,569 shares in consideration for services performed by two consultants, with an aggregate value of $21,000. This offering was exempt from registration under Rule 504 under the Securities Act.

On April 23, 2010, the Company issued 13,256 shares of common stock for services performed by a consultant with an aggregate value of $50,000. This offering was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

Between April 2011 and July 2011, the Company issued a total of 5,256,800 shares of the Company's common stock and warrants to purchase up to an additional 5,256,800 shares of common stock at a price of $1.60 per share, for aggregate gross proceeds of $6,571,000 (the "Private Placement"). All purchasers in the Private Placement were accredited investors, as defined under Regulation D under the Securities Act, and this offering was exempt from registration under Rule 506 under the Securities Act. In connection with the completion of the Private Placement, the Company issued common stock warrants to Dawson James Securities ("Dawson James"), the placement agent for the Private Placement, representing the right to purchase up to 788,520 shares of common stock at a price of $1.25 per share, plus the right to purchase up to 788,520 additional shares of common stock at a price of $1.60 per share. The issuance of the warrants to Dawson James was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving a public offering.

On September 30, 2012, in connection with its acquisition of substantially all of the assets of Acueity Healthcare, Inc. ("Acueity"), the Company issued to the stockholders of Acueity 862,500 shares of common stock (the "Shares") and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, subject to a six-month lock up agreement (the "Warrants"). The Warrants, which have a five-year term, do not have a cashless exercise provision. The Shares and Warrants were issued as consideration for the assets acquired from Acueity: 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), and six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of 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. The issuance of the Shares and the Warrants was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving a public offering. The common stock was valued at $5.00 per share and the warrants were valued at $2.3457 per warrant.

(b) Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-179500) that was declared effective by the SEC on November 7, 2012, which registered an aggregate of 800,000 shares of our common stock for aggregate gross proceeds of $4 million. All of the 800,000 shares of common stock registered under the Registration Statement were sold at a price to the public of $5.00 per share. The offering closed on November 14, 2012. The underwriters have an option to purchase an additional 120,000 shares of our common stock for 45 days from November 7, 2012. Dawson James Securities, Inc. acted as sole book-running manager for the offering.

Net proceeds received were approximately $3.0 million, after deduction of underwriting fees and estimated offering expenses. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We intend to use the proceeds as described in the final prospectus filed with the SEC pursuant to Rule 424(b) on November 9, 2012. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus dated November 7, 2012 filed with the SEC on November 9, 2012.

ITEM 6. EXHIBITS

Exhibit Number	Description
2.1	Agreement and Plan of Reorganization, dated September 30, 2012, by and among the Company, Acueity Healthcare, Inc. and Ted Lachowicz, as Stockholder Representative (1)
3.1	Amended and Restated Certificate of Incorporation (2)
3.2	Amended and Restated Bylaws (3)
4.1	Form of Warrant dated September 30, 2012 (4)
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Previously filed as Exhibit 2.1 with the Company's Registration Statement on Form S-1 (File No. 333-179500), filed October 4, 2012 and incorporated by reference herein.

(2) Previously filed as Exhibit 3.2 with the Company's Registration Statement on Form S-1 (File No. 333-179500), filed June 11, 2012 and incorporated by reference herein.

(3) Previously filed as Exhibit 3.4 with the Company's Registration Statement on Form S-1 (File No. 333-179500), filed June 11, 2012 and incorporated by reference herein.

(4) Previously filed as Exhibit 4.4 with the Company's Registration Statement on Form S-1 (File No. 333-179500), filed October 4, 2012 and incorporated by reference herein.

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.

Atossa Genetics Inc.

Date: December 21, 2012 /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
President and Chief Executive Officer
(as Principal Executive Officer)

Date: December 21, 2012 /s/ Christopher Benjamin
Christopher Benjamin
Chief Financial Officer
(as Principal Financial and Accounting Officer)