

ATOSSA GENETICS INC  
Form 10-Q  
August 14, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM 10-Q**

**(Mark One)**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

**For the quarterly period ended June 30, 2013**

**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**  
(State or other jurisdiction of  
incorporation or organization)

**26-4753208**  
(I.R.S. Employer  
Identification No.)

**1616 Eastlake Ave. East, Suite 510**  
**Seattle, WA**

**98102**  
(Zip Code)

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(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

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

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

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

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

The number of shares of the registrant's common stock, \$0.001 par value per share, outstanding at August 9, 2013 was 15,580,074.

**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**

<u>Assets</u>	June 30, 2013 (Unaudited)	December 31, 2012 (Audited)
Current Assets		
Cash and cash equivalents	\$ 2,439,512	\$ 1,725,197
Accounts receivable	520,424	141,665
Prepaid expense	2,347,701	122,633
Retainers (deposits)	47,500	-
Total Current Assets	5,355,137	1,989,495
Fixed Assets		
Furniture and Equipment, net	205,800	159,967
Total Fixed Assets	205,800	159,967
Other Assets		
Security deposit	36,446	36,447
Intangible assets, net	4,457,619	4,640,224
Total Other Assets	4,494,065	4,676,671
Total Assets	\$ 10,055,002	\$ 6,826,133
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 184,002	\$ 68,217
Accrued expenses	1,289,104	1,374,385
Deferred rent	72,537	-
Payroll Liabilities	196,873	207,996
Other current liabilities	31,654	-
Total Current Liabilities	1,774,170	1,650,598

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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, 15,338,074 and 12,919,367 shares issued and outstanding	15,338	12,919
Additional paid-in capital	22,522,539	14,894,522
Accumulated deficit	(14,257,045)	(9,731,906 )
Total Stockholders' Equity	8,280,832	5,175,535
Total Liabilities and Stockholders' Equity	\$ 10,055,002	\$ 6,826,133

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

## ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended June 30,		For The Six Months Ended June 30,		From April 30, 2009 (Inception) Through June 30, 2013
	2013	2012	2013	2012	
Revenue					
Diagnostic Testing Service	\$ 120,488	\$ 219,972	\$ 289,718	\$ 272,685	\$ 765,120
Product Sales	205,590	3,125	219,030	5,125	226,970
Total Revenue	326,078	223,097	508,748	277,810	992,090
Cost of Revenue					
Diagnostic Testing Service	2,356	17,788	49,955	20,985	85,700
Product Sales	219,804	-	238,669	-	243,833
Total Cost of Revenue	222,160	17,788	288,624	20,985	329,533
Loss on Reduction of Inventory to LCM	-	-	-	23,807	121,910
Gross Profit	103,918	205,309	220,124	233,018	540,647
Selling expenses	319,390	123,832	591,965	194,267	1,231,841
Research and Development expenses	189,955	543,081	410,147	961,071	3,967,533
General and Administrative expenses	2,177,920	704,208	3,742,792	1,305,660	9,565,126
Total operating expenses	2,687,265	1,371,121	4,744,904	2,460,998	14,764,500
Operating Loss	(2,583,347 )	(1,165,812 )	(4,524,780 )	(2,227,980 )	(14,223,853 )
Interest Income	-	310	-	1,173	6,588
Interest Expense	352	2,446	359	4,060	39,530
Net Loss before Income Taxes	(2,583,699 )	(1,167,948 )	(4,525,139 )	(2,230,867 )	(14,256,795 )
Income Taxes	-	-	-	-	250
Net Loss	\$(2,583,699 )	\$(1,167,948 )	\$(4,525,139 )	\$(2,230,867 )	\$(14,257,045 )
Loss per common share - basic and diluted	\$ (0.17 )	\$ (0.10 )	\$ (0.32 )	\$ (0.20 )	\$ (1.63 )

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Weighted average shares outstanding, basic & diluted	14,808,728	11,256,867	14,120,962	11,256,867	8,722,843
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*The accompanying notes are an integral part of these consolidated financial statements.*



**ATOSSA GENETICS, INC.****(A DEVELOPMENT STAGE COMPANY)****CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)**

	For the Six Months Ended June 30,		For The Period From April 30, 2009 (Inception) to June 30, 2013
	2013	2012	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (4,525,139)	\$ (2,230,867)	\$ (14,257,045 )
Common shares issued for services	181,798	-	252,798
Compensation cost for stock options granted	1,011,820	70,662	1,304,084
Loss on reduction of inventory to LCM	20,323	23,807	142,233
Loan initiation fee accrued for notes payable	-	-	2,000
Depreciation and amortization	226,643	17,057	372,818
Adjustments to reconcile net loss to net cash provided by operating activities:			
Increase in accounts receivable	(378,759 )	(177,055 )	(520,424 )
Increase in inventory	(20,323 )	(23,807 )	(142,233 )
Increase in prepaid expenses	(36,526 )	(149,956 )	(159,159 )
Increase in security deposits	(47,500 )	(32,789 )	(83,948 )
Increase in accounts payable	115,785	6,702	184,002
Decrease in accrued payroll	(11,123 )	-	(11,123 )
Increase in deferred rent	72,537	-	72,537
Decrease (Increase) in accrued Expenses	(85,280 )	679,600	1,542,101
Increase in Other Current Liabilities	31,654	-	31,654
Net cash used in operating activities	(3,444,090)	(1,816,646)	(11,269,705 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchase of furniture & fixtures	(81,370 )	-	(272,417 )
Purchase of Software	(8,500 )	-	(88,966 )
Net cash used in investing activities	(89,870 )	-	(361,383 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Net proceeds from issuance of common stocks and warrants	4,248,275	-	14,072,601
(Repayments of) proceeds from bank line of credit	-	(750,000 )	-
Repayments of loans from related parties	-	(6,178 )	(2,000 )
Cash released from (restricted for) commercial line of credit	-	750,000	-
Net cash provided by financing activities	4,248,275	(6,178 )	14,070,601
<b>NET INCREASE (DECREASE) IN CASH &amp; CASH EQUIVALENTS</b>	<b>714,315</b>	<b>(1,822,824)</b>	<b>2,439,513</b>

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CASH & CASH EQUIVALENTS, BEGINNING BALANCE	1,725,197	1,910,821	-
CASH & CASH EQUIVALENTS, ENDING BALANCE	\$2,439,512	\$87,997	\$ 2,439,513
SUPPLEMENTAL DISCLOSURES:			
Interest paid	\$359	\$6,036	\$ 33,066
Income taxes paid	\$-	\$-	\$ 250
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Common stock and warrants issued for asset purchase	\$-	\$-	\$ 4,674,853
Options issued for previously accrued director compensation	\$-	\$-	\$ 45,000
Commitment Shares distributed for Capital contribution	\$2,387,250	\$-	\$ 2,387,250
Amortization of commitment shares issued for distributed shares	\$198,958	\$-	\$ 198,958

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

**ATOSSA GENETICS, INC.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**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 clearances 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. These test 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 purchased assets included 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), 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 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 June 30, 2013, the Company earned \$992,090 in revenue from the sale of its products 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 consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Management's Plan to Continue as a Going Concern

In order to continue as a going concern, the Company will need, 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 or long-term borrowings from banks, stockholders or other party(ies) when needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

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

**NOTE 3: SUMMARY OF ACCOUNTING POLICIES**

**Basis of Presentation:**

The accompanying 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 on an accrual basis for sales to distributors when the above four criteria are met. For sales of MASCT kits and devices directly to physicians, the revenue is typically recognized 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. For sales directly to physicians, 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.

**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. As of June 30, 2013 and December 31, 2012, no allowance for doubtful accounts was assessed or recorded.

**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 period ended June 30, 2013 and December 31, 2012, resulting in the net realizable value of the MASCT System being determined at zero as of June 30, 2013 and December 31, 2012, through taking the average sales price subtracted by selling expenses per unit. The Company assessed and recorded \$0 and \$29,884 loss on reduction of

inventory to the lower of cost or market for the six months ended June 30, 2013 and for the year ended December 31, 2012, 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 June 30, 2013 and December 31, 2012, management had identified no slow moving or obsolete inventory.

The Company provides, either directly or through distributors, the ForeCYTE testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the NRLBH for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase in 2012, the Company distributed the kits to customers at no cost and bundled 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. In 2013, the Company continues the practice of providing the MASCT System directly to certain physicians free of charge, or by offering a rebate to physicians; however, the MASCT System is not provided free of charge to distributors.



**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
Leasehold improvements	2.083

**Intangible assets:**

Intangible assets consist of intellectual property and software acquired in the Acueity asset purchase. At least annually, we evaluate purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense. There was no impairment of intangible assets as of and for the six months ended June 30, 2013 and year ended December 31, 2012, respectively.

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

	Useful Life (in years)
Patents	9-14
Software	3

**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:

	June 30, 2013	December 31, 2012
Prepaid Stock Purchase Agreement Service Fee	\$2,188,542	\$ -
Prepaid Insurance	52,864	62,551
Prepaid Hardware/Software Maintenance and Support Service Fee	37,867	20,000
Prepaid Payroll Taxes	35,950	40,082
Prepaid Rent	25,629	
Prepaid Tradeshow	6,849	-
	\$2,347,701	\$ 122,633

#### NOTE 5: PROPERTY, PLANT, AND EQUIPMENT

Property, plant and equipment consisted of the following:

	June 30, 2013	December 31, 2012
Machinery and equipment	\$178,752	\$ 97,383
Leasehold Improvements	93,665	93,665
Less: Accumulated depreciation	(66,617 )	(31,081 )
Property, plant, and equipment, net	\$205,800	\$ 159,967

Depreciation expense for the six months ended June 30, 2013 and 2012 was \$35,537 and \$8,647, respectively.

#### NOTE 6: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	June 30, 2013	December 31, 2012
Patents	\$4,704,853	\$ 4,704,853
Software	58,966	50,466
Less: Accumulated amortization	(306,200 )	(115,095 )
	\$4,457,619	\$ 4,640,224

Intangible assets amounted to \$4,457,619 and \$4,640,224 as of June 30, 2013 and December 31, 2012 respectively, mainly consisted of patents and software acquired. The acquired software in the amount of \$50,466 and \$58,966 as of June 30, 2013 and December 31, 2012, respectively, is for the purpose of managing laboratory results pursuant to a software installation agreement that was entered into on June 8, 2011. The amortization period for the purchased software is 3 years. Amortization expense related to software for the six months ended June 30, 2013 and 2012 was \$9,591 and \$8,410, respectively.

Patents amounted to \$4,704,853 and \$4,704,853 as of June 30, 2013 and December 31, 2012, respectively, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction (see Note 13). Patent assets will be amortized based on their determined useful life, and tested annually for impairment. The amortization period was from 9 to 14 years. Amortization expense related to patents was \$181,514 and \$0 for the six months ended June 30, 2013 and 2012, respectively.

Future estimated amortization expenses as of June 30, 2013 for the five succeeding years is as follows:

As of June 30,	Amounts
2013	\$382,683
2014	366,022
2015	364,681
2016	363,028
2017	363,028
Thereafter	2,618,177
	\$4,457,619

#### **NOTE 7: ACCRUED EXPENSES**

Accrued expenses consisted of the following:

	June 30, 2013	December 31, 2012
Accrued expenses	\$1,289,104	\$ 1,374,385
Accrued bonus payable	169,375	189,131
Accrued payroll tax liabilities	27,498	18,866
Deferred Rent	72,537	-
	\$1,558,514	\$ 1,582,382

#### **NOTE 8: STOCKHOLDERS' EQUITY**

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

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 service provider 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 website 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 13). 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 14), or \$4,312,500 in total.



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 \$3,454,000 after deducting underwriting discounts and commissions of approximately \$546,000.

On January 24, 2013, the Company issued 32,186 shares of Common Stock to consultants as compensation for the performance of services to the Company. The aggregate value of shares issued was \$143,550, or \$4.46 per share, the fair market value of the Company's Common Stock on the date of issuance.

From March 27, 2013 to June 30, 2013, the Company issued 933,333 shares to Aspire Capital Fund, LLC as part of a stock purchase agreement, including 250,000 shares of Common Stock as a commitment fee, resulting in \$3,969,740 in gross proceeds to the company. The Company incurred placement agent fees of \$119,071 and issued placement agent warrants to purchase 18,000 shares of Common Stock at \$5.80 per share, in connection with these stock sales to Aspire.

From January 1, 2013 to June 30, 2013, the Company issued 5,546 shares of common stock to various employees who elected to exercise their incentive stock options at a price of \$1.25 per share, resulting in \$6,000 in proceeds to the Company

During 2013, the Company issued 1,279,642 shares of Common Stock each upon exercise of outstanding warrants on a cashless basis and 60,000 shares upon exercise of warrants for cash. The non-cash warrants were exercised on a "net" basis without additional consideration received by the Company. These warrants were originally issued in 2011 in connection with the Company's private placement to accredited investors pursuant to Rule 506 of Regulation D under the Act.

#### 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 a 3% non-accountable expense allowance, which resulted in a payment to the Placement Agent of 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, 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 (collectively with the warrants exercisable at \$1.60 per share, 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 the \$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 June 23, 2011 which is the date that the Company completed a "significant private financing" under the terms of the Warrants (the "Initial Exercise Date"). The Warrants shall expire and no longer be exercisable on the fifth anniversary of the Initial Exercise Date (the "Expiration Date"). The Warrants may be exercised for cash or, at the option of the holder, may be exercised on a cashless basis; however if a registration statement is in effect for the resale of the common stock issuable upon exercise of the Warrants then the Warrants cannot be exercised on a cashless basis. As of June 30, 2013 such a registration statement was in effect and, therefore, the Warrants cannot be exercised on a cashless basis. As of June 30, 2013, substantially all of the Placement Agents Warrants have been exercised. There are no redemption features embodied in the 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 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:

	Fair Value Hierarchy Level	April-June2011	December 2011		
		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.

(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 would 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
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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 14).

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 would 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.

Through June 30, 2013, the Company has granted warrants to purchase 18,000 shares of common stock to the placement agent in connection with the financing facility with Aspire Capital. The warrants are exercisable at \$5.80 per share and expire on May 15, 2017. An expense of \$26,053 has been recognized in the second quarter of 2013 for issuance of these warrants.

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) were initially reserved for issuance in connection with awards granted under the 2010 Plan, such number of shares to be subject to adjustment as provided in the plan and in any award agreements entered into by the Company under the plan, and upon the exercise or conversion of any awards granted under the plan. On January 1, 2012, 400,000 shares were added to the 2010 Plan and on January 1, 2013, 500,000 shares were added to the 2010 Plan, as provided under the terms of the 2010 Plan.

On April 4, 2011, 45,000 non-qualified stock options were granted under the 2010 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 2010 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 12).

On April 30, 2012, 19,757 non-qualified stock options were granted under the 2010 Plan to members of the Board of Directors for their services provided to the Company.

On December 17, 2012, 228,000 incentive stock options were granted under the 2010 Plan to employees for their employment with and services to be provided to the Company (see Note 12).

On December 20, 2012, 200,000 inducement stock options were granted outside of the 2010 Plan to an employee for his employment with and services to be provided to the Company (see Note 12).

On January 4, 2013, 405,000 non-qualified stock options were granted outside of the 2010 Plan, and 95,000 incentive stock options were granted under the 2010 Plan, to an employee for his employment with and services to be provided to the Company (see Note 12).

On January 5, 2013, 32,000 incentive stock options were granted under the 2010 Plan to employees for their employment with and services to be provided to the Company (see Note 12).



On March 11, 2013, 70,710 non-qualified stock options were granted under the 2010 Plan to employee directors for their employment with and services provided to the Company in 2012 (see Note 12).

On May 6, 2013, 329,944 non-qualified stock options were granted under the 2010 Plan to the Board of directors for their 2012 and 2013 services on the Board and for committee services annual fees. The 2012 options are fully vested and the 2013 will vest over 12 months.

In June 2013, 250,000 stock options, 87,000 of which were under the 2010 Plan and 163,000 of which were non-qualified and granted outside the 2010 Plan, were granted to the Senior Vice President of Operations as an inducement to enter into employment with the Company. 120,000 additional stock options were also granted under the 2010 Plan during the same time to employees as bonuses and employment incentives.

#### **NOTE 9: 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 June 30, 2013 and December 31, 2012 due to the Company's continuing operating losses.

#### **NOTE 10: CONCENTRATION OF CREDIT RISK**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. At June 30, 2013 and December 31, 2012, the Company had \$2,189,512 and \$1,475,197 in excess of the FDIC insured limit, respectively.

**NOTE 11: 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 year ended December 31, 2012, the Company incurred \$46,529 of rent expense for the lease. The lease was terminated in December 2012, and the rental deposit was applied to the rent of the final month.

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, 2014. For the six months ended June 30, 2013, the Company incurred \$6,600 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 year ended December 31, 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 December 31, 2012. For the six months ended June 30, 2013, the Company incurred \$132,284 of rent expense for the lease, which included leasing office management expenses.

The future minimum lease payments due subsequent to June 30, 2013 under all non-cancelable operating leases for the next five years are as follows:

As of June 30,	Amount
2014	\$323,969
2015	132,737
2016	-
2017	-
2018	-
Thereafter	-
Total minimum lease payments	\$456,706

### Contingencies

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

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified. On July 8, 2013 the court granted the Company's motion to compel arbitration of these claims and therefore this action was dismissed.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director. At the time, Mr. Cononi was the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified. A motion is pending before the court to compel arbitration of these claims.

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of June 30, 2013. 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.

#### FDA Warning Letter

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

The Company is reasonably confident in its responses to the FDA. Consequently, no provision or liability has been recorded as of June 30, 2013 as a result of the Letter. However, it is at least reasonably possible that the Company's estimate of related 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 12: 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 December 31, 2012. The principal balance of \$79,300 and interest of \$1,440 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 Scientific Officer of the Company, who is also the wife of the Company’s Chairman and CEO. 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, and \$0 subsequent to December 31, 2010.

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 11). The \$1,100 security deposit paid to Ensisheim was received as of December 31, 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 Scientific 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 CSO. 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 CSO was \$693,048, of which \$492,095 was recorded to research and development expense. For the year ended December 31, 2012, salaries and bonuses of CEO and CSO amounted to \$322,590 and \$243,554, of which \$161,295 and \$243,554 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 CSO, 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 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 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-fourth (1/4) of the underlying shares monthly thereafter.

On September 1, 2011, 200,000 non-qualified stock options were granted under the 2010 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 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.

On December 17, 2012, 228,000 non-qualified stock options were granted under the 2010 Plan to employees as part of their employment agreements, at an exercise price of \$4.24 per share. On December 20, 2012, 200,000 non-qualified stock options were granted outside of the 2010 Plan, but governed in all respects by the 2010 Plan, to an employee as part of his employment agreement, at an exercise price of \$4.11 per share. These options each 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 employment commence;  
and
- (ii) One-sixteenth (1/16) of the underlying shares quarterly thereafter.

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 \$1,011,820 and \$70,662 for the six months ended June 30, 2013 and 2012, respectively.

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 & CSO	Dr. Hunkapiller	Employees & Officers	Non-employee Directors	Non-employee Directors	Employees	Employees
Date of grant	22-Jul-10	4-Apr-11	1-Sep-11	1-Sep-11	30-Apr-12	17-Dec-12	20-Dec-12
Fair value of common stock on date of grant	\$2.7560(B)	\$0.9060(C)	\$0.9060(C)	\$0.9060(C)	\$6.00 (D)	\$4.24	(E) \$4.11 (E)
Exercise price of the options	\$5.00	\$1.25	\$1.25	\$1.25	\$6.00	\$4.24	\$4.11
Expected life of the options (years)	3.33	5.31	5.65	5.65	5.00	5.74-6.10	6.11
Dividend yield	0.00 % 58.59 %	0.00 % 54.12 %	0.00 % 53.90 %	0.00 % 53.90 %	0.00 % 62.46 %	0.00 % 42.44-44.58 %	0.00 % 42.44 %

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Expected volatility											
Risk-free interest rate	1.03 %	2.26 %	1.08 %	1.08 %	0.89 %	0.91-0.99 %	0.99 %				
Expected forfeiture per year (%)	0.00 %	0.00 % (A)		0.00 %	0.00 %	0.00-10.00 %	0.00 %				
Weighted-average fair value of the options (per unit)	\$0.6744	\$0.3729	\$0.3579	\$0.3579	\$3.0367	\$1.7426-1.7887	\$1.7842				

	Employees &			
	Employee	Officers	Employee	CEO & CSO
	3-Jan-13	4-Jan-13	5-Jan-13	11-Mar-13
Date of grant				
Fair value of common stock on date of grant	\$ 4.31 (E)	\$ 4.11 (E)	\$ 3.95 (E)	\$ 6.57 (E)
Exercise price of the options	\$ 4.31	\$ 4.11	\$ 3.95	\$ 6.57
Expected life of the options (years)	6.11	6.11	6.11	5.00
Dividend yield	0.00 %	0.00 %	0.00 %	0.00 %
Expected volatility	42.23 %	43.79 %	42.22 %	47.09 %
Risk-free interest rate	0.99 %	0.99 %	1.13 %	0.90-1.13%
Expected forfeiture per year (%)	10.00 %	10.00 %	10.00 %	0 %
Weighted-average fair value of the options (per unit)	\$ 1.4712	\$ 1.6922	\$ 1.3511	\$ 2.7022

(A) 0.00% for the first year after the grant date, and 96.35% for every three months thereafter.

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

(B) 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 for the offering.

The fair value of the Company's common stock was derived implicitly from the Private Placement during April

(C) 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.

(E) The fair values of the Company's common stock were derived from the closing prices on the NASDAQ Capital Market as of the dates of grant.

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 five to 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 commenced 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.

Options issued and outstanding as of June 30, 2013 and their activities during the six 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, 2013	1,052,137	\$ 3.78	
Granted	1,302,654	5.02	
Expired	-	-	
Forfeited	(12,709 )	3.10	
Exercised	(5,546 )	1.79	
Outstanding as of June 30, 2013	2,336,536	4.48	8.36
Exercisable as of June 30, 2013	870,501	4.35	6.59
Vested and expected to vest <sup>(1)</sup>	2,178,857	4.48	8.26

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

As of June 30, 2013 and December 31, 2012, the aggregate intrinsic value of options outstanding was \$3,727,412 and \$1,150,416, respectively.

A summary of the status of the Company's unvested shares as of June 30, 2013 and changes during the six month period then ended is presented below:



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Unvested Shares	Shares	Weighted-Average Grant-Date Fair Value
Unvested as of January 1, 2013	520,835	\$ 824,549
Granted	1,302,654	2,592,353
Vested	(339,199 )	(719,032 )
Exercised	(5,546 )	(3,370 )
Forfeited	(12,709 )	(15,623 )
Unvested as of June 30, 2013	1,466,035	\$ 2,678,877

### **NOTE 13: 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 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries), 41 patent applications (32 in the U.S. and 9 in foreign countries), 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; 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, 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 which has since lapsed. 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 8). There are no future financial obligations from the Company to Acueity from the commercialization of the acquired assets.

### **NOTE 14: SUBSEQUENT EVENTS**

Management has evaluated subsequent events through the date of this report which is the date the consolidated financial statements were available to be issued. All subsequent events requiring recognition as of June 30, 2013 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”, except as follows:

From July 1, 2013 through the date of filing of this report, the Company has sold a total of 200,000 shares of Common Stock to Aspire Capital Fund LLC under the stock purchase agreement dated March 27, 2013 with aggregate gross proceeds to the Company of \$930,165.

On July 2013, the Company entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces in our existing building under a separate lease agreement. The lease is from August 2013 through November 2014 and, the gross rent is \$ 4,500 per month.

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

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

**Forward-Looking Statements**

Statements made in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q that are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

- our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;
- our ability to successfully develop and commercialize new tests, tools and technologies currently in development and in the time frames currently expected;
- our ability to engage third-party suppliers to manufacture the MASCT or Microcatheter System and its components at quantities and costs acceptable to us;

- our ability to satisfy ongoing Food and Drug Administration requirements for the MASCT and Microcatheter System and to obtain regulatory approvals for our other products and services in development, including our ability to timely and adequately respond to the warning letter we received from the FDA on February 21, 2013 and any issues resulting therefrom;
- the benefits and clinical accuracy of the ForeCYTE and ArgusCYTE tests and whether any product or service that we commercialize is safer or more effective than competing products and services;
- our ability to establish and maintain intellectual property rights covering our products and services;
- the willingness of health insurance companies, including those who are members of the MultiPlan and FedMed networks, and other third-party payors to approve our products and services for coverage and reimbursement;
- our ability to establish and maintain an independent sales representative force, including with Clarity Women's Health, a division of Diagnostic Test Group LLC, Millennium Medical Devices and their sub-distributors, to market our products and services that we may develop, both regionally and nationally;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;
- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;
- our expectations as to future financial performance, expense levels and liquidity sources;
- our ability to attract and retain key personnel; and
- our ability to sell additional shares of our Common Stock to Aspire Capital Fund, LLC under the terms of our common stock purchase agreement with them dated March 27, 2013.

This report also contains estimates and other statistical data provided by independent parties and by us relating to market size and growth and other industry data. These and other forward-looking statements made in this report are presented as of the date on which the statements are made. We have included important factors in the section entitled “Risk Factors” in our filings with the SEC that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this report. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

## Company Overview

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

Our diagnostic tests consist of patented medical devices that can collect nipple aspirate fluid, or NAF, 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 and DCIS by using our patented microcatheters to deliver, directly into the milk ducts, pharmaceutical formulations that can be used to treat these conditions. 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 or DCIS, potentially promoting efficacy of the treatment while limiting systemic exposure, which has the potential to lower the overall toxicity of these treatments.

## Current Operations

We launched our commercial operations in late 2011. In 2012 we initiated and completed the field experience trial of our first two tests, the ForeCYTE test and the ArgusCYTE test. In January 2013, we announced the national launch of the ForeCYTE test through our distributor Clarity Women’s Health, a division of Diagnostic Testing Services, LLC. On April 30, 2013, the company entered into a Distribution and Marketing Services Agreement with Millennium Medical Devices LLC, pursuant to which Millennium will market and distribute the Company’s MASCT system and ForeCYTE breast health test kits in New York City and Northern New Jersey. Millennium has placed an initial order for 10,000 patient collection kits. In May 2013, we entered into a distribution agreement with Fisher Healthcare, a division of Fisher Scientific Company, LLC.

As we successfully launch the MASCT System and our related laboratory service offerings, we incur additional sales and marketing expenses. In May 2013, the Company hired several direct sales employees in seven different states as an effort to build a regional, and ultimately national, sales force.

As of July 31, 2013, we have enrolled 243 doctors and clinics as providers of the ForeCYTE and/or ArgusCYTE tests and have received, processed, and reported the results to physicians from 2,426 NAF samples processed and reported with our ForeCYTE test (representing 1,213 patients) and 41 ArgusCYTE samples. From inception (April 30, 2009) through June 30, 2013, we have generated \$992,090 in revenue from the sale of our MASCT System and by providing laboratory services. We incurred net losses of \$2,583,699 and \$4,525,139 for the three months and six months ended June 30, 2013 and \$14,257,045 since inception. As of June 30, 2013, we had an accumulated deficit of approximately \$14.3 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 ForeCYTE test kits and generating laboratory service revenue from our tests, and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

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.

On March 27, 2013 we entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of \$30 million of shares of our common stock over the three-year term of the agreement. Under the agreement, Aspire purchased \$1,000,000 of our common stock on March 27, 2013 for \$12 per share and since that date through August 14, 2013 Aspire has purchased an additional 800,000 shares of our common stock for a total aggregate purchase price of \$3,899,905.

## **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 distributors, 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 plan to initially use regional specialty product distributors, with independent sales representatives specializing in Women's Health, to commercialize the ForeCYTE and ArgusCYTE Tests. As of August 14, 2013 we have entered into distribution agreements with Clarity Women's Health, a division of Diagnostic Test Group LLC (DTG), Millennium Medical Devices LLC; and Fisher HealthCare, a division of Fisher Scientific Company, LLC; however, we cannot be certain that we will be able to build additional distributor relationships or that any distributor relationships will adequately address the national market.

## **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 provided for monthly rent of \$3,658 and a security deposit of \$3,658. The lease terms were from September 29, 2010 through March 31, 2011, at which time the lease has converted to month to month. The monthly rent for the lease increased to \$4,267 commencing January 2012. The lease was terminated in December 2012, and the rental deposit was applied to the rent of the final month.

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, 2014. For the six months and three months ended June 30, 2013, the Company incurred \$6,600 and \$3,300 of rent expense, respectively, 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 provided for monthly rent of \$600 and a security deposit of \$1,200. The lease terms were from July 11, 2011 through July 31, 2012. 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 provided for monthly rent of \$1,400 and a security deposit of \$1,000. The lease terms were 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. For the three months and six months ended June 30, 2013, the Company incurred \$66,142 and \$132,284 of rent expense, respectively, which included leasing office management expenses.

In July 2013, the Company entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces in our existing building under a separate lease agreement. The lease is from August 2013 through November 2014, and the gross rent is \$ 4,500 per month.

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

## **Legal Proceedings**

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

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified. On July 8, 2013, the court granted the Company's motion to compel arbitration of these claims and therefore this action was dismissed.

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

time, Mr. Cononi was the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified. A motion is pending before the court to compel arbitration of these claims.

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of June 30, 2013. 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.

### **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, 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) our 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 on an accrual basis for sales to distributors when the above four criteria are met. For sales of MASCT kits and devices directly to physicians, the revenue is typically recognized upon receipt of cash as we have 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. We 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. For sales directly to physicians, once a history of sales and collectability has been established, we 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**

We record 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. We estimate we will utilize the diagnostic testing revenue history

once it reaches 12 months of collection data to determine a proper allowance for doubtful accounts.

### *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 six months ended June 30, 2013 and since inception through June 30, 2013, 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, \$0 and \$29,884 of loss on reduction of inventory to the lower of cost or market was assessed and recorded as of June 30, 2013 and since inception through June 30, 2013, 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 June 30, 2013, management had identified no slow moving or obsolete inventory.

The Company provides, either directly or through distributors, the 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 in 2012, the Company distributed the kits to customers at no cost and bundled 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.

### *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.

### *Intangible Assets*

Intangible assets consist of intellectual property and software acquired. At least annually, we evaluate purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

### *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 Chief Executive Officer, 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 Chief Scientific Officer, 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 (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, 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) 11,250 option shares shall vest one hundred and eighty (180) days after the date of grant;
- (iii) 11,250 option shares shall vest two hundred and seventy (270) days after the date of grant; and
- (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 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 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 option shares shall vest on December 1, 2011;

(iii) 30,000 option shares shall vest on March 1, 2012;

(iv) 30,000 option shares shall vest on June 1, 2012; and

(v) 30,000 option shares shall vest on September 1, 2012.

On April 30, 2012, 19,757 non-qualified stock options were granted under the 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.

On December 17, 2012, 228,000 incentive stock options were granted under the Plan to employees as part of their employment agreements, at an exercise price of \$4.24 per share and on December 20, 2012, an option for 200,000 shares was granted outside of the Plan to an employee as part of his employment agreement, at an exercise price of \$4.11 per share. On January 4, 2013, options to purchase 500,000 shares of common stock were granted pursuant to an employment agreement with our Chief Financial Officer and General Counsel. These options have a ten-year contractual term. One-fourth of the options vest and become exercisable one year from the date of hire and one-sixteenth (1/16) quarterly thereafter over the following three years. On March 11, 2013, fully-vested options to purchase a total of 70,710 shares exercisable at \$6.57 per share were granted to our Chief Executive Officer and Chief Scientific Officer in lieu of cash bonuses for services in 2012.

On May 6, 2013, 329,944 non-qualified stock options were granted under the 2010 Plan to the non-employee members of the board of directors for their 2012 and 2013 services on the board and for committee services annual fees. The 2012 options are fully vested and the 2013 will vest over 12 months.

In June 2013, 250,000 stock options (163,000 non-qualified) were granted under the 2010 Plan to the Senior Vice President of Operations as an inducement to enter into employment with the Company. 120,000 additional stock options were also granted during the same time to employees as bonuses and employment incentives

## Results of Operations

### Three Months and Six Months Ended June 30, 2013 and 2012

*Revenue and Cost of Goods Sold.* For the three months ended June 30, 2013, revenue totaled \$326,078, consisting of \$120,488 diagnostic testing service revenue from our ForeCYTE testing services and \$205,590 in product sales revenue from sales of ForeCYTE kits and MASCT Systems. This represents an increase of \$102,981(46%) from the total revenue of \$223,097 for the three months ended June 30, 2012. Revenue for the six months ended June 30, 2013 totaled \$508,748, consisting of \$289,718 in diagnostic testing and \$219,030 in product sales, an increase of \$230,938 (83%) from the total revenue of \$277,810 in the same period in 2012. The growth in revenue is mainly due to \$205,590 in product sales to Millennium for the initial purchase of 10,000 ForeCYTE kits.

Cost of revenue totaled \$222,160 and \$288,624 for the three and six months ended June 30, 2013, compared to \$17,788 and \$20,985 in the same periods in 2012. The increase in cost of revenue is primarily attributable to cost of product sales to Millennium. 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, 2012, no corresponding cost of goods sold was recorded for the sales of MASCT System during 2013.

For the three months ended June 30, 2013, Gross profit totaled \$103,918 (\$118,132 profit from diagnostic services and \$14,214 loss from the sales of products), compared to \$205,309 profit in the same period in 2012. For the six months ended June 30, 2013, gross profit totaled \$220,124 (\$239,763 gross profit on diagnostic testing and \$19,639 loss on product sales.), compared to \$233,018 in the same period in 2012. Loss on reduction of inventory to lower of cost or market was \$0 for the six months ended June 30, 2013. Our MASCT System is sometimes sold at a price substantially lower than its cost as is customary for laboratories that supply specimen collection kits. For these reasons, the manufacturing cost allocated to each inventory unit is high.

*Operating Expenses.* For the three months ended June 30, 2013, total operating expenses were \$2,687,265 consisting of G&A expenses of \$2,177,920, research and development expenses of \$189,955, and selling expenses of \$319,390, representing an increase of \$1,316,144, or 96% from \$1,371,121 in the same period in 2012, consisting of G&A expenses of \$704,208, research and development expenses of \$543,081, and selling expenses of \$123,832. For the six months ended June 30, 2013, total operating expenses were \$4,744,904, consisting of G&A expenses of \$3,742,792, research and development expenses of \$410,147, and selling expenses of \$591,965, an increase of \$2,283,906 or 92.8% compared to \$2,460,998 in six months ended June 30, 2012.

During the initial marketing phase in 2012, the Company distributed the kits to customers at no cost and bundled 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. We expect that our G&A and selling expenses 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 additional sales and marketing expenses as we continue building a regional, and ultimately national, sales force.

*General and Administrative Expenses.* G&A expenses for the three months ended June 30, 2013 were \$2,177,920, an increase of \$1,473,712, or 210%, from \$704,208 in the same period in 2012. The G&A expenses for the three months ended June 30, 2013 consisted primarily of \$457,165 in salaries and bonus expense, \$162,106 in legal expense, \$330,951 in consulting expense, \$284,895 in professional fees, \$48,059 in travel expense, \$96,588 in insurance expense, \$90,378 in marketing expenses, and \$391,029 in Board of Directors annual fees (consisting primarily of the estimated value of stock options granted to non-employee directors for 2012 and 2013 service). G&A expenses for the six months ended June 30, 2013 were \$3,742,792, an increase of \$2,437,132, or 187%, from \$1,305,660 for the six months ended 2012. The G&A expenses for the six months ended June 2013 consisted of \$964,025 in salaries and bonus expense, \$340,053 in legal expenses, \$609,823 in consulting expense, \$609,276 in professional fees, \$68,545 in travel expense, \$159,510 in insurance expense, \$105,771 in marketing expenses, and \$436,029 in Board of Directors annual fees.

G&A expenses for the three months ended June 30, 2012 were \$704,208 primarily consisted of \$89,928 in salaries and bonus expense, \$346,183 in legal expenses, \$68,428 in consulting expense, \$41,852 in professional fees, \$48,059 in travel expense, \$166,647 in insurance expense, \$90,378 in marketing expenses, and \$13,000 in Board of Directors annual fees. G&A expenses for the six months ended June 30, 2012 were \$1,305,769 and primarily consisted of \$195,216 in salaries and bonus expense, \$573,097 in legal expenses, \$118,693 in consulting expense, \$641,262 in professional fees, \$20,408 in travel expense, \$34,089 in insurance expense, \$4,015 in marketing expenses, and \$13,000 in Board of Directors annual fees.

The increase in G&A expenses over 2012 was primarily attributable to an increase in administrative staff, an increase in consulting and professional fees related to regulatory matters and investor relations, an increased cost of insurance and an increased cost of fees to our non-employee directors resulting from the estimated value of options granted in 2013 for service in 2012 and 2013. We expect our G&A expenses will continue to grow as we hire additional administrative and manufacturing personnel to continue our launch of the MASCT System and our other products under development and as we incur additional costs associated with being a publicly traded company.

*Research and Development Expenses.* Research and Development expenses for the three months ended June 30, 2013 were \$189,955, a decrease of \$353,126, or 65%, from \$543,081 for the three months ended June 30, 2012. R&D expenses for the six months ended June 30, 2013 were \$410,147, a decrease of \$550,924, or 57% from the same period in 2012. The decrease in R&D expenses over the three and six months ended June 30, 2012 is attributed to the completion of the development of the MASCT System for the national launch in 2013. We expect that our R&D expenses will increase as we add additional full time employees and incur additional costs to continue the development of our products and services under development.

*Selling Expenses.* Selling expenses for the three months ended June 30, 2013 were \$319,390, an increase of \$195,558, or 158%, from \$123,832 for the three months ended June 30, 2012. Selling expense for the three months ended June 30, 2013 consisted primarily of \$182,740 in selling and marketing professional fees, \$89,418 in salaries and \$34,368 in advertising. Selling expenses for the six months ended June 30, 2013 were \$591,965, an increase of \$397,698, or 205%, from \$194,267 for the same period in 2012. Selling expense for the six months ended June 30, 2013 consisted primarily of \$332,655 in selling and marketing professional fees, \$186,899 in salaries and \$59,087 in advertising. Selling expenses increased as a result of increased sales and marketing expenses paid to our distributor, and increased salaries and other selling and marketing expenses related to the national launch of ForeCYTE.

## **Liquidity and Capital Resources**

We have a history of operating losses as we have focused our efforts on raising capital and building the MASCT System. The report of our independent auditors issued on our consolidated financial statements as of and for the years ended December 31, 2012 and 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 approximately \$3.5 million.

On March 27, 2013 we entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of \$30 million of shares of our common stock over the three-year term of the agreement. Under the agreement, Aspire purchased \$1,000,000 of our common stock on March 27, 2013 for \$12 per share and since that date through August 14, 2013 Aspire has purchased an additional 800,000 shares of our common stock for a total aggregate purchase price of \$3,899,905.

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 six months ended June 30, 2013, we incurred a net loss of \$4,525,139. Net cash used in operating activities was \$3,444,090, net cash used in investing activities was \$89,870 and net cash provided by financing activities was \$4,248,275. For the for the six months ended June 30, 2012, we incurred a net loss of \$2,230,867, net cash used in operating activities was \$1,816,646, net cash used in investing actives was \$0 and net cash used by financing activities was \$6,178.

## 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. We expect our existing capital resources as of the date of this report to be sufficient to fund our planned operations for at least the next four months. 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 \$10 million of additional capital. 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 funds 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 and speed of patient and physician acceptance of our products and the degree to which third-party payors approve the ForeCYTE and ArgusCYTE Tests for reimbursement.

Since inception (April 30, 2009) through June 30, 2013, we have generated \$992,090 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 our existing resources as of June 30, 2013, to be sufficient to fund our planned operations for at least the next four months of 2013, 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.

### **ITEM 3. QUANTATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not applicable.

### **ITEM 4. CONTROLS AND PROCEDURES**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2013. 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 June 30, 2013, 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 June 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

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

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified. On July 8, 2013 the court granted the Company's motion to compel arbitration of these claims and therefore this action was dismissed.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director. At the time, Mr. Cononi was the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified. A motion is pending before the court to compel arbitration of these claims.

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of June 30, 2013. 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.

#### **ITEM1A. RISK FACTORS**

There have been no material changes to the risk factors described in the Company's Annual Report on Form 10-K, as filed with the SEC on March 28, 2013, except for the following items which have been updated.

##### **Anticipated liquidity issues in the next four to twelve months.**

For the quarter ended June 30, 2013, we generated \$326,078 in revenue from the sale of our products and services and we incurred a net loss of \$2,583,347. Through June 30, 2013 we had an accumulated deficit of approximately \$14.3 million. As of the date of this report, we expect that our existing resources will be sufficient to fund our planned operations for at least the next four months. However, to fund our operations for at least the next 12 months under our current business plan, we estimate that we will need between \$4 million and \$10 million of additional capital. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We may not achieve profitability from the sale of our products and services in the next four to twelve months and other sources of capital may not be available when we need them or on acceptable terms. For example, we may not be able to raise capital by selling Common Stock to Aspire because the Aspire registration statement may not remain effective. If we are unable to raise in a timely fashion the amount of capital we anticipate needing, from Aspire or otherwise, we would be forced to curtail or cease operations.

**We have a history of operating losses, we currently sell the MASCT System for significantly less than it costs to manufacture, and we expect to continue to incur losses in the future.**

We have a limited operating history and have incurred total net losses of approximately \$14.3 million from our incorporation in April 2009 through June 30, 2013. We have recognized \$922,090 in revenue as of June 30, 2013 and we do not expect that we will be in a position to generate significant revenue until we are able to launch our tests more broadly. Additionally, we will continue to incur further losses in connection with inventory costs for our medical test products, marketing and sales expenses in launching our products and services, research and development costs for additional tests, and the maintenance of our CLIA-certified laboratory. For example, our MASCT System is frequently sold at a price lower than its cost as is customary for laboratories that supply specimen collection kits. This practice of selling our MASCT System substantially below its cost and offering rebates negatively impacts our profitability. Although we expect that the cost to manufacture our MASCT System will be substantially lower when we increase the volume of production for post-trial commercial launch and once we have been more successful in penetrating the market, if our expectation is not realized we may not be able to generate significant revenue nor achieve profitability. Accordingly, we may never achieve profitability.

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

During the period covered by this report, the company issued the following securities which were not registered under the Securities Act of 1933:

On June 3, 2013 Peter Carbonaro was granted an option to purchase 250,000 shares of common stock at \$4.58 per share, which was the fair market value on the date of grant, 163,000 of which was outside of our 2010 Stock Option and Incentive Plan as an inducement for Mr. Carbonaro to become the Company's Senior Vice President of Operations. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving any public offering.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

(a) Exhibits

31.1 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay

31.2 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Kyle Guse

32.1 Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay

32.2 Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse

101\* Interactive Data Files pursuant to Rule 405 of Regulation S-T

\* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under these sections.

## SIGNATURES

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

Date: August 14, 2013

/s/ Steven C. Quay

President and Chief  
Executive Officer

(On behalf of the  
Registrant)

/s/ Kyle Guse

Kyle Guse  
Chief Financial Officer, General Counsel and Secretary

(As Principal Financial and Accounting Officer)