

Cytosorbents Corp  
Form 10-Q  
November 06, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 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 September 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: 000-51038**

**CYTOSORBENTS CORPORATION**

**(Exact name of registrant as specified in its charter)**





**CytoSorbents Corporation**

**(a development stage company)**

**FORM 10-Q**

**September 30, 2013**

**TABLE OF CONTENTS**

	Page
<b>PART I - FINANCIAL INFORMATION</b>	
Item 1. Financial Statements (September 30, 2013 and 2012 are unaudited)	3
Consolidated Balance Sheets	3
Consolidated Statements of Operations and Comprehensive Loss	4
Consolidated Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficiency)	5
Consolidated Statements of Cash Flows	6
Notes to Consolidated Financial Statements	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3. Quantitative and Qualitative Disclosures About Market Risk	22
Item 4. Controls and Procedures	22
<b>PART II - OTHER INFORMATION</b>	
Item 1. Legal Proceedings	23
Item 1A. Risk Factors	23
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 3. Defaults of Senior Securities	

	23
Item 4. Mine Safety Disclosures	23
Item 5. Other Information	23
Item 6. Exhibits	23
<b>SIGNATURES</b>	24

**PART I — FINANCIAL INFORMATION****Item 1. Financial Statements.****CYTOSORBENTS CORPORATION**

(a development stage company)

**CONSOLIDATED BALANCE SHEETS**

	September 30, 2013 (Unaudited)	December 31, 2012
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$2,349,994	\$1,729,344
Accounts receivable, net of allowance for doubtful accounts at \$-0-	193,873	51,779
Inventories	362,542	682,372
Prepaid expenses and other current assets	737,655	476,093
<b>Total current assets</b>	<b>3,644,064</b>	<b>2,939,588</b>
Property and equipment – net	143,533	145,600
Other assets	251,409	254,220
<b>Total long-term assets</b>	<b>394,942</b>	<b>399,820</b>
<b>Total Assets</b>	<b>\$4,039,006</b>	<b>\$3,339,408</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$572,014	\$800,670
Accrued expenses and other current liabilities	496,443	349,841
Deferred revenue	435,686	---
Convertible notes payable, net of debt discount in the amount of \$281,424 at September 30, 2013 and \$178,775 at December 31, 2012	1,561,576	926,225
<b>Total current liabilities</b>	<b>3,065,719</b>	<b>2,076,736</b>
<b>Total liabilities</b>	<b>3,065,719</b>	<b>2,076,736</b>
Redeemable Series B Convertible Preferred Stock, par value \$0.001, 200,000 shares authorized at September 30, 2013 and December 31, 2012, respectively, 77,401.49 and 72,073.26 issued and outstanding , respectively	14,583,515	12,887,817
Stockholders' Equity (Deficit):		
10% Series A Convertible Preferred Stock, par value \$0.001, 12,000,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 1,716,743	1,717	1,594

Edgar Filing: Cytosorbents Corp - Form 10-Q

and 1,594,164 shares issued and outstanding, respectively

Common Stock, par value \$0.001, 800,000,000 shares authorized at September 30,

2013 and 500,000,000 shares authorized at December 31, 2012, 245,140,613 and

214,967,503 shares issued and outstanding, respectively

Additional paid-in capital

Deficit accumulated during the development stage

Accumulated other comprehensive loss

Total stockholders' deficit

Total Liabilities and Stockholders' Deficit

245,141	214,968
90,587,894	86,903,415
(104,469,233)	(98,732,460)
24,253	(12,662 )
(13,610,228 )	(11,625,145)

\$4,039,006	\$3,339,408
-------------	-------------

See accompanying notes to consolidated financial statements.

**CYTOSORBENTS CORPORATION****(a development stage company)****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	Period from January 22,1997 (date of inception) to September 30, 2013 (Unaudited)	Nine months ended September 30, 2013		Three months ended September 30, 2012	
		(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:					
Sales	\$ 695,280	\$507,628	\$63,614	\$203,561	\$13,679
Grant and other income	3,227,684	1,035,877	675,000	677,131	591,667
Total revenue	3,922,964	1,543,505	738,614	880,692	605,346
Cost of revenue	1,907,560	1,073,689	261,101	620,623	141,849
Gross profit	2,015,404	469,816	477,513	260,069	463,497
Other Expenses:					
Research and development	55,635,957	1,706,498	1,854,407	294,198	554,266
Legal, financial and other consulting	9,155,600	570,465	385,612	157,926	150,785
Selling, general and administrative	28,312,979	1,901,768	915,402	687,788	359,625
Change in fair value of management incentive units	(6,055,483 )	---	—	—	—
Total expenses	87,049,053	4,178,731	3,155,421	1,139,912	1,064,676
Loss from operations	(85,033,649 )	(3,708,915 )	(2,677,908 )	(879,843 )	(601,179 )
Other (income)/expense:					
Gain on disposal of property and equipment	(21,663 )	—	—	—	—
Gain on extinguishment of debt	(216,617 )	—	—	—	—
Interest expense/(income), net	7,601,355	299,805	447,978	84,946	50,801
Penalties associated with non-registration of	361,495	—	—	—	—
Series A Preferred Stock					
Total other (income) expense, net	7,724,570	299,805	447,978	84,946	50,801



Edgar Filing: Cytosorbents Corp - Form 10-Q

Loss before benefit from income taxes	(92,758,219 )	(4,008,720 )	(3,125,886 )	(964,789 )	(651,980 )
Benefit from income taxes	(939,074 )	—	—	—	—
Net loss	(91,819,145 )	(4,008,720 )	(3,125,886 )	(964,789 )	(651,980 )
Preferred Stock Dividend	12,650,088	1,728,053	1,870,846	525,148	629,725
Net Loss available to common shareholders	\$ (104,469,233 )	\$ (5,736,773 )	\$ (4,996,732 )	\$ (1,489,937 )	\$ (1,281,705 )
Basic and diluted net loss per common share		\$(0.02 )	\$(0.03 )	\$(0.01 )	\$(0.01 )
Weighted average number of shares of common stock outstanding		232,426,316	193,383,650	242,512,486	204,438,894
Net loss	\$ (91,819,145 )	\$ (4,008,720 )	\$ (3,125,886 )	\$ (964,789 )	\$ (651,980 )
Other comprehensive income:					
Currency translation adjustment	24,253	36,915	—	40,184	—
Comprehensive loss	\$ (91,794,892 )	\$ (3,971,805 )	\$ (3,125,886 )	\$ (924,605 )	\$ (651,980 )

See accompanying notes to consolidated financial statements.

## CYTOSORBENTS CORPORATION

(a development stage company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)

	Period from December 31, 2012 to September 30, 2013 (Unaudited)									
	Series B Redeemable Convertible Preferred Stock		Common Stock		Preferred Stock A		Additional	Accumulated	Deficit	
	Shares	Amount	Shares	Par value	Shares	Par Value	Paid-In Capital	Other Comprehens Loss	Accumulat Develop Stage	
Balance at December 31, 2012	72,073.26	\$12,887,817	214,967,503	\$214,968	1,594,164	\$1,594	\$86,903,415	\$(12,662)		\$(98,730)
Stock based compensation - employees, consultants and directors							300,105			
Issuance of common stock for services rendered			500,000	500			64,968			
Issuance of Series A Preferred Stock as dividends					122,579	123	11,846			(11,969)
Issuance of Series B Preferred Stock	5,526.50	1,716,084								(1,716,084)

Edgar Filing: Cytosorbents Corp - Form 10-Q

as dividends

Conversion of  
Series A and  
Series B  
Preferred into  
Common

(198.27 ) (20,386 ) 547,707 548 19,838

Issuance of  
common stock  
for cash

14,842,328 14,842 1,585,125

Conversion of  
convertible  
notes to  
common

9,739,912 9,740 1,216,302

Other  
comprehensive  
income/(loss):  
foreign  
translation  
adjustment

36,915

Relative fair  
value of  
warrants and  
beneficial  
conversion  
feature in  
connection  
with issuance  
of convertible  
notes

331,117

Exercise of  
warrants

3,986,426 3,987 135,540

Exercise of  
stock options

556,737 556 19,638

Net loss

(4,008)

Balance at  
September 30,  
2013

77,401.49 \$14,583,515 245,140,613 \$245,141 1,716,743 \$1,717 \$90,587,894 \$24,253 \$(104,4

See accompanying notes to consolidated financial statements.



**CYTOSORBENTS CORPORATION****(a development stage company)****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Period from January 22, 1997 (date of inception) to September 30, 2013 (Unaudited)	Nine months Ended September 30, 2013 (Unaudited)	Nine months ended September 30, 2012 (Unaudited)
Cash flows from operating activities:			
Net loss	\$ (91,819,145)	\$ (4,008,720)	\$ (3,125,886)
Adjustments to reconcile net loss to net cash used in operating activities:			
Common stock issued as inducement to convert convertible notes payable and accrued interest	3,351,961	—	—
Issuance of common stock to consultant for services	95,468	65,468	—
Depreciation and amortization	2,551,594	47,573	32,121
Amortization of debt discount	2,694,197	228,468	420,506
Gain on disposal of property and equipment	(21,663 )	—	—
Gain on extinguishment of debt	(216,617 )	—	—
Interest expense paid with Series B Preferred Stock in connection with conversion of notes payable	3,147	—	—
Abandoned patents	183,556	—	—
Bad debts - employee advances	255,882	—	—
Contributed technology expense	4,550,000	—	—
Consulting expense	237,836	—	—
Management unit expense	1,334,285	—	—
Expense for issuance of warrants	533,648	—	—
Expense for issuance of options	2,868,293	300,105	16,964
Amortization of deferred compensation	74,938	—	—
Penalties in connection with non-registration event	361,496	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(193,873 )	(142,094 )	(15,863 )
Inventories	(362,542 )	319,830	(194,756 )
Prepaid expenses and other current assets	(429,203 )	318,438	(72,644 )
Other assets	(37,511 )	9,442	880
Accounts payable and accrued expenses	3,144,793	38,989	84,114
Accrued interest expense	1,823,103	—	—
Deferred revenue	435,686	435,686	—

Edgar Filing: Cytosorbents Corp - Form 10-Q

Net cash used by operating activities	(68,580,671)	(2,386,815 )	(2,854,564)
Cash flow from investing activities			
Proceeds from sale of property and equipment	32,491	—	—
Purchases of property and equipment	(2,454,086 )	(33,276 )	—
Patent costs	(517,375 )	(18,861 )	(20,957 )
Purchases of short-term investments	(393,607 )	—	—
Proceeds from sale of short-term investments	393,607	—	—
Loan receivable	(1,632,168 )	—	—
Net cash used by investing activities	(4,571,138 )	(52,137 )	(20,957 )

6

## Cash flows from financing activities:

Proceeds from issuance of common stock	400,490	—	—
Proceeds from issuance of preferred stock	9,579,040	—	—
Equity contributions - net of fees incurred	51,671,278	1,599,967	3,050,000
Proceeds from borrowings	13,151,881	1,263,000	700,000
Proceeds from subscription receivables	499,395	—	—
Proceeds from exercise of stock options	35,940	20,194	—
Proceeds from exercise of warrants	139,526	139,526	—
Net cash provided by financing activities	75,477,550	3,022,687	3,750,000
Effect of exchange rates on cash	24,253	36,915	—
Net change in cash and cash equivalents	2,349,994	620,650	874,479
Cash and cash equivalents – beginning of period	—	1,729,344	1,186,653
Cash and cash equivalents - end of period	\$2,349,994	\$2,349,994	\$2,061,132

**Supplemental disclosure of cash flow information:**

Cash paid during the period for interest	\$590,189	\$—	\$—
--	-----------	-----	-----

**Supplemental schedule of noncash investing and financing activities:**

Increase in other current assets through the issuance of convertible debt	\$580,000	\$580,000	\$—
Debt discount in connection with issuance of convertible debt	\$1,975,322	\$331,117	\$87,700
Fair value of shares issued as costs of raising capital	\$617,520	\$34,034	\$236,565
Note payable principal and interest conversion to equity	\$13,175,491	\$1,226,042	\$685,208
Issuance of member units for leasehold improvements	\$141,635	\$—	\$—
Issuance of management units in settlement of cost of raising capital	\$437,206	\$—	\$—
Change in fair value of management units for cost of raising capital	\$278,087	\$—	\$—
Exchange of loan receivable for member units	\$1,632,168	\$—	\$—
Issuance of equity in settlement of accounts payable	\$1,614,446	\$—	\$—
Issuance of common stock in exchange for stock subscribed	\$399,395	\$—	\$—
Costs paid from proceeds in conjunction with issuance preferred stock	\$768,063	\$—	\$—
Preferred stock dividends	\$12,650,088	\$1,728,053	\$1,870,846
Net effect of conversion of common stock to preferred stock prior to merger	\$559	\$—	\$—

During the nine months ended September 30, 2013 and 2012, 198.27 and 140.87 Series B Preferred Shares were converted into 547,707 and 388,603 Common shares, respectively. During the nine months ended September 30, 2013 and 2012, -0- and 3,003 Series A Preferred Shares were converted into -0- and 30,030 Common shares, respectively. For the period from January 22, 1997 (date of inception) to September 30, 2013, 22,774.45 Series B Preferred Shares and 9,558,112 Series A Preferred Shares were converted into 62,912,304 and 43,728,457 Common Shares, respectively.

See accompanying notes to consolidated financial statements.

7



**CytoSorbents Corporation**

**Notes to Consolidated Financial Statements**

**(UNAUDITED)**

**September 30, 2013**

**1. BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the requirements of Form 10-Q of the Securities and Exchange Commission (the "Commission") and include the results of CytoSorbents Corporation (the "Parent"), CytoSorbents, Inc., its wholly-owned operating subsidiary (the "Subsidiary"), and CytoSorbents Europe GmbH, its wholly-owned European subsidiary (the "European Subsidiary"), collectively referred to as "the Company." Accordingly, certain information and footnote disclosures required in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. Interim statements are subject to possible adjustments in connection with the annual audit of the Company's accounts for the year ended December 31, 2013. In the opinion of the Company's management, the accompanying unaudited consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) which the Company considers necessary for the fair presentation of the Company's consolidated financial position as of September 30, 2013 and the results of its operations and cash flows for the nine and three month periods ended September 30, 2013 and 2012, and for the period January 22, 1997 (date of inception) to September 30, 2013. Results for the nine and three months ended are not necessarily indicative of results that may be expected for the entire year. The unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements of the Company and the notes thereto as of and for the year ended December 31, 2012 as included in the Company's Form 10-K filed with the Commission on April 03, 2013.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has experienced negative cash flows from operations since inception and has a deficit accumulated during the development stage at September 30, 2013 of \$104,469,233. The Company is not currently generating significant revenue and is dependent on the proceeds of present and future financings to fund its research, development and commercialization program. These matters raise substantial doubt about the Company's ability to continue as a going concern. The Company is continuing its fund-raising efforts. Although the Company has historically been successful in raising additional capital through equity and debt financings, there can be no assurance that the Company will be successful in raising additional capital in the future or that it will be on favorable terms. We believe that we have sufficient cash to fund our operations into the second quarter of 2014, following which we will need additional funding before we can complete additional clinical studies and continue to commercialize our products. Furthermore, if the Company is successful in raising the additional financing, there can be no assurance that the amount will be sufficient to complete the Company's plans. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

The Company is a development stage company and has not yet generated significant revenues from inception to September 30, 2013. Since inception, the Company's expenses relate primarily to research and development, organizational activities, clinical manufacturing, regulatory compliance, sales and operational strategic planning. Although the Company has made advances on these matters, there can be no assurance that the Company will continue to be successful regarding these issues, nor can there be any assurance that the Company will successfully implement its long-term strategic plans.

The Company has developed an intellectual property portfolio, including 32 issued U.S. patents, and multiple pending patents, covering materials, methods of production, systems incorporating the technology and multiple medical uses.

## **2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

### **Nature of Business**

The Company, through its subsidiary CytoSorbents, Inc., is engaged in the research, development and commercialization of medical devices with its platform blood purification technology incorporating a proprietary adsorbent polymer technology. The Company, through its European Subsidiary, has commenced initial sales and marketing related operations for the CytoSorb® device in the European Union. The Company is focused on developing this technology for multiple applications in the medical field, specifically to provide improved blood purification for the treatment of acute and chronic health complications associated with blood toxicity. In March 2011, the Company received CE Mark approval for its CytoSorb® device, and in June 2012, officially launched CytoSorb® for commercial sale in Germany and later in Austria and Switzerland with a small direct sales force. As of September 30, 2013, the Company had only limited commercial operations and, accordingly, is in the development stage. The Company has yet to generate significant revenue from product sales and has no assurance of future revenue.

## **Principles of Consolidation**

The consolidated financial statements include the accounts of the Parent, CytoSorbents Corporation, and its wholly-owned subsidiaries, CytoSorbents, Inc. and CytoSorbents Europe GmbH. All significant intercompany transactions and balances have been eliminated in consolidation.

## **Development Stage Corporation**

The accompanying consolidated financial statements have been prepared in accordance with the provisions of accounting and reporting by development stage enterprises.

## **Cash and Cash Equivalents**

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

## **Accounts Receivable**

Accounts receivable are customer obligations due under normal trade terms. The Company sells its devices to various hospitals and distributors. The Company performs ongoing credit evaluations of customers' financial condition and does not require collateral. Management reviews accounts receivable periodically to determine collectability. Balances that are determined to be uncollectible are written off to the allowance for doubtful accounts. The allowance for doubtful accounts contains a general accrual for estimated bad debts and had a balance of zero at September 30, 2013 and December 31, 2012.

## **Inventories**

Inventories are valued at the lower of cost or market. At September 30, 2013 and December 31, 2012 the Company's inventory was comprised of finished goods, which amounted to approximately \$211,000 and \$439,000, respectively, work in process which amounted to approximately \$125,000 and \$195,000, respectively and raw materials, which

amounted to approximately \$26,000 and \$49,000, respectively.

### **Property and Equipment**

Property and equipment are recorded at cost less accumulated depreciation. Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the lesser of their economic useful lives or the term of the related leases. Gains and losses on depreciable assets retired or sold are recognized in the statements of operations in the year of disposal. Repairs and maintenance expenditures are expensed as incurred.

### **Patents**

Legal costs incurred to establish patents are capitalized. When patents are issued, capitalized costs are amortized on the straight-line method over the related patent term. In the event a patent is abandoned, the net book value of the patent is written off.

### **Impairment or Disposal of Long-Lived Assets**

The Company assesses the impairment of patents and other long-lived assets under accounting standards for the impairment or disposal of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and fair value.

### **Revenue Recognition**

*Product Sales:* Revenues from sales of products are recognized at the time of delivery when title and risk of loss passes to the customer. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations.

*Grant Revenue:* Revenue from grant income is based on contractual agreements. Certain agreements provide for reimbursement of costs, while other agreements provide for reimbursement of costs and an overhead margin. Revenues are recognized when milestones have been achieved and revenues have been earned. Costs are recorded as incurred. Costs subject to reimbursement by these grants have been reflected as costs of revenue.

*Deferred Revenue:* The Company defers revenue that has been received but not yet earned on government contracts. This revenue will be recognized as income in the period in which the revenue is earned. All deferred revenue is expected to be earned within a one year of the balance sheet date.

### **Research and Development**

All research and development costs and payments to laboratories and research consultants are expensed when incurred.

### **Income Taxes**

Income taxes are accounted for under the asset and liability method prescribed by accounting standards for accounting for income taxes. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or the entire deferred tax asset will not be realized. Under Section 382 of the Internal Revenue Code, the net operating losses generated prior to the reverse merger may be limited due to the change in ownership. Additionally, net operating losses generated subsequent to the reverse merger may be limited in the event of changes in ownership.

The Company follows accounting standards associated with uncertain tax positions. The Company had no unrecognized tax benefits at December 31, 2012 or 2011. The Company files tax returns in the U.S. with both federal and state jurisdictions and in other countries as required. The Company currently has no open years prior to December 31, 2010 and has no income tax related penalties or interest for the periods presented in these financial statements.

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from these estimates. Significant estimates in these financials are the valuation of options granted, the valuation of preferred shares issued as stock dividends and valuation methods used in determining any debt discount associated with convertible securities.

### **Concentration of Credit Risk**

The Company maintains cash balances, at times, with financial institutions in excess of amounts insured by the Federal Deposit Insurance Corporation. Management monitors the soundness of these institutions in an effort to minimize its collection risk of these balances.

As of September 30, 2013, three customers (one U.S. government grant agency, one distributor, and one direct hospital customer) accounted for approximately 73 percent of outstanding accounts receivable. At December 31, 2012, accounts receivable consisted of five direct hospital customers who in the aggregate represented 100% of outstanding accounts receivable, each of whom individually had more than 10 percent of outstanding accounts receivable. For the nine months ended September 30, 2013, approximately 67 percent of revenues were from two U.S. government grant agencies, and no other agency, distributor, or direct customer represented more than 10% of the Company's revenue. For the nine months ended September 30, 2012, approximately 91 percent of revenue was from two U.S. government grant agencies, each of whom individually comprised more than 10 percent of the Company's total revenue.



## **Financial Instruments**

The carrying values of cash and cash equivalents, short-term investments, accounts payable, notes payable, and other debt obligations approximate their fair values due to their short-term nature.

## **Net Loss Per Common Share**

Basic EPS is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period. The computation of Diluted EPS does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings (See Note 6).

## **Stock-Based Compensation**

The Company accounts for its stock-based compensation under the recognition requirements of accounting standards for accounting for stock-based compensation, for employees and directors whereby each option granted is valued at fair market value on the date of grant. Under these accounting standards, the fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model.

The Company also follows the guidance of accounting standards for accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services for equity instruments issued to consultants.

## **Effects of Recent Accounting Pronouncements**

There have been no recently issued accounting standards, which would have a material impact on the Company's financial statements.

## **Reclassifications**



Certain items for the periods ended September 30, 2012 have been reclassified to conform to the presentation at September 30, 2013. There was no change in net income as a result of these reclassifications.

### 3. CONVERTIBLE NOTES

On September 30, 2013 (the "Closing Date"), the Company issued convertible notes to certain accredited investors (the "Purchasers"), whereby the Company agreed to sell and the Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$745,000 (the "Notes"). The Notes mature one (1) year from the Closing Date (the "Maturity Date"), bear interest at an annual rate of 8%, and automatically convert into shares of the Company's common stock, \$0.001 par value per share (the "Common Stock"), at a conversion price of \$0.10 at maturity or earlier at the option of the Purchaser. Full conversion of the principal value of the Notes would result in the issuance of 7,450,000 shares of Common Stock. In connection with the issuance of the Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at \$0.125 per share (the "Warrants").

Of the \$745,000 principal amount of the Notes, \$165,000 was received and is included in Cash and cash equivalents in the September 30, 2013 Consolidated Balance Sheet. The balance of \$580,000 was received in early October 2013 and is included in Prepaid expenses and other current assets on the September 30, 2013 Consolidated Balance Sheet.

On June 21, 2013 (the "Closing Date"), the Company issued convertible notes to certain accredited investors (the "Purchasers"), whereby the Company agreed to sell and the Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$1,098,000 (the "Notes"). The Notes mature one (1) year from the Closing Date (the "Maturity Date"), bear interest at an annual rate of 8%, and automatically convert into shares of the Company's common stock, \$0.001 par value per share (the "Common Stock"), at a conversion price of \$0.125 at maturity or earlier at the option of the Purchaser. Full conversion of the principal value of the Notes would result in the issuance of 8,784,000 shares of Common Stock. In connection with the issuance of the Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at \$0.15 per share (the "Warrants").

At September 30, 2013, the Company had Convertible Notes totaling approximately \$1,562,000 net of debt discount of approximately \$281,000. The Notes stipulate that in the event at any time during the term of the Note, the Company closes on any debt or equity financing in an aggregate amount greater than or equal to \$750,000, the noteholder will have the right to exchange the note for the equivalent dollar amount of securities sold in the new financing. The Company is not required to repay the Notes in cash, and there are no registration rights on the common stock underlying the Notes or Warrants.

At December 31, 2012 the Company had Convertible Notes totaling \$926,225 net of debt discount of \$178,775 outstanding. In February 2013 all outstanding Convertible Notes plus accrued interest at 8% were converted into 9,739,912 Common Shares and debt discount was charged to interest expense.

The Company allocates the proceeds associated with the issuance of promissory notes based on the relative fair value of the promissory notes and warrants. Additionally, the Company evaluates if the embedded conversion option results in a beneficial conversion feature by comparing the relative fair value allocated to the promissory notes to the market value of the underlying common stock subject to conversion. In connections with the promissory note issuances during the periods ended September 30, 2013 and 2012 the Company received proceeds of \$1,843,000 and \$700,000, respectively. The Company allocated the proceeds in accordance with FASB Codification Topic 470 based on the related fair value as follows for the \$1,843,000: \$1,511,883 was allocated to the promissory notes and \$171,012 to the warrants. Additionally, the embedded conversion feature resulted in a beneficial conversion feature in the amount of \$160,105. For the \$700,000, \$612,300 was allocated to the promissory notes and \$38,788 to the warrants. Additionally, the embedded conversion feature resulted in a beneficial conversion feature in the amount of \$48,912. The value assigned to the warrants resulting from the relative fair value calculation as well as the value of the beneficial conversion feature is recorded as a debt discount and is presented in the consolidated balance sheets. The debt discount is being amortized to interest expense over the term of the promissory notes. During the nine months ended September 30, 2012 Convertible Notes in the principal and accrued interest amount of \$685,208 were converted into 6,852,088 Common shares resulting in a reduction of debt discount and charge to interest expense in the amount of \$235,762.

#### **4. STOCKHOLDERS' EQUITY (DEFICIT)**

Edgar Filing: Cytosorbents Corp - Form 10-Q

During the nine months ended September 30, 2013, the Company recorded non-cash stock dividends totaling approximately \$1,728,000 in connection with the issuance of 5,526.50 shares of Series B Preferred Stock and 122,579 shares of Series A Preferred Stock.

During the nine months ended September 30, 2013, the Company incurred stock-based compensation expense due to the issuance of stock options, and amortization of unvested stock options. The aggregate expense for the nine months ended September 30, 2013 is approximately \$300,000.

The summary of the stock option activity for the nine months ended September 30, 2013 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding, January 1, 2013	36,667,616	\$ 0.23	6.1
Granted	13,985,000	\$ 0.11	5.8
Cancelled	(2,235,000 )	\$ 0.12	—
Exercised	(556,737 )	\$ 0.04	—
Expired	(9,402 )	\$ 2.01	—
Outstanding September 30, 2013	47,851,477	\$ 0.21	5.4

The fair value of each stock option was estimated using the Black Scholes pricing model which takes into account as of the grant date the exercise price (ranging from \$0.106 to \$0.129 per share) and expected life of the stock option (ranging from 5-10 years), the current price of the underlying stock and its expected volatility (approximately 28 percent), expected dividends (zero percent) on the stock and the risk free interest rate (0.8 to 1.9 percent) for the term of the stock option.

At September 30, 2013, the aggregate intrinsic value of options outstanding and currently exercisable amounted to approximately \$842,000.

The summary of the status of the Company's non-vested options for the nine months ended September 30, 2013 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2013	7,394,000	\$ 0.05
Granted	13,985,000	\$ 0.03
Cancelled	(2,035,000 )	\$ 0.06
Vested	(5,926,000 )	\$ 0.05
Non-vested, September 30, 2013	13,418,000	\$ 0.03

As of September 30, 2013, approximately \$104,000 of total unrecognized compensation cost related to stock options is expected to be recognized over a weighted average period of 1.55 years. On April 3, 2013, the Company's Board of Directors approved a 2013 Stock Option Grant totaling 10,305,000 options, available in part to all eligible employees of the Company, that vests only with the achievement of certain pre-determined milestones relating to commercialization of CytoSorb®, financing, business development, and product development. Due to the uncertainty over whether approximately 9,455,000 of the 10,305,000 options granted will vest, no charge for these options has been recorded in the consolidated statements of operations for the nine months ended September 30, 2013. The grant date fair value of these unvested options amounts to approximately \$284,000. The Company will evaluate on an ongoing basis the probability and likelihood of any of these performance milestones being achieved and will accrue charges as it becomes likely that they will be achieved.

In addition, a pool of 22,750,000 shares of restricted stock was allocated, but not awarded, to only be awarded with the achievement of certain long-term milestones. Should these long-term milestones not be met in 2013, these restricted shares would be cancelled.

Edgar Filing: Cytosorbents Corp - Form 10-Q

As of September 30, 2013, the Company has the following warrants to purchase common stock outstanding:

Number of Shares To be Purchased	Warrant Exercise Price per Share	Warrant Expiration Date
397,825	\$ 0.04	September 30, 2014
1,750,000	\$ 0.10	August 16, 2015
1,600,000	\$ 0.13	August 16, 2015
1,333,333	\$ 0.15	August 16, 2015
490,000	\$ 0.10	October 22, 2015
196,000	\$ 0.13	October 22, 2015
163,333	\$ 0.15	October 22, 2015
625,000	\$ 0.10	November 2, 2015
250,000	\$ 0.13	November 2, 2015
208,334	\$ 0.15	November 2, 2015
500,000	\$ 0.10	November 19, 2015
200,000	\$ 0.13	November 19, 2015
166,667	\$ 0.15	November 19, 2015
5,000,000	\$ 0.10	February 15, 2016
2,200,000	\$ 0.13	February 15, 2016
1,833,333	\$ 0.15	February 15, 2016
240,125	\$ 1.25	October 24, 2016
1,166,667	\$ 0.18	February 10, 2017
4,392,000	\$ 0.15	June 21, 2018
3,725,000	\$ 0.12	September 30, 2018
26,437,617		

During the first quarter of 2013, Convertible Notes in the principal and accrued interest amount of \$1,226,042 were converted into 9,739,912 Common shares.

In December 2011, the Company terminated the original Purchase Agreement with Lincoln Park Capital Fund, LLC (“LPC”) and executed a new purchase agreement, or the New Purchase Agreement, and a registration rights agreement, or the New Registration Rights Agreement, with LPC. Under the New Purchase Agreement, LPC is obligated, under certain conditions, to purchase from the Company up to \$8.5 million of our Common Stock, from time to time over a thirty-two (32) month period.

The Company has the right, but not the obligation, to direct LPC to purchase up to \$8,500,000 of its Common Stock in amounts up to \$50,000 as often as every two business days under certain conditions. The Company can also accelerate the amount of its common stock to be purchased under certain circumstances. No sales of shares may occur at a purchase price below \$0.10 per share or without a registration statement having been declared effective. The purchase price of the shares will be based on the market prices of our shares at the time of sale as computed under the New Purchase Agreement without any fixed discount. The Company may at any time at its sole discretion terminate the New Purchase Agreement without fee, penalty or cost upon one business days’ notice.

There was no up-front commitment fee paid to LPC for entering into the new agreement. In the event the Company directs LPC to purchase up to \$8,500,000 of its Common Stock, the Company is obligated to issue up to an additional 1,634,615 commitment fee shares of Common Stock on a pro rata basis. LPC may not assign any of its rights or obligations under the Purchase Agreement.

During the nine months ended September 30, 2013 the Company received approximately \$1,600,000 as proceeds from the sale of approximately 14,529,000 shares of Common Stock per the terms of the Purchase Agreement with LPC at an average price of approximately \$0.110 per share of Common. Per the terms of the Purchase Agreement the Company also issued an additional approximately 308,000 shares of Common Stock as additional Commitment Fee shares. The fair value of the Commitment shares of approximately \$34,000 has been recorded as a cost of raising capital.

As of September 30, 2013, \$3,400,000 remained available under the Purchase Agreement with LPC. The Purchase Agreement terminates in August 2014.

## **5. COMMITMENTS AND CONTINGENCIES**

## **Employment Agreements**

The Company is currently in the process of renewing employment agreements with its Chief Executive Officer and its Chief Operating Officer.

On May 7, 2013, the Company entered into an employment agreement with Kathleen P. Bloch to become the Company's Chief Financial Officer. Ms. Bloch's employment agreement states that she will perform the services and duties that are normally and customarily associated with this position as well as other associated duties as our Board reasonably determines. The agreement commences on May 29, 2013 and expires on May 31, 2014 and calls for an initial base salary of \$200,000 payable in equal semi-monthly installments in accordance with the Company's usual practice. As a signing bonus, Ms. Bloch was also given a ten-year option to purchase 1,000,000 shares of the Company's common stock at an exercise price of \$0.116 per share. This option vests in equal installments over the next two years: 500,000 options at the 12 month anniversary, and 500,000 options at 24 month anniversary of the signing of this employment agreement, provided that Ms. Bloch remains a full-time employee of the Company.

## **Litigation**

The Company is currently not involved, but may at times be involved in various claims and legal actions.

## **Royalty Agreements**

Pursuant to an agreement dated August 11, 2003, an existing investor agreed to make a \$4 million equity investment in the Company. These amounts were received by the Company in 2003. In connection with this agreement, the Company granted the investor a future royalty of 3% on all gross revenues received by the Company from the sale of its CytoSorb® device. For the nine months ended September 30, 2013 the Company has recorded royalty costs of approximately \$15,000.

## **License Agreements**

In an agreement dated September 1, 2006, the Company entered into a license agreement which provides the Company the exclusive right to use its patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the agreement, the Company has agreed to pay royalties of 2.5% to 5% on the sale of certain of its products if and when those products are sold commercially for a term not greater than 18 years commencing with the first sale of such product. For the nine months ended September 30, 2013 per the terms of the license agreement the Company has recorded royalty costs of approximately \$13,000.

## **Warrant Agreement**

As inducement to invest additional funds in the private placement of Series B Preferred Stock, additional consideration was granted to the participants of the Series B Preferred Stock offering in the event that litigation is commenced against CytoSorbents prior to June 30, 2018, claiming patent infringement on certain of the Company's issued patents. In the event this litigation arises the Company may be required to issue warrants to purchase in the aggregate up to a maximum of ten million shares of Common Stock subject to certain adjustments. Through September 30, 2013 no such litigation has arisen and due to the deemed low probability of this potential outcome; the Company has not booked a contingent liability for this agreement.

## **6. NET LOSS PER SHARE**



Basic loss per share and diluted loss per share for the nine months ended September 30, 2013 and 2012 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period.

All outstanding warrants and options representing approximately 74,289,000 and 63,970,000 incremental shares at September 30, 2013 and 2012, respectively, as well as shares issuable upon conversion of Series A and Series B Preferred Stock representing approximately 215,310,000 and 195,595,000 incremental shares at September 30, 2013 and 2012, respectively, as well as potential shares issuable upon Note conversion into Common Stock representing approximately 16,234,000 and 12,030,000 incremental shares at September 30, 2013 and 2012, respectively, have been excluded from the computation of diluted loss per share as they are anti-dilutive.

## **7. SUBSEQUENT EVENTS**

The Company has evaluated subsequent events occurring after the balance sheet date through the date of the issuance of this report and has determined that there are no material subsequent events requiring disclosure in these financial statements.



issued U.S. patents with multiple applications pending.

In March 2011, we received E.U. regulatory approval under the CE Mark and Medical Devices Directive for our flagship product, CytoSorb®, as an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated. The goal of the CytoSorb® is to prevent or treat organ failure by reducing cytokine storm and the potentially deadly systemic inflammatory response syndrome in diseases such as sepsis, trauma, burn injury, acute respiratory distress syndrome, pancreatitis, liver failure, and many others. Organ failure is the leading cause of death in the intensive care unit, and remains a major unmet medical need, with little more than supportive care therapy (e.g. mechanical ventilation, dialysis, vasopressors, fluid support, etc.) as treatment options. By potentially preventing or treating organ failure, CytoSorb® may improve clinical outcome, including survival, while reducing the need for costly intensive care unit treatment, thereby potentially saving significant healthcare costs.

Our CE Mark enables CytoSorb® to be sold throughout the entire European Union. In addition, many countries outside the E.U. accept CE Mark approval for medical devices, but may also require registration with or without additional clinical studies. The broad approved indication enables CytoSorb® to be used “on-label” in diseases where cytokines are elevated including, but not limited to, critical illnesses such as those mentioned above, autoimmune disease flares, and many other conditions where cytokine-induced inflammation plays a detrimental role.

As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst fourteen trial sites in Germany in 2011, with enrollment of one hundred (100) patients with sepsis and respiratory failure. The trial established that CytoSorb® was safe in this critically-ill population, and that it was able to control cytokine storm, and broadly reduce key cytokines.

## **Plan of Operations**

The Company plans to do larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE Mark approval, CytoSorbents also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union. CytoSorbents manufactures CytoSorb® at its manufacturing facilities in New Jersey for sale in the E.U. and for additional clinical studies. In September 2013, the company was granted a 2 year renewal for the CytoSorb® CE Mark. The Company also established a reimbursement path for CytoSorb® in Germany and Austria.

From September 2011 through June 2012, the Company began a controlled market release of CytoSorb® in select geographic territories in Germany with the primary goal of preparing for commercialization of CytoSorb® in Germany in terms of manufacturing, reimbursement, logistics, infrastructure, marketing, contacts, and other key issues.

In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, CytoSorbents began the commercial launch of CytoSorb® for the treatment of critical care illnesses such as sepsis, burn injury, trauma, acute respiratory distress syndrome, pancreatitis and other conditions where inflammation plays a detrimental role, such as cardiac surgery. We hired Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales representatives who joined the Company and completed their sales training in Q3 2012. Q4 2012 represented the first quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland and have established reimbursement in Austria. At the end of Q3 2013, we had more than 100 key opinion leaders (KOLs) in critical care and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future.

We seek to further complement our direct sales efforts with sales to distributors or corporate partners. In 2013, we reached an agreement with distributors in the United Kingdom and Turkey and we are in negotiation with and evaluating other potential distributor networks in other major countries where we are approved to market the device. In September 2013, we entered into a strategic partnership with Biocon Ltd., Asia's largest biotech company with an

initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb®.

We are currently conducting a dose ranging trial in Germany amongst eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used for longer periods of time. Data from this dosing study are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from the Company's first European Sepsis Trial, and help shape the trial protocol for a U.S. based pivotal study.

In the event we are able to successfully commercialize our products in the European market, we will review our plans for the United States to determine whether to conduct clinical trials in support of 510(k) or PMA registration. No assurance can be given that our CytoSorb® product will work as intended or that we will be able to obtain FDA approval to sell CytoSorb® in the United States.

The initial major market focus for CytoSorb® is the adjunctive treatment of sepsis, a systemic inflammatory response to a serious infection. CytoSorb® has been designed to prevent or reduce the accumulation of high concentrations of cytokines in the bloodstream associated with sepsis and is intended for short-term use with standard of care therapy that includes antibiotics. We believe that current state of the art blood purification technology (such as dialysis) is incapable of effectively clearing the toxins that are adsorbed by our CytoSorb® device.

In addition to the sepsis indication, we intend to continue to foster research in other critical care illnesses where CytoSorb® could be used, such as ARDS, trauma, severe burn injury and acute pancreatitis, or in other acute conditions that have demonstrated potential in preliminary studies to prevent or reduce the accumulation of cytokines in the bloodstream. These other conditions include the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery) and damage to organs donated for transplant prior to organ harvest. We are also exploring the potential benefits our technology may have in removing drugs and other substances from blood and physiologic fluids.

The Company's proprietary hemocompatible porous polymer bead technology forms the basis of a broad technology portfolio. Some of our products include:

CytoSorb® - an extracorporeal hemoperfusion cartridge approved in the E.U. for cytokine removal, with the goal of reducing SIRS and preventing or treating organ failure.

HemoDefend™ - a development-stage blood purification technology designed to remove contaminants in blood transfusion products. The goal is to reduce transfusion reactions and improve the safety of older blood

ContrastSorb - a development-stage extracorporeal hemoperfusion cartridge designed to remove IV contrast from the blood of high risk patients undergoing CT imaging with contrast, or interventional radiology procedures such as cardiac catheterization. The goal is to prevent contrast-induced nephropathy

DrugSorb - a development-stage extracorporeal hemoperfusion cartridge designed to remove toxic chemicals from the blood (e.g. drug overdose, high dose regional chemotherapy, etc.)

BetaSorb - a development-stage extracorporeal hemoperfusion cartridge designed to remove mid-molecular weight toxins, such as b2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal is to improve the efficacy of dialysis or hemofiltration

Because of the limited studies we have conducted, we are subject to substantial risk that our technology will have little or no effect on the treatment of any indications that we have targeted.

The Company has been successful in obtaining technology development contracts and support from agencies in the U.S. Department of Defense, including DARPA, the U.S. Army, and the U.S. Air Force.

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States amongst trauma patients with rhabdomyolysis most commonly associated with trauma. The FDA has approved our Investigational Device Exemption (IDE) application for this study, which is anticipated to commence this year.

Following successful contract negotiations in June 2013, the Company began work on its previously announced \$1 million Phase II SBIR U.S. Army contract to further develop its technology for the treatment of burn injury and trauma in animal models. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038 and has now received committed funding of \$1.15 million to date.

In August 2012, the Company was awarded a \$3.8 million contract by the Defense Advanced Research Projects Agency (DARPA) for its “Dialysis-Like Therapeutics” program to treat sepsis. This five-year contract is for advanced technology development of our hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. CytoSorbents has begun work on Year 2 milestones and is currently working with the recently announced systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, who are responsible for integrating the technology developed by CytoSorbents and others into a final medical device design prototype, and evaluating this device in septic animals and eventually in human clinical trials in sepsis. CytoSorbents’ work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199.

In September 2013, the National Heart, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health (“NIH”), awarded the Company a Phase I SBIR (Small Business Innovation Research) contract to further advance its HemoDefend™ blood purification technology for packed red blood cell (pRBC) transfusions. The project, entitled “Elimination of blood contaminants from pRBCs using HemoDefend™ hemocompatible porous polymer beads,” is valued at \$203,351 over six months, with funding to start immediately. The overall goal of this new program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs.

## Results of Operations

### *Comparison for the nine months ended September 30, 2013 and 2012:*

#### *Revenues:*

For the nine months ended September 30, 2013, the Company generated revenue of approximately \$1,544,000 as compared to revenues of approximately \$739,000, for the nine months ended September 30, 2012, an increase of 109%. Revenue from product sales was approximately \$508,000 for the nine months ended September 30, 2013, as compared to approximately \$64,000 in the nine months ended September 30, 2012, an increase of 698%. This increase in sales is a result of the establishment in August 2012 of a four person direct sales force covering Germany, Austria and Switzerland, as well as sales to distributors in other parts of Europe and the Middle East. Product gross margins were approximately 64% for the nine months ended September 30, 2013. Revenue from grants was approximately \$1,036,000 in the nine months ended September 30, 2013, as compared to approximately \$675,000 in the nine months ended September 30, 2012.

#### *Expenses:*

For the nine months ended September 30, 2013, our research and development expenses were approximately \$1,706,000 as compared to research and development expenses of approximately \$1,854,000 for the nine months ended September 30, 2012. The decrease of approximately \$148,000 was primarily due to direct labor being deployed toward grant-funded activities, and as a result, salaries and other costs normally charged to research and development were included in cost of goods sold.

Legal, financial and other consulting expenses were approximately \$570,000 for the nine months ended September 30, 2013 as compared to approximately \$386,000 for the nine months ended September 30, 2012. The increase of approximately \$184,000 was primarily due to approximately \$70,000 of increases related to auditing and legal fees associated with 2013 filings with the Securities and Exchange Commission and other government entities, increases in accounting consulting fees of approximately \$49,000, legal fees associated with patent review related costs of approximately \$11,000 and consulting fees related to new systems and employment related fees totaling approximately \$48,000.

Selling, general, and administrative expenses were approximately \$1,902,000 for the nine months ended September 30, 2013 as compared to approximately \$915,000 for the nine months ending September 30, 2012. The increase in



selling, general, and administrative expenses of approximately \$987,000 was primarily due to the addition of our German sales and support team in August 2012 resulting in increased payroll expenses totaling approximately \$410,000, increases in advertising of approximately 170,000, other selling, general, and administrative expenses of \$180,000, as well as increased royalty expense of approximately \$27,000 and increased option expenses of approximately \$155,000.

For the nine months ended September 30, 2013, our interest expense was approximately \$300,000 as compared to interest expense of approximately \$448,000 for the nine months ended September 30, 2012. The decrease was principally due to the maturity of convertible notes in February 2013 and the related reduction in non-cash charges associated with the amortization of debt discount on the convertible notes.

We have experienced substantial operating losses since inception. As of September 30, 2013, we had a deficit accumulated during the development stage of approximately \$104,469,000 which included losses of approximately \$4,009,000 and \$3,126,000 for the nine month periods ended September 30, 2013 and 2012 respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies, and general and administrative expenses.

***Comparison for the three months ended September 30, 2013 and 2012:***

*Revenues:*

CytoSorbents generated revenues of approximately \$881,000 and \$605,000 for the three months ending September 30, 2013 and September 30, 2012, respectively. Product revenues were approximately \$204,000 for the quarter ended September 30, 2013, as compared to product revenues of approximately \$14,000 for the three months ended September 30, 2012. This increase in product revenues was a result of our direct sales effort to hospitals in Germany, Austria and Switzerland, as well as sales to distributors. For the three months ended September 30, 2013, product sales of CytoSorb were the highest quarterly sales achieved to date, and were approximately 59.1% higher than product sales for the previous quarter ended June 30, 2013. Additionally, grant revenue and other income approximated \$677,000 and \$591,000 for the three month periods ended September 30, 2013 and 2012 respectively. Product gross margins were approximately 71% for the quarter ended September 30, 2013. Overall gross margins were approximately 29.5% for the quarter ended September 30, 2013, as a result of the higher cost of materials and labor associated with grant income.

*Expenses:*

For the three months ending September 30, 2013, our research and development costs were approximately \$294,000, as compared to research and development costs of approximately \$554,000, for the three months ended September 30, 2012. The decrease of approximately \$260,000 was primarily due to direct labor being deployed toward grant-funded activities, and as a result, salaries and other costs normally charged to research and development were included in cost of goods sold.

Legal, financial and other consulting costs were approximately \$158,000 for the three months ending September 30, 2013 as compared to legal financial and other consulting costs of approximately \$151,000 for the three months ended September 30, 2012. This increase of approximately \$7,000 was primarily due to increased accounting fees from consultants.

Our general and administrative costs were approximately \$688,000 for the three months ended September 30, 2013 compared to approximately \$360,000, an increase of approximately \$328,000. This was primarily due to increases in costs related to salaries of approximately \$170,000, increases in advertising of approximately \$96,000, and increases in other selling, general, and administrative costs of approximately \$65,000.

For the three months ending September 30, 2013, the Company's net interest expense was approximately \$85,000, as compared to net interest expense of approximately \$51,000 for the three months ended September 30, 2012. The increase in net interest expense is primarily due to interest expense on convertible notes issued in June 2013.

## **Liquidity and Capital Resources**

Since inception, our operations have been financed through the private placement of the Company's debt and equity securities. As of September 30, 2013, we had cash on hand of approximately \$2,350,000 and current liabilities of approximately \$3,066,000. An additional \$580,000 in cash was received in early October 2013 in connection with the issuance of convertible notes which closed on September 30, 2013. At December 31, 2012, we had cash of approximately \$1,729,000 and current liabilities of approximately \$2,077,000.

We believe that we have sufficient cash to fund our operations into the second quarter of 2014, following which we will need additional funding to permit us to complete additional clinical studies and to continue to commercialize our products. We will need to rely on additional funding to support our operations into the future. We expect to receive such required funding from grant revenue, issuance of new debt and/or equity securities, and sales of our shares to Lincoln Park Capital Fund LLC ("LPC"). (See Note 9 to the Company's Annual Report on Form 10-K filed with the

Commission on April 03, 2013).

***Lincoln Park Capital Fund LLC Purchase Agreement***

Under the terms of its Purchase Agreement with LPC, in the first nine months of 2013, the Company sold approximately 14,529,000 shares of Common Stock to LPC at an average selling price of \$0.110 and in return, the Company received proceeds of approximately \$1,600,000. Per the terms of the Purchase Agreement the Company also issued an additional approximately 308,000 shares of Common Stock as additional Commitment Fee shares. As of September 30, 2013, under its current Purchase Agreement with LPC, the Company has the ability to sell up to an additional \$3,400,000 of shares of Common Stock.

### ***U.S. Army Medical Research Grant***

In June 2013, the Company finalized contract negotiations of a \$1 million Phase 2 SBIR award from the U.S. Army Medical Research and Materiel Command to fund the further development of the Company's technologies to treat trauma and burn injury. As of September 30, 2013, the Company has received approximately \$599,000 out of a total of \$651,000 awarded to CytoSorbents. For the nine months ended September 30, 2013, the Company has recognized approximately \$163,000 of income from this grant.

### ***DARPA Funding***

In the nine months ended September 30, 2013, the Company received approximately \$823,000 from the Defense Advanced Research Projects Agency (DARPA) following achievement of initial milestones of a five year technology development contract valued at \$3.8 million that was awarded in August 2012. In addition, the Company is eligible, pending achievement of certain development milestones in this "Dialysis-Like Therapeutics" initiative to treat sepsis, to receive up to an additional approximately \$1,120,000 (of the \$3.8 million contract) in payments over the next ten months.

The Company is exploring potential eligibility in several other government sponsored grant programs which could, if approved, represent a substantial source of non-dilutive funds for our research programs.

### ***Convertible Note and Warrant Private Offering***

On September 30, 2013 (the "Closing Date"), the Company issued convertible notes to certain accredited investors (the "Purchasers"), whereby the Company agreed to sell and the Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$745,000 (the "Notes"). The Notes mature one (1) year from the Closing Date (the "Maturity Date"), bear interest at an annual rate of 8%, and automatically convert into shares of the Company's common stock, \$0.001 par value per share (the "Common Stock"), at a conversion price of \$0.10 at maturity or earlier at the option of the Purchaser. Full conversion of the principal value of the Notes would result in the issuance of 7,450,000 shares of Common Stock. In connection with the issuance of the Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at \$0.125 per share (the "Warrants").

On June 21, 2013 (the "Closing Date"), the Company issued convertible notes to certain accredited investors (the "Purchasers"), whereby the Company agreed to sell and the Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$1,098,000 (the "Notes"). The Notes mature one (1) year from the Closing Date (the

“Maturity Date”), bear interest at an annual rate of 8%, and automatically convert into shares of the Company’s common stock, \$0.001 par value per share (the “Common Stock”), at a conversion price of \$0.125 at maturity or earlier at the option of the Purchaser. Full conversion of the principal value of the Notes would result in the issuance of 8,784,000 shares of Common Stock. In connection with the issuance of the Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at \$0.15 per share (the “Warrants”).

The Notes stipulate that in the event at any time during the term of the Note, the Company closes on any debt or equity financing in an aggregate amount greater than or equal to \$750,000, the noteholder will have the right to exchange the note for the equivalent dollar amount of securities sold in the new financing. The Company is not required to repay the Notes in cash, and there are no registration rights on the common stock underlying the Notes or Warrants.

We will also continue to seek other funding sources for the long term needs of the Company. There can be no assurance that financing will be available on acceptable terms or at all. If adequate funds are unavailable, we may have to suspend, delay or eliminate one or more of our research and development programs or product launches or marketing efforts, or cease operations.

#### **Off-balance Sheet Arrangements**

We have no off-balance sheet arrangements.

## **Going Concern**

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has experienced negative cash flows from operations since inception and has a deficit accumulated during the development stage at September 30, 2013 of approximately \$104,469,000. The Company is not currently generating significant revenue and is dependent on the proceeds of present and future financings to fund its research, development and commercialization program. These matters raise substantial doubt about the Company's ability to continue as a going concern. The Company is continuing its fund-raising efforts. Although the Company has historically been successful in raising additional capital through equity and debt financings, there can be no assurance that the Company will be successful in raising additional capital in the future or that it will be on favorable terms. Furthermore, if the Company is successful in raising the additional financing, there can be no assurance that the amount will be sufficient to complete the Company's plans. The consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

## **Item 4. Controls and Procedures**

### **Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of September 30, 2013. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were ineffective at such time to ensure that information required to be disclosed by us in the reports filed or submitted under the Securities Exchange Act were recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our principal executive officer and principal financial officer also concluded that our disclosure controls, which are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is accumulated and communicated to management, was inappropriate to allow timely decisions regarding required disclosure.

Additionally, based on management's assessment, the Company determined that there were material weaknesses in its internal control over financial reporting as of September 30, 2013.

Therefore, our internal controls over financial reporting were not effective as of September 30, 2013 based on the material weaknesses described below:

Lack of an independent audit committee or audit committee financial expert. Although our board of directors serves as the audit committee its membership includes some directors who are not independent. Further, we have (1) not identified an audit committee financial expert on our board of directors. These factors are counter to corporate governance practices as defined by the various stock exchanges and may lead to less supervision over management.

Need for greater integration, oversight, communication and financial reporting of the books and records of our (2) German subsidiary.

Our management determined that these deficiencies constituted material weaknesses.

Due to our small size, we were not able to immediately remediate these actions, however, we have begun to address these matters. On May 29, 2013, we hired Kathleen P. Bloch, CPA, MBA, as our Chief Financial Officer. The Company will take additional remedial action to address the remaining material weaknesses in the near future. Notwithstanding the assessment that our Internal Controls over Financial Reporting was not effective and that there were material weaknesses identified herein, we believe that our consolidated financial statements contained in this Quarterly Report fairly present our financial position, results of operations and cash flows for the periods covered thereby in all material respects.

### **Changes in Internal Controls over Financial Reporting**

There has been no change in our internal controls over financial reporting that occurred during the fiscal quarter covered by this Quarterly Report on Form 10-Q 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**

We are not currently involved in any litigation that we believe could have a material adverse effect on our financial condition or results of operations.

### **Item 1A. Risk Factors**

We believe there are no changes that constitute material changes from the risk factors previously disclosed in the Company's 2012 Annual Report filed on Form 10-K.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

### **Item 3. Defaults Upon Senior Securities**

None.



**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None

**Item 6. Exhibits.**

Number	Description
31.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schedule
101.CAL	XBRL Taxonomy Calculation Linkbase
101.DEF	XBRL Taxonomy Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Presentation Linkbase

In accordance with SEC Release 33-8238, Exhibit 32.1 and 32.2 are being furnished and not filed.

**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.

Dated: November 6, 2013 By: /s/ Phillip Chan

Name: Phillip Chan  
Title: Chief Executive Officer  
(Duly Authorized Officer and Principal  
Executive Officer)

Dated: November 6, 2013 By: /s/ Kathleen P. Bloch

Name: Kathleen P. Bloch, CPA  
Title: Chief Financial Officer  
(Duly Authorized Officer and Principal  
Financial and Accounting Officer)