

Cytosorbents Corp  
Form 10-Q  
May 15, 2012

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended March 31, 2012**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number: 000-51038**

**CYTOSORBENTS CORPORATION**

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

Nevada 98-0373793  
(State or other jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

**7 Deer Park Drive, Suite K**

**Monmouth Junction, New Jersey 08852**

**(Address of principal executive offices) (Zip Code)**

**(732) 329-8885**

**(Registrant's telephone number, including area code)**

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 (§232.405 of this chapter) 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 the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐  
Non-accelerated filer ☐ (Do not check if a smaller reporting company) 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 ☐

As of May 14, 2012 there were 194,866,495 shares of the issuer's common stock outstanding.

**CytoSorbents Corporation**

**(a development stage company)**

**FORM 10-Q**

**TABLE OF CONTENTS**

	Page
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. Financial Statements (March 31, 2012 and 2011 are unaudited)	
Consolidated Balance Sheets	3
Consolidated Statements of Operations	4
Consolidated Statements of Changes in Stockholders' Equity (Deficit)	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	18
Item 4. Mine Safety Disclosures	18
<b>PART II. OTHER INFORMATION</b>	
Item 1. Legal Proceedings	19
Item 1A. Risk Factors	19
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	19
Item 3. Defaults of Senior Securities	19
Item 4. (Removed and Reserved)	19
Item 5. Other Information	19
Item 6. Exhibits	19

## PART I — FINANCIAL INFORMATION

### Item 1. Financial Statements.

#### CYTOSORBENTS CORPORATION

(a development stage company)

#### CONSOLIDATED BALANCE SHEETS

	March 31, 2012 (Unaudited)	December 31, 2011
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 1,803,049	\$ 1,186,653
Accounts receivable, net of allowance for doubtful accounts at \$-0-	39,790	36,078
Inventories	468,563	431,022
Prepaid expenses and other current assets	47,068	43,728
Total current assets	2,358,470	1,697,481
Property and equipment – net	148,222	155,067
Other assets	277,411	269,994
Total long-term assets	425,633	425,061
Total Assets	\$ 2,784,103	\$ 2,122,542
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 647,522	\$ 675,160
Accrued expenses and other current liabilities	453,973	558,466
Convertible notes payable, net of debt discount in the amount of \$305,677 at March 31, 2012 and \$53,677 at December 31, 2011	1,147,323	294,323
Total current liabilities	2,248,818	1,527,949

Edgar Filing: Cytosorbents Corp - Form 10-Q

Long Term Liabilities:

Convertible notes payable, net of debt discount in the amount of \$-0- at March 31, 2012 and \$508,750 at December 31, 2011	—	276,250
Total long term liabilities	—	276,250
Total liabilities	2,248,818	1,804,199

Stockholders' Equity (Deficit):

10% Series B Convertible Preferred Stock, Par Value \$0.001, 200,000 shares authorized at March 31, 2012 and December 31, 2011, respectively; 66,936.29 and 65,433.34 shares issued and outstanding, respectively	67	65
10% Series A Convertible Preferred Stock, Par Value \$0.001, 12,000,000 shares authorized at March 31, 2012 and December 31, 2011, respectively; 1,483,339 and 1,447,159 shares issued and outstanding, respectively	1,483	1,447
Common Stock, Par Value \$0.001, 500,000,000 shares authorized at March 31, 2012 and December 31, 2011, 189,843,223 and 177,626,058 shares issued and outstanding, respectively	189,843	177,626
Additional paid-in capital	94,991,947	92,696,747
Deficit accumulated during the development stage	(94,648,055)	(92,557,542 )
Total stockholders' equity	535,285	318,343
Total Liabilities and Stockholders' Equity	\$2,784,103	\$2,122,542

See accompanying notes to consolidated financial statements.

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

	Period from January 22,1997 (date of inception) to March 31, 2012 (Unaudited)	Three months ended March 31, 2012 (Unaudited)	2011 (Unaudited)
Revenue	\$ 52,971	\$ 16,893	\$—
Cost of goods sold	21,840	10,080	—
Gross profit	31,131	6,813	—
Other Expenses:			
Research and development	51,542,619	643,281	759,157
Legal, financial and other consulting	8,119,182	161,292	99,242
Selling, general and administrative	25,325,939	269,466	270,092
Change in fair value of management and incentive units	(6,055,483 )	—	—
Total expenses	78,932,257	1,074,039	1,128,491
Loss from operations	(78,901,126 )	(1,067,226 )	(1,128,491 )
Other (income)/expense:			
Gain on disposal of property and equipment	(21,663 )	—	—
Gain on extinguishment of debt	(216,617 )	—	—
Interest expense/(income), net	7,096,492	359,370	86,093
Penalties associated with non-registration of Series A Preferred Stock	361,495	—	—
Total other (income)/expense, net	7,219,707	359,370	86,093
Loss before benefit from income taxes	(86,120,833 )	(1,426,596 )	(1,214,584 )
Benefit from income taxes	(547,318 )	—	—
Net loss	(85,573,515 )	(1,426,596 )	(1,214,584 )

Edgar Filing: Cytosorbents Corp - Form 10-Q

Preferred Stock Dividend	9,074,540	663,917	741,645
Net Loss available to common shareholders	\$ (94,648,055 )	\$ (2,090,513 )	\$ (1,956,229 )
Basic and diluted net loss per common share		\$(0.01 )	\$(0.01 )
Weighted average number of shares of common stock outstanding		181,150,646	133,098,460

See accompanying notes to consolidated financial statements.



**CYTOSORBENTS CORPORATION****(a development stage company)****CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**

	Period from December 31, 2011 to March 31, 2012 (Unaudited)										
	Member	Common Stock			Preferred Stock B		Preferred Stock A		Additional	Deficit	Total
	Equity	Deferred Compensation	Shares	Par value	Shares	Par Value	Shares	Par Value	Paid-In Capital	Accumulated During the Development Stage	Stock Equity
Balance at December 31, 2011	\$—	\$—	177,626,058	\$177,626	65,433.34	\$65	1,447,159	\$1,447	\$92,696,747	\$(92,557,542)	\$318
Stock based compensation – employees, consultants and directors	—	—	—	—	—	—	—	—	532	—	532
Issuance of Series A Preferred Stock as dividends	—	—	—	—	—	—	36,180	36	4,658	(4,694)	—
Issuance of Series B Preferred Stock as dividends	—	—	—	—	1,634.51	2	—	—	659,221	(659,223)	—
Conversion of Series A and Series B into Common	—	—	363,425	363	(131.56)	—	—	—	(363)	—	—
Issuance of common stock	—	—	7,902,200	7,902	—	—	—	—	1,152,250	—	1,16

for cash, net  
of cost of  
raising capital

Conversion of  
convertible  
notes to  
common

—	—	3,951,540	3,952	—	—	—	—	391,202	—	395
---	---	-----------	-------	---	---	---	---	---------	---	-----

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

—	—	—	—	—	—	—	—	87,700	—	87,7
---	---	---	---	---	---	---	---	--------	---	------

Net loss

—	—	—	—	—	—	—	—	—	(1,426,596 )	(1,4
---	---	---	---	---	---	---	---	---	--------------	------

Balance at  
March 31,  
2012

\$—	\$—	189,843,223	\$189,843	66,936.29	\$67	1,483,339	\$1,483	\$94,991,947	\$(94,648,055)	\$535
-----	-----	-------------	-----------	-----------	------	-----------	---------	--------------	----------------	-------

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 March 31, 2012 (Unaudited)	Three months Ended March 31, 2012 (Unaudited)	Three months ended March 31, 2011 (Unaudited)
Cash flows from operating activities:			
Net loss	\$ (85,573,515 )	\$ (1,426,596 )	\$ (1,214,584 )
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	30,000	—	—
Depreciation and amortization	2,460,122	10,707	7,206
Amortization of debt discount	2,338,827	344,450	86,457
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	2,505,592	532	176,113
Amortization of deferred compensation	74,938	—	—
Penalties in connection with non-registration event	361,496	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(39,790 )	(3,712 )	—
Inventories	(468,563 )	(37,541 )	—
Prepaid expenses and other current assets	(318,616 )	(3,340 )	310,479
Other assets	(56,394 )	—	—
Accounts payable and accrued expenses	3,001,031	43,175	46,375
Accrued interest expense	1,823,103	—	—
Net cash used by operating activities	(63,649,734 )	(1,072,325 )	(587,954 )

Edgar Filing: Cytosorbents Corp - Form 10-Q

Cash flows from investing activities:			
Proceeds from sale of property and equipment	32,491	—	—
Purchases of property and equipment	(2,400,960	) —	—
Patent costs	(490,838	) (11,280	) —
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	(4,491,475	) (11,280	) —
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	47,571,311	1,000,001	718,750
Proceeds from borrowings	11,888,881	700,000	1,250,000
Proceeds from subscription receivables	499,395	—	—
Proceeds from exercise of stock options	5,141	—	—
Net cash provided by financing activities	69,944,258	1,700,001	1,968,750
Net change in cash and cash equivalents	1,803,049	616,396	1,380,796
Cash and cash equivalents - beginning of period	—	1,186,653	1,055,669
Cash and cash equivalents - end of period	\$ 1,803,049	\$ 1,803,049	\$ 2,436,465

See accompanying notes to consolidated financial statements.

## Supplemental disclosure of cash flow information:

Cash paid during the period for interest	\$ 590,189	\$—	\$—
Supplemental schedule of noncash investing and financing activities:			
Debt discount in connection with issuance of convertible debt	\$ 1,644,505	\$ 87,700	\$ 1,250,000
Fair value of shares issued as costs of raising capital	\$ 524,224	\$ 188,274	\$ 23,831
Note payable principal and interest conversion to equity	\$ 12,344,603	\$ 395,154	\$ 691,840
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	\$ 9,074,540	\$ 663,917	\$ 741,645
Net effect of conversion of common stock to preferred stock prior to merger	\$ 559	\$—	\$—

During the three months ended March 31, 2012 and 2011, 131.56 and 7.42 Series B Preferred Shares were converted into 363,425 and 20,497 Common shares, respectively. During the three months ended March 31, 2012 and 2011, -0- and 196,000 Series A Preferred Shares were converted into -0- and 980,000 Common shares, respectively. For the period from January 22, 1997 (date of inception) to March 31, 2012, 22,566.87 Series B Preferred Shares and 9,555,109 Series A Preferred Shares were converted into 62,339,419 and 43,698,427 Common Shares, respectively.

See accompanying notes to consolidated financial statements.

**CytoSorbents Corporation**

**Notes to Consolidated Financial Statements**

**(UNAUDITED)**

**March 31, 2012**

**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, 2012. 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 March 31, 2012 and the results of its operations and cash flows for three month periods ended March 31, 2012 and 2011, and for the period January 22, 1997 (date of inception) to March 31, 2012. Results for the 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, 2011 as included in the Company's Form 10-K filed with the Commission on March 30, 2012.

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 March 31, 2012 of \$94,648,055. 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. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

## Edgar Filing: Cytosorbents Corp - Form 10-Q

The Company is a development stage company and has not yet generated significant revenues from inception to March 31, 2012. Since inception, the Company's expenses relate primarily to research and development, organizational activities, clinical manufacturing, regulatory compliance 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 29 issued 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. As of March 31, 2012, the Company has not commenced full commercial operations and, accordingly, is in the development stage. The Company has yet to generate any significant revenue 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.

### **Inventories**

Inventories are valued at the lower of cost or market. At March 31, 2012 and December 31, 2011 the Company's inventory was comprised of finished goods, which amounted to \$270,020 and \$192,340, respectively, and work in process which amounted to \$198,543 and \$238,682, 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.

## **Research and Development**

All research and development costs, 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 all of the 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, 2011 or 2010. The Company files tax returns in the U.S. federal and state jurisdictions. The Company currently has no open years prior to December 31, 2008 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.

### **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 an impact on the Company's financial statements.

### 3. CONVERTIBLE NOTES

During February 2012 the Company issued 12-month Promissory Notes in the aggregate principal amount of \$700,000, which accrue interest at the rate of 8% per annum. Per the terms of the Promissory Notes issued in February, the investors will be repaid in equity of the Company, not cash. During the term of the Notes, investors may at any time convert outstanding principal and interest into Common Stock of the Company at a rate of \$0.15 per share. In addition, during the term of the Note, should the Company complete any subsequent financing, debt or equity, in an aggregate amount greater or equal to \$750,000, which includes any equity component or the right to convert into equity, the investor shall have the option to exchange any outstanding principal and interest of the Note into the new financing. Pursuant to the terms of the Promissory Note, the note holder will receive warrant coverage in the form of five year warrants to purchase that number of shares of Common Stock equal to the quotient obtained by dividing (x) 25% of the Principal, by (y) \$0.15, with the resulting number of shares having an exercise price equal to \$0.175 per share of Common Stock. The warrants have a cashless exercise provision. The Promissory Notes do not have registration rights for the shares underlying the notes or warrants.

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 connection with the promissory note issuances during the three months ended March 31, 2012 the Company received total proceeds of \$700,000. The Company allocated the total proceeds in accordance with FASB Codification Topic 470 based on the related fair value as follows: \$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 three months ended March 31, 2012 Convertible Notes in the principal and accrued interest amount of \$395,154 were converted into 3,951,540 Common shares resulting in a reduction of debt discount and charge to interest expense in the amount of \$235,762.

### 4. STOCKHOLDERS' EQUITY (DEFICIT)

During the three months ended March 31, 2012, the Company recorded non-cash stock dividends totaling \$663,917 in connection with the issuance of 1,634.51 shares of Series B Preferred Stock and 36,180 shares of Series A Preferred Stock as a stock dividend to its preferred shareholders as of March 31, 2012.

During the three months ended March 31, 2012, 131.56 Series B Preferred Shares were converted into 363,425 Common shares.

During the three months ended March 31, 2012, 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 three months ended March 31, 2012 is \$532 of which \$266 and \$266 is presented in research and development expenses and general and administrative expenses, respectively.

The Company has pre-approved options to purchase in the aggregate, up to a total of 408,000 shares of common stock to be issued and priced at the end of December 2012 to Directors. These options have been valued as of the pre-approval date. The aggregate expense of these options for the three months ended March 31, 2012 is approximately \$6,846, all of which is presented in general and administrative expenses.

The summary of the stock option activity for the three months ended March 31, 2012 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding, January 1, 2012	39,833,438	\$ 0.39	7.2
Granted	468,000	\$ 0.165	9.2
Cancelled	(114,254 )	\$ 33.57	—
Exercised	—	\$ —	—
Outstanding March 31, 2012	40,187,184	\$ 0.29	7.0

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 \$0.165 to \$0.168 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 (-0- percent) on the stock and the risk free interest rate (0.8 to 1.9 percent) for the term of the stock option.

At March 31, 2012, the aggregate intrinsic value of options outstanding and currently exercisable amounted to approximately \$1,700,000.

The summary of the status of the Company's non-vested options for the three months ended March 31, 2012 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2012	11,910,000	\$ 0.051
Granted	468,000	\$ 0.064
Cancelled	—	—
Vested	(1,294,000 )	\$ 0.054
Non-vested, March 31, 2012	11,084,000	\$ 0.051

As of March 31, 2012, approximately \$25,000 of total unrecognized compensation cost related to stock options is expected to be recognized over a weighted average period of 0.97 years.

As of March 31, 2012, the Company has the following warrants to purchase common stock outstanding:

Number of Shares	Warrant Exercise Price per Share	Warrant Expiration Date
To be Purchased		
3,986,429	\$ 0.035	June 25, 2013
397,825	\$ 0.0362	September 30, 2014
1,750,000	\$ 0.100	August 16, 2015
1,600,000	\$ 0.125	August 16, 2015

Edgar Filing: Cytosorbents Corp - Form 10-Q

1,333,333	\$ 0.15	August 16, 2015
490,000	\$ 0.10	October 22, 2015
196,000	\$ 0.125	October 22, 2015
163,333	\$ 0.15	October 22, 2015
625,000	\$ 0.10	November 2, 2015
250,000	\$ 0.125	November 2, 2015
208,334	\$ 0.15	November 2, 2015
500,000	\$ 0.10	November 19, 2015
200,000	\$ 0.125	November 19, 2015
166,667	\$ 0.15	November 19, 2015
240,125	\$ 1.25	October 24, 2016
5,500,000	\$ 0.10	February 15, 2016
2,200,000	\$ 0.125	February 15, 2016
1,833,333	\$ 0.15	February 15, 2016
1,166,667	\$ 0.175	February 10, 2017
22,807,046		

During the three months ended March 31, 2012 Convertible Notes in the principal and accrued interest amount of \$395,154 were converted into 3,951,540 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 three months ended March 31, 2012 the Company received approximately \$1,000,000 as proceeds from the sale of 7,078,905 shares of Common Stock per the terms of the Purchase Agreement with LPC at an average price of approximately \$0.14 per share of Common. Per the terms of the Purchase Agreement the Company also issued an additional 192,302 shares of Common Stock as additional Commitment Fee shares. The fair value of the Commitment shares of \$28,122 has been recorded as a cost of raising capital.



## **5. COMMITMENTS AND CONTINGENCIES**

### **Employment Agreements**

The Company is currently in the process of renewing employment agreements with certain key executives.

### **Litigation**

The Company is currently not involved, but may at times be involved in various claims and legal actions. Management is currently of the opinion that these claims and legal actions would have no merit, and any ultimate outcome will not have a material adverse impact on the consolidated financial position of the Company and/or the results of its operations.

### **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 period ended March 31, 2012 the Company has accrued royalty costs of \$507.

### **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 three months ended March 31, 2012 per the terms of the license agreement the Company has recorded royalty costs of \$372.

### **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 March 31, 2012 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 three months ended March 31, 2012 and 2011 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 62,994,230 and 70,718,917 incremental shares at March 31, 2012 and 2011, respectively, as well as shares issuable upon conversion of Series A and Series B Preferred Stock representing 186,225,263 and 183,872,466 incremental shares at March 31, 2012 and 2011, respectively, as well as potential shares issuable upon Note conversion into Common Stock representing approximately 12,196,667 and 19,152,500 incremental shares at March 31, 2012 and 2011, 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.

During April and May 2012, the Company received approximately \$650,000 as proceeds from the sale of 4,898,277 shares of Common Stock per the terms of the Purchase Agreement with LPC at an average price of \$0.133 per share of Common. Per the terms of the Purchase Agreement the Company also issued an additional 124,995 shares of Common Stock as additional Commitment Fee shares.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

These unaudited condensed consolidated financial statements and management's discussion should be read in conjunction with the audited consolidated financial statements of the Company and the notes thereto as of and for the year ended December 31, 2011 as included in the Company's Form 10-K filed with the Securities and Exchange Commission (the "Commission") on March 30, 2012.

### **Forward-looking statements**

*Statements contained in this Quarterly Report on Form 10-Q, other than the historical financial information, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All such forward-looking statements involve known and unknown risks, uncertainties or other factors which may cause actual results, performance or achievement of the Company to be materially different from any future results, performance or achievement expressed or implied by such forward-looking statements. Primary risk factors include, but are not limited to: ability to successfully develop commercial operations; the ability to obtain adequate financing in the future when needed; dependence on key personnel; acceptance of the Company's medical devices in the marketplace; obtaining government approvals, including required FDA approvals; compliance with governmental regulations; reliance on research and testing facilities of various universities and institutions; product liability risks; limited manufacturing experience; limited marketing, sales and distribution experience; market acceptance of the Company's products; competition; unexpected changes in technologies and technological advances; and other factors detailed in the Company's Annual Report on Form 10-K filed with the Commission on March 30, 2012.*

### **Overview and Plan of Operations**

CytoSorbents is a development stage critical care focused company using blood purification to treat disease. In March 2011, we received European Union (E.U.) regulatory approval under the CE Mark and Medical Devices Directive for our flagship product, CytoSorb®, as an extracorporeal cytokine filter to be used in clinical situations where cytokines are elevated. CytoSorbents has started the process of commercializing its operations with the commencement of initial sales of its CytoSorb® device in the E.U. In mid-September we started to exhibit the CytoSorb® device at conferences in Germany as part of our product marketing under a controlled-market release in select geographic territories in Germany. Because of the limited nature of this initial release, we anticipate only modest sales until we fully expand our marketing efforts into the broader market.

In 2011 as part of the CE Mark approval process we completed our European Sepsis clinical trial with enrollment of one hundred (100) patients with sepsis and respiratory failure with the participation of fourteen trial sites. The purpose of the trial was to demonstrate safety and the broad, and statistically significant reduction of key cytokines

such as IL-6 in these patients. CytoSorb® treatment was well tolerated with no serious device related adverse events reported in over 300 human treatments. In the study CytoSorb® demonstrated its clinical effectiveness in reducing cytokine storm by approximately 30-50% in critically-ill patients. CytoSorb® treatment showed a survival benefit in patients at high risk of death, including patients with high cytokine levels and patients older than age 65, who generally make up two-thirds of patients hospitalized for sepsis.

Our CE Mark enables CytoSorb® to be sold in the European Union for clinical use. Potential uses include many critical care conditions where cytokines are elevated such as sepsis, trauma, ARDS, severe burn injury and acute pancreatitis. CytoSorbents has 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. We intend to continue to research and seek the necessary regulatory approvals to sell our other proposed products, as well as potential label extensions of our current CE Mark.

We are focusing our efforts on the commercialization of our CytoSorb® product and are concluding a controlled-marketing program in select territories in Germany that we initiated in the fourth quarter of 2011. We are in the process of transitioning to a more formal product introduction of the CytoSorb® device into the German market. To assist in this focus on the European market we are in the process of hiring a full time sales team and have established a new subsidiary in Germany for our direct sales and marketing operations as we continue to raise awareness of our technology in the medical community. We are also evaluating potential distributor networks in other major countries where we are approved to market the device.

The initial major market focus for CytoSorb® is the adjunctive treatment of sepsis, a systemic inflammatory response to a serious infection or traumatic event. 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 intended to be absorbed 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 is currently manufacturing CytoSorb® under ISO 13485 Full Quality Systems certification for sale in the E.U. and for additional clinical studies. Concurrent with its commercialization plans, the Company intends to conduct additional clinical studies in sepsis and other critical care diseases to generate additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. Assuming availability of adequate and timely funding, and continued positive

results from our clinical studies, the Company intends to continue commercializing its product in Europe.

The clinical protocol for our European Sepsis Trial was designed to allow us to gather information to support future U.S. studies. 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. Even though we have obtained CE Mark approval, there is no guarantee or assurance that we will be successful in obtaining FDA approval in the United States or approval in any other country or jurisdiction.

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.

## Results of Operations

CytoSorbents generated revenues of \$16,893 and \$-0- for the three months ended March 31, 2012 and 2011 respectively. Revenues in the current quarter were part of an initial test market phase of the CytoSorb device with the company exploring direct sales to hospitals in Germany and sales to distributor networks in other parts of Europe. The device was not available or approved for sale during the first quarter of 2011.

Our research and development costs were, \$643,281 and \$759,157, for the three months ended March 31, 2012 and 2011 respectively. This represents a decrease of approximately 15.3% or \$116,000 for the three months ended March 31, 2012 compared to the same time period in 2011. This decrease is primarily due to net decreases in expenditures in our sepsis study clinical and research programs of approximately \$260,000 and non-cash stock option expense of approximately \$80,000, that were partially offset by increases in patent related expenses of approximately \$62,000 and salaries of approximately \$50,000, plus the receipt of approximately \$33,000 in grant income from a US Army Phase I SBIR grant, which is presented as the financial statements as a reduction in research and development costs.

Our Legal, Financial and other consulting costs were, \$161,292 and \$99,242, for the three months ended March 31, 2012 and 2011 respectively. This represents an increase of approximately 62.5%, or approximately \$62,000 for the three months ended March 31, 2012 compared to the same time period in 2011. This is primarily comprised of an increase in legal fees of approximately \$21,000 associated with patent review related costs, and approximately \$44,000 in accounting fees which were directly related to timing of when we incurred our annual audit related fees.

Our General and Administrative costs were, \$269,466 and \$270,092, for the three months ended March 31, 2012 and 2011 respectively. This represents a decrease of approximately 0.2%, or \$626 for the three months ended March 31, 2012 compared to the same time period in 2011. This is primarily due to decrease in non-cash stock option expense of approximately \$95,000 which was primarily offset by increases in sales and marketing expenses of approximately \$51,000, salaries expense of approximately \$10,000, and insurance related costs of approximately \$10,000.

Our net interest expenses were \$359,370 and \$86,093 for the three months ended March 31, 2012 and 2011 respectively. This represents an increase of approximately 317% or \$273,000 for the three months ended March 31, 2012 compared to the same time period in 2011. The increase is primarily due to an increase of approximately \$258,000 in non-cash related charges associated with the amortization of debt discount, which is presented in the net interest expenses category of our statement of operations.

We have experienced substantial operating losses since inception. As of March 31, 2012, we had an accumulated deficit of \$94,648,055, which included losses of \$1,426,596 three month period ended March 31, 2012. In comparison, we had losses of \$1,214,584 for the three month period ended March 31, 2011. Historically, our losses

have resulted principally from costs incurred in the research and development of our polymer technology, and general and administrative expenses, which together were \$912,747 for the three month period ended March 31, 2012 and \$1,029,249 for the three month period ended March 31, 2011.

### Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of our debt and equity securities. At December 31, 2011 we had cash of \$1,186,653. As of March 31, 2012 we had cash on hand of \$1,803,049, and current liabilities of \$2,248,818.

We believe that we have sufficient cash to fund our operations into the third quarter of 2012, following which we will need additional funding before we can complete additional clinical studies and commercialize our products. The Company has received SEC approval for a registration statement filed for the funding agreement with Lincoln Park Capital Fund LLC. Subject to minimum pricing restrictions per the terms of the funding agreement, Management believes that the Company will be able to receive ongoing funding per the terms of this purchase agreement (See Note 9 of Financial Statements). The agreement with Lincoln Park has the potential to significantly extend the time that we may be able to fund our operations, provided that our share price remains at or above \$0.10. During the three months ended March 31, 2012 we received approximately \$33,000 from the US Department of Defense for our progress under a \$100,000 US Army Phase I SBIR grant that the company was awarded in December 2011. 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. 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 March 31, 2012 of \$94,648,055. 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. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

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

Not applicable to smaller reporting companies.

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

#### Evaluation of Disclosure Controls and Procedures

Pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 ("Exchange Act"), the Company carried out an evaluation, with the participation of the Company's management, including the Company's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of the Company's disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, the Company's CEO and CFO concluded that the Company's disclosure controls and procedures are

effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

#### Changes in Internal Controls

There have been no changes in the Company's internal control over financial reporting during the latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

The Company is currently not involved, but may at times be involved in various claims and legal actions. Management is currently of the opinion that these claims and legal actions would have no merit, and any ultimate outcome will not have a material adverse impact on the consolidated financial position of the Company and/or the results of its operations.

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

Not required to be provided by smaller reporting companies.

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

In February 2012, we issued 12-month Promissory Notes in the aggregate principal amount of \$700,000, which accrue interest at the rate of 8% per annum. Per the terms of the Promissory Notes, the investors may, at any time, convert outstanding principal and interest into Common Stock of the Company at a rate of \$0.15 per share. In connection with the sale of the Promissory Note, we issued each note holder a warrants exercisable into 1,166,667 shares with an exercise price equal to \$0.175 per share of Common Stock. *The shares sold in this transaction were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering.*

### **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 Chief 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 Chief 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 Chief 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 Chief 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.

\* Furnished herewith. XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as

amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is 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.

### **CYTOSORBENTS CORPORATION**

Dated: May 15, 2012 By: /s/ David Lamadrid  
Name: David Lamadrid  
Title: Chief Financial Officer  
(Duly Authorized Officer and Principal  
Financial Officer)