

Cytosorbents Corp
Form 10-Q
November 14, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2011

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
(State or other jurisdiction of
incorporation or organization)

98-0373793
(I.R.S. Employer Identification No.)

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 ☐

Edgar Filing: Cytosorbents Corp - Form 10-Q

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 November 14, 2011 there were 177,283,058 shares of the issuer’s common stock outstanding.

CytoSorbents Corporation
(a development stage company)
FORM 10-Q

TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements (September 30, 2011 and 2010 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	
Item 3. Quantitative and Qualitative Disclosures about Market Risk	18
Item 4. Controls and Procedures	18
PART II. OTHER INFORMATION	
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

	September 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 2,296,147	\$ 1,055,669
Inventories	186,339	—
Prepaid expenses and other current assets	33,516	344,536
Total current assets	2,516,002	1,400,205
Property and equipment - net	144,576	144,146
Other assets	273,857	267,575
Total long-term assets	418,433	411,721
Total Assets	\$ 2,934,435	\$ 1,811,926
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	\$ 784,357	\$ 817,701
Accrued expenses and other current liabilities	566,212	401,418
Convertible notes payable, net of debt discount in the amount of \$11,985 at September 30, 2011 and \$-0- at December 31, 2010	238,015	—
Total current liabilities	1,588,584	1,219,119
Long Term Liabilities:		
Convertible notes payable, net of debt discount in the amount of \$688,182 at September 30, 2011 and \$257,862 at December 31, 2010	224,818	1,077,388
Total long term liabilities	224,818	1,077,388
Total liabilities	1,813,402	2,296,507
Stockholders' Equity (Deficit):		
10% Series B Preferred Stock, Par Value \$0.001, 200,000 shares authorized at September 30, 2011 and December 31, 2010, respectively; 65,647.38 and 60,973.11	66	61

Edgar Filing: Cytosorbents Corp - Form 10-Q

shares issued and outstanding, respectively

10% Series A Preferred Stock, Par Value \$0.001, 12,000,000 shares authorized at September 30, 2011 and December 31, 2010, respectively; 1,411,864 and 5,826,409

shares issued and outstanding, respectively

1,412

5,826

Common Stock, Par Value \$0.001, 500,000,000 shares authorized at September 30, 2011 and December 31, 2010, 172,283,058 and 122,838,411 shares issued and

outstanding, respectively

172,283

122,838

Additional paid-in capital

91,575,243

83,375,544

Deficit accumulated during the development stage

(90,627,971)

(83,988,850)

Total stockholders' equity (deficit)

1,121,033

(484,581)

Total Liabilities and Stockholders' Equity (Deficit)

\$ 2,934,435

\$ 1,811,926

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 Nine months ended September 30Three months ended September 30, September 30, 2011 2011 2010 2011 2010 (Unaudited) (Unaudited) (Unaudited) (Unaudited) (Unaudited)				
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —
Expenses:					
Research and development	50,404,666	2,393,573	1,560,146	779,589	526,043
Legal, financial and other consulting	7,875,714	260,475	242,604	93,703	42,226
General and administrative	24,640,571	814,287	620,061	352,393	212,388
Change in fair value of management and incentive units	(6,055,483)	—	—	—	—
Total expenses	76,865,468	3,468,335	2,422,811	1,225,685	780,657
Other (income)/expenses:					
Gain on disposal of property and equipment	(21,663)	—	—	—	—
Gain on extinguishment of debt	(216,617)	—	—	—	—
Interest expense/(income), net	6,508,599	816,358	10,954	503,242	7,779
Penalties associated with non-registration of Series A Preferred Stock	361,495	—	—	—	—
Total other (income)/expense, net	6,631,814	816,358	10,954	503,242	7,779
Loss before benefit from income taxes	(83,497,282)	(4,284,693)	(2,433,765)	(1,728,927)	(788,436)
Benefit from income taxes	(547,318)	—	—	—	—
Net loss	(82,949,964)	(4,284,693)	(2,433,765)	(1,728,927)	(788,436)
Preferred Stock Dividend	7,678,007	2,354,428	1,596,801	734,857	401,750
Net Loss available to common shareholders	\$ (90,627,971)	\$ (6,639,121)	\$ (4,030,566)	\$ (2,463,784)	\$ (1,190,186)
		\$ (0.04)	\$ (0.04)	\$ (0.02)	\$ (0.01)

Basic and diluted net loss per
common share

Weighted average number of
shares of common stock
outstanding

153,796,011	91,663,158	168,230,680	106,250,720
-------------	------------	-------------	-------------

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, 2010 to September 30, 2011 (Unaudited)											
	Members Equity	Preferred Stock	Common Shares	Stock Par value	Preferred Shares	Stock B Par Value	Preferred Shares	Stock A ParValue	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Stock Equity
Balance at December 31, 2010	\$—	\$—	122,838,411	\$122,838	60,973.11	\$61	5,826,409	\$5,826	\$83,375,544	\$(83,988,850)	\$(4,612,707)
Stock based compensation – employees, consultants and directors	—	—	—	—	—	—	—	—	508,069	—	508,069
Issuance of Series A Preferred Stock as dividends	—	—	—	—	—	—	230,866	231	66,613	(66,844)	—
Issuance of Series B Preferred Stock as dividends	—	—	—	—	4,687.45	5	—	—	2,287,579	(2,287,584)	—
Conversion of Series A and Series B into Common	—	—	11,115,042	11,115	(13.18)	—	(4,645,411)	(4,645)	(6,470)	—	—
Issuance of common stock for cash, net of cost of raising capital	—	—	17,335,942	17,336	—	—	—	—	2,626,431	—	2,626,431
Conversion of convertible	—	—	14,833,310	14,833	—	—	—	—	1,468,497	—	1,468,497

notes to
common

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

— — —

—

—

— —

—

1,250,000

—

1,

Cashless
exercise of
warrants

— —

6,013,478

6,014

—

— —

—

(6,014)

—

—

Exercise of
stock options

— —

146,875

147

—

— —

—

4,994

—

5,

Net loss

— — —

—

—

— —

—

—

(4,284,693) (4,

Balance at
September 30,
2011

\$—\$— 172,283,058 \$172,283 65,647.38 \$66 1,411,864 \$1,412 \$91,575,243 \$90,627,971) \$1,

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, 2011 (Unaudited)	Nine months Ended September 30, 2011 (Unaudited)	Nine months ended September 30, 2010 (Unaudited)
Cash flows from operating activities:			
Net loss	\$ (82,949,964)	\$ (4,284,693)	\$ (2,433,765)
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	2,455,487	45,222	13,258
Amortization of debt discount	1,856,638	807,695	6,851
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	2,147,594	508,069	108,594
Amortization of deferred compensation	74,938	—	—
Penalties in connection with non-registration event	361,496	—	—
Changes in operating assets and liabilities:			
Inventories	(186,339)	(186,339)	—
Prepaid expenses and other current assets	(305,064)	311,020	298,181
Other assets	(56,394)	—	—
Accounts payable and accrued expenses	3,067,999	79,437	197,795
Accrued interest expense	1,823,103	—	—
Net cash used by operating activities	(61,468,471)	(2,719,589)	(1,809,086)
Cash flows from investing activities:			
Proceeds from sale of property and equipment	32,491	—	—
Purchases of property and equipment	(2,400,404)	(34,116)	—
Patent costs	(479,558)	(17,818)	(23,068)
Purchases of short-term investments	(393,607)	—	—
Proceeds from sale of short-term investments	393,607	—	—

Edgar Filing: Cytosorbents Corp - Form 10-Q

Loan receivable	(1,632,168)	—	—
Net cash used by investing activities	(4,479,639)	(51,934)	(23,068)
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	46,571,310	2,756,860	17,500
Proceeds from borrowings	11,188,881	1,250,000	977,250
Proceeds from exercise of stock options	5,141	5,141	—
Proceeds from subscription receivables	499,395	—	—
Net cash provided by financing activities	68,244,257	4,012,001	994,750
Net change in cash and cash equivalents	2,296,147	1,240,478	(837,404)
Cash and cash equivalents - beginning of period	—	1,055,669	1,595,628
Cash and cash equivalents - end of period	\$ 2,296,147	\$ 2,296,147	\$ 758,224

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	\$ 1,556,805	\$ 1,250,000	\$ 112,413
---	--------------	--------------	------------

Fair value of shares issued as costs of raising capital	\$ 335,950	\$ 106,344	\$—
---	------------	------------	-----

Issuance of 6,013,478 shares of common stock pursuant to cashless exercise of warrants	\$—	\$—	\$—
--	-----	-----	-----

Note payable principal and interest conversion to equity	\$ 11,917,649	\$ 1,483,330	\$—
--	---------------	--------------	-----

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	\$ 1,609,446	\$—	\$—
--	--------------	-----	-----

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	\$ 7,678,007	\$ 2,354,428	\$ 1,596,801
---------------------------	--------------	--------------	--------------

Net effect of conversion of common stock to preferred stock prior to merger	\$ 559	\$—	\$—
---	--------	-----	-----

During the nine months ended September 30, 2011 and 2010, 13.18 and 12,862.78 Series B Preferred Shares were converted into 36,408 and 35,532,542 Common shares, respectively. During the nine months ended September 30, 2011 and 2010, 4,645,411 and 819,563 Series A Preferred Shares were converted into 11,078,634 and 8,195,623 Common shares, respectively. For the period from January 22, 1997 (date of inception) to September 30, 2011, 20,625.31 Series B Preferred Shares and 9,555,109 Series A Preferred Shares were converted into 56,975,994 and 43,698,427 Common Shares, respectively.

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation
Notes to Consolidated Financial Statements
(UNAUDITED)
September 30, 2011

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"), and CytoSorbents, Inc., its wholly-owned operating subsidiary (the "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, 2011. 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, 2011 and the results of its operations and cash flows for the nine and three month periods ended September 30, 2011 and 2010, and for the period January 22, 1997 (date of inception) to September 30, 2011. 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, 2010 as included in the Company's Form 10-K filed with the Commission on March 31, 2011.

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, 2011 of \$90,627,971. The Company is not currently generating 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.

The Company is a development stage company and has not yet generated any revenues from inception to September 30, 2011. 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, 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 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 September 30, 2011, the Company has not commenced commercial operations and, accordingly, is in the development stage. The Company has yet to generate any 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 subsidiary, CytoSorbents, Inc. 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 September 30, 2011 and December 31, 2010 the Company's inventory was comprised of finished goods, which amounted to \$42,240 and \$-0-, respectively, and work in process which amounted to \$144,099 and \$-0-, 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. Further, the Company currently has no open tax years which could be subject to audit prior to December 31, 2007.

The Company follows guidance associated with uncertain tax positions which requires that the Company determine whether it is more likely than not that a tax position will not be sustained upon examination by the appropriate taxing authority. If a tax position does not meet the more likely than not recognition criterion, the guidance requires that the tax position be measured at the largest amount of benefit greater than 50 percent not likely of being sustained upon ultimate settlement. Based on the Company's evaluation, management has concluded that there are no significant uncertain tax positions requiring recognition and has no income tax related penalties or interest in these consolidated 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 2011 the Company issued 24-month Promissory Notes in the aggregate principal amount of \$1,250,000, 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 \$0.10 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 as follows: that number of shares of Common Stock equal to the quotient obtained by dividing (x) 50% of the Principal, by (y) \$0.10, with the resulting number of shares having an exercise price equal to \$0.10 per share of Common Stock, plus that number of shares of Common Stock equal to the quotient obtained by dividing (x) 25% of the Principal, by (y) \$0.125, with the resulting number of shares having an exercise price equal to \$0.125 per share of Common Stock, plus 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 \$0.15 per share of Common Stock. The warrants have a cashless exercise provision. If during the term of the Note, and as long as the Note investor continues to own an outstanding balance of the Note, the Company has an equity financing of less than \$750,000 that values the Company on a pre-money basis at or below \$35 million on a fully-diluted basis, the Note investor will have a right of first refusal to participate in the financing per the terms of the Note. 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 nine months ended September 30, 2011 the Company received total proceeds of \$1,250,000. The Company allocated the total proceeds in accordance with FASB Codification Topic 470 based on the related fair value as follows: (\$0) was allocated to the promissory notes and \$466,432 to the warrants. Additionally, the embedded conversion feature resulted in a beneficial conversion feature in the amount of \$783,568. 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, 2011 Convertible Notes in the principal and accrued interest amount of \$1,483,330 were converted into 14,833,310 Common shares resulting in a reduction of debt discount and charge to interest expense in the amount of \$493,758.

4. STOCKHOLDERS' EQUITY (DEFICIT)

During the nine months ended September 30, 2011, the Company recorded non-cash stock dividends totaling \$2,354,428 in connection with the issuance of 4,687.45 shares of Series B Preferred Stock and 230,866 shares of Series A Preferred Stock as a stock dividend to its preferred shareholders as of September 30, 2011.

During the nine months ended September 30, 2011, 13.18 Series B Preferred Shares were converted into 36,408 Common shares. During the nine months ended September 30, 2011, 4,645,411 Series A Preferred Shares were converted into 11,078,634 Common shares.

During the nine months ended September 30, 2011, the Company incurred stock-based compensation expense due to the issuance of stock options, amortization of unvested stock options and the anticipated vesting of stock options

based on satisfaction of certain contingent events. The aggregate expense for the nine months ended September 30, 2011 is \$508,069 of which \$246,262 and \$261,807 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 2011 to Directors. These options have been valued as of the pre-approval date. The aggregate expense of these options for the nine months ended September 30, 2011 is approximately \$18,975, all of which is presented in general and administrative expenses.

The summary of the stock option activity for the nine months ended September 30, 2011 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding, January 1, 2011	39,755,113	\$0.44	8.2
Granted	290,000	\$0.137	8.0
Cancelled	(64,800)	\$31.52	—
Exercised	(146,875)	\$0.035	—
Outstanding September 30, 2011	39,833,438	\$0.39	7.4

The fair value of each stock option was valued using the Black Scholes pricing model which takes into account as of the grant date the exercise price (ranging from \$0.136 to \$0.138 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 27 percent), expected dividends (-0- percent) on the stock and the risk free interest rate (2.1 to 3.4 percent) for the term of the stock option.

At September 30, 2011, the aggregate intrinsic value of options outstanding and currently exercisable amounted to approximately \$2,300,000.

The summary of the status of the Company's non-vested options for the nine months ended September 30, 2011 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2011	17,795,144	\$ 0.047
Granted	290,000	\$ 0.055
Cancelled	—	—
Vested	(6,175,144)	\$ 0.038
Non-vested, September 30, 2011	11,910,000	\$.051

As of September 30, 2011, approximately \$330,000 of total unrecognized compensation cost related to stock options is expected to be recognized over a weighted average period of 0.35 years.

As of September 30, 2011, 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
400,000	\$ 0.40	October 31, 2011
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
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	

Edgar Filing: Cytosorbents Corp - Form 10-Q

			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
22,040,379			

During the nine months ended September 30, 2011, pursuant to cashless exercises, the Company issued an aggregate total of 3,928,035 shares of Common Stock for the full exercise of warrants to purchase 6,275,750 shares of Common Stock at a exercise prices ranging from \$0.10 to \$0.15 per share of Common, and issued an additional 2,085,443 shares of Common Stock for the full exercise and subsequent conversion of a warrant to purchase 525,000 shares of Series A Preferred Stock at an exercise price of \$1.00 per share of Preferred that were convertible into Common Stock at a rate of \$0.10 per share.

During the nine months ended September 30, 2011 Convertible Notes in the principal and accrued interest amount of \$1,483,330 were converted into 14,833,310 Common shares.

In May 2010, the Company executed a purchase agreement (the "Purchase Agreement") and a registration rights agreement with Lincoln Park Capital Fund, LLC ("LPC"). Under the Purchase Agreement, LPC is obligated, under certain conditions, to purchase from the Company up to \$6 million of our Common Stock, from time to time over a 750 day (twenty-five (25) monthly) period.

The Company has the right, but not the obligation, to direct LPC to purchase up to \$6,000,000 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 Purchase Agreement without any fixed discount. The Company may at any time at its sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice. The Company issued 1,153,846 shares of our Common Stock to LPC as a commitment fee for entering into the agreement, and is obligated to issue up to an additional 1,153,846 shares pro rata as LPC purchases up to \$6,000,000 of its Common Stock as directed by the Company. LPC may not assign any of its rights or obligations under the Purchase Agreement.

During the nine months ended September 30, 2011 the Company sold a total of 16,325,814 shares of Common Stock per the terms of the Purchase Agreement with LPC at an average price of approximately \$0.18 per share of Common. Per the terms of the Purchase Agreement the Company also issued an additional 561,603 shares of Common Stock as additional Commitment Fee shares. The fair value of the Commitment shares have been recorded as a cost of raising capital.

5. COMMITMENTS AND CONTINGENCIES

Employment Agreements

The Company has employment agreements with certain key executives through December 2011. The agreements provide for annual base salaries of varying amounts.

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. The Company has not generated any revenue from this product and has not incurred any royalty costs through September 30, 2011. The amount of future revenue subject to the royalty agreement could not be reasonably estimated nor has a liability been incurred, therefore, an accrual for royalty payments has not been included in the consolidated financial statements.

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, CytoSorbents 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. The Company has not generated any revenue from its products and has not incurred any royalty costs through September 30, 2011. The amount of future revenue subject to the license agreement could not be reasonably estimated nor has a liability been incurred, therefore, an accrual for royalty payments has not been included in the consolidated financial statements.

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, 2011 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, 2011 and 2010 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 61,873,817 and 69,690,223 incremental shares at September 30, 2011 and 2010, respectively, as well as shares issuable upon conversion of Series A and Series B Preferred Stock representing 182,601,216 and 185,501,736 incremental shares at September 30, 2011 and 2010, respectively, as well as potential shares issuable upon Note conversion into Common Stock representing approximately 11,630,000 and 9,772,500 incremental shares at September 30, 2011 and 2010, 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 October 2011 a total of 1,810 shares of Series B Preferred Stock were converted into a total of 5,000,000 shares of Common Stock.

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 financial statements of the Company and the notes thereto as of and for the year ended December 31, 2010 as included in the Company's Form 10-K filed with the Securities and Exchange Commission (the "Commission") on March 31, 2011.

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 31, 2011.

Plan of Operations

We are a development stage company and expect to remain so for at least the next several quarters. CytoSorbents is a 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. 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 expand our marketing efforts into the broader market.

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 have completed the targeted enrollment in our European Sepsis clinical trial 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. Although the trial was not powered to demonstrate significant reduction in clinical endpoints such as mortality, these were included as secondary and exploratory endpoints in the trial. Taking into account all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial. The first 22 patients in the study represented a sepsis pilot study. In the next 31 patients, a compromise of the manual randomization schedule at two trial sites led to an imbalance in the severity of illness between the control and treatment patient groups of the study. After a thorough review, the Scientific Advisory Board (SAB) and the

independent Data Safety Monitoring Board (DSMB) both recommended that due to this enrollment bias, these 31 patients should only be used for safety evaluation purposes and that new patients should be enrolled into the trial using electronic web-based randomization to randomly assign patients into either the control or treatment arms. Excluding four patients that withdrew, the remaining forty three (43) patients enrolled under electronic randomization were relatively balanced in terms of the severity of illness in treatment and control patients, confirming the findings of the SAB and DSMB. In these forty three (43) patients the European Sepsis Trial successfully demonstrated, on a statistically significant basis ($p < 0.05$), CytoSorb™'s ability to reduce circulating levels of key cytokines from whole blood in treated patients on the average of 30-50% over the 7 day treatment period. Additionally, post-hoc subgroup analyses of the clinical outcome data from patients enrolled under electronic randomization demonstrated statistically significant reduction in mortality in patients at high risk of death in sepsis, specifically in patients with very high cytokine levels ($IL-6 \geq 1,000$ pg/mL and/or $IL-1ra \geq 16,000$ pg/mL) where 28-day mortality was 0% treated vs 63% control, $p=0.03$, $n=14$ and patients $\geq$ age 65 (14-day mortality: 0% treated vs 36% control, $p=0.04$, $n=21$).

We are focusing our efforts on the commercialization of our CytoSorb™ product and have begun a controlled-marketing program in select territories in Germany. 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 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 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

Our research and development costs were, \$2,393,573 and \$1,560,146, for the nine months ended September 30, 2011 and 2010 respectively and \$779,589 and \$526,043 for the three months ended September 30, 2011 and 2010. We have experienced substantial operating losses since inception. As of September 30, 2011, we had an accumulated deficit of \$90,627,971, which included losses of \$1,728,927 and \$4,284,693 for the three and nine month periods ended September 30, 2011. In comparison, we had losses of \$788,436 and \$2,433,765 for the three and nine month periods ended September 30, 2010. 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 \$1,131,982 and \$3,207,860 for the three and nine month periods ended September 30, 2011 and \$738,431 and \$2,180,207 for the three and nine month periods ended September 30, 2010.

Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of our debt and equity securities. At December 31, 2010 we had cash of \$1,055,669. As of September 30, 2011 we had cash on hand of \$2,296,147, and current liabilities of \$1,588,584.

We believe that we have sufficient cash to fund our operations into the first quarter of 2012, following which we will need additional funding before we can complete additional clinical studies and fully commercialize our products. For our funding agreement with Lincoln Park Capital Fund LLC (LPC), the Company filed a registration statement in June 2010, which was declared effective by the SEC. Pursuant to common stock sales to Lincoln Park Capital all of these registered shares have been issued. Subject to minimum pricing restrictions per the terms of the funding agreement, and based on the remaining funds available in the financing facility, Management believes that the Company will have the option to sell up to an approximate \$2.3 million in common stock to LPC per the terms of this purchase agreement (See Note 4 of Financial Statements). The Company will need to file an additional registration statement and receive SEC approval of same before it can make additional common stock sales to Lincoln Park Capital under the existing agreement. This capital has the potential to significantly extend the time that we may be able to fund our operations. We will continue to seek funding for the long term needs of the Company. There can be no assurance that we will be able to continue to utilize the Lincoln Park funding agreement, or that additional 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

Our Quarterly Report for the period ended September 30, 2011 was prepared assuming we will continue as a going concern, and the auditors' report on our December 31, 2010 financial statements expresses substantial doubt about our ability to continue as a going concern.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)

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	Interactive Data File (Form 10-Q for the quarterly period ended September 30, 2011 furnished in XBRL).

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: November 14, 2011

By:

/s/ David Lamadrid

Name: David Lamadrid

Title: Chief Financial Officer

(Duly Authorized Officer and Principal
Financial Officer)