

Cytosorbents Corp
Form 10-Q
May 14, 2010

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, 2010

or

o 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
(f/k/a MedaSorb Technologies 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)

(732) 329-8885
(Registrant's Telephone Number, Including Area Code)

MEDASORB TECHNOLOGIES CORPORATION
(FORMER NAME OR FORMER ADDRESS, IF CHANGED SINCE LAST REPORT)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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

Edgar Filing: Cytosorbents Corp - Form 10-Q

(§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 definition of “accelerated filer, large accelerated filer”, and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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 12, 2010 there were 97,414,829 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 (March 31, 2010 and 2009 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	15
Item 3. Quantitative and Qualitative Disclosures about Market Risk	17
Item 4(T). Controls and Procedures	17
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	18
Item 1A. Risk Factors	18
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	18
Item 3. Defaults of Senior Securities	18
Item 4. (Removed and Reserved)	18
Item 5. Other Information	18
Item 6. Exhibits	18

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

CYTOSORBENTS CORPORATION
(f/k/a MedaSorb Technologies Corporation)
(a development stage company)

CONSOLIDATED BALANCE SHEETS

	March 31, 2010 (Unaudited)	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 1,346,301	\$ 1,595,628
Prepaid expenses and other current assets	72,489	369,091
Total current assets	1,418,790	1,964,719
Property and equipment - net	17,758	18,853
Other assets	251,583	254,908
Total long-term assets	269,341	273,761
Total Assets	\$ 1,688,131	\$ 2,238,480
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	\$ 888,071	\$ 852,167
Accrued expenses and other current liabilities	260,200	118,598
Notes payable	172,500	—
Total current liabilities	1,320,771	970,765
Total liabilities	1,320,771	970,765
Stockholders' Equity (Deficit):		
10% Series B Preferred Stock, Par Value \$0.001, 200,000 shares authorized at March 31, 2010 and December 31, 2009, respectively; 67,446.24 and 68,723.88 shares issued and outstanding, respectively	67	69
10% Series A Preferred Stock, Par Value \$0.001, 12,000,000 shares authorized at March 31, 2010 and December 31, 2009, respectively; 5,903,306 and 6,255,813 shares issued and outstanding, respectively	5,903	6,256
	79,575	66,375

Edgar Filing: Cytosorbents Corp - Form 10-Q

Common Stock, Par Value \$0.001, 500,000,000 shares authorized at March 31, 2010 and December 31, 2009, 79,574,856 and 66,374,856 shares issued and outstanding, respectively

Additional paid-in capital	80,934,751	80,097,536
Deficit accumulated during the development stage	(80,652,936)	(78,902,521)
Total stockholders' equity (deficit)	367,360	1,267,715
Total Liabilities and Stockholders' Equity (Deficit)	\$ 1,688,131	\$ 2,238,480

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
(f/k/a MedaSorb Technologies Corporation)
(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Period from January 22, 1997 (date of inception) to March 31, 2010 (Unaudited)	Three months ended March 31, 2010 (Unaudited) 2009 (Unaudited)	
Revenue	\$ —	\$ —	\$ —
Expenses:			
Research and development	46,934,938	681,215	488,555
Legal, financial and other consulting	7,380,909	72,932	48,733
General and administrative	23,280,527	213,630	228,334
Change in fair value of management and incentive units	(6,055,483)	—	—
Total expenses	71,540,891	967,777	765,622
Other (income)/expense:			
Gain on disposal of property and equipment	(21,663)	—	—
Gain on extinguishment of debt	(216,617)	—	—
Interest expense (income), net	5,608,669	1,274	(5,471)
Penalties associated with non-registration of Series A Preferred Stock	361,495	—	—
Total other (income)/expense, net	5,731,884	1,274	(5,471)
Loss before benefit from income taxes	(77,272,775)	(969,051)	(760,151)
Benefit from income taxes	(547,318)	—	—
Net loss	(76,725,457)	(969,051)	(760,151)
Preferred stock dividend	3,927,479	781,364	170,574
Net loss available to common shareholders	\$ (80,652,936)	\$ (1,750,415)	\$ (930,725)
Basic and diluted net loss per common share		\$ (0.02)	\$ (0.03)
Weighted average number of shares of common stock outstanding		72,883,745	29,072,876

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION
(f/k/a MedaSorb Technologies Corporation)
(a development stage company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

Period from
December 31, 2008 to
March 31, 2010
(Unaudited)

	Members Equity (Deficit)	Deferred Compensation Shares	Common Stock Shares	Par value	Preferred Stock B Shares	Par Value	Preferred Stock A Shares	Par Value	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
Balance at December 31, 2009	\$ —	—	66,374,856	\$ 66,375	68,723.88	\$ 69	6,255,813	\$ 6,256	\$ 80,097,536	\$(78,902,521)	\$ 1,267,715
Stock based compensation – employees, consultants and directors	—	—	—	—	—	—	—	—	68,696	—	68,696
Issuance of Series A Preferred Stock as dividends	—	—	—	—	—	—	147,493	147	61,943	(62,090)	—
Issuance of Series B Preferred Stock as dividends	—	—	—	—	1,690.76	1	—	—	719,273	(719,274)	—
Conversion of Series A and Series B into Common	—	—	13,200,000	13,200	(2,968.40)	(3)	(500,000)	(500)	(12,697)	—	—
Net loss	—	—	—	—	—	—	—	—	—	(969,051)	(969,051)
Balance at March 31, 2010	—	—	79,574,856	\$ 79,575	67,446.24	\$ 67	5,903,306	\$ 5,903	\$ 80,934,751	\$(80,652,936)	\$ 367,360

CYTOSORBENTS CORPORATION
(f/k/a MedaSorb Technologies Corporation)
(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Period from January 22, 1997 (date of inception) to March 31, 2010 (Unaudited)	Three months ended March 31, 2010 (Unaudited)	Three months Ended March 31, 2009 (Unaudited)
Cash flows from operating activities:			
Net loss	\$ (76,725,457)	\$ (969,051)	\$ (760,151)
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	2,396,881	4,420	12,614
Amortization of debt discount	1,000,000	—	—
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	1,558,896	68,696	65,287
Amortization of deferred compensation	74,938	—	—
Penalties in connection with non-registration event	361,496	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(344,037)	296,602	27,773
Other assets	(56,394)	—	5,003
Accounts payable and accrued expenses	2,975,088	177,506	(134,637)
Accrued interest expense	1,823,103	—	—
Net cash used by operating activities	(56,693,451)	(421,827)	(784,111)
Cash flows from investing activities:			

Edgar Filing: Cytosorbents Corp - Form 10-Q

Proceeds from sale of property and equipment	32,491	—	—
Purchases of property and equipment	(2,226,932)	--	(6,411)
Patent costs	(435,647)	--	(3,498)
Purchases of short-term investments	(393,607)	—	—
Proceeds from sale of short-term investments	393,607	--	199,607
Loan receivable	(1,632,168)	—	—
Net cash used by investing activities	(4,262,256)	--	189,698
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	43,046,952	—	—
Proceeds from borrowings	8,776,131	172,500	—
Proceeds from subscription receivables	499,395	—	—
Net cash provided by financing activities	62,302,008	172,500	—

See accompanying notes to consolidated financial statements.

Net change in cash and cash equivalents	1,346,301	(249,327)	(594,413)
Cash and cash equivalents - beginning of period	—	1,595,628	2,749,208
Cash and cash equivalents - end of period	\$ 1,346,301	\$ 1,346,301	\$ 2,154,795
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	\$ 590,189	\$ —	\$ —
Supplemental schedule of noncash investing and financing activities:			
Note payable principal and interest conversion to equity	\$ 10,434,319	\$ —	\$ —
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	\$ 3,927,479	\$ 781,364	\$ 170,574
Net effect of conversion of common stock to preferred stock prior to merger	\$ 559	\$ —	\$ —

During the three months ended March 31, 2010 and 2009, 2,968.40 and 300.69 Series B Preferred Shares were converted into 8,200,000 and 830,636 Common shares, respectively. During the three months ended March 31, 2010 and 2009, 500,000 and 441,666 Series A Preferred Shares were converted into 5,000,000 and 4,416,666 Common shares, respectively. For the period from January 22, 1997 (date of inception) to March 31, 2010, 9,596.95 Series B Preferred Shares and 4,390,135 Series A Preferred Shares were converted into 26,510,911 and 28,424,170 Common Shares, respectively.

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation
(f/k/a MedaSorb Technologies Corporation)
Notes to Consolidated Financial Statements
(UNAUDITED)
March 31, 2010

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"), formerly known as MedaSorb Technologies Corporation (See Note 7), and CytoSorbents, Inc. (f/k/a MedaSorb Technologies, 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, 2010. 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, 2010 and the results of its operations and cash flows for the three month periods ended March 31, 2010 and 2009, and for the period January 22, 1997 (date of inception) to March 31, 2010. 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, 2009 as included in the Company's Form 10-K filed with the Commission on April 9, 2010.

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, 2010 of \$80,652,936. 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. 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. 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 27 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. As of March 31, 2010, 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.

Short Term Investments

Short-term investments include short-term bank certificates of deposit with original maturities of between three and twelve months. These short-term notes are classified as held to maturity and are valued at cost, which approximates fair value. These investments are considered Level 2 investments under accounting standards for fair value measurements.

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.

9

The Company adopted the accounting standards associated with uncertain tax provisions as of January 1, 2007. The adoption of this standard did not have a material impact on the Company's consolidated statements of operations or financial position. Upon adoption of this accounting standard, the Company had no unrecognized tax benefits. Furthermore, the Company had no unrecognized tax benefits at March 31, 2010. The Company files tax returns in the U.S. federal and state jurisdictions. The Company has no open years prior to December 31, 2006.

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 and the valuation of preferred shares issued as stock dividends.

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 that have an impact on the Company's financial statements.

3. CONVERTIBLE NOTES

In January 2010 the Company issued a 12-month Promissory Note in the principal amount of \$172,500, which bears interest at the rate of 5% per annum. Should the Company complete any financing, debt or equity, which includes any equity component or the right to convert into equity, the entire principal and outstanding interest of the Note shall automatically be converted into the creditor's choice of either 1) the securities issued in such financing under the same terms, conditions, and pricing (the "Conversion Price") or 2) applied toward the exercise of the creditor's existing warrant for Series A Preferred Stock. In addition pursuant to the terms of the Promissory Note, upon conversion, the note holder will receive a five year warrant to purchase that number of shares of Common Stock equal to the quotient obtained by dividing (x) 50% of the principal plus accrued interest of the Note being converted, by (y) the Conversion Price, with the resulting number of shares having an exercise price equal to the Conversion Price. If in the event there is not a new financing prior to the maturity of the Note or the creditor elects to convert the outstanding principal and interest toward the exercise of creditor's existing Series A warrant, then upon conversion, the note holder will receive a five year warrant to purchase that number of shares of Common Stock equal to the quotient obtained by dividing (x) 50% of the principal plus accrued interest of the Note being converted, by (y) \$0.10, with the resulting number of shares having an exercise price equal to \$0.10 per share of common stock.

4. STOCKHOLDERS' EQUITY (DEFICIT)

During the three months ended March 31, 2010 the Company recorded non-cash stock dividends totaling \$781,364 in connection with the issuance of 1,690.76 shares of Series B Preferred Stock and 147,493 shares of Series A Preferred Stock as a stock dividend to its preferred shareholders as of March 31, 2010. Effective January 1, 2010 the Company has changed its basis for estimating the fair market value of the preferred stock dividends from the underlying conversion price of the Series B Preferred Stock to a five day volume weighted average price of actual closing market prices for the Company's common stock. The financial effect of this change in estimating the fair market value resulted in an increase of approximately \$598,000 in the non-cash charge taken for stock dividends for the three months ended March 31, 2010.

During the three months ended March 31, 2010 2,968.40 Series B Preferred Shares were converted into 8,200,000 Common shares. During the three months ended March 31, 2010 500,000 Series A Preferred Shares were converted into 5,000,000 Common shares.

During the three months ended March 31, 2010, the Company issued stock options to employees, consultants and directors resulting in aggregate compensation expense of \$48,747, of which \$25,800 and \$22,947 is presented in research and development expenses and general and administrative expenses, respectively.

During the three months ended March 31, 2010, the Company incurred stock-based compensation expense due to the amortization of unvested stock options. The aggregate expense for the three months ended March 31, 2010 is \$19,949, of which \$9,577 and \$10,372 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 425,000 shares of common stock to be issued and priced at the end of December 2010 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, 2010 is approximately \$8,500, all of which is presented in general and administrative expenses.

The summary of the stock option activity for the three months ended March 31, 2010 is as follows:

Shares	Weighted Average Exercise per Share	Weighted Average Remaining Life (Years)
--------	--	--

Edgar Filing: Cytosorbents Corp - Form 10-Q

Outstanding, January 1, 2010	23,577,704	\$	0.84	8.3
Granted	2,640,000	\$	0.173	9.7
Cancelled	—	\$	—	—
Exercised	—	\$	—	—
Outstanding March 31, 2010	26,217,704	\$	0.77	8.3

Edgar Filing: Cytosorbents Corp - Form 10-Q

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 \$0.154 to \$0.173 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 (2.5 to 3.8 percent) for the term of the stock option.

At March 31, 2010, the aggregate intrinsic value of options outstanding and currently exercisable amounted to approximately \$1,749,000.

The summary of the status of the Company's non-vested options for the three months ended March 31, 2010 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2010	6,801,053	\$ 0.024
Granted	2,640,000	\$ 0.080
Cancelled	—	—
Vested	(3,520,597)	\$ 0.047
Exercised	—	—
Non-vested, March 31, 2010	5,920,456	\$.035

As of March 31, 2010, approximately \$255,000 of total unrecognized compensation cost related to stock options is expected to be recognized over a weighted average period of 1.3 years.

As of March 31, 2010, 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
15,569	\$ 6.64	March 31, 2010
816,691	\$ 4.98	June 30, 2011
1,200,000	\$ 0.90	June 30, 2011
900,000	\$ 0.40	June 30, 2011
339,954	\$ 2.00	September 30, 2011
52,080	\$ 2.00	July 31, 2011
400,000	\$ 0.40	October 31, 2011
240,125	\$ 1.25	October 24, 2016
3,986,429	\$ 0.035	June 25, 2013
397,825	\$ 0.0362	September 30, 2014
12,483,665	\$ 0.107	October 5, 2010
20,832,338		

As of March 31, 2010, the Company has the following warrants to purchase Series A Preferred Stock outstanding:

Edgar Filing: Cytosorbents Corp - Form 10-Q

Number of Shares to be Purchased	Warrant Exercise Price per Preferred Share	Warrant Expiration Date
525,000	\$ 1.00	June 30, 2011

If the holder of warrants for preferred stock exercises in full, the holder will receive additional five-year warrants to purchase a total of 210,000 shares of common stock at \$0.40 per share.

5. COMMITMENTS AND CONTINGENCIES

Employment Agreements

The Company has employment agreements with certain key executives through December 2010. 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.

In February 2008, Alkermes, Inc. commenced an action against us in the United States District Court for the District of Massachusetts, alleging that our use of the name MedaSorb infringes on Alkermes' registered trademark "MEDISORB." In the action, Alkermes sought an injunction against our further use of the name MedaSorb. Pursuant to a Settlement Agreement dated June 18, 2008, to avoid any potential confusion with Alkermes' similarly named product, the Company has ceased using the "MedaSorb" name in its wholly-owned subsidiary, through which the Company conducts all of its operational activities, and renamed our operating subsidiary CytoSorbents, Inc. as of November 2008. The Company has also filed to change the name of the parent company from MedaSorb Technologies Corporation to CytoSorbents Corporation (see Note 7).

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 March 31, 2010. 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 March 31, 2010. 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 March 31, 2010 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, 2010 and 2009 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 47,050,042 and 31,228,552 incremental shares at March 31, 2010 and 2009, respectively, as well as shares issuable upon conversion of Series A and Series B Preferred Stock and Preferred Stock Warrants representing 206,867,686 and 239,010,409 incremental shares at March 31, 2010 and 2009, respectively, as well as potential shares issuable upon Note conversion into Series A Preferred Stock representing approximately 2,587,500 shares 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 2010 a total of 6,458.07 shares of Series B Preferred Stock were converted into 17,839,973 shares of Common Stock.

In May 2010 the Company finalized its name change from MedaSorb Technologies Corporation to CytoSorbents Corporation. The Company stock ticker symbol has been changed from MSBT (OTCBB:MSBT) to CTSO (OTCBB:CTSO).

In May 2010, the Company issued stock options to purchase 13,300,000 shares of Common Stock to employees with an exercise price of \$0.138 per share as part of a long term incentive plan. None of these options vested upon issuance. The stock options shall vest at the discretion of the Board of Directors based on criteria including (but not limited to) a timely completion of the sepsis trial, raising capital for the Company, and partnering and business development.

On May 5, 2010, the Company executed a purchase agreement, or the Purchase Agreement, and a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park Capital Fund, LLC ("LPC"). Under the Purchase Agreement, LPC is obligated, under certain conditions, to purchase from us up to \$6 million of our common stock, from time to time over a 750 day (twenty-five (25) monthly) period.

At such time as the SEC has declared effective a registration statement related to shares underlying this transaction, the Company will have the right 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 \$.10 per share. 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 in our 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 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.

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, 2009 as included in the Company's Form 10-K filed with the Securities and Exchange Commission (the "Commission") on April 9, 2010.

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 Current Report on Form 10-K filed with the Commission on April 9, 2010.

Plan of Operations

We are a development stage company and expect to remain so for at least the next several quarters. We have not generated revenues to date and do not expect to do so until we commercialize and receive the necessary regulatory approvals to sell our proposed products. We will seek to commercialize a blood purification technology that efficiently removes middle molecular weight toxins from circulating blood and physiologic fluids.

We are focusing our efforts on the commercialization of our CytoSorb™ product. The first indication for CytoSorb™ will be in the adjunctive treatment of sepsis (bacterial infection of the blood), which causes systemic inflammatory response syndrome. CytoSorb™ has been designed to prevent or reduce the accumulation of high concentrations of cytokines in the bloodstream associated with sepsis. It is intended for short term use as an adjunctive device to the standard treatment of sepsis. To date, we have manufactured the CytoSorb™ device on a limited basis for testing purposes, including for use in clinical studies. 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.

Following the sepsis indication, we intend to continue our research in other acute conditions where CytoSorb™ has indicated potential in preliminary studies to prevent or reduce the accumulation of cytokines in the bloodstream. These conditions include, but are not limited to, the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery), damage to organs donated for transplant prior to organ harvest, and removing drugs from blood.

In December 2006, we submitted a proposed pilot study for approval to the FDA with respect to our CytoSorb™ device. In the first quarter of 2007, we received FDA approval of our IDE application to conduct a limited study of five patients in the adjunctive treatment of sepsis. Based on management's belief that proceeding with the approved limited study would add at least one year to the approval process for the United States, we made a determination to focus our efforts on obtaining regulatory approval in Europe before proceeding with the FDA.

We estimate that the market potential in Europe for our products is substantially equivalent to that in the U.S. Given the opportunity to conduct a much larger clinical study in Europe, and management's belief that the path to a CE Mark should be faster than FDA approval, we have targeted Europe as the introductory market for our CytoSorb™ product. In July 2007 we prepared and filed a request for a clinical trial with a German Central Ethics Committee. We received approval of the final study design in October of 2007.

We are currently approved by the German Ethics Committee to conduct a clinical study of up to 100 patients with acute respiratory distress syndrome or acute lung injury in the setting of sepsis. The primary endpoint of our clinical trial is cytokine reduction and is the basis of a planned CE Mark application to approve our device for clinical use in Europe.

After reviewing the initial cytokine data from the first 22 patients enrolled in our original protocol, our medical advisors recommended revisions to our protocol to minimize non-device related artifacts that may potentially arise if the samples are not processed or handled appropriately. The revisions to the protocol also include a provision for testing of our targeted endpoints in plasma instead of serum, changes in cytokine processing and analysis, additional options for anti-coagulation that the clinical sites may use, and an increase in the number of patients we may enroll into the study from 80 to 100.

These changes are intended to optimize the accuracy of our cytokine data for CE Mark submission. The proposed protocol changes and rationale for change were submitted to the German Ethics Committee and approved. Given these changes, cytokine data will not be statistically comparable between these first 22 patients and those enrolled subsequently in the study. While the company will continue to review all patient data in the aggregate, including secondary and exploratory endpoints, the primary use of the data from the first 22 patients will be used to support the planned CE Mark application from a safety perspective. Cytokine data from all patients enrolled subsequent to these first 22 patients, as well as safety data on all patients enrolled in the study, will be used for submission to the CE Mark authority.

While we are currently observing an improvement in our enrollment rate, to date patient enrollment has been slower than originally anticipated. The Company has taken a number of steps to improve recruitment, the most significant of which is the increase in the number of our clinical trial sites. With more sites actively seeking to enroll patients, we expect the patient enrollment rate to continue to increase going forward.

By December 31, 2009 we had initiated and opened for enrollment a total of fourteen (14) hospital units to participate in our clinical study. To date the Company has enrolled sixty three (63) patients in the clinical study. We may enroll up to an additional thirty seven (37) patients. In conducting the German Clinical study we have utilized our CytoSorb™ device in approximately 200 treatments to date with no Serious Adverse Events attributable to the device.

Depending on the rate of enrollment, we expect to complete the patient enrollment between the second half of 2010 to the first quarter of 2011. Concurrent with the clinical study, we have commenced our preparation for the CE Mark submission process. Assuming availability of adequate and timely funding, a successful outcome of the study, and CE Mark regulatory approval, the Company intends to commercialize its product in Europe.

The clinical protocol for our European clinical study has been designed to allow us to gather information to support future U.S. studies. In the event we receive the CE Mark and 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 proposed CytoSorb™ product will work as intended or that we will be able to obtain CE Mark (or FDA) approval to sell CytoSorb™. Even if we ultimately obtain CE Mark approval, because we cannot control the timing of responses from regulators to our submissions, there can be no assurance as to when such approval will be obtained.

Results of Operations

Our research and development costs were, \$681,215 and \$488,555, for the three months ended March 31, 2010 and 2009 respectively. We have experienced substantial operating losses since inception. As of March 31, 2010, we had an accumulated deficit of \$80,652,936, which included losses of \$969,051 for the three month period ended March 31,

2010. In comparison, we had losses of \$760,151 for the three month period ended March 31, 2009. 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 \$894,845 and \$716,889 for the three month periods ended March 31, 2010 and 2009, respectively.

Off-balance Sheet Arrangements

We have no off-balance sheet arrangements.

Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of our debt and equity securities. At December 31, 2009 we had cash of \$1,595,628. As of March 31, 2010 we had cash on hand of \$1,346,301, and current liabilities of \$1,320,771.

We believe that we have sufficient cash to fund our operations into the third quarter of 2010, following which we will need additional funding before we can complete our clinical studies and commercialize our products. Assuming the Company is successful in filing and receiving SEC approval for a registration statement to be filed for the funding agreement with Lincoln Park Capital Fund LLC, Management believes that the Company will be able to receive ongoing funding per the terms of this purchase agreement (See Note 7 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. We will continue to seek funding 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.

16

Our Annual Report dated December 31, 2009 was prepared assuming we will continue as a going concern, and the auditors' report on those financial statements expresses substantial doubt about our ability to continue as a going concern.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

No reporting requirement for smaller reporting companies.

Item 4(T). Controls and Procedures.

Management's annual report on internal control over financial reporting

Management of CytoSorbents is responsible for establishing and maintaining adequate internal control over financial reporting under the supervision of the President and Chief Executive Officer and the Chief Financial Officer. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management evaluated the design and operation of our internal control over financial reporting as of March 31, 2010, based on the framework and criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and has concluded that such internal control over financial reporting is effective. There are no material weaknesses that have been identified by management.

An evaluation was performed, under the supervision of, and with the participation of, our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-(e) to the Securities and Exchange Act of 1934). Based on that evaluation, the Company's management, including our Chief Executive Officer and Chief Financial Officer, concluded that the Company's disclosure controls and procedures were adequate and effective, as of March 31, 2010, to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We do not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of control can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the Company have been detected.

This report does not include an attestation report of the company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only management's report in this report.

Changes in internal control over financial reporting

There were no significant changes in our internal controls over financial reporting that occurred subsequent to our evaluation of our internal control over financial reporting for the three months ended March 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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.

In February 2008, Alkermes, Inc. commenced an action against us in the United States District Court for the District of Massachusetts, alleging that our use of the name MedaSorb infringes on Alkermes' registered trademark "MEDISORB." In the action, Alkermes sought an injunction against our further use of the name MedaSorb. Pursuant to a Settlement Agreement dated June 18, 2008, to avoid any potential confusion with Alkermes' similarly named product, the Company has ceased using the "MedaSorb" name in its wholly-owned subsidiary, through which the Company conducts all of its operational activities, and renamed our operating subsidiary CytoSorbents, Inc. as of November 2008. The Company has also changed the name of the parent company from MedaSorb Technologies Corporation to CytoSorbents Corporation.

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)

None.

Item 5. Other Information

None.

Item 6. Exhibits.

Number	Description
10.1	Resolution of the Series B Preferred Shareholders to Waive Registration Penalties
31.1	Certification of Phillip Chan, Chief Executive Officer of the Registrant, pursuant to Rules 13a-14(a) and 15(d)-14(a) of the Securities Exchange Act of 1934
31.2	Certification of David Lamadrid, Chief Financial Officer of the Registrant, pursuant to Rules 13a-14(a) and 15(d)-14(a) of the Securities Exchange Act of 1934

- 32.1 Certification of Phillip Chan, Chief Executive Officer of the Registrant, pursuant to Rules 13a-14(B) and 15(d)-14(b) of the Securities Exchange Act of 1934
- 32.2 Certification of David Lamadrid, Chief Financial Officer of the Registrant, pursuant to Rules 13a-14(B) and 15(d)-14(b) of the Securities Exchange Act of 1934

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 14, 2010

By: /s/ David Lamadrid
Name: David Lamadrid
Title: Chief Financial Officer

(On behalf of the registrant and as
principal accounting officer)