

Cytosorbents Corp  
Form 10-Q  
November 12, 2014

**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  
X ACT OF 1934**

**For the quarterly period ended September 30, 2014**

**Or**

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

**Commission file number: 000-51038**

**CYTOSORBENTS CORPORATION**

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

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

**7 Deer Park Drive, Suite K**

**Monmouth Junction, New Jersey 08852**

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

**(732) 329-8885**

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

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

As of November 7, 2014 there were 581,820,005 shares of the issuer's Common Stock outstanding.

**CytoSorbents Corporation**

**FORM 10-Q**

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

	September 30, 2014 (Unaudited)	December 31, 2013
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$433,423	\$2,183,030
Grants and accounts receivable, net of allowance for doubtful accounts of \$3,236 at September 30, 2014 and \$-0- at December 31, 2013	561,964	453,017
Short-term investments	7,346,994	—
Inventories	387,075	245,608
Prepaid expenses and other current assets	225,004	605,312
Total current assets	8,954,460	3,486,967
Property and equipment – net	191,127	144,393
Other assets	481,017	414,375
Total long-term assets	672,144	558,768
Total Assets	\$9,626,604	\$4,045,735
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$446,167	\$786,517
Accrued expenses and other current liabilities	445,110	361,700
T Deferred revenue	3,333	272,359
Warrant liability	654,840	—
Convertible notes payable, net of debt discount in the amount of \$0 at September 30, 2014 and \$198,644 at December 31, 2013	—	1,644,356
Total current liabilities	1,549,450	3,064,932
Series B 10% Cumulative Convertible Preferred Stock, par value \$0.001, 200,000 Shares authorized; 84,283.99 and 79,336.54 issued and outstanding at September 30, 2014 and December 31, 2013, respectively	18,874,241	15,246,350
Stockholders' Equity/ (Deficiency):	1,895	1,760

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Series A 10% Cumulative Convertible Preferred Stock, 12,000,000 shares authorized; 1,894,969 and 1,759,666 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively

Common Stock, 800,000,000 shares authorized; 322,775,473 and 251,319,547 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively

Common Stock, 800,000,000 shares authorized; 322,775,473 and 251,319,547 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	322,775	251,320
Additional paid-in capital	102,713,676	91,343,135
Accumulated other comprehensive income (loss)	67,196	(55,987 )
Accumulated deficit	(113,902,629)	(105,805,775)
Total stockholders' equity (deficiency)	(10,797,087 )	(14,265,547 )
Total Liabilities and Stockholders' Equity (Deficiency)	\$9,626,604	\$4,045,735

See accompanying notes to consolidated financial statements.

## CYTOSORBENTS CORPORATION

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Nine months ended September 30,		Three months ended September 30,	
	2014	2013	2014	2013
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
Sales	\$2,264,237	\$507,628	\$1,031,761	\$203,561
Grant income	978,271	1,035,877	128,087	677,131
Other revenue	6,666	—	2,499	—
Total revenue	3,249,174	1,543,505	1,162,347	880,692
Cost of revenue	1,804,578	1,073,689	475,890	620,623
Gross profit	1,444,596	469,816	686,457	260,069
Other Expenses:				
Research and development	1,464,059	1,706,498	880,292	294,198
Legal, financial and other consulting	733,056	570,465	182,996	157,926
Selling, general and administrative	3,471,138	1,901,768	1,309,519	687,788
Total expenses	5,668,253	4,178,731	2,372,807	1,139,912
Loss from operations	(4,223,657 )	(3,708,915 )	(1,686,350 )	(879,843 )
Other (income)/expense:				
Interest expense/(income), net	311,458	299,805	46,600	84,946
Change in warrant liability	(208,080 )	—	(234,600 )	—
Total other (income) expense, net	103,378	299,805	(188,000 )	84,946
Loss before benefit from income taxes	(4,327,035 )	(4,008,720 )	(1,498,350 )	(964,789 )
Benefit from income taxes	—	—	—	—
Net loss	(4,327,035 )	(4,008,720 )	(1,498,350 )	(964,789 )
Preferred Stock Dividend	3,769,819	1,728,053	1,281,058	525,148
Net Loss available to common shareholders	\$(8,096,854 )	\$(5,736,773 )	\$(2,779,408 )	\$(1,489,937 )
Basic and diluted net loss per common share	\$(0.03 )	\$(0.02 )	\$(0.01 )	\$(0.01 )
Weighted average number of shares of common stock outstanding	293,189,313	232,426,316	312,400,345	242,512,486
Net loss	\$(4,327,035 )	\$(4,008,720 )	\$(1,498,350 )	\$(964,789 )
Other comprehensive loss:				
Currency translation adjustment	123,183	36,915	118,032	40,184
Comprehensive loss	\$(4,203,852 )	\$(3,971,805 )	\$(1,380,318 )	\$(924,605 )

See accompanying notes to consolidated financial statements.



## CYTOSORBENTS CORPORATION

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

Period from December 31, 2013 to September 30, 2014 (Unaudited):

	Series B 10% Cumulative Convertible Preferred Stock		Common Stock		Series A 10% Cumulative Convertible Preferred Stock		Additional Paid-In Capital	Accumulated Other Comprehensive	
	Shares	Amount	Shares	Par value	Shares	Par Value		Income (Loss)	Accu Defici
<b>Balance at December 31, 2013</b>	79,336.54	\$15,246,350	251,319,547	\$251,320	1,759,666	\$1,760	\$91,343,135	\$(55,987)	\$(105,000)
Stock based compensation - employees, consultants and directors							150,273		
Issuance of common stock for services rendered			1,123,033	1,123			178,977		
Issuance of Series A Preferred Stock as dividends					135,303	135	26,148		(26,148)
Issuance of Series B Preferred Stock as dividends	6,072.18	3,743,536							(3,743,536)
Conversion of Series A & B Preferred	(1,124.73)	(115,645)	3,106,988	3,107			112,538		



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Stock as dividends									
Issuance of common stock for cash		2,483,399	2,483				297,517		
Issuance of common stock - offering		40,800,000	40,800				10,159,200		
Conversion of convertible notes to common		17,532,720	17,533				1,972,907		
Cost of raising capital							(748,545 )		
Other comprehensive income/(loss): foreign translation adjustment									123,183
Cashless exercise of warrants		3,958,716	3,958				(3,958 )		
Exercise of stock options		2,451,070	2,451				88,404		
Warrant liability							(862,920 )		
Net loss									(4,300,000)
<b>Balance at September 30, 2014</b>	84,283.99	\$18,874,241	322,775,473	\$322,775	1,894,969	\$1,895	\$102,713,676	\$67,196	\$(113,000,000)

See accompanying notes to consolidated financial statements.

**CYTOSORBENTS CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Nine months ended September 30, 2014 (Unaudited)	Nine months ended September 30, 2013 (Unaudited)
Cash flows from operating activities:		
Net loss	\$(4,327,035)	\$(4,008,720)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common stock to consultant for services	180,100	65,468
Depreciation and amortization	70,449	47,573
Amortization of debt discount	198,644	228,468
Bad debt expense	3,236	—
Expense for issuance of options	150,273	300,105
Change in warrant liability	(208,080 )	—
Changes in operating assets and liabilities:		
Grants and accounts receivable	(112,183 )	(142,094 )
Inventories	(141,467 )	319,830
Prepaid expenses and other current assets	380,308	318,438
Other assets	(4,568 )	9,442
Accounts payable and accrued expenses	(109,500 )	38,989
Deferred revenue	(269,026 )	435,686
Net cash used by operating activities	(4,188,849)	(2,386,815)
Cash flows from investing activities:		
Purchases of property and equipment	(89,495 )	(33,276 )
Patent costs	(89,762 )	(18,861 )
Purchases of short-term investments	(7,346,994)	—
Net cash used by investing activities	(7,526,251)	(52,137 )
Cash flows from financing activities:		
Equity contributions - net of fees incurred	9,751,455	1,599,967
Proceeds from borrowings	—	1,263,000
Proceeds from exercise of stock options	90,855	20,194
Proceeds from exercise of warrants	—	139,526
Net cash provided by financing activities	9,842,310	3,022,687
Effect of exchange rates on cash	123,183	36,915
Net change in cash and cash equivalents	(1,749,607)	620,650

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Cash and cash equivalents - beginning of period	2,183,030	1,729,344
Cash and cash equivalents - end of period	\$433,423	\$2,349,994

See accompanying notes to consolidated financial statements.

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Supplemental disclosure of cash flow information:

Cash paid during the period for interest	\$—	\$—
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Supplemental schedule of noncash investing and financing activities:

Increase in other current assets through the issuance of convertible debt	\$—	\$580,000
Fair value of warrant liability upon issuance	\$862,920	\$—
Debt discount in connection with issuance of convertible debt	\$—	\$331,117
Fair value of shares issued as costs of raising capital	\$7,137	\$34,034
Note payable principal and interest conversion to equity	\$1,990,440	\$1,226,042
Costs paid from proceeds in conjunction with issuance of common stock and preferred stock	\$748,545	\$—
Preferred stock dividends	\$3,769,819	\$1,728,053

During the nine months ended September 30, 2014 and 2013, 1,124.73 and 198.27 shares of Series B 10% Cumulative Convertible Preferred Stock, \$0.001 par value per share (the “Series B Preferred Stock”) were converted into 3,106,988 and 547,707 shares of Common Stock, \$0.001 par value per share (the “Common Stock”), respectively. During the nine months ended September 30, 2014 and 2013, no shares of Series A 10% Cumulative Convertible Preferred Stock, \$0.001 par value per share (the “Series A Preferred Stock”) were converted into shares of Common Stock.

See accompanying notes to consolidated financial statements.

**CytoSorbents Corporation**

**Notes to Consolidated Financial Statements**

**(UNAUDITED)**

**September 30, 2014**

**1. BASIS OF PRESENTATION**

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with the requirements of Form 10-Q of the Securities and Exchange Commission (the "Commission") and include the results of CytoSorbents Corporation (the "Parent"), CytoSorbents, Inc. (as of October 28, 2014, known as CytoSorbents Medical, Inc.), its wholly-owned operating subsidiary (the "Subsidiary"), and CytoSorbents Europe GmbH, its wholly-owned European subsidiary (the "European Subsidiary"), collectively referred to as "the Company."

Accordingly, certain information and footnote disclosures required in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. Interim statements are subject to possible adjustments in connection with the annual audit of the Company's accounts for the year ended December 31, 2014. 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, 2014 and the results of its operations and cash flows for the nine and three month periods ended September 30, 2014 and 2013. Results for the nine months ended September 30, 2014 and 2013 are not necessarily indicative of results that may be expected for the entire year. The unaudited interim 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, 2013 as included in the Company's Form 10-K filed with the Commission on March 31, 2014.

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. The Company is not currently generating significant revenue and is dependent on the proceeds of present and future offerings to fund its research, development and commercialization program. The Company currently has adequate funding for more than the next twelve months of operations; however, it may have to raise additional capital to fund future operations. Although the Company has historically been successful in raising additional capital through equity and debt offerings, 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 offering, there can be no assurance that the amount will be sufficient to complete the Company's plans. These matters raise substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

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.

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

### **Nature of Business**

The Company, through its subsidiary CytoSorbents, Inc. (as of October 28, 2014, known as CytoSorbents Medical, Inc.), is engaged in the research, development and commercialization of medical devices with its platform blood purification technology incorporating a proprietary adsorbent polymer technology. The Company, through CytoSorbents Europe, GmbH, its European subsidiary, has commenced initial sales and marketing related operations for the CytoSorb® device in the European Union. The Company is focused on developing this technology for multiple applications in the medical field, specifically to provide improved blood purification for the treatment of acute and chronic health complications associated with blood toxicity. In March 2011, the Company received CE Mark approval for its CytoSorb® device.

The technology is based upon biocompatible, highly porous polymer sorbent beads that are capable of extracting unwanted substances from blood and other bodily fluids. The technology is protected by 32 issued U.S. patents with multiple patent applications pending both in the U.S. and internationally. Our intellectual property consists of composition of matter, materials, methods of production systems incorporating the technology, and multiple medical uses with expiration dates ranging from 3 to 12 years.

### **Principles of Consolidation**

The consolidated financial statements include the accounts of CytoSorbents Corporation, the Parent, and its wholly-owned subsidiaries, CytoSorbents, Inc. (as of October 28, 2014, known as CytoSorbents Medical, Inc.) and CytoSorbents Europe GmbH. All significant intercompany transactions and balances have been eliminated in consolidation.

### **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.

### **Grants and Accounts Receivable**

Grants receivable represent amounts due from U.S. government agencies. Accounts receivable are unsecured, non-interest bearing customer obligations due under normal trade terms. The Company sells its devices to various hospitals and distributors. The Company performs ongoing credit evaluations of customers' financial condition. Management reviews accounts receivable periodically to determine collectability. Balances that are determined to be uncollectible are written off to the allowance for doubtful accounts. The allowance for doubtful accounts contains a general accrual for estimated bad debts and had a balance of \$3,236 at September 30, 2014 and \$-0- at December 31, 2013.

### **Short-Term Investments**

Short-term investments include certificates of deposit with original maturities of greater than three months. The cost of the certificates of deposit approximates fair value.

### **Inventories**

Inventories are valued at the lower of cost or market. At September 30, 2014 and December 31, 2013, the Company's inventory was comprised of finished goods, which amounted to approximately \$101,000 and \$107,000, respectively; work in process which amounted to approximately \$250,000 and \$101,000, respectively; and raw materials, which amounted to approximately \$36,000 and \$38,000, respectively. Devices used in clinical trials or for research and development purposes are removed from inventory and charged to research and development expenses at the time of their use.

### **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 and successfully defend 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.

### **Warrant Liability**

The Company recognizes the fair value of the warrants as of the date of the warrant grant using the binomial lattice valuation model. At each subsequent reporting date, the Company again measures the fair value of the warrants, and records a change to the warrant liability as appropriate, and the change is reported in the statement of operations.

### **Revenue Recognition**

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

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

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

### **Research and Development**

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

### **Advertising Expenses**

Advertising costs are charged to activities when incurred. Advertising expenses amounted to approximately \$94,000 and \$30,000 for the nine months ended September 30, 2014 and 2013, respectively, and is included in selling, general, and administrative expenses on the consolidated statement of operations.

### **Income Taxes**

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

The Company follows accounting standards associated with uncertain tax positions. The Company had no unrecognized tax benefits at September 30, 2014 or December 31, 2013. The Company files tax returns in the U.S. federal and state jurisdictions. The Company currently has no open years prior to December 31, 2010 and has no income tax related penalties or interest for the periods presented in these financial statements.

The Company's European subsidiary, CytoSorbents Europe GmbH annually files a corporate tax return, VAT return and a trade tax return in Germany.

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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, valuation methods used to determine the fair value of the warrant liability, and valuation methods used in determining any debt discount associated with convertible securities.

### **Concentration of Credit Risk**

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

As of September 30, 2014, four distributors and one hospital accounted for approximately 64% of outstanding grant and accounts receivable. At December 31, 2013, one U.S. government agency accounted for approximately 66% of outstanding accounts receivable. For the nine months ended September 30, 2014, approximately 19% of revenues were from one U.S. government agency, and no other agency, distributor, or direct customer represented more than 10% of the Company's revenue. For the nine months ended September 30, 2013, approximately 67% of revenues were from two U.S. government grant agencies, and no other agency, distributor, or direct customer represented more than 10% of the Company's revenue.

### **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 7).

### **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

Accounting Standards Update (“ASU”) 2014-10, which for public business entities will be effective for annual reporting periods beginning after December 15, 2014 and interim periods therein, removes the definition of a development stage entity from the Accounting Standards Codification, thereby eliminating the financial reporting distinction between development stage entities from U.S. GAAP. Specifically eliminated are the requirements to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development state entity that in prior years it had been in the development stage. The Company has adopted ASU 2014-10 within its September 30, 2014 financial statements.

In May 2014, the Financial Account Standards Board (“FASB”) issued ASU 2014-09, “Revenue with Contracts from Customers.” ASU 2014-09 supercedes the current revenue recognition guidance, including industry-specific guidance. The ASU introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The updated guidance is effective for public entities for interim and annual periods beginning after December 15, 2016 and early adoption is not permitted. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2014-09 will have a significant impact on its consolidated financial statements.

## Shipping and Handling Costs

The costs of shipping product to customers and distributors is typically borne by the customer or distributor. The Company records other shipping and handling costs in Research and Development. Total freight costs amounted to approximately \$77,000 and \$17,000 for the nine months ended September 30, 2014 and September 30, 2013, respectively.

## 3. CONVERTIBLE NOTES

On June 21, 2013 (the “June Closing Date”), the Company issued convertible notes to certain accredited investors (the “June Purchasers”), whereby the Company agreed to sell and the June Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$1,098,000 (the “June Notes”). The June Notes were to mature one (1) year from the June Closing Date (the “June Maturity Date”), bear interest at an annual rate of 8%, and automatically convert into shares of the Company’s Common Stock at a conversion price of \$0.125 at maturity or earlier at the option of the June Purchaser. In connection with the issuance of the June Notes, the Company issued warrants to purchase shares of

Common Stock, providing 50% coverage, exercisable at \$0.15 per share (the “June Warrants”). On June 21, 2014, all outstanding June Notes were converted into 9,486,720 shares of Common Stock, consisting of 8,784,000 shares related to the principal value of the June Notes and 702,720 shares of Common Stock for payment of interest earned on the June Notes.

On September 30, 2013 (the “September Closing Date”), the Company issued convertible notes to certain accredited investors (the “September Purchasers”), whereby the Company agreed to sell and the September Purchasers agreed to purchase the convertible notes in the aggregate principal amount of \$745,000 (the “September Notes”). The September Notes were to mature one (1) year from the September Closing Date (the “September Maturity Date”), bear interest at an annual rate of 8%, and automatically convert into shares of Common Stock at a conversion price of \$0.10 at maturity, or earlier at the option of the September Purchaser. In connection with the issuance of the September Notes, the Company issued warrants to purchase shares of Common Stock, providing 50% coverage, exercisable at \$0.125 per share (the “September Warrants”). On September 30, 2014, all outstanding September Notes were converted into 7,450,000 shares of Common Stock related to the principal value of the September Notes and 596,000 shares of Common Stock for payment of interest earned on the September Notes.

The Company allocates the proceeds associated with the issuance of convertible notes based on the relative fair value of the convertible 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 convertible notes to the market value of the underlying Common Stock subject to conversion. In connection with the convertible note issuances during the years ended December 31, 2013, the Company received proceeds of \$1,843,000. The Company allocated the proceeds in accordance with FASB Codification Topic 470 based on the related fair value as follows: \$1,511,883 was allocated to the convertible notes and \$171,012 to the warrants. Additionally, the embedded conversion feature resulted in a beneficial conversion feature in the amount of \$160,105. 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 has been amortized to interest expense over the term of the convertible notes. During the nine months ended September 30, 2014 and 2013, debt discount of approximately \$199,000 and \$228,000, respectively, was charged to interest expense.

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

On March 7, 2014, the Company entered into subscription agreements with certain investors providing for the issuance and sale by the Company (the "Offering") of 40,800,000 units (the "Units") for an aggregate purchase price of \$10,200,000. Each Unit is comprised of one share of Common Stock, priced at \$0.25 per share, and a warrant to purchase 0.50 shares of Common Stock at an exercise price of \$0.3125 per share. The warrants are convertible into a total of 20,400,000 shares of Common Stock. Each warrant is exercisable for a period of five (5) years beginning on March 11, 2014, the date of the closing of the sale of the Units, is only exercisable for cash, and is only exercisable if there is an effective registration statement registering the warrants and shares underlying the warrants. The Common Stock underlying these warrants were registered in the registration statement on Form S-1 (File No. 333-193053), which was declared effective by the Commission on February 14, 2014 and an additional registration statement on Form S-1 (File No. 333-194394).

The Company received net proceeds from the Offering of approximately \$9,451,000 million. The net proceeds received by the Company from the Offering is being used for building additional sales and marketing infrastructure, clinical studies, working capital and general corporate purposes.

The Company conducted the Offering pursuant to a registration statement on Form S-1 (File No. 333-193053), which was declared effective by the Commission on February 14, 2014, and an additional registration statement on Form S-1 (File No. 333-194394) to register an additional amount of securities having a proposed maximum aggregate offering price of \$2,762,500, which increased the total registered amount to \$16,575,000 assuming the full cash exercise of the warrants for cash. The Company filed a final prospectus on March 7, 2014, disclosing the final terms of the Offering.

In connection with the Offering, on March 7, 2014, the Company entered into a placement agency agreement with Brean Capital, LLC, pursuant to which Brean Capital, LLC agreed to act as the Company's exclusive placement agent (the "Placement Agent") for the Offering and sale of the Units.

In connection with the successful completion of the Offering, the Placement Agent received an aggregate cash placement agent fee equal to 6% of the gross proceeds of the sale of the Units in the Offering, or \$612,000, and a warrant to purchase 1,224,000 shares of Common Stock at an exercise price of \$0.30 per share exercisable for five years from the effective date of the placement agency agreement (the "Placement Agent Warrant"). The Placement Agent Warrant contains piggy-back registration rights which expire on the fifth anniversary of the effective date of the registration statement. The Company has also agreed to reimburse the Placement Agent for actual out-of-pocket expenses up to a maximum of 2% of gross proceeds from the transaction. The Company also granted the Placement Agent a right of first refusal to participate in any subsequent offering or placement of its securities that takes place within twelve months following the effective date of the registration statement.

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During the nine months ended September 30, 2014, the Company recorded non-cash stock dividends totaling \$3,769,819 in connection with the issuance of 6,072.18 shares of Series B Preferred Stock and 135,303 shares of Series A Preferred Stock as stock dividends to its preferred shareholders.

During the nine months ended September 30, 2014, the Company incurred stock-based compensation expense due to the issuance of stock options, and amortization of unvested stock options. The aggregate expense for the nine months ended September 30, 2014 is approximately \$150,000, of which approximately \$130,000 was recorded in general and administrative expenses and approximately \$20,000 was recorded as research and development expenses.



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The summary of the stock option activity for the nine months ended September 30, 2014 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding, January 1, 2014	47,923,642	\$ 0.20	5.1
Granted	16,135,000	\$ 0.20	9.1
Cancelled	(5,695,250 )	\$ 0.13	7.6
Exercised	(2,466,300 )	\$ 0.04	3.6
Expired	(51,809 )	\$ 0.83	—
Outstanding September 30, 2014	55,845,283	\$ 0.21	6.3

The fair value of each stock option was estimated using the Black-Scholes pricing model which takes into account as of the grant date the exercise price (ranging from \$0.195 to \$0.274 per share) and expected life of the stock option (ranging from 5-10 years), the current price of the underlying stock and its expected volatility (approximately 28%), expected dividends on the stock (0%) and the risk free interest rate (0.8 to 2.1%) for the term of the stock option.

At September 30, 2014, the aggregate intrinsic value of options outstanding and currently exercisable amounted to approximately \$3,552,000.

The summary of the status of the Company's non-vested options for the six months ended September 30, 2014 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2014	13,418,000	\$ 0.034
Granted	16,135,000	\$ 0.058
Cancelled	(4,861,250 )	\$ 0.033
Vested	(2,412,250 )	\$ 0.044
Non-vested, September 30, 2014	22, 279,500	\$ 0.051

As of September 30, 2014, the Company had approximately \$159,000 of total unrecognized compensation cost related to stock options. In March 2014, the Board of Directors set aside a pool of 14,010,000 options to be awarded to the Company's employees if the Company achieves certain specific, predetermined milestones. The grant date fair value of these unvested options amounted to approximately \$791,000. Due to the uncertainty over whether these options will vest, which only occurs if the Company meets the predetermined milestones, no charge for these options has been recorded in the consolidated statements of operations for the nine months ended September 30, 2014. The Company will evaluate on an ongoing basis the probability and likelihood of any of these performance milestones being achieved and will accrue charges as it becomes likely that they will be achieved.

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As of September 30, 2014, 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
1,750,000	\$ 0.1000	August 16, 2015
1,600,000	\$ 0.1250	August 16, 2015
1,333,333	\$ 0.1500	August 16, 2015
490,000	\$ 0.1000	October 22, 2015
196,000	\$ 0.1250	October 22, 2015
163,333	\$ 0.1500	October 22, 2015
500,000	\$ 0.1000	November 19, 2015
200,000	\$ 0.1250	November 19, 2015
166,667	\$ 0.1500	November 19, 2015
700,000	\$ 0.1000	February 15, 2016
1,540,000	\$ 0.1250	February 15, 2016
1,416,666	\$ 0.1500	February 15, 2016
240,125	\$ 1.2500	October 24, 2016
1,166,667	\$ 0.1750	February 10, 2017
4,392,000	\$ 0.1500	June 21, 2018
3,725,000	\$ 0.1250	September 30, 2018
20,400,000	\$ 0.3125	March 11, 2019
1,224,000	\$ 0.3000	March 11, 2019
41,203,791		

In addition, during the nine months ended September 30, 2014, the Company issued 1,123,033 shares of Common Stock valued at \$180,100 to a vendor for consulting services, 2,466,300 options were exercised for 2,451,070 shares of Common Stock, and warrants to purchase 6,460,000 shares of Common Stock were exercised for 3,958,716 shares of Common Stock. On June 21, 2014, \$1,098,000 in convertible notes matured. In accordance with the terms of the notes, the note holders were issued 9,486,720 shares of Common Stock which included 8,784,000 shares of Common Stock for payment of the convertible notes and 702,720 shares representing payment of interest accrued on the convertible notes. On September 30, 2014, \$745,000 in convertible notes matured.

In accordance with the terms of the notes, the note holders were issued 8,046,000 shares of Common Stock, which included 7,450,000 share of Common Stock for payment of the convertible notes and 596,000 shares representing payment of interest accrued on the convertible notes.

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

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

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

During the nine months ended September 30, 2014, the Company received approximately \$300,000 as proceeds from the sale of 2,425,709 shares of Common Stock per the terms of the New Purchase Agreement with LPC at an average price of approximately \$0.124 per share of Common Stock. Per the terms of the New Purchase Agreement, the Company also issued an additional 57,690 shares of Common Stock as additional commitment fee shares.

The Company has not sold any shares of its Common Stock under the New Purchase Agreement since January 17, 2014. The New Purchase Agreement expired pursuant to its terms in August 2014. At the time of expiration, \$2,400,000 remained unused under the new Purchase Agreement with LPC.

## 5. WARRANT LIABILITY

In connection with its March 11, 2014 offering, the Company issued warrants to purchase 20,400,000 shares of Common Stock. The Company recognizes these warrants as liabilities at their fair value on the date of grant, then measures the fair value of the warrants on each reporting date, and records a change to the warrant liability as appropriate. The warrants have certain pricing provisions which apply if the Company sells or issues Common Stock or Common Stock equivalents at a price that is less than the exercise price of the warrants, over the life of the warrants, excluding certain exempt issuances.

The Company recognized an initial warrant liability for the warrants issued in connection with the Offering completed in March 2014. The initial warrant liability recognized on the related warrants totaled \$862,920, which was based on the March 11, 2014 five-day weighted average closing price per share of the Company's Common Stock of \$0.24. On September 30, 2014, the five day weighted average closing price per share of Common Stock was \$0.224. Due to the fluctuations in the market value of the Company's Common Stock from March 11, 2014 through September 30, 2014, the Company recorded a change in the fair value of the warrant liability of \$208,080 during the nine months ended September 30, 2014.

The assumptions used in connection with the valuation of warrants issued utilizing the binomial lattice valuation model were as follows:

	September 30, 2014	Initial Measurement March 11, 2014		
Number of shares underlying the warrants	20,400,000	20,400,000		
Exercise price	\$0.3125	\$ 0.3125		
Volatility	28.3	% 28.3	%	
Risk-free interest rate	1.60	% 1.62	%	

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Expected dividend yield	0	0
Expected warrant life (years)	4.44	5
Stock Price	\$0.224	\$ 0.240

## **6.COMMITMENTS AND CONTINGENCIES**

### **Employment Agreements**

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

### **Litigation**

We are from time to time subject to claims and litigation arising out of the ordinary course of business. We intend to defend vigorously against any future claims and litigation. We are not currently a party to any legal proceedings.

### **Royalty Agreements**

Pursuant to an agreement dated August 11, 2003, an existing investor agreed to make a \$4 million equity investment in the Company. These amounts were received by the Company in 2003. In connection with this agreement, the Company granted the investor a future royalty of 3% on all gross revenues received by the Company from the sale of its CytoSorb® device. For the nine months ended September 30, 2014 the Company has recorded royalty costs of approximately \$68,000.

### **License Agreements**

In September 2006, the Company entered into a license agreement which provides the Company the exclusive right to use its patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the agreement, the Company has agreed to pay royalties of 2.5% to 5% on the sale of certain of its products if and when those products are sold commercially for a term not greater than 18 years commencing with the first sale of such product. For the nine months ended September 30, 2014 per the terms of the license agreement the Company has recorded royalty costs of approximately \$57,000.

### **Warrant Agreement**

As inducement to invest additional funds in the private placement of Series B Preferred Stock, additional consideration was granted to the participants of the Series B Preferred Stock offering in the event that litigation is commenced against the Company prior to June 30, 2018, claiming patent infringement on certain of the Company's issued patents. In the event this litigation arose, the Company may have been 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, 2014 no such litigation has arisen and the Company has not booked a contingent liability for this agreement. On October 9, 2014, all the shares of Series B Preferred Stock were converted into Common Stock (see Note 8, Subsequent Events), and therefore this additional consideration is no longer applicable.

## **7.NET LOSS PER SHARE**

Basic loss per share and diluted loss per share for the three months ended September 30, 2014 and 2013 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period.



All outstanding warrants and options representing approximately 97,049,000 and 74,289,000 incremental shares at September 30, 2014 and 2013, respectively, as well as shares issuable upon conversion of Series A and Series B Preferred Stock representing approximately 234,478,000 and 215,310,000 incremental shares at September 30, 2014 and 2013, respectively, as well as potential shares issuable upon Note conversion into Common Stock representing approximately -0- and 16,234,000 incremental shares at September 30, 2014 and 2013, respectively, have been excluded from the computation of diluted loss per share as they are anti-dilutive.

## 8.SUBSEQUENT EVENTS

### **Conversion of Series A and Series B Preferred Stock into Common Stock.**

On October 9, 2014, the Company filed with the Nevada Secretary of State an Amendment (the "Series A Amendment") to the Certificate of Designation, as amended (the "Series A Certificate of Designation") of the Series A Preferred Stock. The Series A Amendment, which became effective on October 9, 2014, (i) amended the Series A Certificate of Designation to allow the stockholders representing eighty percent (80%) of the issued and outstanding shares of Series A Preferred Stock to elect to convert all issued and outstanding shares of Series A Preferred Stock into Common Stock of the Company, \$0.001 par value per share (the "Common Stock"), at the then-effective "Conversion Price," as defined in the Series A Certificate of Designation, and (ii) as consideration for approving such amendment, amended the Conversion Price from \$1.25 per share to \$0.77 per share, except with respect to the shares of Series A Preferred Stock covered by that certain Agreement and Consent dated as of June 25, 2008 by and among the Company and certain holders of Series A Preferred Stock. Immediately following effectiveness of the Series A Amendment, the stockholders representing over 88 percent (88%) of the then-issued and outstanding Series A Preferred Stock elected to convert all issued and outstanding Series A Preferred Stock into Common Stock at the Conversion Price, as amended. As a result of this election by the holders of Series A Preferred Stock, 1,894,969 shares of Series A Preferred Stock were converted into 2,583,289 shares of Common Stock.

In addition, on October 9, 2014, the Company also filed with the Nevada Secretary of State an Amendment (the "Series B Amendment") to the Certificate of Designation (the "Series B Certificate of Designation") of the Series B Preferred Stock. The Series B Amendment, which became effective on October 9, 2014, amended the Series B Certificate of Designation to allow the holders of a majority of the Series B Preferred Stock, including NJTC Investment Fund, LP, to elect to convert all issued and outstanding shares of Series B Preferred Stock into Common Stock. Immediately following effectiveness of the Series B Amendment, the stockholders representing over 93 percent (93%) of the then-issued and outstanding Series B Preferred Stock elected to convert all issued and outstanding Series B Preferred Stock into Common Stock. Each share of Series B Preferred Stock had a stated value of \$100.00 (the "Series B Stated Value"), and was convertible into that number of shares of Common Stock equal to the Series B Stated Value at a conversion price of \$0.036. As consideration for approving the Series B Amendment, the holders of Series B Preferred Stock received a one-time dividend equal to ten percent (10%) of the shares of Series B Preferred Stock then held. As a result of this election by the holders of Series B Preferred Stock, 84,283.99 shares of Series B Preferred Stock were issued a dividend of 10% and then the 92,712.27 were converted into 256,111,243 shares of Common Stock. As a result of the conversion, the carrying value of the Series B stock was reclassified to permanent

equity.

After giving effect to the conversions of the Series A Preferred Stock and Series B Preferred Stock described above, there are no shares of Preferred Stock of the Company issued and outstanding.

### **Proposed Corporate Actions Subject to Stockholder Consent.**

The Company previously announced its intention to up-list its Common Stock to a national exchange by the end of calendar year 2014. In order to facilitate that process, on November 6, 2014, the Company sought stockholder consent authorizing its Board of Directors to (i) amend the Company's Articles of Incorporation, as amended, to effect a reverse split of its Common Stock, with a reverse split ratio of twenty five-to-one; (ii) amend its Articles of Incorporation, as amended, to reduce the total number of authorized shares of Common Stock from 800,000,000 to 50,000,000, after giving effect to the reverse stock split; (iii) amend its Articles of Incorporation, as amended, to reduce the total number of authorized shares of undesignated preferred stock from 100,000,000 to 5,000,000, after giving effect to the reverse stock split; (iv) implement the form, terms and provisions of the CytoSorbents Corporation 2014 Long-Term Incentive Plan; and (v) change the domicile of the Company from the State of Nevada to the State of Delaware through a merger with and into a newly-organized, wholly-owned subsidiary of the Company which was organized under the laws of the State of Delaware. Assuming such proposals are approved by stockholders, the Company intends to implement such corporate actions in December 2014. There can be no assurances that the stockholders will approve any of the above corporate actions, including the merger, or that the Company will receive approval to list its Common Stock on a national exchange.

### **Subsidiaries.**

On October 28, 2014, the Company formed CytoSorbents Corporation, a wholly-owned subsidiary of the Company, with the Secretary of State of Delaware in order to facilitate the merger discussed above. On the same day, the Company changed the name of its U.S. subsidiary, CytoSorbents, Inc., to CytoSorbents Medical, Inc. with the Secretary of State of Delaware.

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

This discussion of our financial condition and the results of operations should be read together with the financial statements, including the notes contained elsewhere in this Quarterly Report on Form 10-Q, and the financial statements, including the notes thereto, contained in our Annual Report on Form 10-K for the year ended December 31, 2013, as filed on March 31, 2014.

This report includes “forward-looking statements” within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as “may,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “co” similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management’s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements.

Factors which could cause or contribute to such differences include, but are not limited to, the risks discussed in our Annual Report on Form 10-K, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

These unaudited condensed consolidated financial statements and management’s discussion should be read in conjunction with the audited consolidated financial statements of the Company and the notes thereto as of and for the year ended December 31, 2013 as included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission (the “Commission”) on March 31, 2014.

### **Overview**

CytoSorbents Corporation is a critical care focused immunotherapy company that uses blood purification to modulate inflammation with the goal of preventing or treating multiple organ failure in life-threatening illnesses. The technology is based upon biocompatible, highly porous polymer sorbent beads that are capable of extracting unwanted substances from blood and other bodily fluids. The technology is protected by 32 issued U.S. patents with multiple patent applications pending both in the U.S. and internationally. The Company’s intellectual property consists of

composition of matter, materials, methods of production, systems incorporating the technology and multiple medical uses with expiration dates ranging from 3 to 12 years.

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

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

As part of the CE Mark approval process, the Company completed its randomized, controlled, European Sepsis Trial among 14 trial sites in Germany in 2011, with enrollment of 100 patients with sepsis and respiratory failure. The trial established that CytoSorb® was safe in this critically-ill population, and that it was able to broadly reduce key cytokines.

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

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

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

In late June 2012, following the establishment of the Company’s European subsidiary, CytoSorbents Europe GmbH, the Company began the commercial launch of CytoSorb® in Germany with the hiring of Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales representatives who joined the Company and completed their sales training in Q3 2012. The fourth quarter of 2012 represented the first full quarter of direct sales with the full sales team in place. During this period, the Company expanded its direct sales efforts to include both Austria and Switzerland. At the end of Q3 2014, the Company had more than 150 key opinion leaders (“KOLs”) in critical care, cardiac surgery, and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future.

In addition, the Company now has more than 40 investigator-initiated studies being planned in Germany, Austria, and the United Kingdom in multiple applications including sepsis, cardiac surgery, lung injury, trauma, pancreatitis, liver failure, kidney failure, and others, with many already enrolling patients. These studies are being supported by the Company's European Director of Scientific Affairs. As of September 30, 2014, the Company's sales force includes seven direct sales people and two sales support staff. The Company intends to add more staff to the direct sales and marketing team in the future.

The Company has complemented its direct sales efforts with sales to distributors and/or corporate partners. In 2013, the Company reached agreement with distributors in the United Kingdom, Ireland, Turkey, Russia, and the Netherlands. In September 2013, the Company entered into a strategic partnership with Biocon Ltd., Asia's largest biotech company with an initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb®. In April 2014, the Company announced distribution of CytoSorb® in the Middle East, including Saudi Arabia, the United Arab Emirates, Kuwait, Qatar, Bahrain, and Oman (the Gulf Cooperation Council or GCC) and Yemen, Iraq, and Jordan through an exclusive agreement with Techno Orbits. In August 2014, the Company announced exclusive distribution of CytoSorb® in Taiwan with Hemoscien Corporation. The Company is currently evaluating other potential distributor networks in other major countries where it is either approved to market the device or where CE Mark approval is accepted.

The Company is currently conducting a dose ranging trial in Germany among eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used for longer periods of time. Data from this dosing study is intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from the Company's first European Sepsis Trial, and help shape the trial protocol for a pivotal study. In addition, the Company expects to receive additional data from the results of more than thirty investigator-initiated studies in Europe which are either currently underway or planned.

Concurrent with the Company's commercialization plans, the Company intends to conduct or support additional clinical studies in sepsis, cardiac surgery, 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. The Company is currently organizing a pivotal trial in the U.S. using CytoSorb® during cardiac surgery that is intended to be the basis of the Company's application seeking U.S. regulatory approval.

The market focus for CytoSorb® is the prevention or treatment of organ failure due to cardiac surgery, and in life-threatening conditions, including commonly seen illnesses in the intensive care unit such as infection and sepsis, trauma, burn injury, acute respiratory distress syndrome ("ARDS"), and others. Sepsis is a major unmet medical need with no approved products in the U.S. or Europe to treat it. As with other critical care illnesses, multiple organ failure is the primary cause of death in sepsis. When used with standard of care therapy, that includes antibiotics, the goal of CytoSorb® in sepsis is to reduce excessive levels of cytokines and other inflammatory toxins, to help reduce the severe inflammatory response syndrome, or SIRS, response and either prevent or treat organ failure.

In addition to the sepsis indication, the Company intends 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 may benefit by the reduction of cytokines in the bloodstream. Some examples include the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery) and damage to organs donated for transplant prior to organ harvest.

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

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

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

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

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

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



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

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

In June 2013, the Company announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the U.S. amongst trauma patients with rhabdomyolysis most commonly associated with trauma. The FDA has approved the Company’s Investigational Device Exemption (“IDE”) application for this study, and the study began in April 2014.

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

In August 2012, the Company was awarded a \$3.8 million contract by the Defense Advanced Research Projects Agency (“DARPA”) for its “Dialysis-Like Therapeutics” program to treat sepsis. DARPA has been instrumental in funding many of the major technological and medical advances since its inception in 1958, including development of the Internet, the global positioning system (“GPS”), and robotic surgery. The DLT program in sepsis seeks to develop a therapeutic blood purification device that is capable of identifying the cause of sepsis (e.g., cytokines, toxins, pathogens, activated cells) and remove these substances in an intelligent, automated, and efficient manner. The contract is for advanced technology development of the Company’s hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. The Company is in Year 3 of the program and is currently working with the recently announced systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, who are responsible for integrating the technology developed by us and others into a final medical device design prototype, and evaluating this device in septic animals and eventually in human clinical trials in sepsis. The Company’s work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199.

## **Results of Operations**

*Comparison for the nine months ended September 30, 2014 and 2013:*

*Revenues:*

For the nine months ended September 30, 2014, the Company generated revenue of approximately \$3,249,000 as compared to revenues of approximately \$1,544,000, for the nine months ended September 30, 2013, an increase of approximately \$1,424,000 or 110%. Revenue from product sales was approximately \$2,264,000 in the nine months ended September 30, 2014, as compared to approximately \$508,000 in the nine months ended September 30, 2013, an increase approximately \$1,756,000 or 346%. This increase in sales is a result of the efforts of the Company's four person sales team which was established in August 2012 and was expanded in 2014 to seven people, as well as sales to distributors in other parts of Europe and elsewhere in the world.

***Cost of Revenues:***

For the nine months ended September 30, 2014 and 2013, cost of revenue was approximately \$1,805,000 and \$1,074,000, respectively. The increase is due to increased sales and expenditures related to progress on grant objectives.

Overall blended gross margins were approximately 44%, with product gross margins of approximately 66% for the nine months ended September 30, 2014.

***Research and Development Expenses:***

For the nine months ended September 30, 2014, research and development expenses were approximately \$1,464,000, as compared to research and development expenses of approximately \$1,706,000 for the nine months ended September 30, 2013. The decrease of approximately \$242,000 in research and development expenses was primarily due to an increase of \$257,000 in grant costs included in costs of revenue, decreases in consulting costs of approximately \$68,000, a change in the classification of approximately \$170,000 of salaries from research and development expenses in 2013 to selling, general and administrative expenses in 2014 as a result of a change in the duties of an executive of the Company, and decreases in patent expenses of approximately \$62,000, all of which were offset by increased costs for clinical studies and license fees of approximately \$309,000.

***Legal, Financial and Other Consulting Expense:***

Legal, financial and other consulting expenses were approximately \$733,000 for the nine months ended September 30, 2014, as compared to approximately \$570,000 for the nine months ended September 30, 2013. The increase of approximately \$203,000 was due to an increase in fees to consultants, fees to secure certain key employees, and fees to consultants for investor relations and other advisory services.

***Selling, General and Administrative Expense:***

Selling, general and administrative expenses were approximately \$3,471,000 for the nine months ended September 30, 2014 as compared to approximately \$1,902,000 for the nine months ending September 30, 2013. The increase of approximately \$1,568,000 in selling, general, and administrative expenses was primarily due to a change in classification of approximately \$170,000 of payroll costs from research and development expenses to selling, general

and administrative expenses, other increases in payroll, commissions and employee-related expenses of approximately \$674,000, increased royalties of approximately \$93,000, increases in advertising and marketing costs of approximately \$173,000, increased costs of medical conference and congresses of approximately \$187,000, increased loss on foreign exchange of approximately \$141,000 and increases in stock option costs of approximately \$129,000.

***Interest Expense:***

For the nine months ended September 30, 2014, interest expense was approximately \$311,000, as compared to interest expense of approximately \$300,000 for the nine months ended September 30, 2013. The increase was principally due to the interest payable and amortization of financing costs related to the convertible notes.

***Change in Warrant Liability:***

The Company recognizes warrants as liabilities at their fair value on the date of the grant because of price adjustment provisions in the warrants, then measures the fair value of the warrants on each reporting date, and records a change to the warrant liability as appropriate. The change in warrant liability was approximately \$208,000 and \$-0- for the nine months ended September 30, 2014 and 2013, respectively. The change in warrant liability was as a result of the change in the fair value of the warrant liability from March 11, 2014 (the date of the Company's \$10,200,000 2014 offering) to September 30, 2014. There was no warrant liability in 2013, and therefore there was no change in warrant expense in 2013.

***History of Operating Losses:***

The Company has experienced substantial operating losses since inception. As of September 30, 2014, the Company had an accumulated deficit of approximately \$113,903,000, which included losses of approximately \$4,327,000 and \$4,009,000 for the nine month periods ended September 30, 2014 and 2013, respectively. Historically, losses have resulted principally from costs incurred in the research and development of the Company's polymer technology, clinical studies, and general and administrative expenses.

***Comparison for the three months ended September 30, 2014 and 2013:***

***Revenues:***

For the three months ended September 30, 2014, the Company generated revenues of approximately \$1,162,000 as compared to revenues of approximately \$881,000 for the three months ended September 30, 2013. Product revenues were approximately \$1,032,000 for the quarter ended September 30, 2014, as compared to product revenues of \$204,000 for the quarter ended September 30, 2013. This \$828,000 or approximately 406% increase in product revenues was a result of the Company's direct sales effort to hospitals in Germany, Austria and Switzerland which began in 2012, as well as sales to distributors in Europe and elsewhere in the world. Additionally, grant revenue and other income was approximately \$131,000 and \$677,000 for the three month periods ended September 30, 2014 and 2013, respectively.

***Cost of Revenues:***

For the three months ended September 30, 2014, cost of revenue was approximately \$476,000 as compared to cost of revenue of approximately \$621,000 for the three months ended September 30, 2013. The decrease in cost of revenues is due to decreases in grant expenditures, which were partially offset by a increases in the cost of sales related to product sales. For the quarter ended September 30, 2014, overall blended gross margins were approximately 59%, with product gross margins of approximately 65%.

***Research and Development Expenses:***

For the three months ending September 30, 2014, research and development costs were approximately \$880,000, as compared to research and development costs of approximately \$294,000 for the three months ended September 30,

2013. The increase of approximately \$586,000 was primarily due to increases in research and development costs not offset by grant income of approximately \$422,000 and increased costs for clinical studies of approximately \$164,000.

***Legal, Financial and Other Consulting Expense:***

Legal, financial and other consulting costs were approximately \$183,000 for the three months ending September 30, 2014, as compared to legal financial and other consulting costs of approximately \$158,000 for the three months ended September 30, 2013. This increase of approximately \$25,000 was primarily due to increased recruitment and other consulting fees.

***Selling, General and Administrative Expense:***

Selling, general and administrative expenses were approximately \$1,310,000 for the three months ended September 30, 2014, compared to approximately \$688,000 for the three months ended September 30, 2013, an increase of approximately \$622,000. This was primarily due to increases in payroll related costs of approximately \$262,000, advertising and marketing costs of approximately \$115,000, increased royalties due to increased sales of approximately \$50,000, increased loss on foreign exchange of approximately \$139,000 and increases in medical conference and congresses expenses of approximately \$42,000.

***Interest (Income)/Expense Net:***

For the three months ended September 30, 2014, the Company's net interest expense was approximately \$47,000, as compared to net interest expense of approximately \$85,000 for the three months ended September 30, 2013. The decrease in net interest expense is primarily due to interest and amortization of financing costs related to convertible notes.

***Change in Warrant Liability:***

The change in warrant liability was approximately \$235,000 and \$-0- for the three months ended September 30, 2014 and 2013, respectively. The change in warrant liability was as a result of the change in the fair value of the warrant liability from June 30, 2014 to September 30, 2014. There was no warrant liability in 2013, and therefore there was no change in warrant expense in 2013.

**Liquidity and Capital Resources**

Since inception, the Company's operations have been primarily financed through the private placement of its debt and equity securities. At September 30, 2014, the Company had current assets of approximately \$8,954,000, including cash on hand and short-term investments of approximately \$7,780,000 and current liabilities of approximately \$1,549,000. The Company believes it has sufficient cash to fund its operations into 2016; however, the Company may need to raise additional capital to fully fund pivotal trials in the U.S. and/or Germany. The Company will be better able to assess this need once the specific protocols are finalized with appropriate regulatory bodies. In addition, the Company may require additional capital to support its sales and marketing efforts, to fund clinical studies, for expansion of its production capacity, to further develop its products, and for general working capital purposes.

**Off-balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

**Going Concern**

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has experienced negative cash flows from operations since inception and has an accumulated deficit at September 30, 2014 of approximately \$113,902,000. While the Company's revenues are increasing, it remains dependent on the proceeds of present and future offerings to fund its research, development and commercialization program. The Company currently has adequate funding for more than the next twelve months of operations; however, it may have to raise additional capital to fund future operations and/or clinical trials. Although the Company has historically been successful in raising additional capital through equity and debt offerings, 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 offering, there can be no assurance that the amount will be sufficient to complete the Company's plans. These matters raise substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

### **Employment Agreements with Named Executive Officers**

Effective December 31, 2013, the Company renewed the employment agreement by and between Dr. Phillip Chan and the Company as Chief Executive Officer covering the period from January 1, 2013 to December 31, 2013. Effective December 31, 2013, the Company renewed the employment agreement by and between Vincent Capponi and the Company as Chief Operating Officer covering the period January 1, 2013 to December 31, 2013. Executives with expired employment agreements are continuing employment on a month-to-month basis under similar terms.

Effective May 29, 2013 the Company entered into an employment agreement by and between Kathleen P. Bloch and the Company as Chief Financial Officer, which automatically renewed on May 31, 2014 and will expire on May 31, 2015.



Effective December 31, 2013, the Company renewed the consulting agreement by and between Dr. Robert Bartlett and the Company as Chief Medical Officer, which expires on December 31, 2014.

### **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 Rules 13(a)-15(b) and 15(d)-15(e) under the Securities Exchange Act of 1934 (“Exchange Act”), the Company carried out an evaluation, with the participation of management, including the Company’s Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), of the effectiveness of its disclosure controls and procedures (as defined under Rules 13(a)-15(b) and 15(d)-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 its disclosure controls and procedures are not effective to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the Company’s management, including its CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Based upon management’s assessment, the Company determined that its disclosure controls and procedures were not effective to accomplish the foregoing because of a material weakness as a result of the Company’s lack of an independent audit committee and audit committee financial expert as of September 30, 2014.

Although the Company’s board of directors serves the function of an audit committee, the Company has not identified an audit committee financial expert on its board of directors. These factors are counter to corporate governance practices as defined by the various stock exchanges and may lead to less supervision over management.

The Company is taking action to address this material weakness in the near future. Notwithstanding the assessment that the Company’s internal controls over financial reporting were not effective and that there was a material weaknesses identified herein, the Company believes that its consolidated financial statements contained in this report fairly present its financial position, results of operations and cash flows for the periods covered thereby in all material

respects.

### **Changes in Internal Controls**

There have been no changes in the Company's internal control over financial reporting during the third 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**

We are from time to time subject to claims and litigation arising in the ordinary course of business. We intend to defend vigorously against any future claims and litigation. We are not currently a party to any legal proceedings.

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

We believe there are no changes that constitute material changes from the risk factors previously disclosed in the Company's Annual Report filed on Form 10-K for the year ended December 31, 2013.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.** None.

**Item 3. Defaults Upon Senior Securities.** None.

**Item 4. Mine Safety Disclosures.** Not applicable.

**Item 5. Other Information.** None.



**Item 6. Exhibits.**

Number Description

- 3(i).1 Articles of Incorporation, dated April 25, 2002.(1)
- 3(i).2 Certificate of Designation of Series A 10% Cumulative Convertible Preferred Stock, \$.001 Par Value Per Share.(2)
- 3(i).3 Amendment to Articles of Incorporation dated August 1, 2006.(3)
- 3(i).4 Certificate of Designation of Series B 10% Cumulative Convertible Preferred Stock, \$.001 Par Value Per Share.(4)
- 3(i).5 Certificate of Amendment to Certificate of Designation of Series A 10% Cumulative Convertible Preferred Stock, \$.001 Par Value Per Share.(4)
- 3(i).6 Amendment to Articles of Incorporation, dated December 15, 2008.(5)
- 3(i).7 Amendment to Articles of Incorporation, dated April 16, 2013.(5)
- 3(i).8 Certificate of Amendment to Articles of Incorporation, dated February 17, 2010.(6)
- 3(i).9 Certificate of Amendment to the Certificate of Designation of Series A 10% Cumulative Convertible Preferred Stock, \$0.001 par value per share of CytoSorbents Corporation.(7)
- 3(i).10 Certificate of Amendment to the Certificate of Designation of Series B 10% Cumulative Convertible Preferred Stock, \$0.001 par value per share of CytoSorbents Corporation.(7)
- 31.1 Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
- 31.2 Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
- 32.1 Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.\*
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.\*
- 101 The following materials from CytoSorbents Corporation’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at September 30, 2014 and December 31, 2013, (ii) Consolidated Statements of Operations for the nine and three months ended September 30, 2014 and September 30, 2013, (iii) Consolidated Statement of Changes in Redeemable Convertible Preferred Stock and of Stockholders’ Equity for the period from December 31, 2013 to September 30, 2014, (iv) Consolidated Statements of Cash Flows for the nine and three months ended September 30, 2014 and September 30, 2013 and (v) Notes to Consolidated Financial Statements.

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

(1) Incorporated by reference from the Exhibits to the Registrant’s Registration Statement on Form SB-2 (Commission File Number 333-114002), filed on March 29, 2004.

(2) Incorporated by reference from the Exhibits to the Registrant’s Current Report on Form 8-K, filed on July 6, 2006.

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- (3) Incorporated by reference from the Exhibits to the Registrant's Current Report on Form 8-K, filed on August 7, 2006.
- (4) Incorporated by reference from the Exhibits to the Registrant's Current Report on Form 8-K, filed on July 1, 2008.
- (5) Incorporated by reference from the Exhibits to the Registrant's Registration Statement on Form S-1/A (Commission File Number 333-193053), filed on February 14, 2014.
- (6) Incorporated by reference from the Exhibits to the Registrant's Current Report on Form 8-K, filed on May 7, 2010.
- (7) Incorporated by reference from the Exhibits to the Registrant's Current Report on Form 8-K, filed on October 14, 2014.

**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 12, 2014 By: /s/ Phillip Chan  
Name: Phillip Chan  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

Dated: November 12, 2014 By: /s/ Kathleen P. Bloch  
Name: Kathleen P. Bloch, CPA  
Title: Chief Financial Officer  
(Principal Financial and Accounting Officer)