Cytosorbents Corp
Form 10-Q
May 11, 2015

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, 2015

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)

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

7 Deer Park Drive, Suite K

Monmouth Junction, New Jersey 08852

(Address of principal executive offices) (Zip Code)

(732) 329-8885

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. þ 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 þ 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 þ

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

As of May 6, 2015 there were 24,764,744 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

	March 31, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$10,418,627	$3,605,280
Short-term investments	2,939,000	1,944,547
Grants and accounts receivable, net of allowance for doubtful accounts of $3,526 at March 31, 2015 and $3,756 at December 31, 2014	672,676	819,151
Inventories	702,921	537,566
Prepaid expenses and other current assets	148,498	700,462
Total current assets	14,881,722	7,607,006
Property and equipment, net	330,308	245,821
Other assets	652,237	615,798
Total long-term assets	982,545	861,619
Total Assets	$15,864,267	$8,468,625
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$475,213	$698,307
Accrued expenses and other current liabilities	733,869	824,884
T Deferred revenue	—	833
Warrant liability	4,989,344	2,981,418
Total current liabilities	6,198,426	4,505,442
Stockholders’ Equity:		
Preferred Stock, 5,000,000 shares authorized; -0- shares issued and outstanding at March 31, 2015 and December 31, 2014	—	—
Common Stock, 50,000,000 shares authorized; 24,678,415 and 23,304,640 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	24,678	23,305
Additional paid-in capital	138,180,345	128,106,297
Accumulated other comprehensive income	571,880	227,701
Accumulated deficit	(129,111,062)	(124,394,120)

Total stockholders' equity	9,665,841	3,963,183
Total Liabilities and Stockholders' Equity	$15,864,267	$8,468,625

See accompanying notes to consolidated financial statements

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three months ended March 31,	
	2015	**2014**
	(Unaudited)	**(Unaudited)**
Revenue:		
Sales	$ 703,658	$ 569,243
Grant income	18,583	491,262
Other revenue	833	1,667
Total revenue	723,074	1,062,172
Cost of revenue	304,481	662,537
Gross margin	418,593	399,635
Other Expenses:		
Research and development	951,028	236,774
Legal, financial and other consulting	215,518	236,533
Selling, general and administrative	1,963,676	1,080,522
Total expenses	3,130,222	1,553,829
Loss from operations	(2,711,629)	(1,154,194)
Other income/(expense):		
Interest income/(expense), net	2,613	(137,089)
Change in warrant liability	(2,007,926)	316,200
Total other income (expense), net	(2,005,313)	179,111
Loss before benefit from income taxes	(4,716,942)	(975,083)
Benefit from income taxes	—	—
Net loss	(4,716,942)	(975,083)
Preferred Stock Dividends	—	(1,114,516)
Net Loss available to common shareholders	$ (4,716,942)	$ (2,089,599)
Basic and diluted net loss per common share	$ (0.19)	$ (0.20)
Weighted average number of shares of common stock outstanding	24,394,474	10,619,195
Net loss	$ (4,716,942)	$ (975,083)
Other comprehensive income:		
Currency translation adjustment	344,179	833
Comprehensive loss	$ (4,372,763)	$ (974,250)

See accompanying notes to consolidated financial statements.

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CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

Period from December 31, 2014 to March 31, 2015 (Unaudited):

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Par value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2014	23,304,640	$ 23,305	$ 128,106,297	$ 227,701	$ (124,394,120)	$ 3,963,183
Stock based compensation - employees, consultants and directors			63,580			63,580
Issuance of common stock – offering, net of fees incurred	1,250,000	1,250	9,407,334			9,408,584
Other comprehensive income/(loss): foreign translation adjustment				344,179		344,179
Cashless exercise of warrants	19,696	20	(20)			—
Proceeds from exercise of warrants	95,200	95	593,155			593,250
Cashless exercise of stock options	5,479	5	(5)			—
Proceeds from exercise of stock options	3,400	3	10,004			10,007
Net loss					(4,716,942)	(4,716,942)
Balance at March 31, 2015	24,678,415	$ 24,678	$ 138,180,345	$ 571,880	$ (129,111,062)	$ 9,665,841

See accompanying notes to consolidated financial statements.

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CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three months ended March 31, 2015 (Unaudited)	Three months ended March 31, 2014 (Unaudited)
Cash flows from operating activities:		
Net loss	$ (4,716,942)	$ (975,083)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common stock to consultant for services	—	90,100
Depreciation and amortization	21,125	19,591
Amortization of debt discount	—	82,781
Stock-based compensation	63,580	57,372
Change in warrant liability	2,007,926	(316,200)
Changes in operating assets and liabilities:		
Grants and accounts receivable	104,425	125,696
Inventories	(140,711)	99,085
Prepaid expenses and other current assets	543,085	412,281
Other assets	(7,134)	—
Accounts payable and accrued expenses	(283,500)	(240,736)
Deferred revenue	(833)	(154,995)
Net cash used by operating activities	(2,408,979)	(800,108)
Cash flows from investing activities:		
Purchases of property and equipment	(104,005)	(21,370)
Patent costs	(36,167)	(4,541)
Proceeds from sales of short-term investments	1,246,547	—
Purchases of short-term investments	(2,241,000)	(4,745,000)
Net cash used by investing activities	(1,134,625)	(4,770,911)
Cash flows from financing activities:		
Equity contributions - net of fees incurred	9,408,584	9,751,455
Proceeds from exercise of stock options	10,007	51,760
Proceeds from exercise of warrants	593,250	—
Net cash provided by financing activities	10,011,841	9,803,215
Effect of exchange rates on cash	345,110	833
Net change in cash and cash equivalents	6,813,347	4,233,029
Cash and cash equivalents - beginning of period	3,605,280	2,183,030
Cash and cash equivalents - end of period	$ 10,418,627	$ 6,416,059

See accompanying notes to consolidated financial statements.

Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$—	$—
Supplemental schedule of noncash investing and financing activities:		
Fair value of warrant liability upon issuance	$—	$862,920
Fair value of shares issued as cost of raising capital	$—	$7,137
Costs paid from proceeds in conjunction with issuance of common stock and preferred stock	$903,916	$748,545
Preferred stock dividends	$—	$1,114,516

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation

Notes to Consolidated Financial Statements

(UNAUDITED)

March 31, 2015

1. BASIS OF PRESENTATION

The Company's interim financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In the opinion of management, the Company has made all necessary adjustments, which include normal recurring adjustments necessary for a fair statement of the Company's financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These interim financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K. The results for the three months and nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

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 believes that it has adequate funding for more than the next twelve months of operations, however, it may have to raise additional capital to fund its future operations.

As of March 31, 2015, the Company had an accumulated deficit of $129,111,062, which included net losses of $4,716,942 for the three months ended March 31, 2015 and $975,083 for the three months ended March 31, 2014. The Company's losses have resulted principally from costs incurred in the research and development of the Company's polymer technology and selling, general and administrative expenses. The Company intends to continue to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other selling, general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, the Company will achieve profitability are uncertain. The Company's ability to achieve profitability will depend, among other things, on successfully completing the development of the Company's technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of the Company's current CE Mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance the Company's activities. No assurance can be given that the Company's product development efforts will be successful, that the Company's current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of the Company's products will be manufactured at a competitive cost and will be of acceptable quality, or that the Company will be able to achieve profitability or that profitability, if achieved,

can be sustained. 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.

2. PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business

The Company 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 Company, through its subsidiary CytoSorbents Medical Inc.(formerly known as CytoSorbents, Inc.), is engaged in the research, development and commercialization of medical devices with its platform blood purification technology incorporating a proprietary adsorbent, porous polymer technology. The Company, through its European Subsidiary, has commenced initial sales and marketing related operations for the CytoSorb® device in the EU. CytoSorb®, the Company's flagship product, is approved in the European Union and marketed in twenty-nine countries around the world, as a safe and effective extracorporeal cytokine absorber, designed to reduce the "cytokine storm" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, and pancreatitis. CytoSorb® is also being used during and after cardiac surgery to remove inflammatory mediators, such as cytokines and free hemoglobin, which can lead to post-operative complications, including multiple organ failure. 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 can actively remove toxic substances from blood and other bodily fluids by pore capture and surface absorption. The Company has numerous products under development based upon this unique blood purification technology, which is protected by 32 issued U.S. patents and multiple applications pending, including HemoDefend™, ContrastSorb, DrugSorb, and others, with multiple patent applications pending both in the United States and internationally. The Company's intellectual property consists of composition of matter, materials, method of production systems incorporating the technology, and multiple medical uses with expiration dates ranging from 3 to 12 years.

Reverse Stock Split

On December 3, 2014, the Company effected a twenty-five-for-one reverse stock split. As a result of this action, funds were shifted from the common stock account to the additional paid in capital account to reflect the par value of the reduced number of shares. All share, option and warrant information presented in these financial statements and accompanying footnotes has been retroactively adjusted to reflect the reduced number of shares resulting from this action.

Stock Market Listing

On December 17, 2014 the Company's common stock was approved for listing on the NASDAQ Capital Market ("NASDAQ"), and it began trading on NASDAQ on December 23, 2014 under the symbol "CTSO". Previously, the Company's common stock traded in the over-the-counter-market on the OTC Bulletin Board.

Basis of Consolidation and Foreign Currency Translation

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

Translation gains and losses resulting from the process of remeasuring into the U.S. dollar, the foreign currency financial statements of the European subsidiary, for which the U.S. dollar is the functional currency, are included in operations. Foreign currency translation losses included in net loss amounted to approximately $448,509 and $12,000 for the three months ended March 31, 2015 and 2014, respectively. The Company translates assets and liabilities of the European subsidiary, whose functional currency is their local currency, at the exchange rate in effect at the balance sheet date. The Company translates revenue and expenses at the monthly average exchange rates. The Company

includes accumulated net translation adjustments in stockholders' equity as a component of accumulated other comprehensive income.

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.

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 March 31, 2015 and December 31, 2014, the Company's inventory was comprised of finished goods, which amounted to $191,6293 and $142,693, respectively; work in process which amounted to $452,949 and $326,047, respectively; and raw materials, which amounted to $58,343 and $68,826, 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 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 expenses are charged to activities when incurred. Advertising expenses amounted to approximately $51,000 and $116,000 for the three months ended March 31, 2015 and 2014, respectively, and are 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 previously completed 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 March 31, 2015 or December 31, 2014. The Company files tax returns in the U.S. federal

and state jurisdictions. The Company currently has no open years prior to December 31, 2011 and has no income tax related penalties or interest for the periods presented in these financial statements.

The Company’s European subsidiary 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 U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from these estimates. Significant estimates in these financials are the valuation of options granted, the valuation of preferred shares issued as stock dividends and valuation methods used to determine the fair value of the warrant liability.

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 March 31, 2015, three distributors accounted for approximately 55% of outstanding grant and accounts receivable. At December 31, 2014, three distributors accounted for approximately 53% of outstanding grant and accounts receivable. For the three months ended March 31, 2015, approximately 42% of revenues were from three distributors. No other agency, distributor, or direct customer represented more than 10% of the Company's revenue. For the three months ended March 31, 2014, approximately 46% 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 eanings per share is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the period. The computation of Diluted earnings per share 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

In August 2014, the Finaancial Accounting Standards Board ("FASB") issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40). The ASU requires all entities to evaluate for the existence of conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the issuance date of the financial statements. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2014-15 will have a significant impact on its consolidated financial statements but may impact the Company's footnote disclosures.

In May 2014, the FASB issued ASU 2015-09, "Revenue with Contracts from Customers." ASU 2015-09 supersedes 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 2015-09 will have a significant impact on its consolidated financial statements.

Shipping and Handling Costs

The cost 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 $41,000 and $24,000 for the three months ended March 31, 2015 and March 31, 2014, respectively.

Reclassifications

Certain reclassifications have been made to the March 31, 2014 financial statements in order to conform to the 2015 financial statement presentation. There was no change in the reported amount of the accumulated deficit as a result of these reclassifications.

3. STOCKHOLDERS' EQUITY

Preferred Stock

In December 2014, the Company amended its articles of incorporation to reduce the total number of authorized shares of preferred stock. The amended articles of incorporation authorize the issuance of up to 5,000,000 shares of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors.

During the three months ended March 31, 2014, the Company recorded non-cash stock dividends totaling $1,114,516 in connection with the issuance of 1,983.44 shares of Series B Preferred Stock and 43,994 shares of Series A Preferred Stock as stock dividends to its preferred shareholders. In October 2014, all outstanding shares of both the Series A and Series B Preferred Stock were converted to common stock. As a result of these conversions, there are no shares of Preferred Stock issued and outstanding as of March 31, 2015 and December 31, 2014, respectively.

Common Stock

On January 14, 2015, the Company closed an underwritten public offering (the “Offering”) consisting of 1,250,000 shares of common stock at a price of $8.25 per share for an aggregate price of $10,312,500.

The Company received net proceeds from the Offering of approximately $9,409,000 million. The net proceeds received by the Company from the Offering will be used to fund clinical studies, expansion of production capacity, support various sales and marketing efforts, product development and general working capital purposes.

The Company conducted the Offering pursuant to a registration statement on Form S-1 (File No. 333-199762), which was declared effective by the Securities and Exchange Commission on January 8, 2015. The Company filed a final prospectus on January 9, 2015, disclosing the final terms of the Offering.

In connection with the Offering, on January 8, 2015, the Company entered into underwriting agreements with Brean Capital, LLC and H.C. Wainwright & Co., LLC (the “Representatives”), who are acting as book-running managers and as representatives of the underwriters in the Offering.

In connection with the successful completion of the Offering, the underwriters received aggregate discounts and commissions of 6% of the gross proceeds of the sale of the shares in the Offering. In addition, the Company agreed to issue warrants to the Representatives (the “Representatives’ warrants”) that allow for the purchase of 30,000 shares of the Company’s common stock. These warrants had a fair value of approximately $30,000 on the date of the closing. The Representatives’ warrants are exercisable at any time for a period of five years, commencing on the date of the effectiveness of the registration statement, at a price per share equal to 120% of the public offering price per share of the common stock in the Offering. The Company also agreed to reimburse the underwriters for actual out-of-pocket expenses related to the Offering, which amounted to approximately $85,000. The Company also granted the Representatives a right of first refusal to participate in any subsequent offering or placement of the Company’s securities that takes place within nine months following the effective date of the registration statement.

Stock-Based Compensation

During the three months ended March 31, 2015, the Company incurred stock-based compensation expense due to the issuance of stock options and amortization of unvested stock options. The aggregate expense for the three months ended March 31, 2015 is approximately $64,000, of which approximately $48,000 was recorded in general and administrative expenses and approximately $16,000 was recorded as research and development expenses.

The summary of the stock option activity for the three months ended March 31, 2015 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding, January 1, 2015	2,302,187	$ 5.37	6.1
Granted	11,000	4.40	5.5
Cancelled	(106,620)	4.88	9.2
Exercised	(11,396)	4.18	6.1
Expired	—	—	—
Outstanding March 31, 2015	2,195,171	$ 5.39	5.9

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 $8.70 to $11.48 per share) and expected life of the stock option (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 (1.53 to 1.58%) for the term of the stock option.

At March 31, 2015, the aggregate intrinsic value of options outstanding and currently exercisable amounted to approximately $18,350,000.

The summary of the status of the Company’s non-vested options for the three months ended March 31, 2015 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2015	874,530	$ 1.37
Granted	11,000	1.21
Cancelled	(106,620)	0.06
Vested	(384,326)	0.06
Non-vested, March 31, 2015	394,584	$ 0.07

As of March 31, 2015, the Company had approximately $339,000 of total unrecognized compensation cost related to stock options. In April 2015, the Board of Directors set aside a pool of 566,000 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 $1,388,000. 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 three months ended March 31, 2015. 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.

As of March 31, 2015, 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
70,000	$ 2.500	August 16, 2015
64,000	$ 3.125	August 16, 2015
53,335	$ 3.750	August 16, 2015
19,600	$ 2.500	October 22, 2015
7,840	$ 3.125	October 22, 2015
6,535	$ 3.750	October 22, 2015
20,000	$ 2.500	November 19, 2015
8,000	$ 3.125	November 19, 2015
6,667	$ 3.750	November 19, 2015
20,000	$ 2.500	February 15, 2016
56,000	$ 3.125	February 15, 2016
46,669	$ 3.750	February 15, 2016
9,605	$ 31.250	October 24, 2016
46,668	$ 4.375	February 10, 2017
149,600	$ 3.750	June 21, 2018
122,000	$ 3.150	September 30, 2018
48,960	$ 7.500	March 11, 2019
736,000	$ 7.813	March 11, 2019
30,000	$ 9.900	January 14, 2020
1,521,479		

4. WARRANT LIABILITY

In connection with its March 11, 2014 offering, the Company issued warrants to purchase 816,000 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 $6.00. On March 30, 2015 and 2014, the five day weighted average closing price per share of common stock was $13.87 and $5.60, respectively. Due to the fluctuations in the market value of the Company's common stock from December 31, 2014 through March 31, 2015, the Company recorded a change in the fair value of the warrant liability of $2,007,926 during the three months ended March 31, 2015. Due to the fluctuations in the market value of the Company's common stock from March 11, 2014 through March 31, 2014, the Company recorded a change in the fair value of the warrant liability of $316,200 during the three months ended March 31, 2014.

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

	March 31, 2015	March 31, 2014
Number of shares underlying the warrants	736,000	816,000
Exercise price	$7.81	$7.81
Volatility	28.3 %	28.3 %
Risk-free interest rate	1.12 %	1.73 %
Expected dividend yield	0	0
Expected warrant life (years)	3.95	4.95
Stock Price	$13.87	$5.05

5. COMMITMENTS AND CONTINGENCIES

Employment Agreements

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

Litigation

The Company is from time to time subject to claims and litigation arising out of the ordinary course of business. The Company intends to defend vigorously against any future claims and litigation. The Company is 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 three months ended March 31, 2015 and 2014 the Company has recorded royalty costs of approximately $20,000 and $17,000, respectfully.

License Agreements

In March 2006, the Company entered into a license agreement which provides the Company the exclusive right to use its patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the agreement, the Company has agreed to pay royalties of 2.5% to 5% on the sale of certain of its products if and when those products are sold commercially for a term not greater than 18 years commencing with the first sale of such product. For the three months ended March 31, 2015 and 2014, per the terms of the license agreement, the Company has recorded royalty costs of approximately $28,000 and $14,000, respectfully.

6. NET LOSS PER SHARE

Basic loss per share and diluted loss per share for the three months ended March 31, 2015 and 2014 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 3,717,000 and 4,001,000 incremental shares at March 31, 2015 and 2014, respectively, as well as shares issuable upon conversion of Series A and Series B Preferred Stock representing approximately -0- and 9,048,000 incremental shares at March 31, 2015 and 2014, respectively, as well as potential shares issuable upon Note conversion into common stock representing approximately -0- and 649,000 incremental shares at March 31, 2015 and 2014, respectively, have been excluded from the computation of diluted loss per share as they are anti-dilutive.

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, 2014, as filed with the Securities and Exchange Commission (the "Commission") on March 31, 2015.

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 our audited consolidated financial statements and the notes thereto as of and for the year ended December 31, 2014 as included in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Commission on March 31, 2015.

Overview

We are 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 applications pending both in the United States and internationally. Our intellectual property consist of composition of matter, materials, methods of production, systems incorporating the technology and multiple medical uses with expiration dates ranging from three to 12 years.

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

Our CE Mark enables CytoSorb® to be sold throughout all 28 countries of the 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, we completed our randomized, controlled, European Sepsis Trial amongst fourteen 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. We plan to conduct larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE Mark approval, we 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. We have also established a reimbursement path for CytoSorb® in Germany and Austria.

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

In late June 2012, following the establishment of our European subsidiary, CytoSorbents Europe GmbH, we 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 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, we expanded our direct sales efforts to include both Austria and Switzerland. At the end of 2014, we had more than 150 key opinion leaders (KOLs) in our direct sales territories and the UK in critical care, cardiac surgery, and blood purification who were either using CytoSorb® or committed to using CytoSorb® in the near future.

As of May 1, 2015, our sales force includes our VP of Sales and Marketing, our International Sales Director, four active direct sales people, seven sales support staff and one contract sales person.

We have complemented our direct sales efforts with sales to distributors and/or corporate partners. In 2013, we reached agreements with distributors in the United Kingdom, Ireland, Turkey, Russia, and the Netherlands. In April

2014, we announced distribution of CytoSorb® in the Middle East, including Saudi Arabia, the United Arab Emirates, Kuwait, Qatar, Bahrain, and Oman (the Gulf Cooperative Council or GCC) and Yemen, Iraq, and Jordan through an exclusive agreement with Techno Orbits. In August 2014, we announced exclusive distribution of CytoSorb® in Taiwan with Hemoscien Corporation, which was subsequently terminated by us in March 2015 due to the complexity of FDA product registration in Taiwan. In December 2014, we entered into an exclusive agreement with Smart Medical Solutions S.R.L., to distribute CytoSorb® for critical care applications in Romania and the neighboring Republic of Moldova. In January 2015, we announced our exclusive distribution agreement with Aferetica SRL to distribute CytoSorb® in Italy for critical care applications.

We have been expanding the number and scope of our strategic partnerships. In September 2013, we entered into a strategic partnership with Biocon, Ltd., Asia's largest biotech company, with an initial distribution agreement for India and select emerging markets, under which Biocon will have the exclusive commercialization rights for CytoSorb® initially focused on sepsis. In September 2014, the Biocon partnership was expanded to include all critical care applications and cardiac surgery. In addition, Biocon committed to higher minimum purchases of CytoSorb® to maintain distribution exclusivity and to conduct and publish results from multiple Investigator-Initiated studies and patient case studies.

In addition, in November 2014, we entered into an initial partnership agreement with a leading global medical device company in cardiac surgery and other cardiovascular diseases, to use CytoSorb® intra-operatively during cardiac surgery in France. Under the terms of the agreement, the partnership commenced with an initial six-month market evaluation period to determine various market parameters, to obtain clinical data, and to build key opinion leader support in France. Following a successful evaluation, the parties plan to jointly determine how to expand upon both the size and geographic footprint of its partnership.

In February 2015, we entered into a multi-country strategic partnership with Fresenius Medical Care AG & CO KGaA, the world's largest dialysis company, to commercialize the CytoSorb® therapy. Under the terms of the agreement, Fresenius Medical Care has exclusive rights to distribute CytoSorb® for critical care applications in France, Poland, Sweden, Denmark, Norway, and Finland. The partnership will allow Fresenius Medical Care to offer an innovative and easy to use blood purification therapy for removing cytokines in patients that are treated in the intensive care unit. To promote the success of CytoSorb®, Fresenius will also engage in the ongoing clinical development of the product. This includes the support and publication of a number of small case series and patient case reports as well as the potential for larger, clinical collaborations in the future.

We are currently evaluating other potential distributor and strategic partner networks in other major countries where we are approved to market the device.

Concurrent with our commercialization plans, we intend 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. We are currently conducting a matched pairs analysis, dose ranging trial in Germany amongst eight clinical trial sites to evaluate the safety and efficacy of CytoSorb® when used continuously for 7 days. Data from this dosing study are intended to help clinicians with additional treatment options for CytoSorb®, help support the positive clinical data from our first European Sepsis Trial, and help shape the trial protocol for a pivotal sepsis study.

In addition, we now have more than 50 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, which will provide additional clinical data.

In February 2015, the U.S. Food and Drug Administration, or FDA, approved our Investigational Device Exemption, or IDE, application to commence a planned U.S. cardiac surgery feasibility study. This single-arm study in 20 patients and three U.S. clinical sites represents the first part of a larger clinical trial strategy intended to support the approval of CytoSorb® in the United States for intra-operative use during cardiac surgery.

The study is designed to evaluate the safety of CytoSorb® when used intra-operatively in a heart-lung machine to reduce plasma free hemoglobin and cytokines in patients undergoing complex cardiac surgery. The length, complexity and invasiveness of these procedures cause hemolysis and inflammation, leading to high levels of plasma free hemoglobin, cytokines, activated complement, and other substances. These inflammatory mediators directly correlate with the incidence of serious post-operative complications such as kidney injury and failure. The goal of CytoSorb® is to actively remove these inflammatory and toxic substances as they are being generated during the surgery and reduce complications.

Concurrently, we plan to fund a non-interventional study amongst a broader array of U.S. cardiac surgery centers that will assess adverse event rates (e.g. incidence of acute kidney injury and respiratory failure) and levels of free hemoglobin and other inflammatory mediators in patients undergoing complex cardiac surgery. These patients will be selected using similar inclusion and exclusion criteria to the feasibility study. We believe the data from these two studies will help to rapidly validate assumptions in this surgical patient population and help to appropriately power a U.S. pivotal cardiac surgery trial.

The market focus for CytoSorb® is the prevention or treatment of organ failure 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, or ARDS, and others. Sepsis is a major unmet medical need, and currently no approved products in the United States or Europe exist 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 SIRS response and either prevent or treat organ failure.

In addition to the sepsis indication, we intend to continue to foster research in other critical care illnesses where CytoSorb® could be used, such as ARDS, trauma, severe burn injury and acute pancreatitis, or in other acute conditions that 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), rescue therapy in activated T-cell cancer immunotherapy and damage to organs donated for transplant prior to organ harvest.

Our proprietary hemocompatible porous polymer bead technology forms the basis of a broad technology portfolio. Some of our products include:

- CytoSorb® - an extracorporeal hemoperfusion cartridge approved in the 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 with the goal of reducing 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 with the goal of preventing 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 with the goal of improving the efficacy of dialysis or hemofiltration

We have been successful in obtaining technology development contracts 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, or NHLBI, a division of the National Institutes of Health, or NIH, awarded us a Phase I Small Business Innovation Research, or SBIR, contract valued at $231,351 to further advance our HemoDefend™ blood purification technology for packed red blood cell ("pRBC") transfusions. The University of Dartmouth collaborated with us as a subcontractor on the project, entitled "Elimination of blood contaminants from pRBCs using HemoDefend™ hemocompatible porous polymer beads." The overall goal of this program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs. We completed the Phase I program and have been invited to apply for the Phase II SBIR, which has now been submitted.

In June 2013, we announced that the U.S. Air Force will fund a 30 patient, single site, randomized controlled human pilot study in the United States amongst trauma patients with rhabdomyolysis. The primary endpoint is myoglobin removal. The FDA approved our Investigational Device Exemption, or IDE, application for this study and we also received ethics committee approval, allowing the study to commence. However, because of the stringency of our inclusion criteria, and because of the patient mix seen at our single center, we have experienced difficulty in enrolling patients. We have subsequently modified one of the key inclusion criteria and have expanded the number of clinical trial sites to three in a revised protocol which has been submitted to the FDA. Though we do not expect to receive material direct funding from this $3 million budgeted program, the study may generate valuable data that can be used commercially or in future trauma studies.

In September 2012, we were awarded a Phase II SBIR contract by the U.S. Army Medical Research and Material Command to evaluate our technology for the treatment of trauma and burn injury in large animal models. In 2013, we finalized the Phase II SBIR contract which provided for a maximum funding of approximately $753,000 with the granting agency. This work is supported by the U.S. Army Medical Research and Material Command under an amendment to Contract W81XWH-12-C-0038. As of March 31, 2015, we received approximately $649,000 in funding under this contract. The contract will expire in June 2015.

In August 2012, we were awarded a $3.8 million, five-year 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, or 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. Our contract with DARPA is for advanced technology development of our hemocompatible porous polymer technologies to remove cytokines and a number of pathogen and biowarfare toxins from blood. We are in Year 3 of the program and are currently working with the recently announced systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, which are responsible for integrating the technology that we and others have developed into a final medical device design prototype, and evaluating this device in septic animals and eventually in human clinical trials in sepsis. Our work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199. As of March 31, 2015, we have received approximately $2,818,000 and have approximately $988,000 not yet billed under this contract.

Results of Operations

Comparison for the three months ended March 31, 2015 and 2014:

Revenues:

Revenue from product sales was approximately $704,000 in the three months ended March 31, 2015, as compared to approximately $569,000 in the three months ended March 31, 2014, an increase approximately $135,000, or 24%. This increase was largely driven by the continued expansion of sales to our growing distributor network. Product sales were also negatively impacted by the decline in the exchange rate of the Euro. The impact of the decline in the exchange rate of the Euro was approximately $112,000, or 16% of sales, for the three months ended March 31, 2015.

Grant income was approximately $19,000 for the three months ended March 31, 2015 as compared to approximately $491,000 for the three months ended March 31, 2014 as a result of the conclusion during 2014 of several significant grants.

As a result of the decrease in grant income, for the three months ended March 31, 2015, we generated total revenue of approximately $723,000, as compared to revenues of approximately $1,062,000, for the three months ended March 31, 2014, a decrease of approximately $339,000, or 32%.

Cost of Revenues:

For the three months ended March 31, 2015 and 2014, cost of revenue was approximately $304,000 and $663,000, respectively. The decrease is directly related to a decrease of approximately $422,000 of direct labor and other costs being deployed toward grant-funded activities, which has the effect of decreasing the amount of costs allocated to cost of revenue. Product cost of revenues increased approximately $118,000 during the three months ended March 31, 2015 as compared to the three months ended March 31, 2014 due to increased sales. Product gross margins were approximately 59% for the three months ended March 31, 2015, as compared to approximately 61% for the three months ended March 31, 2014.

Research and Development Expenses*:*

For the three months ended March 31, 2015, research and development expenses were approximately $951,000 as compared to research and development expenses of approximately $237,000 for the three months ended March 31, 2014. The increase of approximately $714,000 in research and development expenses was primarily due to a decrease of $422,000 of direct labor and other costs being deployed toward grant-funded activities, which had the effect of increasing the amount of our non-reimbursable research and development costs. In addition, costs related to our various clinical studies increased approximately $156,000 and salaries increased approximately $125,000 during the three months ended March 31, 2015 as compared to the three months ended March 31, 2014.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately $215,000 for the three months ended March 31, 2015, as compared to approximately $237,000 for the three months ended March 31, 2014. The decrease of approximately $22,000 was due to a decrease in fees to consultants of approximately $91,000. The decrease was offset by approximately $51,000 in employment agency fees incurred in 2015 related to the hiring of senior level personnel and an increase in legal fees of approximately $25,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately $1,964,000 for the three months ended March 31, 2015, as compared to approximately $1,081,000 for the three months ending March 31, 2014. The increase of approximately $883,000 in selling, general, and administrative expenses was due to an increase in losses on foreign currency exchange of approximately $437,000 in 2015 due to a large decrease in the exchange rate of the Euro,

salaries, commissions and related costs of approximately $176,000 due to the impact headcount additions, additional sales and marketing costs, which include advertising and conferences of approximately $116,000, an increase in travel and entertainment costs of approximately $40,000 and an increase in costs associated with the business in Europe of approximately $85,000 primarily attributable to increases in operating expenses associated with the ramp up of the business in Germany which occurred during 2014.

Interest Income/(Expense):

For the three months ended March 31, 2015, interest income was approximately $3,000, as compared to interest expense of approximately $137,000 for the three months ended March 31, 2014. The decrease in net interest expense was solely due to the interest payable and amortization of financing costs related to our convertible notes which were converted to common stock during 2014.

Change in Warrant Liability:

We recognize warrants as liabilities at their fair value on the date of the grant because of price adjustment provisions in the warrants, then measure 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 resulted in a charge to other expense approximately $2,008,000 for the three months ended March 31, 2015, and other income of approximately $316,000 for the three months ended March 31, 2014, The change in warrant liability was as a result of the change in the fair value of the warrant liability from December 31, 2014 to March 31, 2015 and from March 11, 2014 (the date of our $10,200,000 2014 offering) to March 31, 2014. See Note 4 to the consolidated financial statements for details related to the calculation of the fair value of the warrant liability.

History of Operating Losses:

We have experienced substantial operating losses since inception. As of March 31, 2015, we had an accumulated deficit of approximately $129,111,000, which included losses of approximately $4,717,000 and $975,000 for the three month periods ended March 31, 2015 and 2014, respectively. Historically, losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies, and general and administrative expenses.

Liquidity and Capital Resources

Since inception, our operations have been primarily financed through the private placement of its debt and equity securities. At March 31, 2015, we had current assets of approximately $14,882,000 including cash on hand and short-term investments of approximately $13,358,000 and current liabilities of approximately $6,198,000. We believe we have sufficient cash to fund our operations into 2016; however, we may need to raise additional capital to fully fund pivotal trials in the United States and/or Germany. We will be better able to assess this need once the specific protocols are finalized with appropriate regulatory bodies. In addition, we may require additional capital to support our sales and marketing efforts, to fund clinical studies, to expand our production capacity, to further develop our products, and for general working capital purposes.

Off-balance Sheet Arrangements

We have no off-balance sheet arrangements.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We believe that we have adequate funding for more than the next twelve months of operations, however, we may have to raise additional capital to fund our future operations.

As of March 31, 2015, we had an accumulated deficit of $129,611,000, which included net losses of $4,717,000 for the three months ended March 31, 2015, and $975,000 for the three months ended March 31, 2014. In part due to these losses, our audited consolidated financial statements were prepared assuming we will continue as a going concern, and the auditors' report on those financial statements expressed substantial doubt about our ability to continue as a going concern. Our losses have resulted principally from costs incurred in the research and development of our polymer technology and selling, general and administrative expenses. We intend to continue to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence, and other selling, general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of our current CE Mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, or that the we will be able to achieve profitability or that profitability, if achieved, can be sustained. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable to smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e)) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this report.. Based upon their evaluation, as of the end of the period covered by this Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective.

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the Company. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon this evaluation, management concluded that internal control over financial reporting was effective as of March 31, 2015.

Changes in Internal Controls

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

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

We may require additional capital in the future to fund our operations

As of March 31, 2015, we had current assets of approximately $14,882,000, including cash on hand of approximately $10,419,000 and short-term investments of approximately $2,939,000 and current liabilities of approximately $6,198,425. On January 14, 2015, we received approximately $9,409,000 in net proceeds in connection with a registered offering of our common stock. Our cash burn was approximately $2,800,000 for the three months ended March 31, 2015. Our current and historical cash burn is not necessarily indicative of our future use of cash and cash equivalents.

We may require additional financing in the future in order to complete additional clinical studies and to support the commercialization of our proposed products. There can be no assurance that we will be successful in our capital raising efforts. Our long-term capital requirements are expected to depend on many factors, including:

- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical studies;
- the time and costs involved in obtaining regulatory clearance in other countries and/or for other indications;
- costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- costs of developing sales, marketing and distribution channels;
- market acceptance and reimbursement of our products; and
- cost for training physicians and other health care personnel.

Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves.

We currently are in the process of commercializing our products, but there can be no assurance that we will be successful in developing commercial operations.

We have been engaged primarily in research and development activities and have generated limited revenues to date. There can be no assurance that we will be able to successfully manage the transition to a commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an

enterprise in the early stage of development, which include unanticipated problems relating to development of proposed products, testing, regulatory compliance, manufacturing, competition, market adoption, product registration, reimbursement, marketing problems and additional costs and expenses that may exceed current estimates. Our proposed products will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization in other countries, such as the United States, and for ongoing compliance for our CE Mark. We will also need to raise significant additional funds to complete additional clinical studies and obtain regulatory approvals in other countries before we can begin selling our products in markets not covered by the CE Mark. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

We have a history of losses and expect to incur substantial future losses, and the report of our auditor on our consolidated financial statements expresses substantial doubt about our ability to continue as a going concern.

We have experienced substantial operating losses since inception. As of March 31, 2015, we had an accumulated deficit of $129,111,062, which included net losses of $4,716,942 for the three months ended March 31, 2015 and $975,083 for the three months ended March 31, 2014. In part due to these losses, our audited consolidated financial statements have been prepared assuming we will continue as a going concern, and the auditors' report on those financial statements express substantial doubt about our ability to continue as a going concern. Our losses have resulted principally from costs incurred in the research and development of our polymer technology and general and administrative expenses. We intend to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence, and other general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of our current CE Mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, or that the we will be able to achieve profitability or that profitability, if achieved, can be sustained.

We depend upon key personnel who may terminate their employment with us at any time.

As of April 30, 2015, we currently have 46 full-time employees and several full-time temporary employees. Our success will depend to a significant degree upon the continued services of our key management and advisors, including, Dr. Phillip Chan, our Chief Executive Officer; Kathleen P. Bloch, our Chief Financial Officer; Vincent Capponi, our Chief Operating Officer; and Dr. Robert Bartlett, our Chief Medical Officer, who works with us on a consulting basis. These individuals do not have long-term employment agreements, and in some cases, including with respect to Dr. Chan and Mr. Capponi, do not have current and effective employment agreements in place. Although we are discussing formalizing our employment and consulting arrangements, as applicable, with Dr. Chan, Mr. Capponi and Dr. Bartlett , there can be no assurance that Dr. Chan, Mr. Capponi, Dr. Bartlett or other members of our management team and advisors will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

Our Chief Medical Officer works with us on a consulting basis.

Our Chief Medical Officer, Dr. Robert Bartlett, works with us on a consulting basis. Because of the part time nature of his consulting agreement, Dr. Bartlett may not always be available to provide us with his services when needed by us in a timely manner.

Acceptance of our medical devices in the marketplace is uncertain, and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our polymer products. Even with our approval to apply the CE Mark to our CytoSorb® device as a cytokine filter, our products may not achieve market acceptance in the European countries that recognize and accept the CE Mark. Additional approvals from other regulatory authorities (such as the U.S. Food and Drug Administration, or FDA) will be required before we can market our device in countries not covered by the CE Mark. There is no guarantee that we will be able to achieve additional regulatory approvals, and even if we do, our products may not achieve market acceptance in the countries covered by such approvals. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration of the advantages, safety and efficacy of the our polymer technology;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;

- our ability to attract corporate partners, including medical device companies, to assist in commercializing our products; and
- our ability to market our products.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. Approval of our CytoSorb® device as a cytokine filter as well as the data we have gathered in our clinical studies to support device usage in this indication may not be sufficient for market acceptance in the medical community. We may also need to conduct additional clinical studies to gather additional data for marketing purposes. If we are unable to obtain regulatory approval or commercialize and market our products when planned, we may not achieve any market acceptance or generate revenue.

Even with our approval to apply the CE Mark to our CytoSorb® device as a cytokine filter, there can be no assurance that the data from our limited clinical studies will be viewed as sufficient by the medical community to support the purchase of our products in substantial quantities or at all.

CytoSorb® is currently reimbursable in Germany and Austria. We plan to seek reimbursement for our product in other EU and non-EU countries to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

We may face litigation from third parties claiming that our products infringe on their intellectual property rights, or seek to challenge the validity of our patents.

Our future success is also dependent on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development. In addition to the Purolite litigation discussed below, we may be exposed to additional future litigation by third parties seeking to challenge the validity of our rights based on claims that our technologies, products or activities infringe the intellectual property rights of others or are invalid, or that we have misappropriated the trade secrets of others.

Since our inception, we have sought to contract with large, established manufacturers to supply commercial quantities of our adsorbent polymers. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers. We believe that these disclosures, while necessary for our business, have resulted in the attempt by potential suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing rights.

We have previously engaged in discussions with the Brotech Corporation and its affiliate, Purolite International, Inc. (collectively, “Purolite”), which had demonstrated a strong interest in being our polymer manufacturer. For a period of time beginning in December 1998, Purolite engaged in efforts to develop and optimize the manufacturing process needed to produce our polymer products on a commercial scale. However, the parties eventually decided not to proceed. In 2003, Purolite filed a lawsuit against us asserting, among other things, co-ownership and co-inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2.5% to 5% on the sale of certain of our products if and when those products are sold commercially.

More than a decade ago, we engaged in discussions with the Dow Chemical Company, which had indicated a strong interest in being our polymer manufacturer. After a Dow representative on our Advisory Board resigned, Dow filed and received several patents naming our former Advisory Board member as an inventor. In management’s view, the Dow patents improperly incorporate our technology and should not have been granted to Dow. The existence of these Dow patents could result in a potential dispute with Dow in the future and additional expenses for us.

We have commenced the process of seeking regulatory approvals of our products, but the approval process involves lengthy and costly clinical studies and is, in large part, not within our control. The failure to obtain government approvals, internationally or domestically, for our polymer products, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of our products and result in the failure to achieve revenues or maintain our operations.

CytoSorb® has already achieved regulatory approval in the EU under the CE Mark and the Medical Devices Directive. It is manufactured at our manufacturing facility in New Jersey under ISO 13485 Full Quality Systems certification. The manufacturing and marketing of our products will be subject to extensive and rigorous government regulation in the European market, the United States, in various states and in other foreign countries. In the United States and other countries, the process of obtaining and maintaining required regulatory approvals is lengthy, expensive, and uncertain. There can be no assurance that we will ever obtain the necessary additional approvals to sell our products in the United States or other non-EU countries. Even if we do ultimately receive FDA approval for any of our products, we will be subject to extensive ongoing regulation. While we have received approval from our Notified Body to apply the CE Mark to our CytoSorb® device, we will be subject to extensive ongoing regulation and auditing requirements to maintain the CE Mark.

Our products will be subject to international regulation as medical devices under the Medical Devices Directive. In Europe, which we expect to provide the initial market for our products, the Notified Body and Competent Authority govern, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the Notified Body under these laws. Current international regulations classify our CytoSorb® device as a Class IIb device. Even though we have received CE Mark certification of the CytoSorb® device, there can be no assurance that we will be able to continue to comply with the required annual auditing requirements or other international regulatory requirements that may be applicable. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted. There can be no assurances that reimbursement will be granted or that additional clinical data may be required to establish reimbursement.

We have conducted limited clinical studies of our CytoSorb® device. Clinical and pre-clinical data is susceptible to varying interpretations, which could delay, limit or prevent additional regulatory clearances.

To date, we have conducted limited clinical studies on our CytoSorb® product. There can be no assurance that we will successfully complete additional clinical studies necessary to receive additional regulatory approvals in markets not covered by the CE Mark. While studies conducted by us and others have produced results we believe to be encouraging and indicative of the potential efficacy of our products and technology, data already obtained, or in the future obtained, from pre-clinical studies and clinical studies do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical studies. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent additional regulatory approvals. A number of companies

in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business. Even though we have received approval to apply the CE Mark to our CytoSorb® device as a cytokine filter, there can be no assurance that we will be able to receive approval for other potential applications of CytoSorb®, or that we will receive regulatory clearance from other targeted regions or countries.

We rely extensively on research and testing facilities at various universities and institutions, which could adversely affect us should we lose access to those facilities.

Although we have our own research laboratories and clinical facilities, we collaborate with numerous institutions, universities and commercial entities to conduct research and studies of our products. We currently maintain a good working relationship with these parties. However, should the situation change, the cost and time to establish or locate alternative research and development could be substantial and delay gaining CE Mark for other potential applications or technologies, and/or FDA approval and commercializing our products.

We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of medical devices. We cannot be sure that claims will not be asserted against us. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We cannot give assurances that we will be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations.

Certain university and other relationships are important to our business and may potentially result in conflicts of interests.

Dr. John Kellum and other critical care advisors and consultants of ours are associated with institutions such as the University of Pittsburgh Medical Center. Their association with these institutions may currently or in the future involve conflicting interests in the event they or these institutions enter into consulting or other arrangements with competitors of ours.

We have limited manufacturing experience, and once our products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost, or without shut-downs or delays.

In March 2011, we received approval from our Notified Body to apply the CE Mark to our CytoSorb® device for commercial sale as a cytokine filter. 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. We will need to maintain compliance on an ongoing basis. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third-party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products.

While we currently believe we have established sufficient production capacity to supply potential near term demand for our CytoSorb® device, we will need to scale up and increase our manufacturing capabilities in the future. No assurance can be given that we will be able to successfully scale up our manufacturing capabilities or that we will have sufficient financial or technical resources to do so on a timely basis or at all.

Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our products.

We expect to enter into agreements with third parties for the commercial marketing, and distribution of our products. There can be no assurance that parties we may engage to market and distribute our products will:

- satisfy their financial or contractual obligations to us;
- adequately market our products; or
- not offer, design, manufacture or promote competing products.

If for any reason any party we engage is unable or chooses not to perform its obligations under our marketing and distribution agreement, we would experience delays in product sales and incur increased costs, which would harm our business and financial results.

Our results of operations can be significantly affected by foreign currency fluctuations and regulations.

A significant portion of our revenues is currently derived in the local currencies of the foreign jurisdictions in which our products are sold. Accordingly, we are subject to risks relating to fluctuations in currency exchange rates. In the future, and especially as we further expand our sales efforts in international markets, our customers will increasingly make payments in non-U.S. currencies. Fluctuations in foreign currency exchange rates could affect our revenues, operating costs and operating margins. In addition, currency devaluation can result in a loss to us if we hold deposits of that currency. We cannot predict the effect of future exchange rate fluctuations on our operating results.

If we are unable to convince physicians and other health care providers as to the benefits of our products, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our products may require physicians and other health care providers to be informed about our products and their intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this education process may adversely affect market acceptance of our products. We may be unable to educate physicians regarding our products in sufficient numbers or in a timely manner to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our products is created, if at all.

The market for our products is rapidly changing and competitive, and new devices and drugs, which may be developed by others, could impair our ability to maintain and grow our business and remain competitive.

The medical device and pharmaceutical industries are subject to rapid and substantial technological change. Developments by others may render our technologies and products noncompetitive or obsolete. We also may be unable to keep pace with technological developments and other market factors. Technological competition from medical device, pharmaceutical and biotechnology companies, universities, governmental entities and others

diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of medical devices is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of medical devices and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations ("HMOs"). Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and medical devices, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

CytoSorb® is currently reimbursable in Germany and Austria. We plan to seek reimbursement for our product in other E.U. and non-E.U. countries to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

Risks Connected to our Securities

The price of our common stock has been highly volatile due to factors that will continue to affect the price of our stock.

Our common stock closed as high as $8.75 and as low as $3.00 per share between January 1, 2014 and December 2, 2014 on the OTCQB. On December 3, 2014, we effected a twenty-five-for-one (25:1) reverse split of our common stock. Immediately after the reverse stock split, on December 3, 2014 we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated December 3, 2014, whereby we merged with and into our recently formed, wholly-owned Delaware subsidiary. On December 17, 2014, CytoSorbents received approval for up-listing to The NASDAQ Capital Market and its common stock began trading on the NASDAQ Capital Market on December 23, 2014. Our common stock closed as high as $14.99 and as low as $6.91 per share between December 23, 2014 and May 7, 2015. On May 7, 2015 the closing price of our common stock, as reported on the NASDAQ Capital Market was $7.95. Historically, the over-the-counter markets for securities such as our common stock have experienced extreme price fluctuations. Some of the factors leading to this volatility include, but are not limited to:

- fluctuations in our operating results;
- announcements of product releases by us or our competitors;
- announcements of acquisitions and/or partnerships by us or our competitors; and

- general market conditions.

Although share of our common stock currently trade on the NASDAQ Capital Market under the symbol “CTSO”, there is no assurance that our stock will not continue to be volatile while listed on NASDAQ in the future.

Directors, executive officers and principal stockholders own a significant percentage of the shares of common stock, which will limit your ability to influence corporate matters.

Our directors, executive officers and principal stockholders together beneficially own a significant percentage of the voting control of our common stock on a fully diluted basis. Accordingly, these stockholders could have a significant influence over the outcome of any corporate transaction or other matter submitted to stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets and also could prevent or cause a change in control. The interests of these stockholders may differ from the interests of our other stockholders. Third parties may be discouraged from making a tender offer or bid to acquire us because of this concentration of ownership.

Our Board of Directors may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of common stock, which will adversely affect the rights of holders of our common stock.

On December 3, 2014, we effected a twenty-five-for-one (25:1) reverse split of our common stock. Immediately after the reverse stock split, on December 3, 2014 we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated December 3, 2014, whereby we merged with and into our recently formed, wholly-owned Delaware subsidiary. Pursuant to the Agreement and Plan of Merger effecting the merger, we adopted the certificate of incorporation, as amended and restated, and bylaws of our Delaware subsidiary as our certificate of incorporation and bylaws at effective time of the merger. As a result, our certificate of incorporation, as amended and restated, authorizes the issuance of up to 5,000,000 shares of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors. Currently, our certificate of incorporation, as amended and restated, which became effective on December 3, 2014, authorizes the issuance of up to 50,000,000 shares of common stock, of which approximately 25,322,000 shares remain available for issuance and may be issued by us without stockholder approval.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.

After giving effect to our merger into our wholly-owned Delaware subsidiary, provisions of our certificate of incorporation, as amended and restated, and our bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change our direction or management. For example, these provisions:

- authorize the issuance of "blank check" preferred stock without any need for action by stockholders;
- eliminate the ability of stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Compliance with changing corporate governance and public disclosure regulations may result in additional expense.

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, and any new SEC regulations will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities.

Our common stock is thinly traded on the NASDAQ Capital Market exchange, and no assurances can be made about stock performance, liquidity, or maintenance of our NASDAQ listing.

Historically, our common stock was quoted on the OTCQB, which provided significantly less liquidity than a securities exchange (such as the New York Stock Exchange or the Nasdaq Stock Market). On December 17, 2014, our common stock was approved for trading on the NASDAQ Capital Market, or NASDAQ. Beginning on December 23, 2014, our common stock began trading on NASDAQ under the symbol “CTSO.” Although currently listed on NASDAQ, there can be no assurance that we will continue to meet NASDAQ’s minimum listing requirements or that of any other national exchange. In addition, there can be no assurances that a liquid market will be created for our common stock. If we are unable to maintain listing on the NASDAQ or if a liquid market for our common stock does not develop, our common stock may remain thinly traded.

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

Item 3. Defaults Upon Senior Securities. None.

Item 4. Mine Safety Disclosures. Not applicable.

Item 5. Other Information. None.

Item 6. Exhibits.

Number	Description
31.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.*
101	The following materials from CytoSorbents Corporation's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at March 31, 2015 and December 31, 2014, (ii) Consolidated Statements of Operations for the three months ended March 31, 2015 and March 31, 2014, (iii) Consolidated Statement of Changes in Stockholders' Equity for the period from December 31, 2014 to March 31, 2015, (iv) Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and March 31, 2014 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.

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 11, 2015 By: /s/ Phillip Chan
Name: Phillip Chan
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: May 11, 2015 By: /s/ Kathleen P. Bloch
Name: Kathleen P. Bloch, CPA
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)