Cytosorbents Corp
Form 10-Q
August 09, 2016

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 June 30, 2016

Or

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

Commission file number: 001-36792

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). Yesþ 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 þ
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of August 3, 2016 there were 25,437,766 shares of the issuer's Common Stock outstanding.

CytoSorbents Corporation

FORM 10-Q

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This Report includes our trademarks and trade names, such as CytoSorb®, BetaSorb™ and HemoDefend™, which are protected under applicable intellectual property laws and are the property of CytoSorbents Corporation and its subsidiaries. This Report also contains the trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Report may appear without the ™, ®, or SM symbols, but such references are not intended to indicate, in any way,

that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, trade names and service marks. We do not intend to use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED BALANCE SHEETS

	June 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$8,670,390	$5,316,851
Short-term investments	249,000	2,192,000
Grants and accounts receivable, net of allowance for doubtful accounts of $6,556 at June 30, 2016 and $3,275 at December 31, 2015	944,777	648,869
Inventories	1,047,911	1,190,681
Prepaid expenses and other current assets	161,790	511,927
Total current assets	11,073,868	9,860,328
Property and equipment, net	599,788	557,289
Other assets	1,037,468	836,749
Total Assets	$12,711,124	$11,254,366
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$1,021,535	$684,633
Accrued expenses and other current liabilities	1,103,288	723,018
Warrant liability at fair value	1,808,347	1,636,128
Total current liabilities	3,933,170	3,043,779
Long-term debt, net	4,881,167	—
Total liabilities	8,814,337	3,043,779
Stockholders’ Equity:		
Preferred Stock, 5,000,000 shares authorized; -0- shares issued and outstanding at June 30, 2016 and December 31, 2015	—	—
Common Stock, 50,000,000 shares authorized; 25,437,766 and 25,397,056 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	25,438	25,397
Additional paid-in capital	140,755,208	140,126,731

Accumulated other comprehensive income	483,544	584,317
Accumulated deficit	(137,367,403)	(132,525,858)
Total stockholders' equity	3,896,787	8,210,587
Total Liabilities and Stockholders' Equity	$12,711,124	$11,254,366

See accompanying notes to consolidated financial statements

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME/(LOSS)

	Six months ended June 30,		Three months ended June 30,	
	2016 (Unaudited)	2015 (Unaudited)	2016 (Unaudited)	2015 (Unaudited)
Revenue:				
Sales	$3,450,119	$1,476,770	$1,852,670	$773,112
Grant income	582,401	198,240	369,668	179,657
Other revenue	—	12,003	—	11,170
Total revenue	4,032,520	1,687,013	2,222,338	963,939
Cost of revenue	1,692,765	769,912	873,266	465,431
Gross profit	2,339,755	917,101	1,349,072	498,508
Other expenses:				
Research and development	1,948,192	1,752,684	1,092,070	801,656
Legal, financial and other consulting	573,735	513,431	319,184	297,913
Selling, general and administrative	4,595,293	3,141,565	2,625,189	1,626,398
Total expenses	7,117,220	5,407,680	4,036,443	2,725,967
Loss from operations	(4,777,465)	(4,490,579)	(2,687,371)	(2,227,459)
Other income/(expense):				
Interest income , net	5,488	5,652	1,582	3,039
Gain (loss) on foreign currency transactions	102,651	(386,603)	(128,941)	61,906
Change in warrant liability	(172,219)	1,588,906	(190,513)	3,596,832
Total other income (expense), net	(64,080)	1,207,955	(317,872)	3,661,777
Income (loss) before benefit from income taxes	(4,841,545)	(3,282,624)	(3,005,243)	1,434,318
Benefit from income taxes	—	—	—	—
Net income (loss) available to common shareholders	$(4,841,545)	$(3,282,624)	$(3,005,243)	$1,434,318
Net income (loss) per common share:				
Basic	$(0.19)	$(0.13)	$(0.12)	$0.06
Diluted	$(0.19)	$(0.13)	$(0.12)	$0.05
Weighted average number of shares of common stock outstanding:				
Basic	25,408,599	24,582,590	25,416,077	24,768,639
Diluted	25,408,599	24,582,590	25,416,077	28,826,158
Net income (loss)	$(4,841,545)	$(3,282,624)	$(3,005,243)	$1,434,318
Other comprehensive income (loss):				
Currency translation adjustment	(100,773)	267,818	144,723	(76,361)
Comprehensive income (loss)	$(4,942,318)	$(3,014,806)	$(2,860,520)	$1,357,957

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

Period from December 31, 2015 to June 30, 2016 (Unaudited):

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Par value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2015	25,397,056	$ 25,397	$ 140,126,731	$ 584,317	$ (132,525,858)	$ 8,210,587
Stock based compensation - employees, consultants and directors	—	—	474,709	—	—	474,709
Other comprehensive income/(loss): foreign translation adjustment	—	—	—	(100,773)	—	(100,773)
Issuance of restricted stock units	26,665	27	125,032	—	—	125,059
Cashless exercise of warrants	4,045	4	(4)	—	—	—
Proceeds from exercise of warrants	8,000	8	24,992	—	—	25,000
Proceeds from exercise of stock options	2,000	2	3,748	—	—	3,750
Net loss	—	—	—	—	(4,841,545)	(4,841,545)
Balance at June 30, 2016	25,437,766	$ 25,438	$ 140,755,208	$ 483,544	$ (137,367,403)	$ 3,896,787

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months ended June 30, 2016 (Unaudited)	Six months ended June 30, 2015 (Unaudited)
Cash flows from operating activities:		
Net loss	$(4,841,545)	$(3,282,624)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	69,423	44,428
Stock-based compensation	599,768	146,428
Change in warrant liability	172,219	(1,588,906)
Foreign currency transaction (gain)/loss	(102,651)	284,969
Changes in operating assets and liabilities:		
Grants and accounts receivable	(292,517)	284,278
Inventories	149,347	(496,208)
Prepaid expenses and other current assets	352,594	416,932
Other assets	(1,019)	(7,134)
Accounts payable and accrued expenses	710,819	(360,356)
Deferred revenue	—	(833)
Net cash used by operating activities	(3,183,562)	(4,559,026)
Cash flows from investing activities:		
Purchases of property and equipment	(98,330)	(192,554)
Patent costs	(212,409)	(45,402)
Proceeds from redemptions of short-term investments	1,943,000	2,442,547
Purchases of short-term investments	—	(3,686,000)
Net cash provided (used) by investing activities	1,632,261	(1,481,409)
Cash flows from financing activities:		
Equity contributions - net of fees incurred	—	9,408,584
Proceeds from long-term debt	5,000,000	—
Payment of debt acquisition costs	(118,833)	—
Proceeds from exercise of stock options	3,750	249,335
Proceeds from exercise of warrants	25,000	818,250
Net cash provided by financing activities	4,909,917	10,476,169
Effect of exchange rates on cash	(5,077)	(23,670)
Net change in cash and cash equivalents	3,353,539	4,412,064
Cash and cash equivalents - beginning of period	5,316,851	3,605,280

Cash and cash equivalents - end of period	$8,670,390	$8,017,344
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$1,139	$—
Supplemental schedule of noncash investing and financing activities:		
Costs paid from proceeds in conjunction with issuance of common stock	$—	$903,916

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation

Notes to Consolidated Financial Statements

(UNAUDITED)

June 30, 2016

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, 2015 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 9, 2016. The results for the three and six months ended June 30, 2016 and 2015 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.

As of June 30, 2016, the Company had an accumulated deficit of $137,367,403, which included net losses of $4,841,545 for the six months ended June 30, 2016 and $3,282,624 for the six months ended June 30, 2015. 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 is 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 previously received 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 the Company 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 leader in critical care immunotherapy commercializing its CytoSorb blood purification technology to reduce deadly uncontrolled inflammation in hospitalized patients around the world, 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 blood purification technology platform which incorporates a proprietary adsorbent, porous polymer technology. The Company, through its European Subsidiary, CytoSorbents Europe GmbH, conducts sales and marketing related operations for the CytoSorb device. In March 2016, the Company formed CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH. This subsidiary, which began operations during the second quarter of 2016, provides marketing and direct sales in Switzerland. CytoSorb**,** the Company's flagship product, is approved in the European Union, and is marketed and distributed in thirty-seven countries around the world as a safe and effective extracorporeal cytokine adsorber, 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 patent applications pending both in the United States and internationally, including HemoDefend, ContrastSorb, DrugSorb, and others. 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 approximately 1 to 10 years. The Company has patents expiring at various dates through 2026 that relate to the current technology. The patents expiring in the next twelve months relate to technology no longer utilized by the Company. Accordingly, management believes that any expiring patents will not have a significant impact on our ongoing business.

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. In addition, the financial statements include CytoSorbents Switzerland GmbH, a wholly owned subsidiary of 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 CytoSorbents Europe GmbH, for which the U.S. dollar is the functional currency, are included in operations. Foreign currency transaction gains/(loss) included in net loss amounted to $102,651 and $(386,603) for the six months ended June 30, 2016 and 2015, respectively. Foreign currency transaction (gain/loss) amounted to $(128,941) and $61,906 for the three months ended June 30, 2016 and 15, respectively. The Company translates assets and liabilities of the European subsidiaries, 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 daily average exchange rates. The Company includes accumulated net translation adjustments in accumulated other comprehensive income (loss) as a component of stockholder's equity.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Short-Term Investments

Short-term investments include certificates of deposit with original maturities of greater than three months. The cost of the certificates of deposit approximates fair value. The Company classifies these investments as held-to-maturity securities in accordance with the provisions of ASC-320-10.

Grants and Accounts Receivable

Grants receivable represent amounts due from U.S. government agencies and are included in Grants and Accounts Receivable.

Accounts receivable are unsecured, non-interest bearing customer obligations due under normal trade terms. The Company sells its devices to various hospitals and distributors. The Company performs ongoing credit evaluations of customers' financial condition. Management reviews accounts receivable periodically to determine collectability. Balances that are determined to be uncollectible are written off to the allowance for doubtful accounts. The allowance for doubtful accounts contains a general accrual for estimated bad debts and amounted to $6,556 and $3,275 at June 30, 2016 and December 31, 2015, respectively.

Inventories

Inventories are valued at the lower of cost or market. At June 30, 2016 and December 31, 2015, the Company's inventory was comprised of finished goods, which amounted to $262,117 and $382,099, respectively; work in process which amounted to $731,956 and $758,562, respectively; and raw materials, which amounted to $53,838 and $50,020, 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.

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 $125,000 and $117,000 for the six months ended June 30, 2016 and 2015, respectively, and approximately $45,000 and $66,000 for the three months ended June 30, 2016 and 2015, 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 June 30, 2016 or December 31, 2015. The Company files tax returns in the U.S. federal and state jurisdictions. The Company currently has no open years prior to December 31, 2012 and has no income tax related penalties or interest for the periods presented in these financial statements.

The Company utilizes the Technology Business Tax Certificate Transfer Program to sell a portion of its New Jersey Net Operating Loss carry forwards to an industrial company.

CytoSorbents Europe GmbH annually files a corporate tax return, VAT return and a trade tax return in Germany.

Use of Estimates

The preparation of financial statements in conformity with 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, 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 June 30, 2016, two distributors and one government agency accounted for approximately 43% of outstanding grant and accounts receivable. At December 31, 2015, three distributors accounted for approximately 48% of outstanding grant and accounts receivable. For the six months ended June 30, 2016, one direct customer accounted for approximately 11% of the Company’s total revenue. No other agency, distributor, or direct customer represented more than 10% of the Company’s revenue. For the six months ended June 30, 2015, approximately 12% of revenues were from one U.S. government grant agency. No other agency, distributor, or direct customer represented more than 10% of the Company’s revenue. For the three months ended June 30, 2016, one direct customer accounted for approximately 13% of the Company’s total revenue. No other agency, distributor, or direct customer represented more than 10% of the Company’s revenue. For the three months ended June 30, 2015, no 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 Income (Loss) Per Common Share

Basic earnings 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 common share is computed using the treasury stock method on the basis of the weighted-average number of shares of common stock plus the dilutive effect of potential common shares outstanding during the period. Dilutive potential common shares include outstanding warrants, stock options and restricted shares. 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 7).

Stock-Based Compensation

The Company accounts for its stock-based compensation under the recognition requirements of accounting standards for accounting for stock-based compensation, for employees and directors whereby each option granted is valued at fair market value on the date of grant. Under these accounting standards, the fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model. The Company values its performance based stock awards based on the market price of the Company’s common stock on the date of the award.

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 Financial Accounting Standards Board (FASB) issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40). ASU 2014-15 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. While the Company does not believe that the adoption of ASU 2014-15 will have a significant impact on its consolidated financial statements, it may impact the Company's footnote disclosures.

In May 2014, the FASB issued ASU 2014-09, "Revenue with Contracts from Customers." ASU 2014-09 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. In August 2014, the FASB issued ASU 2015-14 which deferred the effective date by one year. Accordingly, the updated guidance is effective for public entities for interim and annual periods beginning after December 15, 2017 and early adoption is permitted as of the beginning of an interim or annual reporting period beginning after December 31, 2016. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2014-09 will have a significant impact on its consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, "Interest-Imputation of Interest." ASU 2015-03 requires that debit issuances costs and debt discounts and premiums to be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability. The updated guidance is effective for the fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company has adopted the provisions of this ASU during the six months ended June 30, 2016.

In July 2015, the FASB issued ASU 2015-11, "Inventory: Simplifying the Measurement of Inventory." ASU 2015-11 clarifies current guidance regarding the valuation of inventory. ASU 2015-11 requires that inventory be measured at the lower of cost or net realizable value. This ASU does not apply to inventory that is measured using the last-in, first-out (LIFO) or the retail inventory method. The updated guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2015-11 will have a significant impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)". ASU 2016-02 outlines reporting requirements for Lessees to recognize a right-of-use asset and corresponding liability on the balance sheet for all leases covering a

period of greater than 12 months. The liability is to be measured as the present value of the future minimum lease payments, plus any initial direct costs. The minimum payments are discounted using the rate implicit in the lease, or, if not known, the lessee's incremental borrowing rate. The updated guidance is effective for public entities for fiscal years beginning after December 31, 2018. The Company is currently evaluating the impact of the updated guidance on the consolidated financial statements.

In March 2016, the FASB issued ASU 2016-08 "Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net)." The amendments in this Update affect the guidance in Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606), which is discussed above and is not yet effective. The effective date and transition requirements for the amendments in this Update are the same as the effective date and transition requirements of Update 2015-14, also discussed above. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2016-08 will have a significant impact on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, “Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”. The areas for simplification in this Update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The updated guidance is effective for public entities for fiscal years beginning after December 15, 2016. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2014-09 will have a significant impact on its consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10 “Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing.” The amendments in this Update affect entities with transactions included within the scope of Topic 606. The scope of that Topic includes entities that enter into contracts with customers to transfer goods or services (that are an output of the entity’s ordinary activities) in exchange for consideration. The effective date and transition requirements for the amendments in this Update are the same as the effective date and transition requirements of Update 2015-14, which is discussed above. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2016-10 will have a significant impact on its consolidated financial statements.

In May 2016, the FASB issued ASU 2016-12, “Revenue from Contracts with Customers (Topic 606), Narrow Scope Improvements and Practical Expedients.” The amendments in ASU 2016-12 affect only the narrow aspects of Topic 606 that are outlined in ASU 2016-12. The effective date and transition requirements for the amendments in this Update are the same as the effective date and transition requirements of Update 2015-14, which is discussed above. The Company is currently evaluating the impact of the updated guidance, but the Company does not believe that the adoption of ASU 2016-10 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 $71,000 and $67,000 for the six months ended June 30, 2016 and 2015, respectively, and approximately $37,000 and $26,000 for the three months ended June 30 2016 and 2015, respectively.

3. STOCKHOLDERS' EQUITY

Preferred Stock

In December 2014, the Company amended and restated its articles of incorporation to reduce the total number of authorized shares of preferred stock. The amended and restated 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.

Common Stock

Shelf Registration

On July 29, 2015, the Company’s registration statement on Form S-3, as filed with the SEC on July 23, 2015, was declared effective using a “shelf” registration process. Under this shelf registration statement, the Company may issue, in one or more offerings, any combination of common stock, preferred stock, senior or subordinated debt securities, warrants, or units, up to a total dollar amount of $100 million.

November 4, 2015 Controlled Equity Offering

On November 4, 2015, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald and Co., as agent ("Cantor"), pursuant to which the Company may offer to sell, from time to time through Cantor, shares of the Company's common stock, having an aggregate offering price of up to $25,000,000 (the "Shares") Any Shares offered and sold will be issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-205806), and the related prospectus previously declared effective by the Securities and Exchange Commission (the "SEC") on July 29, 2015 (the "Registration Statement"), as supplemented by a prospectus supplement, dated November 4, 2015, which the Company filed with the SEC pursuant to Rule 424(b)(5) under the Securities Act.

Under the Sales Agreement, Cantor may sell Shares by any method permitted by law and deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The NASDAQ Capital Market, on any existing trading market for the Common Stock or to or through a market maker. In addition, under the Sales Agreement, Cantor may sell the Shares by any other method permitted by law, including in privately negotiated transactions. The Company may instruct Cantor not to sell Shares if the sales cannot be effected at or above the price designated by the Company from time to time.

The Company is not obligated to make any sales of Shares under the Sales Agreement, and if it elects to make any sales, the Company can set a minimum sales price for the Shares. The offering of Shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all the shares subject to the Sales Agreement and (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. Since it was established on November 4, 2015 through June 30, 2016, the Company sold 28,880 shares at an average selling price of $8.02 per share, generating net proceeds of approximately $225,000 under the Sales Agreement. There were no sales during the six months ended June 30, 2016.

The Company pays a commission rate of 3.0% of the aggregate gross proceeds from each sale of Shares and has agreed to provide Cantor with customary indemnification and contribution rights. The Company has also reimbursed Cantor $50,000 for certain specified expenses in connection with entering into the Sales Agreement.

The Company intends to use the net proceeds raised through "at the market" sales for research and development activities, which include the funding of additional clinical studies and costs of obtaining regulatory approvals in countries not covered by the CE Mark, capital expenditures and other costs necessary to expand production capacity, support of various sales and marketing efforts, product development and general working capital purposes.

January 14, 2015 Public Offering

On January 14, 2015, the Company closed an underwritten public offering ("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. The net proceeds received by the Company from the Offering are being used to fund clinical studies, expand 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 SEC 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 ("Representatives"), who acted 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 ("Representatives' Warrants") that allow for the purchase of 30,000 shares of the Company's common stock. The Representative 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

Stock Options:

Total share-based employee, director, and consultant compensation for the six months and three months ended June 30, 2016 and 2015 amounted to approximately $475,000 and $146,000, and $368,000 and $83,000 respectively. These amounts are included in the statement of operations under the captions research and development ($92,000 and $34,000 for the six months ended June 30, 2016 and 2015, and $62,000 and $19,000 for the three months ended June 30, 2016 and 2015) and selling, general and administrative ($383,000 and $112,000 for the six months ended June 30, 2016 and 2015 and $306,000 and $64,000 for the three months ended June 30, 2016 and 2015).

The summary of the stock option activity for the six months ended June 30, 2016 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding, December 31, 2015	2,477,279	$ 6.56	6.2
Granted	1,031,219	$ 4.67	9.9
Forfeited	(500,150)	$ 8.04	8.8
Expired	(5,673)	$ 31.25	—
Exercised	(2,000)	$ 1.88	4.4
Outstanding, June 30, 2016	3,000,675	$ 5.62	6.6

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 $3.67 to $5.63 per share) and expected life of the stock option (10 years), the current price of the underlying stock and its expected volatility (ranging from 66.8% to 67.1%), expected dividends (-0-%) on the stock and the risk free interest rate (1.24% to 1.81%) for the term of the stock option.

The aggregate intrinsic value is calculated at the difference between the market value as of June 30, 2016 of $4.55 and the exercise price of the shares.

Options Outstanding

Range of Exercise Price	Number Outstanding at June 30, 2016	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$0.88 - $166.00	3,000,675	$ 5.62	6.6	$1,783,498

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Options Exercisable		
Number Exercisable at June 30, 2016	Weighted Average Exercise Price	Aggregate Intrinsic Value
1,839,808	$ 4.81	$1,740,445

The summary of the status of the Company's non-vested options for the six months ended June 30, 2016 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2016	794,708	$ 2.72
Granted	1,031,219	2.71
Forfeited	(499,650)	3.30
Vested	(165,410)	2.23
Non-vested, June 30, 2016	1,160,867	$ 2.52

As of June 30, 2016, the Company had approximately $513,000 of total unrecognized compensation cost related to stock options, which will be amortized over 0.76 years. In April 2015, the Board of Directors granted options to purchase 566,000 shares of common stock to the Company's employees which options would only vest upon achievement of certain specific, predetermined milestones related to 2015 operating performance. The grant date fair value of these unvested options amounted to approximately $1,388,000. On June 7, 2016, based upon the finalization of its review of the Company's progress to meeting the predetermined milestones, the Board of Directors determined that 72,400 of these options would immediately vest. Accordingly, a $241,000 charge related to these options has been recorded in the consolidated statements of operations for the six and three month periods ended June 30, 2016.

In addition, on June 7, 2016, the Board of Directors granted options to purchase 900,100 shares of common stock to the Company's employees which will vest upon the achievement of certain specific, predetermined milestones related to the Company's 2016 operations. The grant date fair value of these unvested options amounted to approximately $2,437,000. Due to 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 six and three month periods ended June 30, 2016.

In April 2015, the Board of Directors also granted 960,000 restricted stock units, valued at $7,747,200, to Company employees and 240,000 restricted stock units, valued at $1,936,000, to the members of the Board of Directors, which

will only vest upon a Change in Control of the Company, as defined in the Company's 2014 Long-Term Incentive Plan (a "Change in Control"). Of these restricted stock units granted to Company employees in April 2015, 75,000 have been forfeited. In June 2016, the Board of Directors granted an additional 414,000 restricted stock units to Company employees, valued at $1,941,660 at the time of issuance, which will only vest upon a Change in Control, bringing the total amount of restricted stock units outstanding to 1,539,000. Due to the uncertainty over whether these restricted stock units will vest, which only happens upon a Change in Control, no charge for these restricted stock units has been recorded in the consolidated statement of operations for the six months and three months ended June 30, 2016.

Performance Based Stock Awards:

Pursuant to a review of the compensation of the senior management of the Company, on June 7, 2016, the Board of Directors granted 80,000 restricted stock units to certain senior managers of the Company. These awards were valued at $375,200 at the date of issuance, based upon the market price of the Company's common stock at the date of the grant, and vest one third on the date of the grant, one third on the first anniversary of the date of the grant, and one third on the second anniversary of the date of the grant. These awards are charged to expense at their fair value on each vesting date. For the six and three months ended June 30, 2016, the Company recorded a charge of approximately $125,000 related to the vested portion of these restricted stock unit awards. The following table outlines the restricted stock unit activity for the six months ended June 30, 2016:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2016	—	$ —
Granted	80,000	4.69
Vested	(26,665)	4.69
Non-vested, June 30, 2016	53,335	$ 4.69

Warrants:

As of June 30, 2016, 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
9,605	$ 31.250	October 24, 2016
40,001	$ 4.375	February 10, 2017
117,600	$ 3.750	June 21, 2018
118,000	$ 3.125	September 30, 2018
48,960	$ 7.500	March 11, 2019
736,000	$ 7.8125	March 11, 2019
30,000	$ 9.900	January 14, 2020
1,100,166		

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 June 30, 2016 and 2015, the closing price per share of common stock was $4.55 and $6.80, respectively. Due to the fluctuations in the market value of the Company's common stock from December 31, 2015 through June 30, 2016, the Company recorded an increase in the fair value of the warrant liability of $172,219 during the six months ended June 30, 2016. Due to fluctuations in the market value of the Company's common stock from March 31, 2016 to June 30, 2016, the Company recorded an increase in the fair market value of the warrant liability of $190,513 during the three months ended June 30, 2016. Due to the fluctuations in the market value of the Company's common stock from December 31, 2014 through June 30, 2015, the Company recorded a decrease in the fair value of the warrant liability of $1,588,906 during the six months ended June 30, 2015. Due to fluctuations in the market value of the Company's common stock from March 31, 2015 to June 30, 2015, the Company recorded a decrease in the fair market value of the warrant liability of $3,596,832 during the three months ended June 30, 2015.

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

	June 30, 2016	June 30, 2015
Number of shares underlying the warrants	736,000	736,000
Exercise price	$7.81	$7.81
Volatility	72.80 %	41.30 %
Risk-free interest rate	0.67 %	1.23 %
Expected dividend yield	0	0
Expected warrant life (years)	2.70	3.70
Stock Price	$4.55	$6.80

5. LONG-TERM DEBT, NET

Loan and Security Agreement:

On June 30, 2016 (the ”Closing Date”), the Company and its wholly-owned subsidiary CytoSorbents Medical, Inc. (together, the “Borrower”), entered into a Loan and Security Agreement (the “Loan and Security Agreement”) with Bridge Bank, a division of Western Alliance Bank, (the “Bank”), pursuant to which the Bank agreed to loan up to an aggregate of $10 million to the Company, to be disbursed in two equal tranches of $5 million (the first tranche, the “Term A Loan”, the second tranche, the “Term B Loan”, and the Term A Loan and Term B Loan together, the “Term Loans”). The Company received the proceeds of the Term A Loan on June 30, 2016. The proceeds from the Term Loans will be used for working capital purposes and to fund general business requirements in accordance with the terms of the Loan and Security Agreement. Outstanding balances on the Term Loans bear interest at the thirty (30) day US dollar LIBOR rate reported in the Wall Street Journal plus 7.75%, adjusted monthly. This rate was 8.1993% at June 30, 2016.

On the Closing Date, the Company was required to pay a non-refundable closing fee of $50,000 and expenses incurred by the Bank related to the Loan and Security Agreement of $24,000. In addition, the Company incurred legal expenses related to the Loan and Security Agreement of $44,833. These costs, which total $118,833, have been presented as a direct deduction from the proceeds of the loan on the consolidated balance sheet in accordance with the provisions of ASC 850. In addition, after accounting for the various costs outlined above, the effective interest rate on the Term A Loan was 10.0% as of June 30, 2016. Commencing on the first calendar day of the calendar month after a Term Loan is made, the Company shall make monthly payments of interest only during the term of each Term Loan. Commencing on August 1, 2017, if the Term B Loan is not made, the Company shall make equal monthly payments of principal of $138,889, together with accrued and unpaid interest. Commencing on February 1, 2018, subject to certain conditions as outlined in the Loan and Security Agreement, if the Term B Loan is made, which is at the

Company’s discretion, the Company shall make equal monthly payments of principal of $333,333, together with accrued and unpaid interest. In either event, all unpaid principal and accrued and unpaid interest shall be due and payable in full on July 1, 2020. In addition, the Loan and Security Agreement requires the Company to pay a non-refundable final fee equal to 2.5% of the principal amount of each Term Loan funded upon the earlier of the (i) July 1, 2020 maturity date or (ii) termination of the Term Loan via acceleration or prepayment. The Term Loans shall be evidenced by one or more secured promissory notes issued to the Bank by the Company. If the Company elects to prepay the Term Loan(s) pursuant to the terms of the Loan and Security Agreement, it will owe a prepayment fee to the Bank, as follows: (1) for a prepayment made on or after the funding date of a Term Loan through and including the first anniversary of such funding date, an amount equal to 2.0% of the principal amount of such Term Loan prepaid; (2) for a prepayment made after the first anniversary of the funding date of a Term Loan through and including the second anniversary of such funding date, an amount equal to 1.5% of the principal amount of such Term Loan prepaid; and (3) for a prepayment made after the second anniversary of the funding date of a Term Loan through June 30, 2020, an amount equal to 1.0% of the principal amount of such Term Loan prepaid.

Events of default which may cause repayment of the Term Loans to be accelerated include, among other customary events of default, (1) non-payment of any obligation when due, (2) the failure to perform any obligation required under the Loan and Security Agreement and to cure such default within a reasonable time frame, (3) the occurrence of a Material Adverse Event (as defined in the Loan and Security Agreement), (4) the attachment or seizure of a material portion of the Borrower's assets if such attachment or seizure is not released, discharged or rescinded within 10 days, and (5) if the Borrower becomes insolvent or starts an insolvency proceeding or if an insolvency proceeding is brought by a third party against the Borrower and such proceeding is not dismissed or stayed within 30 days. The Loan and Security Agreement includes customary loan conditions, Borrower representations and warranties, Borrower affirmative covenants and Borrower negative covenants for secured transactions of this type.

The Company's and CytoSorbents Medical, Inc.'s obligations under the Loan and Security Agreement are joint and severable. The obligations under the Loan and Security Agreement are secured by a first priority security interest in favor of the Bank with respect to the Company's Shares and the Borrower's Collateral, which definition excludes the Borrower's intellectual property and other customary exceptions.

Success Fee Letter:

In connection with the Loan and Security Agreement, the Borrower simultaneously entered into a Success Fee Letter (the "Letter") with the Bank. Pursuant to the Letter, the Borrower shall pay to the Bank a success fee in the amount equal to 6.37% of the funded amount of the Term Loans (the "Success Fee") upon the first occurrence of any of the following events (each a "Liquidity Event"): (a) a sale or other disposition by the Borrower of all or substantially all of its assets; (b) a merger or consolidation of the Borrower into or with another person or entity, where the holders of the Borrower's outstanding voting equity securities as of immediately prior to such merger or consolidation hold less than a majority of the issued and outstanding voting equity securities of the successor or surviving person or entity as of immediately following the consummation of such merger or consolidation; (c) a transaction or a series of related transactions in which any "person" or "group" (within the meaning of Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of a sufficient number of shares of all classes of stock then outstanding of the Borrower ordinarily entitled to vote in the election of directors, empowering such "person" or "group" to elect a majority of the Board of Directors of the Borrower, who did not have such power before such transaction; or (d) the closing price per share for the Company's common stock on the NASDAQ Capital Market being $8.00 (after giving effect to any stock splits or consolidations effected after the date hereof) or more for five successive business days.

If the Success Fee is due pursuant to a Liquidity Event described in clause (d) of the definition thereof, the Company may elect, in lieu of paying the Success Fee in cash, to issue and sell to the Bank, in exchange for the Success Fee, such number of shares of the Company's common stock as would be equal to the quotient (calculated by rounding up the nearest whole number) obtained by dividing (a) the Success Fee by (b) the volume weighted average price per share of the Company's common stock for the same five successive business days on which the closing price per share

of the Company's common stock caused the Success Fee to become payable. The Bank's right to receive the Success Fee and the Borrower's obligation to pay such Success Fee terminate on June 30, 2021, and shall survive the termination of the Loan and Security Agreement and any prepayment of the Term Loans.

Long-term debt consists of the following at June 30, 2016:

Principal amount	$5,000,000
Less debt acquisition costs	118,833
Long-term debt, net	$4,881,167

Principal payments of long-term debt are due as follows at June 30, 2016;

2017	$—
2018	1,666,667
2019	1,666,667
2020	1,666,666
Total	$5,000,000

6. COMMITMENTS AND CONTINGENCIES

Employment Agreements

On July 14, 2015, CytoSorbents Corporation entered into executive employment agreements with its principal executives, Dr. Phillip P. Chan, President and Chief Executive Officer, Vincent Capponi, Chief Operating Officer, and Kathleen P. Bloch, Chief Financial Officer. Each of these agreements has an initial term of three years, and became retroactively effective as of January 1, 2015. These agreements provide for base salary and other customary benefits which include participation in group insurance plans, paid time off and reimbursement of certain business related expenses, including travel and continuing educational expenses, as well as bonus and/or equity awards at the discretion of the Board of Directors. In addition, the agreements provide for certain termination benefits in the event of termination without Cause or voluntary termination of employment for “Good Reason”, as defined in each agreement. The agreements also provide for certain benefits in the event of a Change in Control of the Company, as defined in each agreement.

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 six months ended June 30, 2016 and 2015, the Company has recorded royalty costs of approximately $102,000 and $43,000, respectfully. For the three months ended June 30, 2016 and 2015, the Company has recorded royalty costs of approximately $55,000 and $22,000, respectively.

License Agreements

In August 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, which expires on August 7, 2024. 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 for a term not greater than 18 years. For the six months ended June 30, 2016 and 2015, per the terms of the license agreement, the Company has recorded royalty costs of approximately $136,000 and $57,000, respectfully. For the three months ended June 30, 2016 and 2015, the Company has recorded royalty costs of approximately $73,000 and $29,000, respectively.

7. NET INCOME (LOSS) PER SHARE

Basic loss per share and diluted loss per share for the six months ended June 30, 2016 and 2015 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 4,100,841 and 4,058,000 incremental shares at June 30, 2016 and 2015 have been excluded from the computation of diluted loss per share for the six months ended June 30, 2016 and 2015 and three months ended June 30, 2016, as they are anti-dilutive. For the three months ended June 30, 2015, outstanding warrants and options representing approximately 4,058,000 shares have been included in the calculation of diluted earnings per share.

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

Cautionary Notes Regarding Forward Looking Statements

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," "continue" and 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.

Overview

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, 2015, as filed with the SEC on March 9, 2016.

We are a leader in critical care immunotherapy commercializing our CytoSorb blood purification technology to reduce deadly uncontrolled inflammation in hospitalized patients around the world, 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 U.S. 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 approximately one to 10 years. The Company has patents expiring at various dates to 2026 that relate to the current technology. The patents

expiring in the next twelve months relate to technology no longer utilized by the Company. Accordingly, management believes that any expiring patents will not have a significant impact on our ongoing business.

In March 2011, our flagship product, CytoSorb, an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated, received CE mark approval. The CE Mark demonstrates that a conformity assessment has been carried out and the product complies with the Medical Devices Directive 93/42/EEC in the EU. 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 and the countries in the European Economic Area. 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, cytokine release syndrome, 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 14 trial sites in Germany in 2011, with enrollment of 100 patients with sepsis and respiratory failure. The trial established that CytoSorb was safe in this critically-ill population, and that it was able to broadly reduce key cytokines in the blood of these patients. 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. We manufacture CytoSorb at our manufacturing facilities in New Jersey for sale in the EU and for additional clinical studies. We 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 joined us and completed their sales training in the third quarter of 2012. The fourth quarter of 2012 represented the first full quarter of direct sales with the four-person sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland. At the end of 2015, we had hundreds of Key Opinion Leaders (KOLs) in our commercialized territories worldwide in critical care, cardiac surgery, and blood purification who were either using CytoSorb or supporting its use in clinical practice or clinical trials.

In March 2016, we established CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH, to conduct marketing and direct sales in Switzerland. This subsidiary began operations during the second quarter of 2016.

As of August 1, 2016, our sales force includes 12 direct sales people, one contract sales person and 12 sales support staff.

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 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 (GCC)) and Yemen, Iraq, and Jordan through an exclusive agreement with Techno Orbits, 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 2015, we announced exclusive distribution agreements with Aferetica SRL to distribute CytoSorb in Italy, AlphaMedix Ltd. to distribute CytoSorb in Israel, TekMed Pty Ltd. to distribute CytoSorb in Australia and New Zealand, and Hoang Long Pharma to distribute CytoSorb in Vietnam. In June 2016, we announced an exclusive distribution agreement with Palex Medical SA to distribute CytoSorb in Spain and Portugal.

We have been working to expand the number and scope of our strategic partnerships. In September 2013, we entered into a strategic partnership with Biocon, Ltd., India’s largest biotech company, with an initial distribution agreement for India and select emerging markets, under which Biocon has 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. Following a positive evaluation of the device during the term of the agreement, we are now in discussions with multiple potential cardiac surgery partners for distribution rights to CytoSorb in the field of cardiac surgery.

In December 2014, we entered into a multi-country strategic partnership with Fresenius Medical Care AG & CO KGaA 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 future larger, clinical collaborations.

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 expend the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. We have completed a single arm, dose ranging trial in Germany amongst several clinical trial sites to evaluate the safety and efficacy of CytoSorb when used 24 hours per day for seven days, each day with a new device, and are conducting final statistical analysis of the data. Patients are being stratified for age, cytokine levels, and co-morbid illnesses in this matched pairs analysis.

In addition, we now have more than 55 investigator-initiated studies in various stages, with 16 in an advanced stage, eight ready to enroll, and four completed around the world. These trials, which are funded and supported by well-known university hospitals and KOLs, are designated to evaluate the safety and efficacy of CytoSorb in a variety of different clinical applications, such as the treatment of sepsis, cardiac surgery, trauma, and many other indications, and if successful, are anticipated to be integral in helping to drive additional usage and adoption of CytoSorb.

In February 2015, the FDA approved our Investigational Device Exemption (IDE) application to commence a planned U.S. cardiac surgery feasibility study called REFRESH I (REduction of FREe plaSma Hemoglobin) amongst 20 patients and three U.S. clinical sites. The FDA subsequently approved an amendment to the protocol, expanding the trial to be a 40 patient randomized controlled study (20 treatment, 20 control) in eight clinical centers. REFRESH I represents the first part of a larger clinical trial strategy intended to support the approval of CytoSorb in the U.S. 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. As of August 1, 2016, the trial has enrolled 44 patients with a target of 40 patients who have completed all aspects of the study.

The market focus of CytoSorb is 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 (ARDS), and others. Severe sepsis and septic shock, a potentially life-threatening systemic inflammatory response to a serious infection, accounts for approximately 10% to 20% of all ICU admissions and is one of the largest target markets for CytoSorb. Sepsis is a major unmet medical need with no approved products in the U.S. or Europe to treat it. As with other critical care illnesses, multiple organ failure is the primary cause of death in sepsis. When used with standard of care therapy, that includes antibiotics, the goal of CytoSorb in sepsis is to reduce the excessive levels of cytokines and other inflammatory toxins, to help reduce the systemic inflammatory response syndrome (SIRS) response and either prevent or treat organ failure.

We intend to conduct or support additional clinical studies in sepsis, cardiac surgery, and other critical care diseases where CytoSorb could be used, such as ARDS, trauma, sever burn injury, acute pancreatitis, and other acute conditions that may benefit by the reductions of cytokines in the bloodstream. Some examples include the prevention of post-operative complications of cardiac surgery (cardiopulmonary bypass surgery) and damage to organs for transplant prior to organ harvest. We intend 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.

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. The goal of HemoDefend is to reduce transfusion reactions and improve the safety of transfused blood products.

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

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

- BetaSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove mid-molecular weight toxins, such as b 2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal of BetaSorb is to improve 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 Defense Advanced Research Projects Agency (DARPA), the U.S. Army, and the U.S. Air Force.

In July 2016, we were awarded a Phase I Small Business Innovation Research (SBIR) contract for its development program entitled “Investigation of a sorbent-based potassium adsorber for the treatment of hyperkalemia induced by traumatic injury and acute kidney injury in austere conditions”. The objective of this Phase I project is to develop two novel and distinct treatment options for life-threatening hyperkalemia, both employing the peritoneal cavity fluid. This

work is being funded by the U.S. Army Medical Research Acquisition Activity (USAMRAA) under contract W81XWH-16-C-0080 and provides for maximum funding of approximately $150,000.

In June 2016, we were awarded a Phase I Small Business Technology Transfer (STTR) contract for its development program entitled “Use of Highly Porous Polymer Beads to Remove Anti-A and Anti-B antibodies from Plasma for Transfusion”. The purpose of this contract is to develop our HemoDefend blood purification technology to potentially enable universal plasma. This work is being funded by the USAMRAA under contract W81XWH-16-C-0025 and provides for maximum funding of $150,000. As of June 30, 2016, we received approximately $50,000 and have approximately $100,000 remaining under this contract.

In March 2016, we were awarded a Phase I SBIR, contract for its development program entitled “Mycotoxin Absorption with Hemocompatible Porous Polymer Beads.” The purpose of this contract is to develop effective blood purification countermeasures for weaponized mycotoxins that can be easily disseminated in water, food and air. This work is being funded by the U.S. Joint Program Executive Office for Chemical and Biological Defense, or JPEO-CBD, under contract number W911QY-16-P-0048 and provides for maximum funding of $150,000. As of June 30, 2016, we received approximately $100,000 and have approximately $50,000 remaining under this contract.

In October 2015, we were awarded a Phase II SBIR contract by the National Heart, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health, to help advance our HemoDefend blood purification technology towards commercialization for the purification of packed red blood cell(pRBC) transfusions. The contract, entitled “pRBCs Contaminant Removal with Porous Polymer Beads” (contract number HHSN-268201-600006C), provides for maximum funding of approximately $1,520,000 over a two year period. As of June 30, 2016, we have received approximately $227,000 and have approximately $1,293,000 remaining under this contract.

In September 2013, the NHLBI awarded us a Phase I SBIR contract (contract number HHSN-268201-300044C), valued at $203,351, to further advance our HemoDefend blood purification technology for 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.

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 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.

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 $803,000 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. In July 2016, this contract was further amended to increase the maximum funding by $443,000 to approximately $1,246,000. As of June 30, 2016, we received approximately $803,000 in funding under this contract and have approximately $443,000 remaining under this contract.

In August 2012, we were awarded a $3.8 million, five-year contract by DARPA for our “Dialysis-Like Therapeutics” (DLT), 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, development of 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 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 5 of the program and are currently working with the systems integrator, Battelle Laboratories, and its subcontractor NxStage Medical, who are responsible for integrating the technology developed by

us and others into a final medical device design prototype, and evaluating this device in septic animals and eventually in human clinical trials in sepsis. Our work is supported by DARPA and SSC Pacific under Contract No. N66001-12-C-4199. In June 2016, this contract was amended to change the maximum funding to approximately $3,825,000. As of June 30, 2016, we have received approximately $3,696,000 in funding under this contract and have approximately $129,000 remaining under this contract.

Results of Operations

Comparison for the six months ended June 30, 2016 and 2015:

Revenues:

Revenue from product sales was approximately $3,450,000 in the six months ended June 30, 2016, as compared to approximately $1,477,000 in the six months ended June 30, 2015, an increase of approximately $1,973,000, or 134%. This increase was largely driven by an increase in direct sales from both new customers and repeat orders from existing customers, along with an increase in distributor sales.

Grant income was approximately $582,000 for the six months ended June 30, 2016, as compared to approximately $198,000 for the six months ended June 30, 2015, an increase of approximately $384,000, or 194%. This increase was a result of revenue recognized from new grants and billable milestones achieved on existing grants.

As a result of the increases in both product sales and grant income, for the six months ended June 30, 2016, we generated total revenue of approximately $4,033,000, as compared to total revenue of approximately $1,687,000, for the six months ended June 30, 2015, an increase of approximately $2,346,000, or 139%.

Cost of Revenues:

For the six months ended June 30, 2016 and 2015, cost of revenue was approximately $1,693,000 and $770,000, respectively, an increase of approximately $923,000. Product cost of revenues increased approximately $634,000 during the six months ended June 30, 2016 as compared to the six months ended June 30, 2015 due to increased sales. Product gross margins were approximately 65% for the six months ended June 30, 2016, as compared to approximately 61% for the six months ended June 30, 2015 due to a favorable mix of sales prices. Grant income related expenses increased due to direct labor and other costs being deployed toward grant-funded activities, an increase of approximately $289,000 during the six months ended June 30, 2016 as compared to the six months ended June 30, 2015.

Research and Development Expenses*:*

For the six months ended June 30, 2016, research and development expenses were approximately $1,948,000, as compared to research and development expenses of approximately $1,753,000 for the six months ended June 30, 2015, an increase of approximately $195,000. This increase was due to an increase in costs related to the various clinical studies of approximately $504,000. The increase was offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately $289,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs, and decreases in other research and development costs of approximately $20,000.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately $574,000 for the six months ended June 30, 2016, as compared to approximately $513,000 for the six months ended June 30, 2015. The increase of approximately $61,000 was due to an increase in accounting and auditing fees of approximately $61,000 due to fees incurred related to the audit of our internal controls as required by The Sarbanes-Oxley Act of 2002 and increases in legal fees of approximately $26,000 and consulting fees of approximately $25,000. These increases were offset by a decrease in employment agency fees of approximately $51,000 related to fees incurred in 2015 related to the hiring of senior level personnel that did not recur in 2016.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately $4,595,000 for the six months ended June 30, 2016, as compared to approximately $3,142,000 for the six months ending June 30, 2015, an increase of $1,453,000. The increase in selling, general, and administrative expenses was due to an increase in salaries, commissions and related costs of approximately $747,000 due to headcount additions and increases in product sales, an increase in royalty expenses of approximately $138,000 due to the increase in sales, additional sales and marketing costs, which include advertising, and conferences of approximately $129,000 and an increase in travel and entertainment costs and other expenses of approximately $43,000 due to the increased volume and an increase in stock-based compensation of approximately $396,000 due to 2015 milestone options awarded to the Company’s employees and restricted stock units awarded to the Company’s executive staff during the six months ended June 30, 2016.

Gain (Loss) on Foreign Currency Transactions:

For the six months ended June 30, 2016, the gain on foreign currency transactions was approximately $103,000, as compared to a loss of approximately $387,000 for the six months ended June 30, 2015. The 2016 gain is directly related to the increase in the exchange rate of the Euro at June 30, 2016, as compared to December 31, 2015. The exchange rate of the Euro to the U.S. dollar was $1.12 per Euro at June 30, 2016 as compared to $1.08 per Euro at December 31, 2015. The 2015 loss is directly related to the decrease in the exchange rate of the Euro at June 30, 2015, as compared to December 31, 2014. The exchange rate of the Euro to the U.S. dollar was $1.11 per Euro at June 30, 2015 as compared to $1.22 per Euro at December 31, 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 record a change to the warrant liability as appropriate. The change in warrant liability resulted in other expense of approximately $172,000 for the six months ended June 30, 2016, and other income of approximately $1,589,000 for the six months ended June 30, 2015. The change in warrant liability was a result of the change in the fair value of the warrant liability from December 31, 2015 to June 30, 2016 and from December 31, 2014 to June 30, 2015. See Note 4 to the consolidated financial statements for details related to the calculation of the fair value of the warrant liability.

Comparison for the three months ended June 30, 2016 and 2015:

Revenues:

Revenue from product sales was approximately $1,853,000 in the three months ended June 30, 2016, as compared to approximately $773,000 in the three months ended June 30, 2015, an increase of approximately $1,080,000, or 140%. This increase was largely driven by an increase in direct sales from both new customers and repeat orders from existing customers, along with an increase in distributor sales.

Grant income was approximately $370,000 for the three months ended June 30, 2016 as compared to approximately $180,000 for the three months ended June 30, 2015, an increase of approximately $190,000, or 106%. This increase was a result of revenue recognized from new grants.

As a result of the increases in both product sales and grant income, for the three months ended June 30, 2016, we generated total revenue of approximately $2,222,000, as compared to total revenue of approximately $964,000 for the three months ended June 30, 2015, an increase of approximately $1,258,000, or 130%.

Cost of Revenues:

For the three months ended June 30, 2016 and 2015, cost of revenue was approximately $873,000 and $465,000, respectively, an increase of approximately $408,000. Product cost of revenues increased approximately $313,000 during the three months ended June 30, 2016 as compared to the three months ended June 30, 2015 due to increased sales. Product gross margins increased to approximately 68% for the three months ended June 30, 2016, as compared to approximately 63% for the three months ended June 30, 2015 due to a favorable mix of sales prices. Grant income related expenses increased due to direct labor and other costs being deployed toward grant-funded activities, an increase of approximately $95,000 during the three months ended June 30, 2016 as compared to the three months ended June 30, 2015.

***Research and Development Expenses**:*

For the three months ended June 30, 2016, research and development expenses were approximately $1,092,000, as compared to research and development expenses of approximately $802,000 for the three months ended June 30, 2015, an increase of approximately $290,000. This increase was due to an increase in costs related to the various clinical studies of approximately $353,000, and increases in salaries and other research and development costs of approximately $32,000. The increase was offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately $95,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately $319,000 for the three months ended June 30, 2016, as compared to approximately $298,000 for the three months ended June 30, 2015, an increase of approximately $21,000. This increase was due to an increase in accounting fees of approximately $13,000 due to fees incurred related to the audit of our internal controls as required by the Sarbanes-Oxley Act of 2002 and an increase in legal and other consulting fees of approximately $8,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately $2,625,000 for the three months ended June 30, 2016, as compared to approximately $1,626,000 for the three months ending June 30, 2015, an increase of approximately $999,000. This increase was due to an increase in salaries, commissions and related costs of approximately $506,000 due to headcount additions and increases in product sales, an increase in royalty expenses of approximately $77,000 due to the increase in sales, additional sales and marketing costs, which include advertising and conferences of approximately $43,000, and an increase in travel and entertainment costs and other expenses of approximately $29,000 due to the increased volume and an increase in stock-based compensation of approximately $366,000 due to 2015 milestone options awarded to the Company’s employees and restricted stock units awarded to the Company’s executive staff during the three months ended June 30, 2016. These increases were offset by a decrease in stock exchange listing and transfer fees of approximately $13,000 as a result of fees incurred related to our public offering in 2015 that did not recur in 2016 and decreases in other general and administrative costs of approximately $9,000.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended June 30, 2016, the loss on foreign currency transactions was approximately $129,000, as compared to a gain of approximately $62,000 for the three months ended June 30, 2015. The loss for the three months ended June 30, 2016 is directly related to the decrease in the exchange rate of the Euro at June 30, 2016 as compared to March 31, 2016. The exchange rate of the Euro to the U.S. dollar was $1.12 per Euro at June 30, 2016 as compared to $1.14 per Euro at March 31, 2016. The gain for the three months ended June 30, 2015 is directly related to the increase in the exchange rate of the Euro at June 30, 2015 as compared to March 31, 2015. The exchange rate of the Euro to the U.S. dollar was $1.11 per Euro at June 30, 2015 as compared to $1.08 per Euro at March 31, 2015.

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 record a change to the warrant liability as appropriate. The change in warrant liability resulted in other expense of approximately $191,000 for the three months ended June 30, 2016, and other income of approximately $3,597,000 for the three months ended June 30, 2015. The change in warrant liability was a result of the change in the fair value of the warrant liability from March 31, 2016 to June 30, 2016 and from March 31, 2015 to June 30, 2015. 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 June 30, 2016, we had an accumulated deficit of approximately $137,367,000 which included losses of approximately $4,842,000 and $3,283,000 for the six month periods ended June 30, 2016 and 2015, 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 debt and equity securities. At June 30, 2016, we had current assets of approximately $11,074,000 including cash on hand and short-term investments of approximately $8,919,000, and current liabilities of approximately $3,933,000. We believe we have sufficient cash to fund our operations for the next twelve months; 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.

Contractual Obligations

The Company entered into an amended and restated Fourteenth Amendment to Lease Agreement with Princeton Corporate Plaza, LLC (the Landlord), which extends the term of the Company's lease for its corporate headquarters and manufacturing facility through May 31, 2018 and, effective August 1, 2016, increases the Company's space to approximately 12,900 square feet and the Company's rent obligation to $24,756 per month. In return, the Landlord has agreed to make certain improvements to the property. The lease amendment also provides the Company with an option to extend the term of the lease for an additional one year period through May 31, 2019 upon certain conditions.

The following table summarizes our obligations with regard to our contractual obligations as of June 30, 2016, and the expected timing of maturities of those contractual obligations.

	Less than 1 Year	1-3 Years	3-5 Years	Over 5 Years
Operating Lease Obligations	$ 294,350	$272,316	$–	–
Long-term debt	–	3,333,334	1,666,666	–

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 do not believe that we have adequate funding for more than the next 12 months of operations. We will have to raise additional capital to fund our future operations.

As of June 30, 2016, we had an accumulated deficit of approximately $137,347,000, which included net losses of approximately $4,842,000 for the six months ended June 30, 2016, and $3,283,000 for the six months ended June 30, 2015. 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.

We are exposed to certain market risks in the ordinary course of business. These risks result primarily from changes in foreign currency exchange rates and interest rates. In addition, international operations are subject to risks related to differing economic conditions, changes in political climate, differing tax structures and other regulations and restrictions.

To date we have not utilized derivative financial instruments or derivative commodity instruments. We do not expect to employ these or other strategies to hedge market risk in the foreseeable future. Cash is held in checking, savings, and money market funds, which are subject to minimal credit and market risk. We divide sales among both dollars and euros. In addition, should sales decline due to foreign currency changes, expenses related to our European subsidiary would also decline. Both of these produce a natural currency hedge. We believe that the market risks associated with these financial instruments are immaterial, although there can be no guarantee that these market risks will be immaterial to us.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures designed to ensure information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

No change in our internal control over financial reporting occurred during the three months ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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 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 June 30, 2016, we had an accumulated deficit of approximately $137,367,000, which included net losses of approximately $4,842,000 for the six months ended June 30, 2016 and $3,283,000 for the six months ended June 30, 2015. 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 obtaining additional requisite regulatory approvals in markets not covered by the CE Mark, establishing 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, that we will be able to achieve profitability or that profitability, if achieved, can be sustained, or our ability to raise additional capital when needed or on terms acceptable to us. Our failure with respect to any or all of the matters would have a material adverse effect on our business, operating results, financial condition and prospects.

We will require additional capital in the future to fund our operations.

As of June 30, 2016, we had current assets of approximately $11,074,000, including cash on hand of approximately $8,670,000, short-term investments of approximately $249,000, and current liabilities of approximately $3,933,000. For the six months ended June 30, 2016, our cash burn was approximately $3.9 million. Our current and historical cash burn is not necessarily indicative of our future use of cash and cash equivalents.

We will 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.

We have a $100 million shelf registration in effect with the SEC which enables us to raise up to $100 million in equity financing. We entered into a Controlled Equity Offering[SM] Sales Agreement with Cantor Fitzgerald & Co. in November 2015 for the offer and sale of up to an aggregate of $25,000,000 of shares of our common stock. In addition, we entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank, to provide up to an aggregate of $10,000,000 to the Company. We expect we will require additional financing, and should the financing we require be unavailable or on terms unacceptable to us 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.

Although historically we have been a research and development company, we are in the process of commercializing our products. There can be no assurance that we will be successful in developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.

We have historically been engaged primarily in research and development activities and have generated limited revenues to date. With the launch of our CytoSorb product in the EU and abroad, there can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an enterprise in balancing development, which include unanticipated problems relating to testing, product registration, regulatory compliance and manufacturing, with commercialization, which includes problems with market adoption, reimbursement, marketing problems and additional costs. Our products and product candidates 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 U.S., 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 our CE Mark. In addition, we may be required to spend significant funds on building out our commercial operations. 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 depend upon key personnel who may terminate their employment with us at any time.

As of August 1, 2016 we currently have 64 full-time employees and several temporary employees. Our success will depend to a significant degree upon the continued services of our key management team 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. Although these individuals have long-term employment and consulting agreements, there can be no assurance that key management personnel 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 products. Even with CE Mark approval for our CytoSorb device as a cytokine filter, our products and product candidates may not achieve market acceptance in the countries that recognize and accept the CE Mark. Additional approvals from other regulatory authorities (such as the 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 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 effectively 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.

If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and product candidates similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products and product candidates that are important to our business. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we apply for in the future with respect to one or more of our products and product candidates, or that issued or granted patents will not later be found to be invalid and/or unenforceable.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our products or product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Changes in the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions.

We cannot be certain that our patents and patent rights will be effective in protecting our products, product candidates and technologies. In addition, certain of our existing patents expire over the next 1 to 10 years. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects.

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 in part 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 referred to as 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.

Several years 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. In the event such a dispute arises, we may be forced to spend significant time and resources to defending our position. There can be no assurances that such efforts will be successful and not have a material adverse effect on our business, operating results, financial condition and prospects.

The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing, and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our products and product candidates. Patents covering our products and product candidates normally provide market exclusivity, which is important in order for our products and product candidates to become profitable.

Certain of our patents will expire in the next one to ten years. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and product candidates, we may be open to competition from generic versions of such methods and devices.

We have commenced the process of seeking regulatory approvals of our products and product candidates, but the approval process involves lengthy and costly clinical studies and is, in large part, not in our control. The failure to obtain government approvals, internationally or domestically, for our products and product candidates, 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 EU regulatory approval 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 U.S., in various states and in other foreign countries. In the U.S. 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 will 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 facilities could be substantial and delay gaining CE Mark for other potential applications of our products, our other product candidates 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 others are critical care advisors and consultants of ours and 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. 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. We manufacture CytoSorb at our manufacturing facilities in New Jersey for sale in the EU and for additional clinical studies. Manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (cGMP). As such, we are subject to continual review and periodic inspections to assess compliance with cGMP as required by our International notified body and those FDA regulations governing companies that export medical products for sale outside the United States. Accordingly, we must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. 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 the 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 EU and non-EU countries to help further adoption. There can be no assurance when, or if, this additional

reimbursement might be approved.

Our business may be negatively affected if the United States and/or the countries in which we sell our products participate in wars, military actions or are otherwise the target of international terrorism.

Involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products globally or (iv) our inability to access capital markets, our business and results of operations could be materially and adversely affected. We are unable to predict whether acts of international terrorism or the involvement in a war or other military actions by the United States and/or the countries in which we sell our products will result in any long-term commercial disruptions or if such involvement or responses will have any long-term material adverse effect on our business, results of operations, or financial condition.

We could be adversely affected by violations of the Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

We are subject to the Foreign Corrupt Practices Act (FCPA), which generally prohibits companies and their intermediaries from making payments to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to anti-bribery laws in the jurisdictions in which we operate. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with the FCPA and other anti-bribery laws, there is no assurance that such policies or procedures will protect us against liability under the FCPA or other laws for actions taken by our agents, employees and intermediaries with respect to our business or any businesses that we acquire. We do business in a number of countries in which FCPA violations have recently been enforced. Failure to comply with the FCPA, other anti-bribery laws or other laws governing the conduct of business with foreign government entities, including local laws, could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the federal government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

Cyberattacks and other security breaches could compromise our proprietary and confidential information which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, contractor, or other third-party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyber-attacks, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information, and subject us to additional costs which could adversely affect our business.

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.

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, we received approval for up-listing to The NASDAQ Capital Market and our common stock began trading on The NASDAQ Capital Market on December 23, 2014. Our Common Stock closed as high as $5.68 and as low as $3.21 per share between January 1, 2016 and June 30, 2016 on The NASDAQ Capital Market. On August 4, 2016 the closing price of our common stock, as reported on The NASDAQ Capital Market, was $4.86. Historically, medical device company 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 shares 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 the 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 adversely affecting 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 was effective December 3, 2014, authorizes the issuance of up to 50,000,000 shares of common stock, of which approximately 24,562,000 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 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 the direction or management of us. 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, new SEC regulations will require an increased

amount of management attention and external resources. In addition, prior to the merger, our current management team was not subject to these laws and regulations, as we were a private corporation. 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.

Prior to December 23, 2014, 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 (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.

Future sales of our common stock could cause our share price to fall.

In November 2015, we entered into a sales agreement with Cantor Fitzgerald & Co. to offer shares of our common stock from time to time through "at-the-market" offerings, pursuant to which we offer and sell shares of our common stock for an aggregate offering price of up to $25 million. We are not obligated to make or continue to make any sale of shares of our common stock under the "at-the-market" offerings. Any sale of securities pursuant to the "at-the-market" offerings will result in dilution of our stockholders and could cause our share price to fall.

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.

On August 5, 2016, we entered into an Amended and Restated Fourteenth Amendment to Lease Agreement (the "Lease Amendment") with Princeton Corporate Plaza, LLC which, among other things, extends the term of the lease for our corporate headquarters and manufacturing facility through May 31, 2018, provides an option to extend the term of the Lease Amendment for an additional year period through May 31, 2019 upon certain conditions, and beginning June 1, 2016, reduces our base rent to $23 per square foot. In accordance with the Lease Amendment, effective August 1, 2016, we expanded our premises by approximately 1,420 square feet, which will be utilized primarily as manufacturing facilities. Our base rent obligation for the period beginning August 1, 2016 will be $24,756 per month.

The foregoing summary of the Lease Amendment is qualified in its entirety by reference to the complete text of the Lease Amendment, which is filed herewith as Exhibit 10.3 to this Report, and is incorporated herein by reference.

Item 6. Exhibits.

Number	Description
10.1	Loan and Security Agreement, dated as of June 30, 2016, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc., and Western Alliance Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 1, 2016).
10.2	Success Fee Letter, dated as of June 30, 2016, by and among CytoSorbents Corporation, CytoSorbents Medical, Inc., and Western Alliance Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 1, 2016).
10.3	Amended and Restated Fourteenth Amendment to Lease Agreement by and between the Registrant and Princeton Corporate Plaza LLC, dated August 5, 2016.
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 June 30, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2016 and June 30, 2015, (iii) Consolidated Statement of Changes in Stockholders' Equity for the period from December 31, 2015 to June 30, 2016, (iv) Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and June 30, 2015 and (v) Notes to Consolidated Financial Statements.

*In accordance with SEC Release 33-8238, Exhibits 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: August 9, 2016 By: /s/ Phillip P. Chan
Name: Phillip P. Chan
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 9, 2016 By: /s/ Kathleen P. Bloch
Name: Kathleen P. Bloch, CPA
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)