

Cytosorbents Corp  
Form 10-Q  
August 07, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended June 30, 2017**

**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      (I.R.S. Employer Identification No.)**  
**incorporation or organization)**

**7 Deer Park Drive, Suite K**

**Monmouth Junction, New Jersey 08852**

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

**(732) 329-8885**

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 2, 2017 there were 28,133,986 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 ™, ®, Ⓜ 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, 2017 (Unaudited)	December 31, 2016
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 16,402,330	\$ 5,245,178
Grants and accounts receivable, net of allowance for doubtful accounts of \$74,743 at June 30, 2017 and \$65,414 at December 31, 2016	2,058,815	1,433,468
Inventories	889,739	833,976
Prepaid expenses and other current assets	390,328	315,802
Total current assets	19,741,212	7,828,424
Property and equipment, net	725,138	569,409
Other assets	1,620,109	1,296,011
Total long-term assets	2,345,247	1,865,420
Total Assets	\$22,086,459	\$9,693,844
<b>LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)</b>		
Current Liabilities:		
Accounts payable	\$ 1,581,401	\$ 1,330,072
Current maturities of long-term debt	2,000,000	833,333
Accrued expenses and other current liabilities	1,602,130	2,114,666
Warrant liability at fair value	1,046,441	1,811,547
Total current liabilities	6,229,972	6,089,618
Long term debt, net of current maturities and debt acquisition costs	7,940,568	4,078,314
Total Liabilities	14,170,540	10,167,932
Commitment and Contingencies (Note 6)		
Stockholders' Equity/(Deficit):		
Preferred Stock, Par Value \$0.001, 5,000,000 shares authorized; -0- shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common Stock, Par Value \$0.001, 50,000,000 shares authorized; 28,133,986 and 25,483,966 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	28,134	25,484
Additional paid-in capital	154,690,112	143,066,477

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Accumulated other comprehensive income	156,801	898,684
Accumulated deficit	(146,959,128)	(144,464,733)
Total stockholders' equity/(deficit)	7,915,919	(474,088 )
Total Liabilities and Stockholders' Equity/(Deficit)	\$22,086,459	\$9,693,844

See accompanying notes to consolidated financial statements.

## CYTOSORBENTS CORPORATION

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
Sales	\$ 3,041,012	\$ 1,852,670	\$ 5,637,145	\$ 3,450,119
Grant income	525,214	369,668	1,042,599	582,401
Total revenue	3,566,226	2,222,338	6,679,744	4,032,520
Cost of revenue	1,482,010	873,266	2,736,493	1,692,765
Gross profit	2,084,216	1,349,072	3,943,251	2,339,755
Other expenses:				
Research and development	487,613	1,092,070	957,160	1,948,192
Legal, financial and other consulting	443,196	319,184	723,141	573,735
Selling, general and administrative	3,484,315	2,625,189	6,151,336	4,595,293
Total expenses	4,415,124	4,036,443	7,831,637	7,117,220
Loss from operations	(2,330,908 )	(2,687,371 )	(3,888,386 )	(4,777,465 )
Other income/(expense):				
Interest income(expense), net	(123,454 )	1,582	(243,903 )	5,488
Gain (loss) on foreign currency transactions	719,734	(128,941 )	872,788	102,651
Change in warrant liability	618,248	(190,513 )	765,106	(172,219 )
Total other income (expense), net	1,214,528	(317,872 )	1,393,991	(64,080 )
Loss before benefit from income taxes	(1,116,380 )	(3,005,243 )	(2,494,395 )	(4,841,545 )
Benefit from income taxes	—	—	—	—
Net loss	(1,116,380 )	(3,005,243 )	(2,494,395 )	(4,841,545 )
Basic and diluted net loss per common share	\$(0.04 )	\$(0.12 )	\$(0.09 )	\$(0.19 )
Weighted average number of shares of common stock outstanding	27,953,542	25,416,077	26,735,416	25,408,599
Net loss	\$(1,116,380 )	\$(3,005,243 )	\$(2,494,395 )	\$(4,841,545 )
Other comprehensive income (loss):				
Currency translation adjustment	(610,333 )	144,723	(741,883 )	(100,773 )
Comprehensive loss	\$(1,726,713 )	\$(2,860,520 )	\$(3,236,278 )	\$(4,942,318 )

See accompanying notes to consolidated financial statements.





## CYTOSORBENTS CORPORATION

## CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

Period from December 31, 2016 to June 30, 2017 (Unaudited):

	Common Stock Shares	Par value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity/(Deficit)
Balance at December 31, 2016	25,483,966	\$ 25,484	\$ 143,066,477	\$ 898,684	\$(144,464,733)	\$(474,088 )
Stock based compensation - employees, consultants and directors	—	—	890,994	—	—	890,994
Issuance of common stock – net of fees incurred	2,555,555	2,556	10,318,216	—	—	10,320,772
Other comprehensive income/(loss): foreign translation adjustment	—	—	—	(741,883 )	—	(741,883 )
Proceeds from exercise of stock options	11,000	11	31,897	—	—	31,908
Cashless exercise of stock options	2,074	2	(2 )	—	—	—
Issuance of restricted stock units	41,390	41	207,566	—	—	207,607
Proceeds from exercise of warrants	40,001	40	174,964	—	—	175,004
Net loss	—	—	—	—	(2,494,395 )	(2,494,395 )
Balance at June 30, 2017	28,133,986	\$ 28,134	\$ 154,690,112	\$ 156,801	\$(146,959,128)	\$ 7,915,919

See accompanying notes to consolidated financial statements.

## CYTOSORBENTS CORPORATION

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months Ended June 30, 2017 (Unaudited)	Six months ended June 30, 2016 (Unaudited)
Cash flows from operating activities:		
Net loss	\$(2,494,395 )	\$(4,841,545 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	103,561	69,423
Amortization of debt costs	30,481	—
Bad debt	3,791	—
Stock-based compensation	890,994	599,768
Change in warrant liability	(765,106 )	172,219
Foreign currency transaction gain	(872,788 )	(102,651 )
Changes in operating assets and liabilities:		
Grants and accounts receivable	(534,647 )	(292,517 )
Inventories	(38,565 )	149,347
Prepaid expenses and other current assets	(56,235 )	352,594
Other assets	(15,000 )	(1,019 )
Accounts payable and accrued expenses	(119,960 )	710,819
Net cash used by operating activities	(3,867,869 )	(3,183,562 )
Cash flows from investing activities:		
Purchases of property and equipment	(229,619 )	(98,330 )
Payments for patent costs	(327,366 )	(212,409 )
Proceeds from redemptions of short-term investments		1,943,000
Net cash used by investing activities	(556,985 )	1,632,261
Cash flows from financing activities:		
Proceeds from long-term debt	5,000,000	5,000,000
Payment of debt acquisition costs	(1,560 )	(118,833 )
Equity contributions – net of fees incurred	10,320,772	
Proceeds from exercise of stock options	31,908	3,750
Proceeds from exercise of warrants	175,004	25,000
Net cash provided by financing activities	15,526,124	4,909,917
Effect of exchange rates on cash	55,882	(5,077 )
Net change in cash and cash equivalents	11,157,152	3,353,539
Cash and cash equivalents - beginning of period	5,245,178	5,316,851
Cash and cash equivalents - end of period	\$16,402,330	\$8,670,390



	Six months Ended June 30, 2017 (Unaudited)	Six months ended June 30, 2016 (Unaudited)
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 216,236	\$ 1,139
Supplemental schedule of noncash investing and financing activities:		
Settlement of accrued bonuses with restricted stock units	\$ 207,566	\$ —

See accompanying notes to consolidated financial statements.

**CytoSorbents Corporation**

**Notes to Consolidated Financial Statements**

**(UNAUDITED)**

**June 30, 2017**

**1. BASIS OF PRESENTATION**

The interim financial statements of CytoSorbents Corporation (the “Company”) 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, 2016 included in the Company’s Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 3, 2017. The results for the three and six months ended June 30, 2017 and 2016 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, 2017, the Company had an accumulated deficit of \$146,959,128, which included net losses of \$2,494,395 for the six months ended June 30, 2017 and \$4,841,545 for the six months ended June 30, 2016. The Company’s losses have resulted principally from costs incurred in the research and development of the Company’s polymer technology and selling, general and administrative expenses. The Company intends to continue to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other selling, general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, the Company will achieve profitability are uncertain. The Company’s ability to achieve profitability will depend, among other things, on successfully completing the development of the Company’s technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark 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, including clinical trials. 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, investigating and commercializing its CytoSorb blood purification therapy 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 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 services in Switzerland. CytoSorb, the Company's flagship product, is approved in the EU and marketed in and distributed in forty-four 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, CytoSorb was "CE Marked" in the European Union ("EU") allowing for commercial marketing.

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 include HemoDefend, ContrastSorb, DrugSorb, and others. As of June 30, 2017, the Company owns 32 issued United States patents and has multiple issued patents and pending patent applications worldwide. Our patent portfolio includes 16 issued United States patents as well as multiple issued patents and pending patent applications directed to various compositions and methods of use related to our blood purifications technologies, which are expected to expire between 2018 and 2031, absent any patent term extensions. 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, par value \$0.001 per share ("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 the European subsidiary, for which the U.S. dollar is the functional currency, are included in other comprehensive income. Foreign currency transaction gain/(loss) included in net loss amounted to \$719,734 and \$(128,941) for the three months ended June 30, 2017 and 2016, respectively. Foreign currency transaction gains included in net loss amounted to \$872,788 and \$102,651 for the six months ended June 30, 2017 and 2016, respectively. The Company translates assets and liabilities of CytoSorbents Europe GmbH, 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 stockholders' equity as a component of accumulated other comprehensive income.

### **Cash and Cash Equivalents**

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

**Grants and Accounts Receivable**

Grants receivable represent amounts due from U.S. government agencies 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 approximately \$75,000 and \$65,000 at June 30, 2017 and December 31, 2016, respectively.

### **Inventories**

Inventories are valued at the lower of cost or market under the first in, first out (FIFO) method. At June 30, 2017 and December 31, 2016, the Company's inventory was comprised of finished goods, which amounted to \$319,769 and \$307,483, respectively; work in process which amounted to \$508,733 and \$467,663, respectively; and raw materials, which amounted to \$61,237 and \$58,830, 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 Monte Carlo simulation 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 \$37,000 and \$45,000 for the three months ended June 30, 2017 and 2016, respectively, and approximately \$87,000 and \$125,000 for the six months ended June 30, 2017 and 2016 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, 2017 or December 31, 2016. The Company files tax returns in the U.S. federal and state jurisdictions.

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.

Each of CytoSorbents Europe GmbH and CytoSorbents Switzerland GmbH files an annual corporate tax return, VAT return and a trade tax return in Germany and Switzerland, respectively.

### **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.

A significant portion of our revenues are from product sales in Germany. Substantially all of our grant and other income are from grant agencies in the United States. The following table provides a geographic summary of revenues for the three and six months ended June 30, 2017 and 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Product Sales:				
Germany	\$ 1,852,022	\$ 1,321,216	\$ 3,395,126	\$ 2,327,242
All other countries	1,188,990	531,454	2,242,019	1,122,877
Grant and other income:				
United States	525,214	369,668	1,042,599	582,401
Total revenue	\$ 3,566,226	\$ 2,222,338	\$ 6,679,744	\$ 4,032,520

As of June 30, 2017, one distributor accounted for approximately 13% of outstanding grant and accounts receivable. At December 31, 2016, one distributor and one government agency accounted for approximately 22% of outstanding grant and accounts receivable. For the three months ended June 30, 2017, no 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 represented 13% of the company's total revenue. For the six months ended June 30, 2017, no agency, distributor, or direct customer represented more than 10% of the Company's revenue. For the six months ended June 30, 2016, one direct customer accounted for approximately 11% of the company's revenue.

## Financial Instruments

The carrying values of cash and cash equivalents, short-term investments, accounts payable, notes payable, and other debt obligations approximate their fair values due to their short-term nature.

## Net Loss Per Common Share

Basic 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

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

The Company also follows the guidance of accounting standards for accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services for equity instruments issued to consultants.

## Effects of Recent Accounting Pronouncements

In 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 has evaluated the impact of the updated guidance and has determined that the adoption of ASU 2014-09 is not expected to have a significant impact on its consolidated financial statements.

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 has evaluated the impact of the updated guidance and has determined that the adoption of ASU 2015-11 is not expected to 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 evaluating the impact of the updated guidance and has determined that the adoption of ASU 2016-02 may impact certain financial statement disclosures, particularly with regard to leases of premises.

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 has evaluated the impact of the updated guidance and has determined that the adoption of ASU 2016-08 is not expected to 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 has evaluated the impact of the updated guidance and has determined that the adoption of ASU 2016-10 is not expected to 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 has evaluated the impact of the updated guidance and has determined that the adoption of ASU 2016-12 is not expected to have a significant impact on its consolidated financial statements.



In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force).” The amendments in this Update relate to eight specific types of cash receipts and cash payments which current GAAP either is unclear or does not include specific guidance on the cash flow classification issues. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company will adopt the provisions of this ASU for its fiscal year beginning January 1, 2017. The adoption of ASU 2016-15 is not expected to have a significant impact on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation (Topic 718). The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments in this Update should be applied prospectively to an award modified on or after the adoption date. The Company is evaluating the impact of the revised guidance and believes that this will not have a significant impact on its consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, “Earning Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815). Part I of this Update addresses the complexity of accounting for certain financial instruments with down round features. The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company is evaluating the impact of the revised guidance and believes that this may 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 \$45,000 and \$37,000 for the three months ended June 30, 2017 and 2016, respectively and approximately \$128,000 and \$71,000 for the six months ended June 30, 2017 and 2016, respectively.

### **3. STOCKHOLDERS' EQUITY**

#### **Preferred Stock**

In December 2014, the Company amended its articles of incorporation to reduce the total number of authorized shares of preferred stock. The amended articles of incorporation authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock, par value \$0.001 per share ("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.

### April 5, 2017 Equity Offering

On April 5, 2017, the Company closed on the sale of an aggregate of 2,222,222 shares of Common Stock pursuant to the Company's existing shelf registration statement (Registration No. 333-205806) on Form S-3. The Company received gross proceeds of approximately \$10,000,000, based on a public offering price of \$4.50 per share. On April 11, 2017, the Company closed the sale of an additional 333,333 shares of the Company's Common Stock, pursuant to the underwriters' full exercise of an over-allotment option. The Company received gross proceeds of approximately \$1,500,000 as a result of the exercise of the option. As a result, the company received total gross proceeds of \$11,500,000, and, after deducting the underwriting discounts and commissions and expenses related to the offering, the Company received total net proceeds of approximately \$10,300,000. As a result of this offering, the exercise price of the warrants issued in connection with the Company's March 11, 2014 public offering was reduced to \$4.50 in accordance with the pricing provisions of those warrants (see Note 4). There was no change in the number of warrants which were repriced. These warrants remain exercisable on a cash-only basis.

### November 4, 2015 Controlled Equity Offering

On November 4, 2015, the Company entered into a Controlled Equity Offering<sup>SM</sup> 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 NASDAQ, 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 December 31, 2015, 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 year ended December 31, 2016 or for the six months ended June 30, 2017.

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. In 2015, the Company reimbursed Cantor \$50,000 for certain specified expenses in connection with the execution of 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.

### Stock-Based Compensation

Total share-based employee, director, and consultant compensation for the three and six months ended June 30, 2017 and 2016 amounted to approximately \$799,000 and \$368,000, and \$891,000 and \$475,000 respectively. These amounts are included in the statement of operations under the captions research and development (\$30,000 and \$62,000 for the three months ended June 30, 2017 and 2016, and \$45,000 and \$92,000 for the six months ended June 30, 2017 and 2016) and selling, general and administrative (\$769,000 and \$306,000 for the three months ended June 30, 2017 and 2016 and \$846,000 and \$383,000 for the six months ended June 30, 2017 and 2016).

The summary of the stock option activity for the six months ended June 30, 2017 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding, December 31, 2016	2,762,177	\$ 4.69	6.0
Granted	1,179,950	\$ 5.45	9.7
Forfeited	(17,640 )	\$ 4.65	—
Expired	(32,120 )	\$ 36.33	—
Exercised	(23,960 )	\$ 3.87	—
Outstanding, June 30, 2017	3,868,407	\$ 4.66	6.8

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 \$3.45 to \$6.20 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 71.1 percent), expected dividends (-0- percent) on the stock and the risk free interest rate (ranging from 1.85 to 2.21 percent) for the term of the stock option.

The intrinsic value is calculated as the difference between the market value as of June 30, 2017 of \$4.30 and the exercise price of the shares.

Options Outstanding

Range of Exercise Price	Number Outstanding at June 30, 2017	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
\$0.88 - \$11.48	3,868,407	4.66	6.8	\$1,464,408

Options Exercisable

Number Exercisable at June 30, 2017	Weighted Average Exercise Price	Aggregate Intrinsic Value
2,608,593	\$ 4.28	\$1,438,394

The summary of the status of the Company's non-vested options for the six months ended June 30, 2017 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2016	912,547	\$ 2.55
Granted	1,179,950	\$ 0.58
Forfeited	(1,000 )	\$ 2.41
Vested	(831,683 )	\$ 2.33
Non-vested, June 30, 2017	1,259,814	\$ 0.68

As of June 30, 2017, the Company had approximately \$609,000 of total unrecognized compensation cost related to stock options which will, on average, be amortized over one year.

On February 24, 2017, the Board of Directors granted options to purchase 953,200 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 2017 operations. The grant date fair value of these unvested options amounted to approximately \$3,284,000. As of June 30, 2017, the Company has determined that it has met certain milestones that equate to a twenty percent vesting of these options. Accordingly, the Company has recorded an expense of approximately \$658,000 in the consolidated statement of operations.

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 change of control restricted stock units outstanding to 1,539,000. In February 2017, the Board of Directors granted an additional 129,500 restricted stock options to Company employees, Directors, and consultants valued at approximately \$725,200 at the time of issuance, which will only vest upon a Change in Control, bringing the total amount of Change of Control restricted stock units outstanding to 1,668,500. 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 three and six months ended June 30, 2017.

*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 over the period which they vest. For the six and three months ended June 30, 2017, the Company recorded a charge of approximately \$45,000 and \$14,000 related to these restricted stock unit awards.

Pursuant to a review of the compensation of the senior management of the Company and managements' performance in 2016, on February 24, 2017, the Board of Directors granted 125,000 restricted stock units to certain senior managers of the Company in order to settle bonuses accrued as of December 31, 2016. These awards were valued at approximately \$700,000 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 grant, and one third on the second anniversary of the date of the grant. For the six and three months ended June 30, 2017, the Company recorded a charge of approximately \$117,000 and \$58,000 related to these restricted stock unit awards.



The following table outlines the restricted stock unit activity for the year ended June 30, 2017:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2017	53,335	\$ 4.69
Granted	125,000	5.60
Vested	(68,332 )	5.24
Non-vested, June 30, 2017	110,003	\$ 5.38

*Warrants:*

As of June 30, 2017, 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
113,600	\$ 3.750	June 21, 2018
110,000	\$ 3.125	September 30, 2018
48,960	\$ 7.500	March 11, 2019
736,000	\$ 4.500	March 11, 2019
30,000	\$ 9.900	January 14, 2020
1,038,560		

#### 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. In addition, these warrants may only be exercised with cash. In April 2017, the Company closed on an underwritten public offering. The price of this offering was \$4.50 per share of Common Stock which is less than the exercise price of the warrants. Accordingly, the exercise price of the warrants has been reduced to \$4.50 per warrant. There was no change in the number of warrants which were repriced. (see Note 3).

The Company recognized an initial warrant liability of \$862,920 for the warrants issued in connection with the offering completed in March 2014, 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, 2017 and 2016, the closing price per share of common stock was \$4.30 and \$4.55, respectively. During the three months ended June 30, 2017, the warrant liability decreased \$618,248 from \$1,664,689 as of March 31, 2017 to \$1,046,441 at June 30, 2017. As of June 30, 2017, the warrant liability was \$1,046,441, a decrease of \$765,106 from the warrant liability as of December 31, 2016 of \$1,811,547. This reduction in the warrant liability for the three and six months ended June 30, 2017 was primarily due to a decrease in the market value of the Company's common stock from December 31, 2016 to June 30, 2017 and a reduction in management's estimate of the probable need for additional equity financing through the expiration date of the warrants. During the three months ended June 30, 2016, the warrant liability increased \$190,513 from 1,617,834 as of March 31, 2016 to \$1,808,347 at June 30, 2016. This increase for the three months ended June 30, 2017 was primarily due to an increase in the market value of the Company's common stock from March 31, 2016 to June 30, 2016. As of June 30, 2016, the warrant liability was \$1,808,347, an increase of \$172,219 from the warrant liability as of December 31, 2015 of \$1,636,128. This increase for the six months ended June 30, 2016 was primarily due to an increase in the market value of the Company's common stock from December 31, 2015 to June 30, 2016.

The assumptions used in connection with the valuation of warrants issued utilizing the Monte Carlo simulation valuation model were as follows:

	June 30, 2017	June 30, 2016		
Number of shares underlying the warrants	736,000	736,000		
Exercise price	\$4.50	\$7.81		
Volatility	62.40	72.80	%	%
Risk-free interest rate	1.33	0.67	%	%
Expected dividend yield	0	0		
Expected warrant life (years)	1.70	2.70		
Stock Price	\$4.30	\$4.55		

## 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 and the proceeds from Term Loan B on June 30, 2017. 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. The Term Loans are secured by substantially all the assets of the Company, with the exception of any intellectual Property. 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 8.97% at June 30, 2017.

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. On June 30, 2017, in connection with the closing of the Term B Loan, the Company was required to pay expenses incurred by the Bank of \$1,560. In addition, the Company incurred legal expenses related to the Loan and Security Agreement of \$44,833. These costs, which total \$120,393, 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. These costs are being amortized over the loan period as a charge to interest expense. For the three and six months ended June 30, 2017, the Company recorded interest expense amounting to \$7,428 and \$14,855, respectively, related to these costs. 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 the Term Loans. Commencing on February 1, 2018, subject to certain conditions as outlined in the Loan and Security Agreement, the Company shall make equal monthly payments of principal of \$333,333, together with accrued and unpaid interest. 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. This final fee is being accrued and charged to interest expense over the term of the loan. For the three and six months ended June 30, 2017, the Company recorded interest expense of \$7,813 and \$15,625, respectively, related to the final fee. The Term Loans are evidenced by 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.

Effective with the issuance of Term Loan B on June 30, 2017, the Company is required to meet a financial covenant which requires the Company to achieve consolidated trailing six month revenue from product sales equal to at least 75% of the projected revenue for such period in accordance with financial projections supplied to the Bank by the Company.

The Borrower's obligations under the Loan and Security Agreement are joint and severable, are secured by a first priority security interest in favor of the Bank with respect to the Shares (as defined in the Loan and Security Agreement) and the Collateral (as defined in the Loan and Security Agreement), 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 NASDAQ 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, 2017:

	June 30, 2017	December 31, 2016
Principal amount	\$ 10,000,000	\$ 5,000,000
Less unamortized debt acquisition costs	(90,682 )	(103,978 )
Plus accrued final fee	31,250	15,625
Subtotal	9,940,568	4,911,647
Less Current maturities	2,000,000	833,333
Long-term debt net of current maturities	\$ 7,940,568	\$ 4,078,314

Principal payments of long-term debt are due as follows at June 30, 2017:

2018	\$2,000,000
2019	4,000,000
2020	4,000,000
Total	\$10,000,000

## 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 is retroactively effective as of January 1, 2015. On May 30, 2017, CytoSorbents Corporation announced the appointment of Eric R. Mortensen M.D., Ph.D as the Company's Chief Medical Officer, pursuant to the terms of an employment agreement dated May 23, 2017. Dr. Mortensen's employment agreement provides for an initial term commencing on

June 1, 2017 and ending on December 31, 2019. These employment agreements each 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, 2017 and 2016, the Company has recorded royalty costs of approximately \$166,000 and \$102,000, respectfully. For the three months ended June 30, 2017 and 2016, the Company has recorded royalty costs of approximately \$89,000 and \$55,000, respectively.

## **License Agreements**

In March 2006, the Company entered into a license agreement which provides the Company the exclusive right to use its patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the agreement, the Company has agreed to pay royalties of 2.5% to 5% on the sale of certain of its products if and when those products are sold commercially for a term not greater than 18 years commencing with the first sale of such product. For the six months ended June 30, 2017 and 2016, per the terms of the license agreement, the Company has recorded royalty costs of approximately \$277,000 and \$136,000, respectfully. For the three months ended June 30, 2017 and 2016, the Company has recorded royalty costs of approximately \$149,000 and \$73,000, respectively.

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

Basic loss per share and diluted loss per share for the three months ended June 30, 2017 and 2016 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, options and restricted stock awards representing approximately 5,017,000 and 4,101,000 incremental shares at June 30, 2017 and 2016 have been excluded from the computation of diluted loss per share as they are anti-dilutive.

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

### **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, 2016, as filed with the SEC on March 3, 2017.

We are a leader in critical care immunotherapy, investigating and commercializing our CytoSorb blood purification therapy 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 and cardiac surgery. Organ failure is the cause of nearly half of all deaths in the intensive care unit (“ICU”), with little to improve clinical outcome. CytoSorb, our flagship product, is approved in the European Union (“EU”) as a safe and effective extracorporeal cytokine filter and is 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. These are conditions where the mortality is extremely high, yet no effective treatments exist. In addition, CytoSorb can be used in other

inflammatory conditions such as cardiac surgery, autoimmune disease flares, and potentially for cancer, cytokine release syndrome in cancer immunotherapy, and cancer cachexia, a common syndrome that affects cancer patients, where cytokines play a major role in the cause of inflammation. CytoSorb has been used globally in more than 27,000 human treatments to date. Our purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. We have numerous products under development based upon this unique blood purification technology. As of June 30, 2017, we own 32 issued United States patents and have multiple issued and multiple pending patent applications in major markets worldwide. Our patent portfolio includes 16 issued United States patents as well as multiple issued and pending patent applications in major markets worldwide directed to various compositions and methods of use related to our blood purifications technologies, which are expected to expire between 2018 and 2031, absent any patent term extensions.

In March 2011, CytoSorb, as an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated, was “CE marked” in the EU, allowing for commercial marketing. The CE mark demonstrates that a conformity assessment has been carried out and the product complies with the Medical Devices Directive. The goal of CytoSorb is to prevent or treat organ failure by reducing cytokine storm and the potentially deadly systemic inflammatory response syndrome (“SIRS”) in diseases such as sepsis, trauma, burn injury, acute respiratory distress syndrome, pancreatitis, cytokine release syndrome in cancer immunotherapy, liver failure, and many others. Organ failure is the leading cause of death in the ICU, 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 ICU treatment, thereby potentially saving significant healthcare costs.

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

As part of the CE Mark approval process, we completed our randomized, controlled, European Sepsis Trial amongst 14 trial sites in Germany in 2011, with enrollment of 100 patients with sepsis and respiratory failure. The trial established that CytoSorb was sufficiently safe in this critically-ill population to support the CE Mark, the device showed clearance for a broad range of cytokines. We plan to conduct larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE marking, 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 commercial sales abroad and for additional clinical studies. In September 2016, we were granted a two-year renewal for the CytoSorb CE Mark. In June 2016, we successfully completed an ISO 13485:2003 annual surveillance audit maintaining our good standing with our Notified Body. 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. The purpose of this program was to prepare 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 CytoSorbents Europe GmbH, a wholly-owned operating subsidiary of CytoSorbents Corporation, 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 during the third quarter of 2012. The fourth quarter of 2012 represented the first quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland.

Fiscal year 2013 represented the first full year of CytoSorb commercialization. We focused our direct sales efforts in Germany, Austria and Switzerland with four sales representatives. The focus of the team was to encourage acceptance and usage by key opinion leaders (“KOLs”) throughout these countries. By the end of 2015, we had hundreds of KOLs in critical care, cardiac surgery, and blood purification who are either using CytoSorb or planning to use CytoSorb in the near future. We believe our relationships with KOLs will be essential to drive adoption and recurrent usage of

CytoSorb, facilitate purchases by hospital administration, arrange reimbursement, and generate data for papers and presentations. In addition, we now currently have more than 58 investigator initiated studies in Europe, with approximately half in the planning stages, and half started, enrolling, or completed in multiple applications including sepsis, cardiac surgery, lung injury, trauma, pancreatitis, liver failure, kidney failure, and others. These studies are being supported by our European Medical Director.

In March 2016, we established CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH, our wholly-owned subsidiary, to conduct marketing and direct sales in Switzerland. This indirect subsidiary began operations during the second quarter of 2016. In the third quarter of 2016, we expanded our direct sales force efforts to include Belgium and Luxembourg.

As of August 1, 2017, our sales force includes 13 direct sales people, one contract sales person and 14 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, the Netherlands, Russia and Turkey. In April 2014, we announced the 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 TechnoOrbits. In December 2014, we entered into an exclusive agreement with Smart Medical Solutions S.R.L., to distribute CytoSorb for critical care applications in Romania and the neighboring Republic of Moldova. In 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. In September 2016, we announced an exclusive agreement with Armaghan Salamat Kish Group (Arsak) to distribute CytoSorb in Iran. In October 2016, we announced an exclusive agreement with Foxx Medical Chile SpA to distribute CytoSorb in Chile. In July 2017, we announced an exclusive agreement with Drogueria Ramon Gonzalez Revilla S.A. to distribute CytoSorb in Panama.

We have been expanding our strategic partnerships by number and scope. In September 2013, we entered into a strategic partnership with Biocon Ltd., India’s largest biopharmaceuticals 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 October 2014, the Biocon partnership was expanded to include all critical care applications and cardiac surgery. In addition, Biocon committed to higher annual minimum purchases of CytoSorb to maintain distribution exclusivity and committed to conduct and publish results from multiple investigator initiated studies and patient case studies.

In December 2014, we entered into a multi-country strategic partnership with Fresenius Medical Care AG & Co KGaA (“Fresenius”) to commercialize the CytoSorb therapy. Under the terms of this agreement, Fresenius has exclusive rights to distribute CytoSorb for critical care applications in France, Poland, Sweden, Denmark, Norway, and Finland. The partnership will allow Fresenius to offer an innovative and easy way to use blood purification therapy for removing cytokines in patients that are treated in the ICU. 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. In January 2017, the Fresenius partnership was expanded. The terms of the revised three-year agreement extend Fresenius’ exclusive distributorship of CytoSorb for all critical care applications in their existing territories through 2019 and include guaranteed minimum quarterly orders and payments, evaluable every one and a half years. In addition, we have entered into a new comprehensive co-marketing agreement with Fresenius. Under the terms of the agreement, Cytosorbents and Fresenius will jointly market CytoSorb and Fresenius’ CytoSorb compatible blood tubing sets to Fresenius’ critical care customer base in all countries where CytoSorb is being actively commercialized. CytoSorb will continue to be sold by our direct sales force or through our international network of distributors and partners, while Fresenius will sell all ancillary products to their customers. Fresenius will also provide a written endorsement of

CytoSorb for use with their multiFiltrate and multiFiltratePRO acute care dialysis machines that can be used by us and our distribution partners to promote CytoSorb worldwide. Training and preparation for this co-marketing program is ongoing and it is expected co-marketing activity will commence during the second half of 2017.

In September 2016, we entered into a multi-country strategic partnership with Terumo Cardiovascular Group to commercialize CytoSorb for cardiac surgery applications. Under the terms of the agreement, Terumo has exclusive rights to distribute the CytoSorb cardiopulmonary bypass (“CPB”) procedure pack for intra-operative use during cardiac surgery in France, Sweden, Denmark, Norway, Finland and Iceland. Terumo launched the product in these six countries in December 2016.

In March 2017, we entered into a partnership with Dr. Reddy’s Laboratories Ltd. for the South African market. Under the terms of the agreement, Dr. Reddy’s has the exclusive right to distribute CytoSorb for intensive care, cardiac surgery, and other hospital applications in South Africa. This is a multi-year agreement and is subject to annual minimum purchases of CytoSorb to maintain exclusivity.

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

Concurrent with our commercialization plans, we intend to conduct or support additional clinical studies in sepsis, cardiac surgery, and other critical care diseases to generate additional clinical data to expand the scope of clinical experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. We 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 58 investigator-initiated studies planned, with approximately half in an advanced stage, ready to enroll, or completed around the world. These trials, which are funded and supported by well-known university hospitals and KOLs, are the equivalent of Phase II clinical studies. They will provide invaluable information regarding the success of the device in the treatment of sepsis, cardiac pulmonary bypass surgery, trauma, and many other indications, and if successful, will be integral in helping to drive additional usage and adoption of CytoSorb.

In February 2015, the U.S. Food and Drug Administration (“FDA”) approved our Investigational Device Exemption (“IDE”) application to commence a planned U.S. cardiac surgery feasibility study called REFRESH I (REduction of FREe 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 REFRESH I study was designed to evaluate the safety and feasibility 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 study was not powered to measure effect on clinical outcomes. 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 are correlated with the incidence of serious post-operative complications such as kidney injury, renal failure and other organ dysfunction. The goal of CytoSorb is to actively remove these inflammatory and toxic substances as they are being generated during the surgery and reduce complications. Enrollment was completed with 46 patients. A total of 38 patients were evaluable and completed all aspects of the study.



The primary safety and efficacy endpoints of the study were the assessment of serious device related adverse events and the change in plasma free hemoglobin levels, respectively. On October 5, 2016, we announced positive top-line safety data. In addition, following a detailed review of all reported adverse events in a total of 46 enrolled patients, the independent Data Safety Monitoring Board (“DSMB”) found no safety concerns related to the CytoSorb device, achieving the primary safety endpoint of the trial. In addition, the therapy was well-tolerated and technically feasible, implementing easily into the cardiopulmonary bypass circuit without the need for an additional external blood pump. This study represents the first randomized controlled trial demonstrating the safety of intra-operative CytoSorb use in patients undergoing high risk cardiac operations.

Investigators of the REFRESH I trial submitted an abstract with data, including free hemoglobin data, from the REFRESH I trial which was selected for a podium presentation at the American Association of Thoracic Surgery conference on May 1, 2017. On May 5, 2017, we announced additional REFRESH I data, including data on plasma free hemoglobin and activated complement from the study and disclosed that investigators of the study have submitted a manuscript of the REFRESH I trial for publication. In parallel, the Company plans to meet with the FDA to discuss the results of REFRESH I in anticipation of filing an IDE application to initiate a pivotal REFRESH 2 trial in 2017.

The market focus for CytoSorb is the prevention or treatment of organ failure in life-threatening conditions, including commonly seen illnesses in the ICU such as infection and sepsis, trauma, burn injury, 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 excessive levels of cytokines and other inflammatory toxins, to help reduce the SIRS response and either prevent or treat organ failure.

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

VetResQ - a broad spectrum blood purification adsorber designed to help treat deadly inflammation and toxic injury in animals with critical illnesses such as septic shock, toxic shock syndrome, severe systemic inflammation, toxin-mediated diseases, pancreatitis, trauma, liver failure, and drug intoxication.

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 older blood.

ContrastSorb – a development-stage extracorporeal hemoperfusion cartridge designed to remove IV contrast from the blood of high risk patients undergoing CT imaging with contrast, or interventional radiology procedures such as cardiac catheterization. The goal 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 governmental agencies such as the National Institutes of Health and the U.S. Department of Defense, including, for example, the Defense Advanced Research Projects Agency, or DARPA, the U.S. Army, U.S. Special Operations Command, and the U.S. Air Force.

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 have completed our work under the contract with DARPA and SSC Pacific under Contract No. N66001-12-C-4199 that provided for maximum funding of approximately \$3,825,000. As of June 30, 2017, we have received approximately \$3,825,000 in funding under this contract and no funding remains.

In September 2012, we were awarded a Phase II Small Business Innovation Research (“SBIR”) contract by the U.S. Army Medical Research and Materiel 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 Materiel Command under an amendment to Contract W81XWH-12-C-0038. In June 2016, this contract was further amended to increase the maximum funding by \$443,000 to approximately \$1,246,000. As of June 30, 2017, we received approximately \$1,213,000 in funding under this contract and have approximately \$33,000 remaining under this contract.

In September 2013, the National Heart, Lung and Blood Institute (“NHLBI”), a division of the National Institutes of Health, 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 packed red blood cell (“pRBC”) transfusions. The University of Dartmouth collaborated with us as a subcontractor on the project, entitled “Elimination of blood contaminants from pRBCs using HemoDefend hemocompatible porous polymer beads.” The overall goal of this program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs. Our performance under this contract has been completed.

In October 2015, we were awarded a Phase II SBIR contract by the NHLBI, with support from U.S. SOCOM, to help advance our HemoDefend blood purification technology towards commercialization for the purification of pRBC transfusions. The contract, entitled “pRBCs Contaminant Removal with Porous Polymer Beads” (contract number HHSN-268201-600006C), provides for maximum funding of approximately \$1,522,000 over a two year period. As of June 30, 2017, we have received approximately \$928,000 and have approximately \$594,000 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, 2017, we received approximately \$150,000 and no funding is remaining under this contract.

In June 2016, we were awarded a Phase I Small Business Technology Transfer (“STTR”) contract for a 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 U.S. Army Medical Research Acquisition Activity (“USAMRAA”) under contract W81XWH-16-C-0025 and provides for maximum funding of \$150,000. As of June 30, 2017, we received approximately \$150,000 and no funding is remaining under this contract.

In July 2016, we were awarded a Phase I 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. This work is being funded by the USAMRAA under contract W81XWH-16-C-0080 and provides for maximum funding of approximately \$150,000. As of June 30, 2017, we received approximately \$150,000 and no funding is remaining under this contract.

In January 2017, the Company was awarded a Phase II SBIR contract to continue development of CytoSorb for fungal mycotoxin blood purification. This program will focus on demonstrating the ability of CytoSorb to absorb mycotoxins in vivo and improve survival in animals. This contract provides for maximum funding of \$999,996 over two years. This program is funded by the Chemical and Biological Defense (“CBD”) SBIR program under Contract number W911QY-17-C-0007. As of June 30, 2017, we have received approximately \$196,000 and have approximately \$804,000 remaining under this contract.

In May 2017, the Company was awarded a Phase II STTR contract Titled “Use of Highly Porous Polymer Beads to Remove Anti-A and Anti-B Antibiotics from Plasma Transfusion”. The purpose of this contract is to continue development of our HemoDefend blood purification technology to potentially enable universal plasma. CytoSorbents will collaborate with researchers at Penn State University on this project. This contract provides for maximum funding of \$999,070 over two years. This work is being funded by the USAMRAA under contract number W81XWH-17-C-0053. As of June 30, 2017, we have received approximately \$40,000 and have approximately \$959,070 remaining under this contract.

In May 2017, the Company was awarded a Congressionally Directed Medical Research Program (“CDMRP”) Phase I contract to improve delayed evacuation and prolonged field care for severe burn injury via novel hemoadsorbptive and hydration therapies. This work is being funded by the USAMRAA under contract number W81WH-17-2-0013. This contract provides for maximum funding of \$719,000 over four years. As of June 30, 2017, we have received approximately \$6,000 and have approximately \$713,000 remaining under this contract.

## **Results of Operations**

### ***Comparison for the three months ended June 30, 2017 and 2016:***

#### ***Revenues:***

Revenue from product sales was approximately \$3,041,000 in the three months ended June 30, 2017, as compared to approximately \$1,853,000 in the three months ended June 30, 2016, an increase of approximately \$1,188,000, or 64%. 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 \$525,000 for the three months ended June 30, 2017 as compared to approximately \$370,000 for the three months ended June 30, 2016, an increase of approximately \$155,000. 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, 2017, we generated total revenue of approximately \$3,566,000, as compared to total revenues of approximately \$2,222,000, for the three months ended June 30, 2016, an increase of approximately \$1,344,000 or 60%.

***Cost of Revenues:***

For the three months ended June 30, 2017 and 2016, cost of revenue was approximately \$1,482,000 and \$873,000, respectively, an increase of approximately \$609,000. Product cost of revenues increased approximately \$458,000 during the three months ended June 30, 2017 as compared to the three months ended June 30, 2016 due to increased sales. Product gross margins were approximately 65% for the three months ended June 30, 2017, as compared to approximately 68% for the three months ended June 30, 2016. This decrease in gross margin was primarily due to the mix of direct and distributor sales.

***Research and Development Expenses:***

For the three months ended June 30, 2017, research and development expenses were approximately \$488,000 as compared to research and development expenses of approximately \$1,092,000 for the three months ended June 30, 2016. The decrease of approximately \$604,000 was due to a decrease in costs related to our various clinical studies and trials of approximately \$469,000 and an increase in direct labor and other costs being deployed toward grant-funded activities of approximately \$151,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs. These decreases were offset by an increase in our non-clinical research and development activities of approximately \$16,000.

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

Legal, financial and other consulting expenses were approximately \$443,000 for the three months ended June 30, 2017, as compared to approximately \$319,000 for the three months ended June 30, 2016. The increase of approximately \$124,000 was due to an increase in employment agency fees of approximately \$80,000 related to the recruitment of senior level personnel and an increase in legal fees of approximately \$63,000 related to certain corporate initiatives and an increase in consulting fees of approximately \$5,000. These increases were offset by decreases in auditing and other consulting fees of approximately \$24,000 due to fees incurred related to the audit of our internal controls as required by The Sarbanes-Oxley Act of 2002 in 2016 that did not recur in 2017.

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

Selling, general and administrative expenses were approximately \$3,484,000 for the three months ended June 30, 2017, as compared to approximately \$2,625,000 for the three months ending June 30, 2016. The increase of \$859,000 was due to an increase in non-cash stock-based compensation expense of approximately \$411,000 primarily based upon progress toward meeting the 2017 operating milestones, increases in salaries, commissions and related costs of approximately \$82,000 due to headcount additions and personnel related costs, an increase in royalty expenses of approximately \$110,000 due to the increase in product sales, additional sales and marketing costs, which include advertising and conferences of approximately \$48,000, an increase in travel and entertainment and other costs of approximately \$70,000, an increase in rent expense of approximately \$29,000 related to the new expanded office facility in Germany, an increase in public relations costs of approximately \$27,000, an increase in stock transfer fees of approximately \$9,000 and other general and administrative cost increases of approximately \$73,000.

***Interest Income (Expense):***



For the three months ended June 30, 2017, interest expense was approximately \$123,000, as compared to interest income of approximately \$2,000 for the three months ended June 30, 2016. This increase in interest expense of approximately \$125,000 is directly related to interest expense incurred and amortization of loan acquisition costs related to the Company's financing facility with Bridge Bank on which \$5,000,000 was drawn on June 30, 2016 and was outstanding for the three months ended June 30, 2017.

***Gain (Loss) on Foreign Currency Transactions:***

For the three months ended June 30, 2017, the gain on foreign currency transactions was approximately \$720,000 as compared to a loss of approximately \$129,000 for the three months ended June 30, 2016. The 2017 gain is directly related to the increase in the exchange rate of the Euro at June 30, 2017 as compared to March 31, 2017. The exchange rate of the Euro to the U.S. dollar was \$1.14 per Euro at June 30, 2017 as compared to \$1.07 per Euro at March 31, 2017. The 2016 loss 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 \$1.11 per Euro at June 30, 2016 as compared to \$1.14 per Euro at March 31, 2016.

***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 non-cash other income of approximately \$618,000 for the three months ended June 30, 2017 as compared to non-cash other expense approximately \$190,000 for the three months ended June 30, 2016. The change in warrant liability was a result of the change in the fair value of the warrant liability from March 31, 2017 to June 30, 2017 and from March 31, 2016 to June 30, 2016. 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 six months ended June 30, 2017 and 2016:***

***Revenues:***

Revenue from product sales was approximately \$5,637,000 in the six months ended June 30, 2017, as compared to approximately \$3,450,000 in the six months ended June 30, 2016, an increase of approximately \$2,187,000, or 63%. 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 \$1,043,000 for the six months ended June 30, 2017, as compared to approximately \$582,000 for the six months ended June 30, 2016, an increase of approximately \$461,000, or 79%. 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 six months ended June 30, 2017, we generated total revenue of approximately \$6,680,000, as compared to total revenue of approximately \$4,032,000, for the six months ended June 30, 2016, an increase of approximately \$2,648,000, or 66%.

***Cost of Revenues:***

For the six months ended June 30, 2017 and 2016, cost of revenue was approximately \$2,736,000 and \$1,693,000, respectively, an increase of approximately \$1,043,000. Product cost of revenues increased approximately \$687,000

during the six months ended June 30, 2017 as compared to the six months ended June 30, 2016 due to increased sales. Product gross margins were approximately 66% for the six months ended June 30, 2017, as compared to approximately 65% for the six months ended June 30, 2016 primarily due to the mix of direct and distributor sales. Grant income related expenses increased due to direct labor and other costs being deployed toward grant-funded activities, an increase of approximately \$356,000 during the six months ended June 30, 2017 as compared to the six months ended June 30, 2016.

***Research and Development Expenses:***

For the six months ended June 30, 2017, research and development expenses were approximately \$957,000, as compared to research and development expenses of approximately \$1,948,000 for the six months ended June 30, 2016, a decrease of approximately \$991,000. This decrease was due to a reduction in costs related to the various clinical studies of approximately \$672,000 and, an increase in direct labor and other costs being deployed toward grant-funded activities of approximately \$356,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs. These decreases were offset by increases in other research and development costs of approximately \$37,000.

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

Legal, financial and other consulting expenses were approximately \$723,000 for the six months ended June 30, 2017, as compared to approximately \$574,000 for the six months ended June 30, 2016. The increase of approximately \$149,000 was due to an increase in employment agency fees of approximately \$110,000 related to the hiring of senior level personnel and increases in legal fees of approximately \$85,000 related to various corporate initiatives. These increases were offset by decreases in accounting and audit fees of approximately \$25,000 due to fees incurred related to the audit of our internal controls as required by The Sarbanes-Oxley Act of 2002 in 2016 that did not recur in 2017 and a decrease in consulting fees of approximately \$21,000.

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

Selling, general and administrative expenses were approximately \$6,151,000 for the six months ended June 30, 2017, as compared to approximately \$4,595,000 for the six months ending June 30, 2016, an increase of \$1,556,000. The increase in selling, general, and administrative expenses was due to an increase in non-cash stock compensation expense of approximately \$500,000 primarily based upon progress toward meeting the 2017 operating milestones, increases in salaries, commissions and related costs of approximately \$395,000 due to headcount additions and increases in product sales, an increase in royalty expenses of approximately \$204,000 due to the increase in sales, additional sales and marketing costs, which include advertising and conferences of approximately \$141,000 and an increase in travel and entertainment costs and other expenses of approximately \$126,000, an increase in occupancy cost of approximately \$55,000 related to the new expanded office facility in Germany, an increase in public relations expense of approximately \$22,000, an increase in office supplies and related expenses of approximately \$57,000 and other general and administrative cost increases of approximately \$56,000.

***Interest Income (Expense):***

For the six months ended June 30, 2017, interest expense was approximately \$244,000, as compared to interest income of approximately \$5,000 for the six months ended June 30, 2016. This increase in interest expense of approximately \$249,000 is directly related to interest expense incurred and amortization of loan acquisition costs related to the Company's financing facility with Bridge Bank on which \$5,000,000 was drawn on June 30, 2016 and was outstanding for the six months ended June 30, 2017.

***Gain (Loss) on Foreign Currency Transactions:***

For the six months ended June 30, 2017, the gain on foreign currency transactions was approximately \$873,000, as compared to approximately \$103,000 for the six months ended June 30, 2016. The 2017 gain is directly related to the increase in the exchange rate of the Euro at June 30, 2017, as compared to December 31, 2016. The exchange rate of the Euro to the U.S. dollar was \$1.14 per Euro at June 30, 2017 as compared to \$1.05 per Euro at December 31, 2016. 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.

***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 non-cash other income of approximately \$765,000 for the six months ended June 30, 2017, and non-cash other expense of approximately \$172,000 for the six months ended June 30, 2016. The change in warrant liability was a result of the change in the fair value of the warrant liability from December 31, 2016 to June 30, 2017 and from December 31, 2015 to June 30, 2016. 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, 2017, we had an accumulated deficit of approximately \$146,959,000, which included losses of approximately \$2,494,000 and \$4,842,000 for the six month periods ended June 30, 2017 and 2016, 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 issuance of debt and equity securities. At June 30, 2017, we had current assets of approximately \$19,741,000 including cash on hand of approximately \$16,402,000 and current liabilities of approximately \$6,230,000.

On June 30, 2016, the Company and its wholly-owned subsidiary, CytoSorbents Medical, Inc., 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. We received the proceeds from the first tranche on June 30, 2016 and from the second tranche on June 30, 2017.

In addition, on April 5, 2017, the Company closed on the sale of an aggregate of 2,222,222 shares of Common Stock pursuant to the Company's existing shelf registration statement (Registration No. 333-205806) on Form S-3. The Company received gross proceeds of approximately \$10 million, based on a public offering price of \$4.50 per share. On April 11, 2017, the Company closed the sale of an additional 333,333 shares of the Company's Common Stock, pursuant to the underwriters' full exercise of an over-allotment option. The Company received gross proceeds of approximately \$1.5 million as a result of the exercise of the option. As a result, the Company received total gross proceeds of \$11.5 million, and, after deducting the underwriting discounts and commissions and estimated expenses related to the offering, the Company received total net proceeds of approximately \$10.3 million.

As a result of the receipt of additional proceeds both under the Loan and Security Agreement in June 2017 and in conjunction with the closing of the equity financing in April 2017, we believe we have sufficient liquidity to fund our operations through 2018; 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.

## **Contractual Obligations**

In April 2017, the Company entered into a Fifteenth Amendment to Lease Agreement with Princeton Corporate Plaza, LLC, which expands our space to approximately 15,100 square feet and extended the term of the lease for its corporate headquarters and manufacturing facility through May 31, 2019 and, effective June 1, 2017, increased the Company's base rent obligation to \$27,083 per month. In addition, the lease amendment provides the Company with an option to extend the term of the lease for an additional one year period through May 31, 2020 upon certain conditions.

In September 2016, the Company entered into a five year lease agreement with Klimik GmbH for 600 square meters of office and warehouse space for its wholly-owned subsidiary CytoSorbents Europe GmbH. The lease, which commenced on September 1, 2016, has a rent obligation of \$6,789 per month. The lease expires on August 31, 2021. The lease also provides the Company with an option to extend the term of the lease for an additional five year period through August 31, 2026.

The following table summarizes our obligations with regard to our contractual obligations as of June 30, 2017, 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	\$325,221	\$460,861	\$95,053	–
Long-term debt	2,000,000	4,000,000	2,000,000	–
	\$2,325,221	\$4,460,861	\$2,095,053	–

### **Off-balance Sheet Arrangements**

We have no off-balance sheet arrangements.

### **Going Concern**

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We believe that we have adequate cash for more than the next 12 months of operations, however, we may need have to raise additional capital to support clinical trials in the U.S. and/or elsewhere. We will be better able to address this need once the specific protocols of these trials are finalized.

As of June 30, 2017, we had an accumulated deficit of approximately \$146,959,000, which included net losses of approximately \$2,494,000 for the six months ended June 30, 2017, and \$4,842,000 for the six months ended June 30, 2016. 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 generate sales in both dollars and euros most significantly, the majority of our sales are in Euros and changes in the exchange rate of the Euro to the U.S. dollar may positively or negatively impact our revenue. On the other hand, should sales decline due to a devaluation of the Euro relative to the U.S. dollar, expenses related to CytoSorbents Europe GmbH would also decline. This produces 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 in the future.

#### **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 (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 Exchange Act) 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 Exchange Act 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, 2017 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, 2017, we had an accumulated deficit of approximately \$146,959,000, which included net losses of approximately \$2,494,000 and \$4,842,000 for the six months ended June 30, 2017 and 2016, respectively. Due in part 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 continued adoption and usage of our products in the market, obtaining additional regulatory approvals in markets not covered by the CE Mark, establishing sales and marketing arrangements with third parties, satisfactory reimbursement in key territories, 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 reimbursement will be available or satisfactory, 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 these 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, 2017, we had current assets of approximately \$19,741,000, including cash on hand of approximately \$16,402,000 and current liabilities of approximately \$6,230,000. For the six months ended June 30, 2017, our cash burn was approximately \$4.2 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 an effective shelf registration statement with the SEC which enables us to raise up to \$100 million in equity financing. We entered into a Controlled Equity Offering <sup>SM</sup> 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.

On June 30, 2016, we entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank (the “Bank”), pursuant to which the Bank agreed to loan us up to an aggregate of \$10,000,000, to be disbursed in two equal tranches of \$5,000,000. We received the proceeds from the first tranche on June 30, 2016 and from the second tranche on June 30, 2017. In addition, in April 2017, we raised net proceeds of approximately \$10.3 million from the sale of 2,555,555 shares of our common stock. Despite the foregoing, we expect we will require additional financing in the future. Should the financing we require be unavailable to us, or on terms unacceptable to us when we require it, the consequences could have 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 non-dilutive 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. Such events may have a material adverse effect on our business, operating results, financial condition and prospects.

***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 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.

***If users of our products are unable to obtain adequate reimbursement from third-party payers, or if reimbursement is not available in specific countries, 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, 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.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets often have a combination of government-managed and privately-managed healthcare systems that govern reimbursement for medical devices and related procedures. Socialized medicine is common in the EU, and reimbursement and the pricing of medical devices is often subject to governmental control. Application for reimbursement, subsequent approvals, if any, and pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. Private insurance has similar challenges. CytoSorb is currently reimbursed in Germany under government-funded insurance, and in other countries may be covered under the DRG, or “lump sum payment” reimbursement, or other generalized reimbursement for acute care medical products. We are continuously working to obtain or improve upon the type and amount of reimbursement available to us in countries where CytoSorb is available, and as we attempt to move from an existing reimbursement platform to a new reimbursement platform, we may experience interruptions and/or reductions in the amount available for reimbursement. Because of this, there can be no assurance that new reimbursement will be obtained or that existing reimbursement will continue or that such reimbursement will be sufficient to adequately cover the cost of the device or treatment. As a result, our future revenues, profitability and access to capital may be negatively affected by any interruption or reduction in amounts of reimbursement. We plan to seek reimbursement for our product in other EU and non-EU countries to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved.

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

As of August 1, 2017, we have 76 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. Eric R. Mortensen, our Chief Medical Officer. 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.

***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 one 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 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 10 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 marketing authorization in the EU under the CE marking process 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 EU, as well as in the U.S. and in other 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. At the same time, relationships with these individuals and entities are the subject of heightened scrutiny and may present the potential for future healthcare enforcement risk.***

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. In addition, our interactions, communications, and financial relationships with these individuals and entities present future healthcare enforcement risks.

***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.

***Our business could be harmed by adverse economic conditions in Germany, our primary geographical market, or by economic and/or political instability in the EU caused by Brexit, or other factors.***

For the six months ended June 30, 2017, we derived a majority of our net product sales from sales in Germany. Despite modest European and global growth, there are many economic and political issues that could negatively impact the health of Germany's economy, the broader EU economy, and the world economy overall. Examples include the uncertainty over the United Kingdom's intent to leave the EU, also known as "Brexit," economic instability in a number of EU member countries, and changes in the political leadership in the EU and United States. Germany and other European countries face additional risks to their local economies, some of which include the impact of foreign exchange fluctuations, unemployment, tightening of monetary policy, the economic burden of immigration, diminished liquidity and reliance on debt, the rising cost of healthcare, and other factors. In addition, the German government, insurance companies, health maintenance organizations and other payers of healthcare costs continue to focus on healthcare reform and containment of healthcare costs. We cannot predict whether Germany's economy will continue to grow or decline consistent with the overall global economy, which decline would negatively impact the demand for medical devices and healthcare technologies generally and lead to reduced spending on the products we provide. In addition, continued healthcare cost containment efforts may result in lower prices and a reduction or elimination of reimbursement for our products. Due to the concentration of our product sales in this country, any of the foregoing may have a negative impact on our revenues, business operations and financial condition.

***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 (the “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.

***We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.***

Our products are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the

U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or changes in applicable export or import laws and regulations may create delays in the introduction and sale of our products in international markets or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws and regulations, shift in the enforcement or scope of existing laws and regulations, or change in the countries, governments, persons, products, or technologies targeted by such laws and regulations, could also result in decreased use of our products, or in our decreased ability to export or sell our products to existing or potential customers. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business, financial condition and results of operations.

*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, 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 (“NASDAQ”) and our Common Stock began trading on NASDAQ on December 23, 2014 under the symbol “CTSO.” Our Common Stock closed as high as \$6.30 and as low as \$3.45 per share between January 1, 2017 and June 30, 2017 on NASDAQ. On August 3, 2017, the closing price of our Common Stock, as reported on NASDAQ, was \$4.85. 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 and our competitors; and
- general market conditions.

There is no assurance that the price of our Common Stock will not continue to be volatile.

***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, 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 21,866,000 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 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 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 may cause our share price to fall.***

In November 2015, we entered into a Controlled Equity Offering<sup>SM</sup> 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. Although any sale of securities pursuant to the “at-the-market” offerings will result in a concomitant increase in cash for each share sold, it may result in shareholder dilution and may 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.** None.

**Item 6. Exhibits.**

Number Description

10.1	Employment Agreement by and between the Registrant and Dr. Eric M. Mortensen, M.D., Ph.D., dated May 23, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed on May 30, 2017).
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.*
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## Edgar Filing: Cytosorbents Corp - Form 10-Q

The following materials from CytoSorbents Corporation's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2017 and December 31, 2016, (ii) Consolidated Statements of Operations for the three and six months ended June 30, 2017 and June 30, 2016, (iii) Consolidated Statement of Changes in Stockholders' Equity for the period from December 31, 2016 to June 30, 2017, (iv) Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and June 30, 2016 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 7, 2017 By: /s/ Phillip P. Chan

Name: Phillip P. Chan

Title: President and Chief Executive Officer

(Principal Executive Officer)

Dated: August 7, 2017 By: /s/ Kathleen P. Bloch

Name: Kathleen P. Bloch, CPA

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)