Cytosorbents Corp
Form 10-Q
November 06, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

Or

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

Commission file number: 001-36792

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

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

7 Deer Park Drive, Suite K

Monmouth Junction, New Jersey 08852

(Address of principal executive offices) (Zip Code)

(732) 329-8885

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically 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 such files). Yes þ 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 ¨	Accelerated filer þ
Non-accelerated filer ¨	Smaller reporting companyþ
	Emerging growth company ¨

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 þ No

As of October 31, 2018 there were 31,651,821 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", "CytoSorb XL", "BetaSorb", "ContrastSorb", "DrugSorb", "HemoDefend", and "VetResQ", which are protected under applicable intellectual property laws and are the property of CytoSorbents Corporation and its subsidiaries. This Report also contains the trademarks, trade names and

service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Report may appear without the ™, ®, or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, trade names and service marks. We do not intend our 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

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$24,911,264	$17,321,862
Grants and accounts receivable, net of allowance for doubtful accounts of $80,873 at September 30, 2018 and $72,698 at December 31, 2017	3,642,510	2,205,859
Inventories	779,425	795,657
Prepaid expenses and other current assets	617,119	415,962
Total current assets	29,950,318	20,739,340
Property and equipment, net	1,677,049	1,402,782
Other assets	2,622,104	1,961,185
Total Assets	$34,249,471	$24,103,307
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$1,859,328	$1,244,411
Current maturities of long-term debt	-	4,000,000
Accrued expenses and other current liabilities	2,401,975	2,603,920
Total current liabilities	4,261,303	7,848,331
Long term debt, net of current maturities and debt issuance costs	9,917,439	5,992,141
Total Liabilities	14,178,742	13,840,472
Commitments and Contingencies (Note 6)		
Stockholders’ Equity:		
Preferred Stock, 5,000,000 shares authorized; -0- shares issued and outstanding at September 30, 2018 and December 31, 2017	-	-
Common Stock, Par Value $0.001, 50,000,000 shares authorized; 31,633,432 and 28,973,679 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	31,633	28,974
Additional paid-in capital	184,089,635	162,907,482
Accumulated other comprehensive income (loss)	70,097	(360,985)
Accumulated deficit	(164,120,636)	(152,312,636)

Total stockholders' equity	20,070,729	10,262,835
Total Liabilities and Stockholders' Equity	$34,249,471	$24,103,307

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three months ended September 30,		Nine months ended September 30,	
	2018 (Unaudited)	2017 (Unaudited)	2018 (Unaudited)	2017 (Unaudited)
Revenue:				
CytoSorb sales	$5,102,748	$3,416,461	$14,693,699	$9,029,606
Other sales	-	32,200	87,900	56,200
Total product sales	5,102,748	3,448,661	14,781,599	9,085,806
Grant income	640,225	375,638	1,641,464	1,418,237
Total revenue	5,742,973	3,824,299	16,423,063	10,504,043
Cost of revenue	2,052,696	1,516,864	5,406,195	4,253,357
Gross profit	3,690,277	2,307,435	11,016,868	6,250,686
Other expenses:				
Research and development	1,943,417	643,193	5,299,475	1,555,491
Legal, financial and other consulting	416,634	238,303	1,290,783	961,444
Selling, general and administrative	4,040,847	3,574,984	14,426,272	9,771,182
Total expenses	6,400,898	4,456,480	21,016,530	12,288,117
Loss from operations	(2,710,621)	(2,149,045)	(9,999,662)	(6,037,431)
Other income/(expense):				
Interest expense, net	(185,238)	(253,780)	(1,264,161)	(497,683)
Gain (loss) on foreign currency transactions	(108,903)	348,546	(544,177)	1,221,334
Total other income (expense), net	(294,141)	94,766	(1,808,338)	723,651
Loss before benefit from income taxes	(3,004,762)	(2,054,279)	(11,808,000)	(5,313,780)
Benefit from income taxes	-	-	-	-
Net loss	(3,004,762)	(2,054,279)	(11,808,000)	(5,313,780)
Dividend, warrant exercise price adjustment	-	-	-	(335,731)
Net loss available to common stockholders	(3,004,762)	(2,054,279)	(11,808,000)	(5,649,511)
Basic and diluted net loss per common share	$(0.10)	$(0.07)	$(0.39)	$(0.21)
Weighted average number of shares of common stock outstanding	31,305,620	28,206,437	30,394,326	27,231,145
Net loss	$(3,004,762)	$(2,054,279)	$(11,808,000)	$(5,313,780)
Other comprehensive income (loss):				
Currency translation adjustment	99,286	(280,078)	431,082	(1,021,961)
Comprehensive loss	$(2,905,476)	$(2,334,357)	$(11,376,918)	$(6,335,741)

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

For the nine months ended September 30, 2018 (Unaudited):

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Par value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2017	28,973,679	$28,974	$162,907,482	$ (360,985)	$(152,312,636)	$10,262,835
Stock based compensation - employees, consultants and directors	-	-	2,863,739	-	-	2,863,739
Issuance of common stock, net of fees	1,498,230	1,498	13,915,465	-	-	13,916,963
Other comprehensive income: foreign translation adjustment	-	-	-	431,082		431,082
Proceeds from exercise of stock options	576,936	578	1,940,133	-	-	1,940,711
Cashless exercise of stock options	50,032	49	(49)	-	-	-
Cashless exercise of warrants	89,556	89	(89)	-	-	-
Issuance of restricted stock units	62,406	62	545,631	-	-	545,693
Proceeds from exercise of warrants	313,802	314	1,280,392	-	-	1,280,706
Success fee – Bridge Bank	68,791	69	636,931	-	-	637,000
Net loss	-	-	-	-	(11,808,000)	(11,808,000)
Balance at September 30, 2018	31,633,432	$31,633	$184,089,635	$ 70,097	$(164,120,636)	$20,070,729

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine months ended September 30, 2018 (Unaudited)	Nine months ended September 30, 2017 (Unaudited)
Cash flows from operating activities:		
Net loss	$ (11,808,000)	$ (5,313,780)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	637,000	-
Non-cash compensation	734,308	251,729
Depreciation and amortization	256,794	161,688
Amortization of debt costs	73,286	56,268
Bad debt	16,722	3,897
Stock-based compensation	2,863,739	1,851,020
Foreign currency transaction loss (gain)	544,177	(1,221,334)
Changes in operating assets and liabilities:		
Grants and accounts receivable	(1,518,237)	(803,348)
Inventories	14,259	(227,882)
Prepaid expenses and other current assets	(209,683)	(8,528)
Other assets	(6,414)	(15,000)
Accounts payable and accrued expenses	269,511	(785,951)
Net cash used by operating activities	(8,132,538)	(6,051,221)
Cash flows from investing activities:		
Purchases of property and equipment	(495,526)	(579,944)
Payments for patent costs	(701,306)	(516,203)
Net cash used by investing activities	(1,196,832)	(1,096,147)
Cash flows from financing activities:		
Proceeds from long-term debt	666,667	5,000,000
Repayment of long-term debt	(666,667)	-
Payment of debt acquisition costs	(147,988)	(1,560)
Equity contributions - net of fees incurred	13,916,963	11,775,046
Proceeds from exercise of stock options	1,940,711	181,480
Proceeds from exercise of warrants	1,280,706	260,504
Net cash provided by financing activities	16,990,392	17,215,470
Effect of exchange rates on cash	(71,620)	87,068
Net change in cash and cash equivalents	7,589,402	10,155,170
Cash and cash equivalents - beginning of period	17,321,862	5,245,178

Cash and cash equivalents - end of period	$ 24,911,264	$ 15,400,348
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 667,427	$ 407,347
Supplemental disclosure of non-cash investing and financing activities:		
Settlement of accrued bonuses with restricted stock units	$ 545,693	$ 207,608
Dividend, warrant exercise price adjustment	$ -	$ 335,731
Proceeds from sale of stock not yet received	$ -	$ 196,417
Settlement of Success Fee with common stock	$ 637,000	$ -

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation

Notes to Consolidated Financial Statements

(UNAUDITED)

September 30, 2018

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, 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, 2017 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (the "SEC") on March 8, 2018. The results for the three and nine months ended September 30, 2018 and 2017 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 September 30, 2018, the Company had an accumulated deficit of $164,120,636, which included net losses of $11,808,000 for the nine months ended September 30, 2018 and $5,313,780 for the nine months ended September 30, 2017. 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 net 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 its technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE mark previously received for the Company's CytoSorb product and for potential label extensions of the current CE mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance the Company's activities. No assurance can be given that the Company's product development efforts will be successful, that the Company's current CE mark will enable it 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 using blood purification technology to treat deadly inflammation in critically-ill and cardiac surgery patients around the world. 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 wholly owned European subsidiary, CytoSorbents Europe GmbH, conducts sales and marketing related operations for the CytoSorb device. In March 2016, the Company formed CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH. This subsidiary, which began operations during the second quarter of 2016, provides marketing and direct sales services in Switzerland. CytoSorb, the Company's flagship product, was approved in the European Union ("EU") in March 2011,and is currently being marketed in and distributed in fifty-three countries around the world, as a safe and effective extracorporeal cytokine absorber, designed to reduce the "cytokine storm" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, and pancreatitis. In May 2018, the Company received a label extension for CytoSorb covering use of the device for the removal of bilirubin and myoglobin which allows for the use of the device in the treatment of liver failure and trauma, respectively. 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.

The technology is based upon biocompatible, highly porous polymer sorbent beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface absorption. The Company has numerous products under development based upon this unique blood purification technology, which is protected by 19 issued U.S. patents and multiple international patents, with applications pending both in the U.S. and internationally, including HemoDefend, ContrastSorb, DrugSorb, and others. These patents and patent applications are directed to various compositions and methods of use related to our blood purification technologies and are expected to expire between 2020 and 2035, absent any patent term extensions. Management believes that any near term 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, 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 direct and indirect wholly-owned subsidiaries, CytoSorbents Medical, Inc, CytoSorbents Europe GmbH and CytoSorbents Switzerland GmbH. All significant intercompany transactions and balances have been eliminated in consolidation.

Translation gains and losses resulting from the process of remeasuring into the U.S. dollar, the foreign currency financial statements of CytoSorbents Europe GmbH, for which the local currency is the functional currency, are included in other comprehensive income. Foreign currency transaction gains (loss) included in net loss amounted to approximately $(109,000) and $349,000 for the three months ended September 30, 2018 and 2017, respectively. Foreign currency transaction gains (loss) included in net loss amounted to approximately $(544,000) and $1,221,000 for the nine months ended September 30, 2018 and 2017, 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 its customers' financial conditions. 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 $81,000 and $73,000 at September 30, 2018 and December 31, 2017, respectively.

Inventories

Inventories are valued at the lower of cost or net realizable value under the first in, first out (FIFO) method. At September 30, 2018 and December 31, 2017, the Company's inventory was comprised of finished goods, which amounted to $159,998 and $151,872, respectively; work in process which amounted to $390,497 and $528,039, respectively; and raw materials, which amounted to $228,930 and $115,746, 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.

Revenue Recognition

Product Sales: Revenues from sales of products to both direct and distributor/strategic partner customers are recognized at the time when control passes to the customer, in accordance with the terms of their respective contracts. Recognition of revenue occurs as each performance obligation is completed.

*Grant Income***:** 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 the associated performance obligation is fulfilled. 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 $40,000 and $45,000 for the three months ended September 30, 2018 and 2017, respectively, and approximately $126,000 and $132,000 for the nine months ended September 30, 2018 and 2017, 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. The Company has provided a valuation allowance against all deferred tax assets. 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 Tax Cuts and Job Act was enacted on December 22, 2017 and reduces the U.S. Federal corporate income tax rate from 35% to 21%.

The Company follows accounting standards associated with uncertain tax positions. The Company had no unrecognized tax benefits at September 30, 2018 or December 31, 2017. 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 change in fair value of the down round feature related to certain of the Company's outstanding warrants.

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. (See Note 4 for further information relating to the Company's revenue.)

As of September 30, 2018, one distributor accounted for approximately 14% of outstanding grants and accounts receivable. As of September 30, 2017, two distributors accounted for approximately 33% of outstanding grants and accounts receivable. As of December 31, 2017, two distributors accounted for approximately 28% of outstanding grants and accounts receivable. For the three and nine months ended September 30, 2018 and 2017, no agency, distributor, or direct customer represented more than 10% of the Company's total 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 loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is computed using the treasury stock method on the basis of the weighted-average number of shares of common stock plus the dilutive effect of potential common shares outstanding during the period. Dilutive potential common shares include outstanding warrants, stock options and restricted shares. The computation of diluted earnings per share does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings (See Note 7).

Stock-Based Compensation

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

The Company 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 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 has evaluated the impact of the updated guidance and has determined that the adoption of ASU 2016-02 is not expected to 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 cost of revenue. Total freight costs amounted to approximately $67,000 and $50,000, respectively, for the three months ended September 30, 2018 and 2017, and $273,000 and $178,000, respectively, for the nine months ended September 30, 2018 and 2017.

Reclassifications

Certain reclassifications have been made to the September 30, 2017 financial statements in order to conform to the 2018 financial statement presentation. There was no change in the reported amount of the accumulated deficit as a result of these reclassifications.

3.STOCKHOLDERS' EQUITY

Preferred Stock

In December 2014, the Company amended and restated its certificate of incorporation to reduce the total number of authorized shares of preferred stock. The amended and restated certificate of incorporation authorizes the issuance of up to 5,000,000 shares of “blank check” preferred stock, par value $0.001 per share, 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 (the “2015 Shelf”), was declared effective using a “shelf” registration process. On July 26, 2018, in anticipation of the expiration of the 2015 Shelf, the Company filed a new registration statement on Form S-3 with the SEC (as amended, the “2018 Shelf”). The 2018 Shelf, which was declared effective on August 7, 2018, enables the Company to offer and sell, in one or more offerings, any combination of common stock, preferred stock, senior or subordinated debt securities, warrants and units, up to a total dollar amount of $150 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 2015 Shelf. The Company received gross proceeds of approximately $10,000,000, from the sale of such shares 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 from the exercise of the option. As a result, the Company received total gross proceeds of $11,500,000 from the offering, and, after deducting the underwriting discounts and commissions and related expenses, 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. There was no change in the number of warrants which were repriced. As a result of the repricing of the warrants which occurred in connection with the April 2017 equity offering, the Company recorded a dividend of $335,731 during the year ended December 31, 2017.

November 4, 2015 Controlled Equity Offering

On November 4, 2015, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & 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 (the "Shares"). Any Shares hereafter offered and sold will be issued pursuant to the Company's 2018 Shelf, and the related prospectus which the Company filed with the SEC pursuant to Rule 424(b)(5) under the Securities Act.

On July 26, 2018, the Company entered into that certain Amendment No. 1 to the Sales Agreement (the "Sales Agreement Amendment") to extend the term of the Sales Agreement until the expiration of the 2018 Shelf. The other provisions of the Sales Agreement remain unchanged. References herein to "Sales Agreement" shall refer to the Sales Agreement, as amended by the Sales Agreement Amendment.

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, 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 expiration of the 2018 Shelf (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. From November 4, 2015 through December 31, 2015, the Company sold 28,880 shares, generating net proceeds of approximately $225,000 under the Sales Agreement. There were no sales during the year ended December 31, 2016. During the year ended December 31, 2017, the Company sold 550,000 shares at an average price of $6.31 per share, generating net proceeds of approximately $3,367,000. During the nine months ended September 30, 2018, the Company sold 1,498,320 shares at an average cost of $9.58 per share, generating net proceeds of approximately $13,917,000. From October 1, 2018 through October 31, 2018, the Company sold 17,030 shares at an average cost of $12.69 per share, generating net proceeds of approximately $209,000. In the aggregate, the Company has sold 2,094,230 shares at an average selling price of $8.72 per share, generating net proceeds of approximately $17,718,000 under the terms of the Sales Agreement.

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 to fund clinical studies in the United States and abroad, expand production capacity, support its sales and marketing efforts, further develop its products, and for general working capital purposes.

Stock-Based Compensation

Total share-based employee, director, and consultant compensation for the three and nine months ended September 30, 2018 and 2017 amounted to approximately $274,000 and $960,000, and $2,864,000 and $1,851,000, respectively. These amounts are included in selling, general and administrative expenses on the consolidated statement of operations.

The summary of the stock option activity for the nine months ended September 30, 2018 is as follows:

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding, December 31, 2017	3,578,538	$ 4.64	6.3
Granted	1,428,175	$ 7.98	9.5

Forfeited	(55,324	)	$ 5.57	—
Expired	(800	)	$ 2.88	—
Exercised	(719,610	)	$ 3.78	—
Outstanding, September 30, 2018	4,230,979		$ 5.90	7.3

The fair value of each stock option was estimated using the Black Scholes pricing model which takes into account as of the grant date the exercise price (ranging from $6.85 to $14.80 per share) and expected life of the stock option (10 years), the current price of the underlying stock and its expected volatility (61.6 to 66.4 percent), expected dividends (-0- percent) on the stock and the risk free interest rate (ranging from 2.09 to 3.00 percent) for the term of the stock option.

The intrinsic value is calculated at the difference between the market value as of September 30, 2018 of $12.90 and the exercise price of the shares.

Options Outstanding				
Range of Exercise Price	Number Outstanding at September 30, 2018	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$2.00 - $14.80	4,230,979	$ 5.90	7.3	$29,640,061

Options Exercisable		
Number Exercisable at September 30, 2018	Weighted Average Exercise Price	Aggregate Intrinsic Value
2,501,456	$ 4.82	$20,253,186

The summary of the status of the Company's non-vested options for the nine months ended September 30, 2018 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2017	1,070,959	$ 0.70
Granted	1,428,175	$ 4.83
Forfeited	(35,326)	$ 2.43
Vested	(734,285)	$ 3.41
Non-vested, September 30, 2018	1,729,523	$ 4.52

As of September 30, 2018, the Company had approximately $926,000 of total unrecognized compensation cost related to stock options which will be amortized over twenty-one months.

Awards of Stock Options:

On March 15, 2018, the Board of Directors granted options to purchase 531,900 shares of common stock to the Company's management. On April 23, 2018, the Board of Directors granted options to purchase 668,550 shares of common stock to the Company's employees. These grants, which total 1,200,450 shares of common stock, will vest upon the achievement of certain specific, predetermined milestones related to the Company's 2018 operations. The grant date fair value of these unvested options amounted to approximately $5,635,634. Based upon an assessment by management, which was reviewed by the Board of Directors, as of September 30, 2018, the Company has met 37.5% of these milestones, and accordingly we have recorded approximately $-0- and $2,113,000 of stock option expense related to these options in the three and nine months ended September 30, 2018, respectively. The Company will continue to assess the likelihood of meeting these milestones throughout 2018 and will record additional stock option expense as appropriate.

Change in Control-Based Awards of Restricted Stock Units:

The Board of Directors has granted restricted stock units to members of the Board of Directors, to the Company's executive officers, and to employees of the Company. These restricted stock units will only vest upon a Change in Control of the Company, as defined in the Company's 2014 Long-Term Incentive Plan.

The following table is a summary of these restricted stock units:

	Restricted Stock Units				
	Board of Directors	Executive Management	Other Employees	Total	Intrinsic Value
December 31, 2017	264,000	675,300	729,200	1,668,500	$ 10,845,250
Granted	13,200	49,200	329,350	391,750	
Forfeited	—	—	(42,750)	(42,750)	
September 30, 2018	277,200	724,500	1,015,800	2,017,500	$ 26,025,750

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 nine months ended September 30, 2018.

Performance-Based Awards of Restricted Stock Units:

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. No charge was required to be charged for the three months ended September 30, 2018, as these restricted stock units became fully vested during the quarter ended June 30, 2018. The Company recorded a charge of approximately $14,000 during the three months ending September 30, 2017 on these restricted stock units. During the nine months ended September 30, 2018 and 2017, respectively, the Company recorded a charge of $240,000 and $77,000, respectively, 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 three and nine months ended September 30, 2018 and 2017, the Company recorded a charge of approximately $58,000 for each period. For the nine months ended September 30, 2018 and 2017, the Company recorded a charge of approximately $271,000 and $175,000, respectively, 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 2017, on February 28, 2018, the Board of Directors granted 146,200 restricted stock units to certain senior managers of the Company in order to settle bonuses accrued as of December 31, 2017. These awards were valued at approximately $1,148,000 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 three and nine months ended September 30, 2018, the Company recorded a charge of approximately $96,000 and $223,000 related to these restricted stock unit awards.

The following table outlines the restricted stock unit activity for the nine months ended September 30, 2018:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, January 1, 2018	110,003	$ 5.38
Granted	146,200	$ 7.85
Vested	(117,065)	$ 6.33
Non-vested, September 30, 2018	139,138	$ 7.18

Warrants:

As of September 30, 2018, 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
48,960	$ 7.500	March 11, 2019
351,398	$ 4.500	March 11, 2019
30,000	$ 9.900	January 14, 2020
430,358		

4. REVENUE

On January 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers and all related amendments (the “new revenue standard”) to all contracts with customers using the modified retrospective method. The adoption of the new revenue standard had no impact on retained earnings as of December 31, 2017 and, accordingly, no cumulative adjustment was required. We do not expect the new revenue standard to have a significant impact on our net income on an ongoing basis.

The following table disaggregates the Company’s revenue by customer type and geographic area for the three months ended September 30, 2018:

United States

	Direct	Distributors/ Strategic Partners	Government Agencies	Total
Product sales:				
United States	$–	$ –	$ –	$–
Germany	2,766,922	–	–	2,766,922
All other countries	613,491	1,722,335	–	2,335,826
Total product revenue	3,380,413	1,722,335	–	5,102,748
Grant and other income:				
United States	–	–	640,225	640,225
Total revenue	$3,380,413	$ 1,722,335	$ 640,225	$5,742,973

The following table disaggregates the Company's revenue by customer type and geographic area for the three months ended September 30, 2017:

	Direct	Distributors/ Strategic Partners	United States Government Agencies	Total
Product sales:				
United States	$32,200	$ –	$ –	$32,200
Germany	2,093,792	–	–	2,093,792
All other countries	485,677	836,992	–	1,322,669
Total product revenue	2,611,669	836,992	–	3,448,661
Grant and other income:				
United States	–	–	375,638	375,638
Total revenue	$2,611,669	$ 836,992	$ 375,638	$3,824,299

The following table disaggregates the Company's revenue by customer type and geographic area for the nine months ended September 30, 2018:

	Direct	**Distributors/ Strategic Partners**	**United States Government Agencies**	**Total**
Product sales:				
United States	$18,900	$ –	$ –	$18,900
Germany	8,686,596	–	–	8,686,596
All other countries	2,034,080	4,042,023	–	6,076,103
Total product revenue	10,739,576	4,042,023	–	14,781,599
Grant and other income:				
United States	–	–	1,641,464	1,641,464
Total revenue	$10,739,576	$ 4,042,023	$ 1,641,464	$16,423,063

The following table disaggregates the Company's revenue by customer type and geographic area for the nine months ended September 30, 2017:

	Direct	**Distributors/ Strategic Partners**	**United States Government Agencies**	**Total**
Product sales:				
United States	$56,200	$ –	$ –	$56,200
Germany	5,433,209	–	–	5,433,209
All other countries	1,175,001	2,421,396	–	3,596,397
Total product revenue	6,664,410	2,421,396	–	9,085,806

Grant and other income:				
United States	–	–	1,418,237	1,418,237
Total revenue	$6,664,410	$ 2,421,396	$ 1,418,237	$10,504,043

The Company has two primary revenue streams: (1) sales of the CytoSorb device and related device accessories and (2) grant income from contracts with various agencies of the United States government. Both of these revenue streams are within the scope of this accounting pronouncement. The following is a brief description of each revenue stream.

CytoSorb Sales

The Company sells its CytoSorb device using both its own sales force (direct sales) and through the use of distributors and/or strategic partners. All sales of the device are outside the United States, as CytoSorb is not yet approved in the United States. Direct sales are fulfilled from the Company's office in Berlin, Germany. Direct sales relate to sales to hospitals located in Germany, Switzerland, Austria, Belgium and Luxembourg. There are no formal sales contracts with any direct customers relating to product price or minimum purchase requirements. However, there are agreements in place with certain direct customers that provide for either free of charge product or rebate credits based upon achieving minimum purchase levels. The Company records the value of these items as earned as a reduction of revenue. These customers submit purchase orders and the order is fulfilled and shipped directly to the customer. Prices to all direct customers are based on a standard price list based on the packaged quantity (6 packs vs 12 packs).

Distributor and strategic partner sales make up the remaining product sales. These distributors are located in various countries throughout the world. The Company has a formal written contract with each distributor/strategic partner. These contracts have terms ranging from 1-5 years in length, with three years being the typical term. Each distributor's/strategic partner's contract has minimum annual purchase requirements in order to maintain exclusivity in their respective territories. Except for Fresenius Medical Care ("FMC"), there is no additional consideration or monetary penalty that would be required to be paid to CytoSorbents if a distributor does not meet the minimum purchase commitments included in the contract, however, at the discretion of the Company, the distributor may lose its exclusive rights in the territory if such commitments are not met. The FMC agreement provides that FMC must make specific minimum quarterly purchases. In the event that FMC does not meet the minimum quarterly purchase amounts as stipulated in their agreement, FMC would be required to make minimum quarterly payments. If this situation should occur, which is not anticipated, the Company would record these minimum payments as other income in the financial statements. In addition, certain distributors are eligible for volume discount pricing if their unit sales are in excess of the base amount in the contract.

Government Grants

The Company has been the recipient of various grant contracts from various agencies of the United States government, primarily the Department of Defense, to perform various research and development activities. These contacts fall into one of the following categories:

1. Fixed price – the Company invoices the contract amount in equal installments over the term of the contract without regard to the timing of the costs incurred related to this contract.
2. Cost reimbursement – the Company submits monthly invoices during the term of the contract for the amount of direct costs incurred during that month plus an agreed percentage that relates to allowable overhead and general and administrative expenses. Cumulative amounts invoiced may not exceed the maximum amount of funding stipulated

in the contract.

3. Cost plus – this type of contract is similar to a cost reimbursement contract but this type also allows for the Company to additionally invoice for a fee amount that is included in the contract.

In summary, the contracts the Company has with customers are the distributor/strategic partner contracts related to CytoSorb product sales, agreements with direct customers related to free-of-charge product and credit rebates based upon achieving minimum purchase levels, and contracts with various government agencies related to the Company's grants. The Company does not currently incur any outside/third party incremental costs to obtain any of these contracts. The Company does incur internal costs, primarily salary related costs, to obtain the contracts related to the grants. Company employees spend time reviewing the program requirements and developing the budget and related proposal to submit to the grantor agency. There may additionally be travel expenditures involved with meeting with government agency officials during the negotiation of the contract. These internal costs are expensed as incurred.

The following table provides information about receivables and contract liabilities from contracts with customers:

	September 30, 2018	December 31, 2017
Receivables, which are included in grants and accounts receivable	$ 2,381,031	$ 1,267,459
Contract liabilities	$ 35,113	$ 30,380

Contract liabilities represent the value of free of charge goods and credit rebates earned in accordance with the terms of certain direct customer agreements during the periods ended September 30, 2018 and December 31, 2017, and deferred revenue on distributor/strategic partner contracts. Deferred revenue is the difference between the average selling price anticipated for the year ended 2018 and the actual price invoiced during the nine months ended September 30, 2018. There was no deferred revenue liability as of December 31, 2017.

5. LONG-TERM DEBT, NET

On June 30, 2016, the Company and its wholly-owned subsidiary, CytoSorbents Medical, Inc. (together, the "Borrower"), entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank, (the "Bank"), pursuant to which the Company borrowed $10 million in two equal tranches of $5 million (the "Original Term Loans"). On March 29, 2018 (the "Closing Date"), the Original Term Loans were refinanced with the Bank pursuant to an Amended and Restated Loan and Security Agreement by and between the Bank and the Borrower (the "Amended and Restated Loan and Security Agreement"), under which the Bank agreed to loan the Borrower up to an aggregate of $15 million to be disbursed in two tranches (1) one tranche of $10 million (the "Term A Loan"), which was funded on the Closing Date and used to refinance the Original Term Loans, and (2) a second tranche of $5 million which may be disbursed at the Borrower's sole request prior to March 31, 2019 provided certain conditions are met (the "Term B Loan" and together with the Term A Loan, the "Term Loans"). The proceeds of the Term Loans will be used for general business requirements in accordance with the Amended and Restated Loan and Security Agreement. Outstanding balances on the Term Loans bear interest at the prime rate reported in the Wall Street Journal plus 3.66%. This rate was 8.91% at September 30, 2018.

On the Closing Date, the Company was required to pay a non-refundable closing fee of $25,000, expenses incurred by the Bank related to the Amended and Restated Loan and Security Agreement of $11,000 and a portion of the final fee for the period the Original Term Loans were outstanding of $85,938. In addition, the Company incurred legal expenses related to the Amended and Restated Loan and Security Agreement of $20,050. As of the Closing Date, the total unamortized loan costs related to the Term Loans amounted to $130,060. These costs 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 nine months ended September 30, 2018 and 2017, the Company recorded interest expense amounting to $8,129 and $7,558, respectively, and $23,807 and $22,413, respectively, related to these costs. After accounting for the various costs outlined above, the effective interest rate on the Term A Loan was 9.1% as of March 29, 2018. Commencing on the first calendar day of the calendar month after a Term Loan is made, the Company shall make monthly payments of

interest only during the term of each Term Loan. Commencing on November 1, 2019, if the Term B Loan is not made, the Company shall make equal monthly payments of principal of $333,333, together with accrued and unpaid interest. Commencing on May 1, 2020, subject to certain conditions as outlined in the Amended and Restated Loan and Security Agreement, if the Term B Loan is made, which is at the Company's sole discretion, the Company shall make equal monthly payments of principal of $625,000, together with accrued and unpaid interest. In either event, all unpaid principal and accrued and unpaid interest shall be due and payable in full on April 1, 2022. In addition, the Amended and Restated 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) April 1, 2022 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 nine months ended September 30, 2018 and 2017, the Company recorded interest expense of $15,625 and $18,229, respectively, and $49,479 and $33,854, respectively, related to the final fee. The Term Loans shall be evidenced by one or more secured promissory notes issued to the Bank by the Company. If the Company elects to prepay the Term Loan(s) pursuant to the terms of the Amended and Restated 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 April 1, 2022, 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 Amended and Restated 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 Amended and Restated 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 Amended and Restated Loan and Security Agreement includes customary loan conditions, Borrower representations and warranties, Borrower affirmative covenants and Borrower negative covenants for secured transactions of this type.

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

Success Fee Letters:

Pursuant to that certain Success Fee Letter (the "2016 Letter") entered into between the Borrower and the Bank in connection with the Original Term Loans, the Borrower agreed to pay to the Bank a success fee in the amount equal to 6.37% of the funded amount of the Original Term Loans (the "2016 Letter Success Fee") upon the first occurrence of any of the following events: (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 thereof) or more for five successive business days. On May 18, 2018, the 2016 Letter Success Fee became due to the Bank as result of an occurrence of the event described in clause (d) above. The Company elected to satisfy the 2016 Letter Success Fee by issuing shares of its common stock, which was permitted under the terms of the 2016 Letter. On May 23, 2018, the Company issued 68,791 shares of its common stock in full satisfaction of the 2016 Letter Success Fee, and the obligations of the Borrower under the 2016 Letter. The 2016 Letter Success Fee was valued at $637,000 and was charged to interest expense in the accompanying Statement of Operations and Comprehensive Loss.

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In connection with the Amended and Restated Loan and Security Agreement, the Borrower entered into an additional Success Fee Letter (the "2018 Letter"), which will only be effective if the Term B Loan is drawn. Pursuant to the 2018 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 B Loan (the "2018 Letter Success Fee") upon the first occurrence of any of the following events: (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 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 the greater of (i) 70% or more over $7.05, the closing price of the Company's common stock on March 29, 2018 (after giving effect to any stock splits or consolidations effected after the date thereof) for five successive business days, or (ii) at least 26.13% more than the closing price of the Company's common stock on the date of the funding of the Term B Loan.

If the 2018 Letter Success Fee is due pursuant an event described in clause (d) of the two preceding paragraphs, the Company may elect, in lieu of paying the 2018 Letter Success Fee in cash, to issue and sell to the Bank, in exchange for the 2018 Letter 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 2018 Letter 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 2016 Letter Success Fee to become payable.

The Bank's right to receive the 2018 Letter Success Fee and the Borrower's obligation to pay such 2018 Letter Success Fee terminate on the fifth anniversary of the funding of the Term B Loan, and shall survive the termination of the Amended and Restated Loan and Security Agreement and any prepayment of the Term Loans.

Long-term debt consists of the following at September 30, 2018:

Principal amount	$10,000,000
Less unamortized debt acquisition costs	(113,811)
Plus accrued final fee	31,250
Subtotal	9,917,439
Less Current maturities	–

Long-term debt net of current maturities	$9,917,439

Principal payments of long-term debt are due as follows at September 30, 2018:

2019	$–
2020	3,666,667
2021	4,000,000
2022	2,333,333
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. After 2017, these employment agreements automatically renew for one year, unless terminated by the Company or the employee. On May 30, 2017, CytoSorbents Corporation announced the appointment of Dr. Eric R. Mortensen 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 such terms are defined in each agreement. The agreements also provide for certain benefits in the event of a "Change of Control" of the Company, as such term is 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 three months ended September 30, 2018 and 2017, the Company has recorded royalty costs of approximately $152,000 and $101,000, respectfully. For the nine months ended September 30, 2018 and 2017, the Company has recorded royalty costs of approximately $438,000 and $267,000, 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 three months ended September 30, 2018 and 2017, per the terms of the license agreement, the Company has recorded royalty costs of approximately $253,000 and $169,000, respectfully. For the nine months ended September 30, 2018 and 2017, the Company recorded royalty costs of approximately $731,000 and $446,000, respectively.

7. NET LOSS PER SHARE

Basic loss per share and diluted loss per share for the three months ended September 30, 2018 and 2017 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period.

All outstanding warrants and options and restricted stock awards representing approximately 4,800,000 and 4,949,000 incremental shares at September 30, 2018 and 2017 have been excluded from the computation of diluted loss per share as they are anti-dilutive.

8. SUBSEQUENT EVENT

From October 1, 2018 through October 31, 2018, the Company sold 17,030 shares of its common stock at an average cost of $12.69 per share under the terms of its Sales Agreement. The sales of these shares generated net proceeds of approximately $209,000 (See Note 3).

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 stockholders 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, 2017, as filed with the SEC on March 8, 2018.

We are a leader in critical care immunotherapy, investigating and commercializing our CytoSorb blood purification technology to reduce deadly uncontrolled inflammation in hospitalized patients around the world, with the goal of preventing or treating multiple organ failure in life-threatening illnesses 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 51,000 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 September 30, 2018, the technology is protected by 19 issued U.S. patents, multiple issued foreign patents, and multiple applications pending both in the U.S. and internationally. Our intellectual property consists of composition of matter, materials, methods of production, systems incorporating the technology and multiple medical uses with expiration dates ranging from 2 to 17 years.

In March 2011, CytoSorb was “CE marked” in the EU, allowing for commercial marketing as an extracorporeal cytokine filter indicated for use in clinical situations where cytokines are elevated. In May 2018, the Company received a label extension for CytoSorb covering use of the device for the removal of bilirubin and myoglobin which allows for the on-label use of the device in the treatment of liver failure and trauma, respectively. 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, 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 all 28 countries of the EU. In addition, many countries outside the EU accept CE mark approval for medical devices, but may also require registration with or without additional clinical studies. The broad approved indication enables CytoSorb to be used “on-label” in diseases where cytokines are elevated including, but not limited to, critical illnesses such as those mentioned above, autoimmune disease flares, cancer cachexia, elevated levels of bilirubin and myoglobin, 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, and that it was able to broadly reduce key cytokines in the blood of these patients. We plan to conduct larger, prospective studies in septic patients in the future to confirm the European Sepsis Trial findings.

In addition to CE mark approval, we also achieved ISO 13485:2003 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the EU. We manufacture CytoSorb at our manufacturing facilities in New Jersey for sale and for additional clinical studies. We also established general reimbursement for CytoSorb in Germany.

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

In late June 2012, following the establishment of our wholly owned European subsidiary, CytoSorbents Europe GmbH, we began the commercial launch of CytoSorb in Germany with the hiring of Dr. Christian Steiner as Vice President of Sales and Marketing and three additional sales representatives. The fourth quarter of 2012 represented the first full quarter of direct sales with the full sales team in place. During this period, we expanded our direct sales efforts to include both Austria and Switzerland. In 2016, a dedicated reimbursement code was established for CytoSorb in Germany. At the end of 2017, we had hundreds of key opinion leaders (“KOLs”) in our commercialized territories worldwide in critical care, cardiac surgery, and blood purification, who were either using CytoSorb or supporting its use in clinical practice or clinical trials.

In March 2016, we established CytoSorbents Switzerland GmbH, a wholly-owned subsidiary of CytoSorbents Europe GmbH, to conduct marketing and direct sales in Switzerland. This subsidiary began operations during the second quarter of 2016. In 2017, we further expanded our direct sales efforts into Belgium and Luxembourg.

In the second quarter of 2018, we officially opened a new expanded CytoSorb manufacturing facility in New Jersey that quadruples manufacturing capacity and is expected to improve product gross margins in the future.

As of October 31, 2018, our European sales, marketing and clinical support team included 26 direct sales people, one contract sales person and 18 sales support staff.

We have complemented our direct sales efforts with sales to distributors and/or corporate partners. In 2013, we reached agreements with distributors in the United Kingdom, Ireland, Turkey, Russia, and the Netherlands. In 2014, we announced distribution of CytoSorb in the Middle East, including Saudi Arabia, the United Arab Emirates, Kuwait, Bahrain, and Oman (the GCC) and Yemen, Iraq, and Jordan through an exclusive agreement with Techno Orbits. 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 April 2017, we entered into a distribution agreement with KRA Technical Services to distribute CytoSorb in Qatar. In July 2017, we announced an exclusive agreement with Droguería, Ramón, González, Revilla (DRGR) S.A. to distribute CytoSorb in Panama. In April 2018, we entered into exclusive agreements with Pharmaworld and Chong Lap (H.K.) Co. Ltd. to distribute CytoSorb in Lebanon and Hong Kong, respectively. In July 2018, we disclosed an expansion to 53 countries, including Bosnia, Herzegovina, and Croatia with Medis, d.o.o.; Estonia, Latvia, and Lithuania with SIA Scanmed; and Montenegro and Serbia with Mar Medica, d.o.o. We also disclosed a change in our distributor in the United Kingdom, focused on England and Ireland, with Chalice Medical, Ltd. In July 2018, we entered into a distribution agreement with Cardiotec Vascular Ltda., to distribute CytoSorb in Chile.

We have been working to expand the number and scope of our strategic partnerships. In September 2013, we entered into a strategic partnership with Biocon Ltd. (“Biocon”), 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 2017, the Biocon partnership was further expanded to include exclusive distribution of CytoSorb in Malaysia. Under the terms of the agreement, Biocon has committed to minimum annual purchases in Malaysia to maintain exclusivity this territory. In addition, the term of the original agreement was extended to December 2022.

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 allows 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 agreed to 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. Fresenius launched the product in these six countries in May 2016. 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 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 has also provided 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 began in five initial countries in late 2017 and is continuing, with implementation of the co-marketing program in additional countries planned for the future.

In September 2016, we entered into a multi-country strategic partnership with Terumo Cardiovascular Group ("Terumo") 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 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 60 investigator-initiated studies planned, enrolling or completed in Germany, Austria, Switzerland, the Netherlands, Hungary, the United Kingdom, France, India, Italy and Slovenia. Approximately 20 of these studies are currently enrolling patients. Others have been completed. These trials, which are funded and supported by well-known university hospitals and KOLs, are the equivalent of Phase II clinical studies. They have provided and will continue to provide invaluable information regarding the success of the device in the treatment of sepsis, cardiac 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 (the "FDA") approved our Investigational Device Exemption ("IDE") application to commence a planned U.S. cardiac surgery feasibility study called REFRESH I (REduction of FREe 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 represented 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 with a heart-lung machine to reduce plasma free hemoglobin (pfHb) 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 for pfHb 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 found no serious device related adverse events with 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 from the study on the reduction of pfHb and activated complement, and disclosed that investigators of the study have submitted a manuscript of the REFRESH I trial for publication.

In December 2017, the FDA approved our IDE application for our REFRESH 2-AKI study, a pivotal trial designed to provide the key safety and efficacy data needed to support United States regulatory approval for CytoSorb in cardiac surgery via the premarket approval (PMA) pathway. The REFRESH 2-AKI trial is a randomized, controlled, multi-center, clinical trial designed to evaluate intraoperative CytoSorb use as a therapy to reduce the incidence and severity of AKI, as measured by Kidney Disease Improving Global Outcomes (KDIGO) criteria, following complex cardiac surgery. Postoperative AKI following cardiac surgery is common and is associated with 1-5 year mortality, and is a risk factor for developing chronic kidney disease requiring hemodialysis in the future. . The trial will enroll up to 400 patients at increased risk of cardiovascular surgery-associated AKI, undergoing elective, non-emergent open-heart surgery for either valve replacement, or aortic reconstruction with hypothermic cardiac arrest. In April 2018, we announced first patient enrollment into the pivotal U.S. REFRESH 2-AKI trial. Based on the recommendations of key clinical advisors, a protocol amendment was submitted to the FDA on July 18, 2018 to improve operational aspects of the patient screening process and expand the inclusion criteria. It was the preference of clinical trial sites to defer enrollment until the amendment was approved by the FDA, which occurred on August 17, 2018. Following the subsequent ethics committee approvals of the amended protocol at many of our trial sites, as of November 6, 2018, the trial currently has 14 actively recruiting sites, 6 additional sites that are finalizing contracts and are pending initiation and another 5 sites being evaluated and with whom we have initiated start-up activities. As of November 6, 2018, the trial has now enrolled 20 patients. We anticipate that the REFRESH 2-AKI trial will take at least two years to complete, and could take longer if enrollment challenges or other factors causing delays are encountered.

The German government, via the German Federal Ministry of Education and Research, is funding a 250 patient, multi-center randomized, controlled study (“REMOVE”) using CytoSorb during valve replacement open heart surgery in patients with infective endocarditis. The study enrolled its first patient in January 2018. As of October 31, 2018, the trial has enrolled 62 patients. Investigators of the study are currently conducting an interim analysis of the first 50 patients, evaluating safety, and reduction of cytokines. Continued funding of the trial by the German government is contingent upon this interim analysis.

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, liver failure, pancreatitis, lung 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.

- CytoSorb XL – an intended next generation successor to CytoSorb currently in advanced pre-clinical testing designed to reduce a broad range of cytokines and inflammatory mediators, including lipopolysaccharide (LPS) endotoxin, from blood.

- 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. VetResQ is being commercialized in the United States.

- HemoDefend – a development-stage blood purification technology designed to remove non-infectious contaminants in blood transfusion products, with the goal of reducing transfusion reactions and improving the quality and safety of blood. With the support from NHLBI, we plan to initiate a U.S. pivotal trial designed to support U.S. FDA approval, expected to begin in the second quarter of 2019.

- 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 b2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal of BetaSorb is to improve the efficacy of dialysis or hemofiltration.

Regulation

The medical devices that we manufacture are subject to regulation by numerous regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device receives approval for commercial distribution.

In the EU, medical devices are required to comply with the Medical Devices Directive and obtain CE Mark certification in order to market medical devices. The CE Mark certification, granted following approval from an independent Notified Body, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. Distributors of medical devices may also be required to comply with other foreign regulations such as Ministry of Health Labor and Welfare approval in Japan. The time required to obtain these foreign approvals to market our products may be longer or shorter than that required in the U.S., and requirements for those approvals may differ from those required by the FDA. In Europe, our devices are classified as Class IIb, and will need to conform to the Medical Devices Directive.

In March 2011, we successfully completed our technical file review with our Notified Body, and received approval to apply the CE Mark to the CytoSorb device as an extracorporeal 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. In February 2015, we extended the coverage of our ISO 13485 Certificate with the inclusion of Canadian Quality Systems requirements. This additional level of certification will allow us to apply for product approvals in Canada in the future.

In June 2016, we successfully completed an ISO 13485:2003 annual surveillance audit maintaining our good standing with our Notified Body. In September 2016, we were granted a two-year renewal for the CytoSorb CE Mark. In June 2018, we received clearance from our notified body to begin production in our new manufacturing facility. In July 2018, we successfully completed an audit upgrade from an ISO 13485:2003 certification to an ISO 13485:2016 certification.

In the U.S., specific permission from the FDA to distribute a new device is usually required (that is, other than in the case of very low risk devices), and we expect that some form of marketing authorization will be necessary for our devices. Device companies typically seek the least burdensome path to market that will allow marketing for a commercially viable indication for a product. The path to market possible for a particular device and one or more particular indications will depend on the regulatory framework described below, and also on the FDA's interpretation and application of the laws that comprise that regulatory framework. The FDA may provide advice and guidance to medical device companies during product development in a variety of ways, ranging from guidance documents and informal feedback to more formal submissions or meetings including "Pre-Submissions," also referred to as "Pre-Subs."

Marketing authorization is generally sought and obtained in one of two ways. The first process requires that a pre-market notification (510(k) Submission) be made to the FDA to demonstrate that the device is as safe and effective as, or "substantially equivalent" to, a legally marketed device that is not subject to pre-market approval ("PMA"). A legally marketed device is a device that (i) was legally marketed prior to May 28, 1976 (provided it has not been significantly modified or changed since then, and provided the FDA has not issued a regulation requiring a PMA application – referred to as a "pre-amendment device"), (ii) has been reclassified from Class III to Class II or I, or (iii) has been found to be substantially equivalent to another legally marketed device following a 510(k) Submission. The legally marketed device to which equivalence is drawn is known as the "predicate" device. Applicants must submit descriptive data and, when necessary, performance data to establish that the device is substantially equivalent to a predicate device. In some instances, data from human clinical studies must also be submitted in support of a 510(k) Submission. If so, these data must be collected in a manner that conforms with specific requirements in accordance with federal regulations including the Investigational Device Exemption (IDE) and human subjects protections or "Good Clinical Practice" regulations. After the 510(k) application is submitted, the applicant cannot market the device unless the FDA issues "510(k) clearance" deeming the device substantially equivalent. After an applicant has obtained clearance, the changes to existing devices covered by a 510(k) Submission which do not significantly affect safety or effectiveness can generally be made without additional 510(k) Submissions, but evaluation of whether a new 510(k) is needed is a complex regulatory issue, and changes must be evaluated on an ongoing basis to determine whether a proposed change triggers the need for a new 510(k), or even PMA. The 510(k) clearance pathway is not available for all devices: whether it is a suitable path to market depends on several factors, including regulatory classifications, the intended use of the device, and technical and risk-related issues for the device. In the case where no substantially equivalent predicate exists, but where a 510(k) submission would otherwise be the most appropriate path, an alternative path to approval is through a *de novo* 510(k) submission.

The second, more rigorous, process requires that an application for PMA be made to the FDA to demonstrate that the device is safe and effective for its intended use as manufactured. This approval process applies to most Class III devices. A PMA submission includes data regarding design, materials, bench and animal testing, and human clinical data for the medical device. Again, clinical trials are subject to extensive FDA regulation. Following completion of clinical trials and submission of a PMA, the FDA will authorize commercial distribution if it determines there is reasonable assurance that the medical device is safe and effective for its intended purpose. This determination is based on the benefit outweighing the risk for the population intended to be treated with the device. This process is much more detailed, time-consuming, and expensive than the 510(k) process. Also, the FDA may impose a variety of conditions on the approval of a PMA.

In the U.S., we believe that our potential devices, if we were to pursue marketing authorization, would likely fall under the classification for “Sorbent Hemoperfusion Systems” (21 C.F.R. § 876.5870). This category of device was a pre-amendment Class III device. Under current regulations, based on a final order issued by the FDA in 2014, this category of product has been down-classified as Class II (subject to a 510(k) and special controls) when the device is intended for the treatment of poisoning and drug overdose, and Class III (subject to premarket approval) when the device is intended for the treatment of life-threatening illnesses. Special and general controls are designed to establish reasonable assurance of safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.

Both before and after a device for the U.S. market is commercially released, we would have ongoing responsibilities under the FDA's regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We would also be subject to periodic inspection by the FDA for compliance with the FDA's quality system regulations, which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, and servicing of all finished medical devices intended for human use. In addition, the FDA and other U.S. regulatory bodies (including the Federal Trade Commission, the Office of the Inspector General of the Department of Health and Human Services, the Department of Justice (DOJ), and various state Attorneys General) monitor the manner in which we promote and advertise our products. Although physicians are permitted to use their medical judgment to employ medical devices for indications other than those cleared or approved by the FDA, we are prohibited from promoting products for such "off-label" uses, and can only market our products for cleared or approved uses. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health, order a recall, repair, replacement, or refund of such devices, detain or seize adulterated or misbranded medical devices, or ban such medical devices. The FDA may also impose operating restrictions, enjoin and/or restrain certain conduct resulting in violations of applicable law pertaining to medical devices, including a hold on approving new devices until issues are resolved to its satisfaction, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the DOJ. Conduct giving rise to civil or criminal penalties may also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by our conduct.

The delivery of our devices in the U.S. market would be subject to regulation by the U.S. Department of Health and Human Services and comparable state agencies responsible for reimbursement and regulation of health care items and services. U.S. laws and regulations are imposed primarily in connection with the Medicare and Medicaid programs, as well as the government's interest in regulating the quality and cost of health care.

Federal health care laws apply when we or customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally-funded health care programs. The principal federal laws include: (1) the False Claims Act which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; (2) the Anti-Kickback Statute which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of items or services reimbursable by a Federal health care program; (3) the Stark law which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider; and (4) health care fraud statutes that prohibit false statements and improper claims to any third-party payer. There are often similar state false claims, anti-kickback, and anti-self referral and insurance laws that apply to state-funded Medicaid and other health care programs and private third-party payers. In addition, the U.S. Foreign Corrupt Practices Act can be used to prosecute companies in the U.S. for arrangements with physicians, or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country.

The laws applicable to us are subject to change, and subject to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including substantial fines and damages, and exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

The process of obtaining clearance to market products is costly and time-consuming in virtually all of the major markets in which we expect to sell products and may delay the marketing and sale of our products. Countries around the world have recently adopted more stringent regulatory requirements, which are expected to add to the delays and uncertainties associated with new product releases, as well as the clinical and regulatory costs of supporting those releases. No assurance can be given that any of our other medical devices will be approved on a timely basis, if at all, or that our CytoSorb® device will be approved for CE Mark labeling in other potential medical applications or that it will be approved for cytokine adsoprtion in markets not covered by the CE Mark on a timely basis, or at all. In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Pertaining to our VetResQ™ device (offered for veterinary use only), in the U.S., the FDA does not require submission of a 510(k), PMA, or any pre-market approval for devices used in veterinary medicine. Device manufacturers who exclusively manufacture or distribute veterinary devices are not required to register their establishments and list veterinary devices and are exempt from post-marketing reporting. The FDA does have regulatory oversight over veterinary devices and can take appropriate regulatory action if a veterinary device is misbranded or adulterated. It is the responsibility of the manufacturer and/or distributor of these articles to assure that these animal devices are safe, effective, and properly labeled.

Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries medical devices are regulated. Frequently, device companies may choose to seek and obtain regulatory approval of a device in a foreign country prior to application in the U.S., as we have done, given the differing regulatory requirements. However, this does not ensure approval of a device in the U.S.

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 the Defense Advanced Research Projects Agency (“DARPA”), the U.S. Army, U.S. Special Operations Command (“USSOCOM”), and others.

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 was 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 September 30, 2018, we received approximately $3,825,000 in funding under this contract and no funding remains.

In September 2013, the National Heart Lung and Blood Institute ("NHLBI") awarded us a Phase I Small Business Innovation Research ("SBIR") contract, (number HHSN-268201-300044C), valued at $203,351, to further advance our HemoDefend blood purification technology for pRBC transfusions. The University of Dartmouth collaborated with us as a subcontractor on the project, entitled "Elimination of blood contaminants from pRBCs using HemoDefend hemocompatible porous polymer beads." The overall goal of this program is to reduce the risk of potential side effects of blood transfusions, and help to extend the useful life of pRBCs. Our performance under this contract has been completed.

In October 2015, we were awarded a Phase II SBIR contract by the NHLBI and USSOCOM 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 $1,524,000 over a two year period. As of September 30, 2018, we received approximately $1,524,000 in funding under this contract and no funding remains.

In March 2016, we were awarded a Phase I SBIR contract for the development program entitled “Mycotoxin Adsorption 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 September 30, 2018, we received approximately $150,000 and no funding remains under this contract.

In June 2016, we were awarded a Phase I Small Business Technology Transfer (“STTR”) contract for its development program entitled “Use of Highly Porous Polymer Beads to Remove Anti-A and Anti-B antibodies from Plasma for Transfusion”. The purpose of this contract was to develop our HemoDefend blood purification technology to potentially enable universal plasma. This work is being funded by the USAMRAA under contract W81XWH-16-C-0025 and provides for maximum funding of $150,000. As of September 30, 2018, we received approximately $150,000 and no funding remains 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 U.S. Army Medical Research Acquisition Activity (“USAMRAA”) under contract W81XWH-16-C-0080 and provides for maximum funding of approximately $150,000. As of September 30, 2018, we received approximately $150,000 and no funding remains under this contract.

In January 2017, we were 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, W911QY-17-C-0007, provides for maximum funding of $999,996 over two years. This program is funded by the Joint Program Executive Office - Chemical and Biological Defense (“CBD”) SBIR program. As of September 30, 2018, we received approximately $768,000 in funding under this contract and have approximately $232,000 remaining under this contract.

In May 2017, we were 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. We 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 September 30, 2018, we received approximately $639,000 and have approximately $360,000 remaining under this contract.

In May 2017, we were 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 hemoadsorptive 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 September 30, 2018, we received approximately $187,000 and have approximately $531,000 remaining under this contract.

In September 2017, we were awarded a Phase IIB 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". The purpose of this contract is to continue development of two novel and distinct treatment options for life-threatening hyperkalemia. This work is being funded by the USAMRAA under contract W81XWH-17-C-0142 and provides for maximum funding of approximately $1,000,000. As of September 30, 2018, we received approximately $280,000 and have approximately $720,000 remaining under this contract.

In August 2018, we were awarded a Phase IIB Bridge SBIR contract by the NHLBI to facilitate and accelerate the commercialization of our HemoDefend blood purification technology for the purification of pRBC transfusions. The contract, entitled "pRBCs Contaminant Removal with Hemocompatible Porous Polymer Beads" (award number 2R44HL141928-03), provides for maximum funding of approximately $2,971,000 over a three year period. As of September 30, 2018, we received approximately $106,000 in funding under this contract and have approximately $2,894,000 remaining under this contract. Under the terms of this contract, we must make a matching contribution equal to the funds awarded thereunder.

Results of Operations

Comparison for the three months ended September 30, 2018 and 2017:

Revenues:

Revenue from product sales was approximately $5,103,000 in the three months ended September 30, 2018, as compared to approximately $3,449,000 in the three months ended September 30, 2017, an increase of approximately $1,654,000, or 48%. This increase was primarily driven by an increase in direct sales from both new customers and repeat orders from existing customers and an increase in distributor sales.

Grant income was approximately $640,000 for the three months ended September 30, 2018 as compared to approximately $376,000 for the three months ended September 30, 2017, an increase of approximately $264,000. This increase was a result of timing of certain grant revenue and income recognized from a new grant.

Total revenues were approximately $5,743,000 for the three months ended September 30, 2018, as compared to total revenues of approximately $3,824,000 for the three months ended September 30, 2017, an increase of approximately $1,919,000, or 50%.

Cost of Revenues:

For the three months ended September 30, 2018 and 2017, cost of revenue was approximately $2,053,000 and $1,517,000, respectively, an increase of approximately $536,000. Product cost of revenues increased approximately $339,000 during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 due to increased sales. Product gross margins were approximately 72% for the three months ended September 30, 2018, as compared to approximately 69% for the three months ended September 30, 2017. This increase in gross margin of 3% was due to a year over year reduction in the cost of devices manufactured as a result of production efficiencies achieved.

Research and Development Expenses:

For the three months ended September 30, 2018, research and development expenses were approximately $1,943,000 as compared to research and development expenses of approximately $643,000 for the three months ended September 30, 2017. The increase of approximately $1,300,000 was due to increase in costs related to our clinical studies and trials of approximately $922,000, an increase in our clinical related salaries and related expenses of approximately $104,000, an increase in non-clinical research and development salaries of approximately $89,000, an increase in new product development costs of approximately $28,000, an increase in lab supplies of approximately $35,000, an increase in patent costs of approximately $34,000 and an increase in non-grant related research and development costs of approximately $88,000.

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately $417,000 for the three months ended September 30, 2018, as compared to approximately $238,000 for the three months ended September 30, 2017. The increase of approximately $179,000 was due to an increase in legal fees of approximately $150,000 related to certain corporate initiatives, an increase in accounting and auditing fees of approximately $26,000, and an increase in other professional fees of approximately $3,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately $4,041,000 for the three months ended September 30, 2018, as compared to approximately $3,575,000 for the three months ending September 30, 2017. The increase of $466,000 was due to an increase in salaries, commissions and related costs of approximately $582,000 related to headcount additions and increased sales, an increase in restricted stock expense of approximately $64,000 related to restricted stock units granted to the Company executive officers, an increase in royalty expense of approximately $135,000 due to increased sales, an increase in travel and entertainment costs of approximately $150,000, an increase in investor outreach and public relations expense of approximately $15,000 and an increase in office related expenses and other general and administrative costs, which include office supplies, rent, utilities and commercial insurance of approximately $156,000. These increases were offset by a decrease in non-cash stock based compensation expense of approximately $610,000 related to progress related to the attainment of the Company's 2018 operating milestones and a decrease in sales and marketing costs (which includes advertising and conferences) of approximately $26,000.

Interest Expense, net:

For the three months ended September 30, 2018, interest expense was approximately $185,000, as compared to interest expense of approximately $254,000 for the three months ended September 30, 2017. This decrease in interest expense of approximately $69,000 is due to the increase in interest earned on our cash balances during the three months ended September 30, 2018 which were significantly higher than cash on hand during the three months ended September 30, 2017.

Gain (Loss) on Foreign Currency Transactions:

For the three months ended September 30, 2018, the loss on foreign currency transactions was approximately $109,000 as compared to a gain of approximately $349,000 for the three months ended September 30, 2017. The 2018 loss is directly related to the decrease in the exchange rate of the Euro to the U.S. dollar at September 30, 2018 as compared to June 30, 2018. The exchange rate of the Euro to the U.S. dollar was $1.16 per Euro at September 30, 2018, as compared to $1.17 per Euro at June 30, 2018. The 2017 gain is directly related to the increase in the exchange rate of the Euro at September 30, 2017 as compared to June 30, 2017. The exchange rate of the Euro to the U.S. dollar was $1.17 per Euro at September 30, 2017 as compared to $1.14 per Euro at June 30, 2017.

Comparison for the nine months ended September 30, 2018 and 2017:

Revenues:

Revenue from product sales was approximately $14,782,000 in the nine months ended September 30, 2018, as compared to approximately $9,086,000 in the nine months ended September 30, 2017, an increase of approximately $5,696,000, 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. Approximately $906,000 of this increase was due to the increase in the Euro to U.S. dollar exchange rate for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017.

Grant income was approximately $1,641,000 for the nine months ended September 30, 2018, as compared to approximately $1,418,000 for the nine months ended September 30, 2017, an increase of approximately $223,000, or 16%, due to revenue recognized from a new grant and timing of other grant revenues.

Total revenues were approximately $16,423,000 for the nine months ended September 30, 2018, as compared to total revenue of approximately $10,504,000, for the nine months ended September 30, 2017, an increase of approximately $5,919,000, or 56%.

Cost of Revenues:

For the nine months ended September 30, 2018 and 2017, cost of revenue was approximately $5,406,000 and $4,253,000, respectively, an increase of approximately $1,153,000, primarily due to increased sales. Product gross margins were approximately 73% for the nine months ended September 30, 2018, as compared to approximately 67% for the nine months ended September 30, 2017. This increase in gross margin of 6% was due to a reduction in the cost of devices manufactured as a result of production efficiencies achieved and, to a lesser extent, the impact of the increase in the exchange rate of the Euro.

***Research and Development Expenses**:*

For the nine months ended September 30, 2018, research and development expenses were approximately $5,299,000, as compared to research and development expenses of approximately $1,555,000 for the nine months ended September 30, 2017, an increase of approximately $3,744,000. This increase was due to increase in costs related to our clinical studies and trials of approximately $2,449,000, an increase in our clinical related salaries and related expenses of approximately $577,000, an increase in non-clinical research and development salaries of approximately $302,000, an increase in new product development costs of approximately $93,000, an increase in lab supplies of approximately $100,000, an increase in patent costs of approximately $36,000 and an increase in non-grant related research and development costs of approximately $373,000. These increases were offset by an increase in direct labor and other costs being deployed toward grant-funded activities of approximately $186,000, which had the effect of decreasing the amount of our non-reimbursable research and development costs

Legal, Financial and Other Consulting Expense:

Legal, financial and other consulting expenses were approximately $1,291,000 for the nine months ended September 30, 2018, as compared to approximately $961,000 for the nine months ended September 30, 2017. The increase of approximately $330,000 was due to an increase in employment agency fees of approximately $82,000 related to the recruitment of senior level personnel, an increase in legal fees of approximately $208,000 related to certain corporate initiatives and an increase in other professional fees of approximately $40,000.

Selling, General and Administrative Expense:

Selling, general and administrative expenses were approximately $14,426,000 for the nine months ended September 30, 2018, as compared to approximately $9,771,000 for the nine months ending September 30, 2017, an increase of $4,655,000. The increase in selling, general, and administrative expenses was due to an increase in salaries, commissions and related costs of approximately $1,630,000 related to headcount additions and increased sales, an increase in stock based compensation of approximately $1,085,000 related to progress related to the attainment of the Company’s 2018 operating milestones, an increase in restricted stock expense of $483,000 related to restricted stock units granted to the Company executive officers, an increase in royalty expense of approximately $456,000 due to increased sales, an increase in sales and marketing costs (which include advertising and conferences) of approximately $331,000, an increase in travel and entertainment costs of approximately $249,000, an increase in investor outreach and public relations expense of approximately $90,000 and an increase in office related expenses and other general and administrative costs, which include office supplies, rent, utilities and commercial insurance of approximately $331,000.

Interest Expense, net:

For the nine months ended September 30, 2018, interest expense was approximately $1,264,000, as compared to interest expense of approximately $498,000 for the nine months ended September 30, 2017. This increase in interest expense of approximately $766,000 is directly related to the settlement of the Success Fee with Bridge Bank in the amount of $637,000 that became due in May 2018 in accordance with the terms of the 2016 Success Fee Letter with Bridge Bank and the additional interest related to the drawdown of the Term B Loan (as defined in the Loan and Security Agreement dated June 30, 2016 with Bridge Bank) on June 30, 2017 in the amount of $5,000,000.

Gain (Loss) on Foreign Currency Transactions:

For the nine months ended September 30, 2018, the loss on foreign currency transactions was approximately $544,000, as compared to a gain of approximately $1,221,000 for the nine months ended September 30, 2017. The 2018 loss is directly related to the decrease in the exchange rate of the Euro to the U.S. dollar at September 30, 2018 as compared to December 31, 2017. The exchange rate of the Euro to the U.S. dollar was $1.16 per Euro at September 30, 2018, as compared to $1.20 per Euro at December 31, 2017. The 2017 gain is directly related to the increase in the exchange rate of the Euro at September 30, 2017, as compared to December 31, 2016. The exchange rate of the Euro to the U.S. dollar was $1.17 per Euro at September 30, 2017 as compared to $1.05 per Euro at December 31, 2016.

History of Operating Losses*:*

We have experienced substantial operating losses since inception. As of September 30, 2018, we had an accumulated deficit of approximately $164,121,000, which included losses of approximately $11,808,000 and $5,314,000 for the nine month periods ended September 30, 2018 and 2017, 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 September 30, 2018, we had current assets of approximately $29,950,000 including cash on hand of approximately $24,911,000 and current liabilities of approximately $4,261,000.

On June 30, 2016, the Company and its wholly-owned subsidiary, CytoSorbents Medical, Inc. (together, the "Borrower"), entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank, (the "Bank"), pursuant to which the Company borrowed $10 million in two equal tranches of $5 million (the "Original Term Loans"). On March 29, 2018 (the "Closing Date"), the Original Term Loans were refinanced with the Bank pursuant to an Amended and Restated Loan and Security Agreement by and between the Bank and the Borrower (the "Amended and Restated Loan and Security Agreement"), under which the Bank agreed to loan the Borrower up to an aggregate of $15 million to be disbursed in two tranches: (1) one tranche of $10 million (the "Term A Loan") which was funded on the Closing Date and used to refinance the Original Term Loans, and (2) a second tranche of $5 million which may be disbursed at the Borrower's sole request prior to March 31, 2019 provided certain conditions are met (the "Term B Loan" and together with the Term A Loan, the "Term Loans"). The proceeds of the Term Loans will be used for general business requirements in accordance with the Amended and Restated Loan and Security Agreement.

In addition, during the nine months ended September 30, 2018, the Company sold 1,498,320 shares of its common stock under the terms of its Controlled Equity Offering℠ Sales Agreement with Cantor Fitzgerald & Co. (as amended, the "Sales Agreement") at an average cost of $9.58 per share, generating net proceeds of approximately $13,917,000, and during the period from October 1, 2018 through October 31, 2018, the Company sold an additional 17,030 shares of its common stock at an average cost of $12.69 per share, generating net proceeds of approximately $209,000.

As a result of the equity financing under the terms of the Sales Agreement and the availability of additional debt financing under the Amended and Restated Loan and Security Agreement with Bridge Bank, we believe we have sufficient liquidity to fund our operations into the second half of 2020.

Contractual Obligations

In July 2018, the Company entered into a Seventeenth Amendment to Lease Agreement with Princeton Corporate Plaza, LLC, which expands our space to approximately 17,947 square feet. The lease for our corporate headquarters and manufacturing facility expires May 31, 2019. Effective August 8, 2018, the Company's base rent obligation increased to $30,963 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's wholly-owned subsidiary, CytoSorbents Europe GmbH, entered into a five year lease agreement with Klimik GmbH for 760 square meters of office and warehouse space. In May 2018, CytoSorbents Europe GmbH entered into an additional lease agreement with Klimik GmbH which expanded its office and warehouse space to 960 square meters. The leases have a total rent obligation of $8,996 per month. Both leases expire on August 31, 2021. The leases also provide the Company with an option to extend the terms for an additional five year period through August 31, 2026.

The following table summarizes our obligations with regard to our contractual obligations as of September 30, 2018, and the expected timing of maturities of those contractual obligations.

	Less than 1 Year	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Operating Lease Obligations	$333,620	$206,886	$–	$ –
Long-Term Debt	$–	$7,666,667	$2,333,333	$ –

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 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 September 30, 2018, we had an accumulated deficit of approximately $164,121,000, which included net losses of approximately $11,808,000 for the nine months ended September 30, 2018, and $5,314,000 for the nine months ended September 30, 2017. 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, clinical studies 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 September 30, 2018 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 September 30, 2018, we had an accumulated deficit of approximately $164,121,000, which included net losses of approximately $11,808,000 and $5,314,000 for the nine months ended September 30, 2018 and 2017, 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, clinical studies 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 net 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 September 30, 2018, we had current assets of approximately $29,950,000, including cash on hand of approximately $24,911,000 and current liabilities of approximately $4,261,000. For the nine months ended September 30, 2018, our cash burn was approximately $7,589,000. 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. The amount of long-term capital needed is expected to depend on many factors, including:

·rate of sales growth and adoption of our products in the marketplace;

·· product gross margin;

· 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 $150 million in one or more offerings, through the issuance and sale of any combination of equity securities, debt securities, warrants and units.

In addition, we are party to that certain Controlled Equity Offering[SM] Sales Agreement, as amended (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which we may offer to sell, from time to time through Cantor, shares of the Company's common stock. During the nine months ended September 30, 2018, we sold a total of 1,498,230 shares of our common stock at an average price of $9.58 per share, under the terms of the Sales Agreement, generating net proceeds of approximately $13,917,000 million. From October 1, 2018 through October 31, 2018 we sold an additional 17,030 shares of our common stock at an average price of $12.69 per share, generating net proceeds of approximately $209,000.

On March 29, 2018, we entered into an Amended and Restated 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 $15,000,000, to be disbursed in two tranches; of $10 million and $5 million, respectively. The proceeds from the first tranche of $10 million were used to refinance our existing indebtedness with the Bank. The second tranche of $5 million is available to us through March 31, 2019, subject to certain conditions as outlined in the Amended and Restated Loan and Security Agreement.

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 October 31, 2018, we had 117 full-time and part-time employees as well as several consultants and 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;
- the development by our competitors of products or product candidates that are similar or identical to ours;
- 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 between 2020 and 2035. 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 expire between 2020 and 2035. 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 may pursue various indications for our product candidates, and they may be subject to different FDA regulatory pathways for marketing authorization, and under the jurisdiction of different FDA review divisions within the FDA's Office of Device Evaluation.

As we seek to determine commercially viable indications for our product candidates, we may consider pursuing a variety of indications that may be approved through one of several different FDA regulatory clearance or approval pathways, and under the jurisdiction of different FDA review divisions within the FDA's Office of Device Evaluation. We expect the pathways available to us will be impacted by the FDA regulatory history of the category of "sorbent hemoperfusion systems" and our options may also be impacted by the FDA's interpretations and application of these and other regulatory standards to our product candidates. The regulatory pathways available to us may impact the level and type of data necessary to support our applications, and the post-marketing requirements to which we and our products will be subject.

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.

In the second quarter of 2018, we commissioned our expanded CytoSorb manufacturing facility in New Jersey that quadruples manufacturing capacity. While we currently believe we have established sufficient production capacity to supply potential near term demand for the CytoSorb device, we will likely 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 nine months ended September 30, 2018, 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 intended exit from 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, tariffs, 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, tariffs, and regulations. If we fail to comply with these laws, tariffs, 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, tariffs, 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, tariffs, and regulations, or change in the countries, governments, persons, products, or technologies targeted by such laws, tariffs, 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.

The recently passed Tax Cuts and Jobs Act (the "TCJA") could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the TCJA, which significantly reforms the Internal Revenue Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits. Federal net operating losses arising in taxable years ending after December 31, 2017 will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal

health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on 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 Nasdaq and our common stock began trading on Nasdaq on December 23, 2014 under the symbol “CTSO.” Our common stock closed as high as $14.80 and as low as $6.55 per share between January 1, 2018 and September 30, 2018 on Nasdaq. On October 31, 2018, the closing price of our common stock, as reported on Nasdaq, was $10.00. 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 18,367,000 shares remain available for issuance as of September 30, 2018 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.

We are party to a Controlled Equity Offering[SM] Sales Agreement, as amended, with Cantor Fitzgerald & Co. pursuant to which we may offer shares of our common stock from time to time through "at-the-market" offerings. 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	Amendment No. 1 to Sales Agreement, dated as of July 26, 2018, by and between CytoSorbents Corporation and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on July 26, 2018).
31.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of Sarbanes Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes Oxley Act of 2002.*
101	The following materials from CytoSorbents Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at September 30, 2018 and December 31, 2017, (ii) Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017, (iii) Consolidated Statement of Changes in Stockholders' Equity for the period from December 31, 2017 to September 30, 2018, (iv) Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and September 30, 2017 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: November 6, 2018 By: /s/ Phillip P. Chan
Name: Phillip P. Chan
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 6, 2018 By: /s/ Kathleen P. Bloch
Name: Kathleen P. Bloch, CPA
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)