Cytosorbents Corp Form 10-Q November 13, 2015
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015
Or
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number: 000-51038
CYTOSORBENTS CORPORATION (Exact name of registrant as specified in its charter)
Delaware 98-0373793 (State or other jurisdiction of (I.R.S. Employer Identification No.)

incorporation or organization)

7 Deer Park Drive, Suite K

Monmouth Junction, New Jersey 0885	Monmouth	Junction.	New.	Jersev	08852
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(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. b Yes "No

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

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

Large accelerated filer " Accelerated filer " Accelerated filer " Smaller reporting company by Smaller

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

As of November 10, 2015 there were 25,365,673 shares of the issuer's Common Stock outstanding.

CytoSorbents Corporation

FORM 10-Q

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED BALANCE SHEETS

ASSETS	September 30, 2015 (Unaudited)	December 31, 2014
Current Assets: Cash and cash equivalents Short-term investments Grants and accounts receivable, net of allowance for doubtful accounts of \$4,474 at September 30, 2015 and \$3,756 at December 31, 2014 Inventories Prepaid expenses and other current assets Total current assets	\$7,385,591 1,943,000 553,383 1,337,185 372,332 11,591,491	\$3,605,280 1,944,547 819,151 537,566 700,462 7,607,006
Property and equipment, net Other assets Total Assets LIABILITIES AND STOCKHOLDERS' EQUITY	479,537 731,272 \$12,802,300	245,821 615,798 \$8,468,625
Current Liabilities: Accounts payable Accrued expenses and other current liabilities Deferred revenue Warrant liability Total current liabilities	\$526,670 756,336 — 2,163,840 3,446,846	\$698,307 824,884 833 2,981,418 4,505,442
Stockholders' Equity: Preferred Stock, 5,000,000 shares authorized; -0- shares issued and outstanding at September 30, 2015 and December 31, 2014 Common Stock, 50,000,000 shares authorized; 25,177,005 and 23,304,640 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively Additional paid-in capital Accumulated other comprehensive income Accumulated deficit		23,305 128,106,297 227,701 (124,394,120)

Total stockholders' equity	9,355,454	3,963,183
Total Liabilities and Stockholders' Equity	\$12,802,300	\$8,468,625

See accompanying notes to consolidated financial statements

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Nine months September 30		Three months September 30	
	2015	2014	2015	2014
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
Sales	\$2,548,229	\$2,264,237	\$1,071,459	\$1,031,761
Grant income	470,406	978,271	272,166	128,087
Other revenue	11,987	6,666	_	2,499
Total revenue	3,030,622	3,249,174	1,343,625	1,162,347
Cost of revenue	1,408,742	1,804,578	638,830	475,890
Gross profit	1,621,880	1,444,596	704,795	686,457
Other expenses:				
Research and development	2,619,018	1,464,059	866,334	880,292
Legal, financial and other consulting	802,153	451,731	288,722	49,221
Selling, general and administrative	4,841,600	3,518,374	1,700,035	1,240,497
Total expenses	8,262,771	5,434,164	2,855,091	2,170,010
Loss from operations	(6,640,891)	(3,989,568)	(2,150,296)	(1,483,553)
Other income/(expense):				
Interest income (expense), net	8,842	(311,458)	3,190	(46,600)
Gain (loss) on foreign currency transactions	(315,594)		70,993	(202,797)
Change in warrant liability	817,578	208,080	(771,328)	`
Total other income (expense), net	510,826	(337,467)	(697,145)	(14,797)
Loss before benefit from income taxes Benefit from income taxes	(6,130,065)	(4,327,035)	(2,847,441)	(1,498,350)
Net loss	(6,130,065)	(4,327,035)	(2,847,441)	(1,498,350)
Preferred stock dividend	_	3,769,819	— (_ ,5 . <i>,</i> ,)	1,281,058
Net loss available to common shareholders	\$(6.130.065)		\$(2.847.441)	\$(2,779,408)
Basic and diluted net loss per common share				\$(0.22)
Weighted average number of shares of common stock outstanding:	24,812,707	11,727,573	25,037,538	12,496,014
Net loss	\$(6,130,065)	\$(4,327,035)	\$(2,847,441)	\$(1,498,350)
Other comprehensive income (loss):				
Currency translation adjustment	218,011	123,183	(49,807)	- /
Comprehensive loss	\$(5,912,054)	\$(4,203,852)	\$(2,897,248)	\$(1,380,318)

See accompanying notes to consolidated financial statements

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

Nine Months Ended September 30, 2015 (Unaudited):

	Common Sto	ock	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Par value	Capital	Income	Deficit	Equity
Balance at December 31, 2014	23,304,640	\$23,305	\$128,106,297	\$ 227,701	\$(124,394,120)	\$3,963,183
Stock based compensation - employees, consultants and directors	_	_	260,232	_	_	260,232
Issuance of common stock – offering, net of fees incurred	1,250,000	1,250	9,407,334	_	_	9,408,584
Other comprehensive income/(loss): foreign translation adjustment	_	_	_	218,011	_	218,011
Cashless exercise of warrants	51,810	52	(52)	_	_	_
Proceeds from exercise of warrants	305,202	305	1,272,119	_	_	1,272,424
Cashless exercise of stock options	10,648	11	(11)	· —	_	_
Proceeds from exercise of stock options	254,705	254	362,831	_	_	363,085
Net loss Balance at September 30, 2015	 25,177,005	- \$25,177	 \$139,408,750	— \$ 445,712	(6,130,065) \$(130,524,185)	(6,130,065) \$9,355,454

See accompanying notes to consolidated financial statements.

CYTOSORBENTS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine months ended September 30, 2015 (Unaudited)	Nine months ended September 30, 2014 (Unaudited)
Cash flows from operating activities: Net loss Adjustments to reconcile net loss to net cash used in operating activities: Issuance of common stock to consultant for services Depreciation and amortization	\$ (6,130,065 — 78,430) \$ (4,327,035) 180,100 70,449
Amortization of debt discount Bad debt expense Stock-based compensation Change in warrant liability Foreign currency transaction losses		198,644 3,236 150,273) (208,080)
Changes in operating assets and liabilities: Grants and accounts receivable Inventories Prepaid expenses and other current assets Other assets	237,202 (769,352 322,000 (7,134	(112,183)) (141,467) 380,308) (4,568)
Accounts payable and accrued expenses Deferred revenue Net cash used by operating activities	(206,763 (833) (109,500)) (269,026)) (4,188,849)
Cash flows from investing activities: Purchases of property and equipment Patent costs Proceeds from sales of short-term investments Purchases of short-term investments Net cash used by investing activities	(127,848 3,936,547 (3,935,000) (89,495)) (89,762) —) (7,346,994)) (7,526,251)
Cash flows from financing activities: Proceeds from the issuance of common stock Proceeds from exercise of stock options Proceeds from exercise of warrants Net cash provided by financing activities Effect of exchange rates on cash Net change in cash and cash equivalents	9,408,584 363,085 1,272,424 11,044,093 (18,805 3,780,311	9,751,455 90,855 — 9,842,310) 123,183 (1,749,607)
Cash and cash equivalents - beginning of period	3,605,280	2,183,030

Cash and cash equivalents - end of period

\$ 7,385,591

\$ 433,423

See accompanying notes to consolidated financial statements.

Supplemental schedule of noncash investing and financing activities:

Fair value of warrant liability upon issuance	\$ —	\$862,920
Fair value of shares issued as cost of raising capital	\$ —	\$7,137
Note payable principal and interest conversion to equity	\$ —	\$1,990,440
Costs paid from proceeds in conjunction with issuance of common stock and preferred stock	\$903,916	\$748,545
Preferred stock dividends	\$—	\$3,769,819

See accompanying notes to consolidated financial statements.

CytoSorbents Corporation

Notes to Consolidated Financial Statements

(UNAUDITED)

September 30, 2015

1. BASIS OF PRESENTATION

The Company's interim financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In the opinion of management, the Company has made all necessary adjustments, which include normal recurring adjustments necessary for a fair statement of the Company's financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These interim financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K, as filed with the SEC on March 31, 2015. The results for the three months and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

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

As of September 30, 2015, the Company had an accumulated deficit of \$130,524,185, which included net losses of \$6,130,065 for the nine months ended September 30, 2015 and \$4,327,035 for the nine months ended September 30, 2014. The Company's losses have resulted principally from costs incurred in the research and development of the Company's polymer technology and selling, general and administrative expenses. The Company intends to continue to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other selling, general and administrative expenses, are expected to result in continuing operating losses for the foreseeable future. The amount of future losses and when, if ever, the Company will achieve profitability are uncertain. The Company's ability to achieve profitability will depend, among other things, on successfully completing the development of the Company's technology and commercial products, obtaining additional requisite regulatory approvals in markets not covered by the CE Mark and for potential label extensions of the Company's current CE Mark, establishing manufacturing and sales and marketing arrangements with third parties, and raising sufficient funds to finance the Company's activities. No assurance can be given that the Company's product development efforts will be successful, that the Company's current CE Mark will enable us to achieve profitability, that additional

regulatory approvals in other countries will be obtained, that any of the Company's products will be manufactured at a competitive cost and will be of acceptable quality, or that the Company will be able to achieve profitability or that profitability, if achieved, can be sustained. These matters raise substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments related to the outcome of this uncertainty.

2.PRINCIPAL BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business

The Company is a leader in critical care immunotherapy commercializing its CytoSorb® blood purification technology to reduce deadly uncontrolled inflammation in hospitalized patients around the world, with the goal of preventing or treating multiple organ failure in life-threatening illnesses. The Company, through its subsidiary CytoSorbents Medical Inc. (formerly known as CytoSorbents, Inc.), is engaged in the research, development and commercialization of medical devices with its blood purification technology platform which incorporates a proprietary adsorbent, porous polymer technology. The Company, through its European Subsidiary, conducts sales and marketing related operations for the CytoSorb® device. CytoSorb®, the Company's flagship product, is approved in the European Union and marketed in and distributed in thirty-one countries around the world, as a safe and effective extracorporeal cytokine absorber, designed to reduce the "cytokine storm" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, and pancreatitis. CytoSorb® is also being used during and after cardiac surgery to remove inflammatory mediators, such as cytokines and free hemoglobin, which can lead to