Cytosorbents Corp
Form 8-K
November 30, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of Earliest Event Reported): November 23, 2015

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**000-51038**	**98-0373793**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

7 Deer Park Drive, Suite K,

Monmouth Junction, New Jersey	**08852**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (**732) 329-8885**

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On November 13, 2015, CytoSorbents Corporation (the "Company"), announced that it had submitted an Expedited Access Pathway ("EAP") application to the U.S. Food and Drug Administration (the "FDA") to request EAP designation status for treatment of sepsis with the Company's CytoSorb® device. EAP designation is equivalent to "Breakthrough" designation for drugs and biologics, but designed for medical devices that address major unmet medical needs.

On November 23, 2015, the FDA notified the Company that additional data were necessary to be eligible for EAP designation status consideration. The Company has engaged with the FDA and is currently in the process of scheduling a teleconference to discuss the amount and type of data required in greater detail. Although the Company is confident that additional data are available, there can be no assurances that such data are sufficient to obtain EAP designation for CytoSorb to treat sepsis at this time. In the event the Company does not receive EAP designation status for CytoSorb at this time, the Company plans to seek feedback from the FDA on its draft data development plan and clinical trial design during the pre-submission review process in preparation of either resubmitting an EAP application when the appropriate data are available, or filing an investigational device exemption ("IDE") to conduct a sepsis study in the United States towards a pre-market approval ("PMA") pathway.

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 hereunto duly authorized.

Dated: November 30, 2015

CYTOSORBENTS CORPORATION

By: /s/ Dr. Phillip P. Chan
Name: Dr. Phillip P. Chan
Title: President and Chief Executive Officer