Cytosorbents Corp
Form 8-K
December 18, 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): December 14, 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 23, 2015, CytoSorbents Corporation, a Delaware corporation (the "Company"), announced that following submission of its Expedited Access Pathway ("EAP") application proposing the use of surrogate endpoint data for its proposed registration trial to the U.S. Food and Drug Administration (the "FDA"), the FDA notified the Company that additional data were necessary in order for the Company's CytoSorb device to be eligible for consideration for EAP designation status for the treatment of sepsis. The EAP process and associated guidance documents were designed to allow the potential use of surrogate endpoints in conjunction with a data development plan to shorten the path to market for new medical devices that address a significant unmet medical need. In a subsequent Company joint discussion with representatives from both the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) branches of the FDA about the Company's EAP application, the FDA indicated that 28-day all-cause mortality would be the appropriate primary endpoint regarding CytoSorb and the treatment of sepsis. CDER noted that historically, in many other sepsis trials unrelated to CytoSorb, there has been a lack of utility or correlation in surrogate endpoints when predicting mortality improvement in sepsis outcomes. Given this feedback, the Company concluded there would be no significant time or cost advantage associated with pursuing the EAP designation for CytoSorb for the treatment of sepsis, and that a traditional IDE trial followed by a PMA application as originally planned by the Company is the preferable route to seek approval of CytoSorb for treatment of sepsis that would potentially also not require a post-market efficacy study required by the EAP. The FDA has offered to assist the Company with evaluation of its sepsis clinical trial design once submitted under a formal IDE.

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: December 18, 2015

CYTOSORBENTS CORPORATION

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