Cytosorbents Corp
Form 8-K
January 10, 2017

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): January 4, 2017

CYTOSORBENTS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-36792**	**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.

In June 2013, CytoSorbents Corporation, a Delaware corporation (the "Company"), announced that the U.S. Air Force was funding a Company-sponsored, 30 patient, single site, randomized controlled human pilot study of the Company's CytoSorb® product to evaluate patients with severe trauma and rhabdomyolysis (the "Study"). The primary endpoint for the Study was myoglobin removal. Though the Company did not expect to receive material direct funding from this $3.0 million budgeted program, it was hoped that the Study would generate valuable data that could be used commercially by the Company or in the Company's future trauma studies.

However, because of the stringency of the inclusion criteria, and because of the patient mix seen at the single clinical trial site, the Study experienced difficulty in enrolling patients. In an effort to increase enrollment, in 2015 the Company amended the applicable Study protocol to modify the key inclusion criteria and expand the number of clinical trial sites. Unfortunately, these amendments did not result in increased enrollment. In December 2016, the Company contacted the Contracting Officer's Representative for the Study to discuss potential options and alternatives, including closing the Study. Due to the continued difficulty in enrolling patients in this Study and likelihood this would continue without significant modification to the protocol, the Company and U.S. Air Force determined to close the Study. This included notification of the San Antonio Military Medical Center (primary Study site) Ethics Committee, that occurred and was acknowledged on January 4, 2017. In addition, the Company is in the process of notifying the U.S. Food and Drug Administration that it will officially close the Study.

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: January 10, 2017

CYTOSORBENTS CORPORATION

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