# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 6, 2017

## CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-34375 (Commission File Number) 33-0827593 (IRS Employer Identification No.)

3020 Callan Road San Diego, California (Address of principal executive offices)

92121 (Zip Code)

Registrant's telephone number, including area code: (858) 458-0900

 $\begin{tabular}{ll} Not Applicable \\ Former name or former address, if changed since last report \\ \end{tabular}$ 

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:	
	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 Items.

On April 6, 2017, Cytori Therapeutics, Inc. (the "Company") received approval from the U.S. Food and Drug Administration ("FDA") of an Investigational Device Exemption ("IDE") for a pilot clinical trial to evaluate Cytori Cell Therapy $^{\text{IM}}$  in patients with thermal burn injury. This trial, named the RELIEF trial, is a continuation of the Company's research and development efforts under its contract with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services.

The RELIEF trial will assess safety and feasibility of intravenous delivery of Cytori Cell Therapy $^{\text{TM}}$  as an adjunct to usual care in patients with thermal burn injuries covering between 20% and 50% of their body surface area. The trial is approved to enroll up to 30 patients in up to 10 U.S. sites. Initiation of RELIEF is dependent upon execution of a contract option by BARDA to provide the necessary funds.

The RELIEF Trial is designed as a prospective, open-label, parallel group, usual care controlled, multi-center randomized (2:1, active: usual care alone) safety and feasibility study targeting thermal burns. Subjects will have at least one deep partial or full thickness burn wound that is to be autografted with a meshed split thickness skin graft (STSG). Subjects randomized to Cytori Cell Therapy will undergo small volume fat harvest (100 to 150 mL) during scheduled burn surgery followed by intravenous delivery of Cytori Cell Therapy. Subjects randomized to usual care will not undergo a fat harvesting procedure.

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#### **Cautionary Statement Regarding Forward-Looking Statements**

This Current Repot on Form 8-K includes forward-looking statements regarding events, trends and business prospects, which may affect our future operating results and financial position. Such statements, including, but not limited to, statements regarding potential BARDA funding of the pilot clinical trial and conduct of the RELIEF clinical trial, are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks and uncertainties include: a possible adverse decision by BARDA to delay, suspend or reduce funding of Cytori's proposed RELIEF clinical trial or other development efforts under its contract with BARDA or other changes in BARDA's funding and procurement priorities that may adversely affect our thermal burn injury program; BARDA's ability to reduce, modify or terminate its contract (and contract options) with us if it determines it is in the government's best interests to do so; the risk that Cytori is unable to complete development work necessary to receive BARDA funding; the risks that quality of data supporting IDE approval and execution of BARDA contract options is deemed insufficient for regulatory approval; risks in the collection and results of clinical data; risks associated with final clinical outcomes; regulatory risks and uncertainties; risks related to dependence on third party performance, and other risks and uncertainties described under the "Risk Factors" section in Cytori's Securities and Exchange Commission Filings on Form 10-K and Form 10-Q. Cytori assumes no responsibility to update or revise any forward-looking statements contained in this press release to reflect events, trends or circumstances after the date of this communication.

#### **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.

### CYTORI THERAPEUTICS, INC.

By: /s/ Jeremy Hayden

Name: Jeremy Hayden Title: General Counsel

April 10, 2017