

**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): September 15, 2016

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
(I.R.S. Employer
Identification Number)

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

92121
(Zip Code)

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

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:

- 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))
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Item 1.01 Entry Into a Material Definitive Agreement.

On September 15, 2016, Cytori Therapeutics, Inc., a Delaware corporation (the “Company”), entered into that certain Amendment of Solicitation/Modification of Contract (Amendment No. 0005), effective as of September 9, 2016 (the “Amendment”), to Option 1 (the “Option”) of its contract (Contract HHSO100201200008C) with the U.S. Department of Health and Human Service’s Biomedical Advanced Research and Development Authority (“BARDA”), as amended, for the evaluation and development of Company’s cell therapy for the treatment of thermal burns combined with radiation injury (the “BARDA Agreement”).

The Amendment provides for additional funding in the amount of approximately \$2.5 million, bringing total amounts awarded to the Company pursuant to Option 1 to approximately \$16.6 million. The supplemental funds from this Amendment will be used to support the remaining activities necessary to seek Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration for a pilot clinical trial investigating the use of the Company’s cell therapy in thermal burn injuries and to support clinical readiness. The foregoing is only a brief description of the material terms of the Amendment and does not purport to be a complete description of the rights and obligations of the parties there under. The foregoing description is qualified in its entirety by reference to the Amendment, which will be filed as an exhibit to the Company’s next Quarterly Report on Form 10-Q.

On September 19, 2016, the Company issued a press release announcing the Amendment. A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Cytori Therapeutics, Inc. Press Release, dated September 19, 2016

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.

September 19, 2016

By: /s/ Jeremy Hayden
Name: Jeremy Hayden
Title: General Counsel and VP of Business Development

Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Cytori Therapeutics, Inc. Press Release, dated September 19, 2016
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BARDA Increases Contract Option with Cytori to Advance Countermeasure Clinical Trial

Increased Option Value to \$16.6 Million for Burn Wound Treatment

September 19, 2016

SAN DIEGO--(BUSINESS WIRE)-- Cytori Therapeutics (NASDAQ: CYTX) (the “Company”) today announced that the Company and Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services, increased the contract option originally signed in August 2014 to fund continued investigation and development of Cytori Cell Therapy™ for use in thermal burn injuries.

The amended option is valued at \$16.6 million, an increase of approximately \$2.5 million from its previous value of \$14.1 million. Upon Investigational Device Exemption (IDE) approval by the FDA, if received, Cytori will request that BARDA provide additional funding to cover costs associated with the completion of a pilot clinical trial. This trial will employ IV administration of Cytori Cell Therapy.

The supplemental funds from this amended contract will be used to support the remaining activities necessary to seek approval of the IDE and support clinical readiness. The original contract includes additional options, exercisable at BARDA’s discretion, valued at up to \$68 million to fund both pilot and pivotal clinical trials and additional work in thermal burn complicated by radiation exposure.

“BARDA and Cytori continue to work closely to develop this technology in the interests of the nation,” said Dr. Marc Hedrick, President and Chief Executive Officer of Cytori. “Additional funding allows Cytori to complete activities necessary for conduct of a pilot trial with the objective of getting Cytori Cell Therapy into the clinic for thermal burn in 2017.”

The current healthcare system is ill-prepared for large numbers of patients requiring simultaneous treatment for thermal burns associated with radiation exposure. Current standard of care consists of dressings, skin grafts and skin substitutes. Despite these treatments, patients with severe burns commonly suffer from prolonged pain, aggressive scarring, skin contracture and reduced range of motion. Cellular therapeutics such as those offered by Cytori may have the potential to improve the quality and rate of wound healing and reduce scarring and also can be deployed in a cost effective manner, even in mass casualty situations.

According to the American Burn Association, there were approximately 450,000 burn injuries in 2013 that required medical treatment in the United States, with approximately 40,000

requiring hospitalization. In a mass casualty event, the Government Accountability Office estimates that as many as 10,000 patients could require thermal burn care. The limited number of specialist surgeons and burn centers in the U.S. creates a public health need for a burn wound therapy that can be quickly and broadly applied by non-specialist medical personnel following such an event.

About Cytori Therapeutics, Inc.

Cytori Therapeutics is a late stage cell therapy company developing autologous cell therapies from adipose tissue to treat a variety of medical conditions. Data from preclinical studies and clinical trials suggest that Cytori Cell Therapy™ acts principally by improving blood flow, modulating the immune system, and facilitating wound repair. As a result, Cytori Cell Therapy™ may provide benefits across multiple disease states and can be made available to the physician and patient at the point-of-care through Cytori's proprietary technologies and products. For more information, visit www.cytori.com.

Cautionary Statement Regarding Forward-Looking Statements

This communication 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 IDE approval, Cytori's use of the proceeds of BARDA's \$2.5 million option exercise, anticipated future BARDA funding, and clinical efficacy and cost-effectiveness of Cytori Cell Therapy, 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 FDA decision regarding our IDE submission, changes in government funding and procurement priorities that may adversely affect our thermal burn injury program, the government's sole discretion in determining funding timing and amounts, the government's ability to reduce, modify or terminate the contract 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 FDA IDE approval and/or future BARDA funding, the quality of data supporting IDE approval and execution of BARDA contract options, risks in the collection and results of clinical data, final clinical outcomes, regulatory uncertainties, 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.

CYTORI THERAPEUTICS CONTACT

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