

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 17, 2014**

**CYTORI THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

**001-34375**

**33-0827593**

(State or Other Jurisdiction of Incorporation)

(Commission File  
Number)

(I.R.S. Employer Identification Number)

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**3020 Callan Road, San Diego, California 92121**  
(Address of principal executive offices, with zip code)

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

**n/a**  
(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))
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**Item 1.01 Entry Into a Material Definitive Agreement.**

On December 17, 2014, Cytori Therapeutics, Inc., a Delaware corporation (the “Company”), entered into an amendment of its Option 1 of its September 27, 2012 contract with the U.S. Department of Health and Human Service’s Biomedical Advanced Research and Development Authority (BARDA) for the evaluation and development of Company’s cell therapy for the treatment of thermal burns combined with radiation injury (the “BARDA Agreement”).

The Option 1 amendment includes a net increase of approximately \$2 million from its original value of \$12.1 million to support the Company’s activities including verification, testing and validation for delivery and processing of adipose-derived regenerative cells (ADRCs™), which enables the Company to continue to perform research, development, regulatory, clinical and other tasks required for initiation of a pilot clinical trial of the Celution System in thermal burn injury pursuant to Option 1 of the BARDA Agreement. The amended Option 1 also includes amendments to the Statement of Work. The total cost plus fixed fee for the performance of the amended Option 1 is up to approximately \$14.1 million. Upon Investigational Device Exemption (IDE) approval by the FDA, BARDA anticipates providing additional funding to cover costs associated with the completion of a clinical trial, currently estimated at \$8.3 million, bringing the combined contract option value up to \$22.4 million.

The foregoing is only a brief description of the material terms of the Option 1 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 Contract HHSO100201200008C Amendment No. 2 dated December 17, 2014, which will be filed as an exhibit to the Company’s Annual Report Form 10-K.

On December 19, 2014, the Company issued a press release announcing the Option 1 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 December 19, 2014

\* Exhibit 99.1 hereto 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.

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**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.**

Date: December 19, 2014

By: /s/ Tiago Girao

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Tiago Girao

VP Finance and Chief Financial Officer

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## **Cytori and BARDA Amend Contract Option to Accelerate the Advancement of a Thermal Burn Injury Countermeasure**

### ***Increased Option Value of \$14.1 Million plus \$8.3 Million for FDA Approved Clinical Trial***

San Diego, CA - Cytori Therapeutics (NASDAQ: CYTX) 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, executed an amendment of a 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 \$14.1 million, an increase of approximately \$2 million from its original value of \$12.1 million. Upon Investigational Device Exemption (IDE) approval by the FDA, BARDA anticipates providing additional funding to cover costs associated with the completion of a clinical trial, currently estimated at \$8.3 million, bringing the combined contract option value up to \$22.4 million.

The supplemental funds from this amended contract will be primarily used to support 2015 activities such as verification, testing and validation for delivery and processing of adipose-derived regenerative cells (ADRCs™). Reports generated by the funded activities will be submitted to the FDA as part of an IDE package for a proposed clinical trial using Cytori Cell Therapy in thermal burn injury. The original contract retains two additional options to fund a pivotal clinical trial and additional work in thermal burn complicated by radiation exposure valued at up to \$45 million and \$23 million, respectively.

“We are pleased to see that once again, BARDA continues to show strong support and interest in Cytori Cell Therapy for this indication”, said Dr. Marc Hedrick, President and Chief Executive Officer of Cytori. “With these incremental funds, we can expedite the product development and clinical timelines by several months.”

The treatment of thermal burns remains a critical unmet medical need. Despite standard of care primarily consisting of dressings, skin grafts and skin substitutes, patients frequently suffer from pain, scarring, skin contracture and reduced range of motion. Autologous cell therapies such as those offered by Cytori have the potential to improve the quality and rate of wound healing and reduce scarring.

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 reports 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 solutions. For more information: visit [www.cytori.com](http://www.cytori.com) or follow Cytori on Twitter [www.twitter.com/cytori](http://www.twitter.com/cytori).

#### **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, those regarding an FDA Investigational Device Exemption (IDE) approval for a pilot clinical trial of Cytori Cell Therapy in thermal burn, and anticipated BARDA funding of approximately \$8.3 million to cover the costs of the pilot clinical trial for thermal burn, further extensions, option exercises or additional contract work that may be sponsored by BARDA, 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 future Government funding and procurement priorities, 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 quality of data supporting 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.

#### **SOURCE: Cytori Therapeutics, Inc.**

Shawn Richardson

+1.858.875.5279

[ir@cytori.com](mailto:ir@cytori.com)

