

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): **July 1, 2019**

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)

4200 Marathon Blvd., Suite 200, Austin, Texas 78756
(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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Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	CYTX	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

On July 1, 2019, Cytori Therapeutics, Inc. (the “Company”) announced that it received feedback from the United States Food and Drug Administration (“FDA”) regarding the development of ATI-1123. Key feedback from the FDA included that a 505(b)(2) application appears to be an acceptable regulatory approach with docetaxel injection as a potentially acceptable listed drug (“LD”). Furthermore, the FDA agreed that the completed nonclinical studies are sufficient to support the initiation of the clinical trial of ATI-1123 in patients with platinum-sensitive small cell lung cancer who have progressed at least 60 days after initiation of first-line therapy.

The purpose of the Company’s FDA submission was to clarify certain key aspects of the Company’s future development plan including: (1) the suitability of the 505(b)(2) pathway for approval of the proposed ATI-1123 drug product, including the proposed LD, (2) the adequacy of the referenced clinical, nonclinical and pharmaceutical quality information, in combination with the proposed drug development program, to support the new drug application and (3) any concerns that the FDA may have with regard to other filing issues specific to the product.

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Current Report on Form 8-K are forward-looking statements, including statements regarding the planned development of ATI-1123 and the potential of acceptance of ATI-1123 as a LD by the FDA. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this Current Report on Form 8-K and are subject to a number of risks, uncertainties and assumptions, including: the sufficiency of the Company’s capital resources to conduct clinical trials; the ability of the Company to regain compliance with Nasdaq continued listing requirements, failure of which could result in the Company’s common stock being delisted from the exchange; and the risks described under the “Risk Factors” section in the Company’s Securities and Exchange Commission filings, included in the Company’s annual and quarterly reports. The events and circumstances reflected in the Company’s forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the Company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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.

Date: July 1, 2019

CYTORI THERAPEUTICS, INC.

By: /s/ Gary Titus

Gary Titus

Chief Financial Officer