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 24, 2017**

CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-34375**	**33-0827593**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

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)

Indicate by check mark whether the registrant is an emerging growth company as defined in 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).

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. ☐

Emerging growth company ☐

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.

On July 24, 2017, Cytori Therapeutics, Inc. (the "Company" or "Cytori") announced top-line, preliminary data from its Phase III pivotal STAR trial of Habeo™ Cell Therapy™ in patients with scleroderma. The U.S. multi-center STAR trial enrolled and evaluated 88 patients with scleroderma, including 51 patients within the diffuse cutaneous subset and 37 with limited cutaneous scleroderma. While the primary endpoint did not reach statistical significance at 24 or 48 weeks, the trial data reported clinically meaningful improvement in the primary and secondary endpoints of both hand function and scleroderma-associated functional disability, for Habeo treated patients compared to placebo, in a subgroup of patients with diffuse cutaneous scleroderma.

In the combined study population, the primary endpoint, specifically mean improvement in the Cochin Hand Function Score, did not show statistical difference between treated patients and those receiving placebo at 24 weeks and 48 weeks as determined by both analysis of covariance and mixed model repeated measure analysis. The Raynaud's Condition Score, a secondary endpoint, improved in both the treatment and placebo group but was not statistically different between the Habeo-treated and placebo groups.

However, in the pre-specified subgroup analysis of patients with diffuse cutaneous scleroderma, a more severe form of the disease, improvements in the Cochin Hand Function Score and the Health Assessment Questionnaire-Disability Index (HAQ-DI), a measure of functional disability and an important secondary endpoint, met or exceeded the published criteria for minimally important clinical differences in these measures (6.5 points for Cochin[1], 0.22 points for HAQ-DI[2]).

Endpoint	Timepoint	Habeo † / ‡	Placebo † / ‡	p value † / ‡
All Subjects		**n=48**	**n=40**	
CHF - mean improvement	24 weeks	11.5 / 11.8	10.2 / 9.8	0.442 / 0.3943
	48 weeks	11 / 11.3	8.9 / 8.51	0.2989 / 0.2650
HAQ-DI - mean improvement	48 weeks	0.22 / NA	0.11 / NA	0.105 / NA
Diffuse Cutaneous Subgroup		**n=32**	**n=19**	
CHF - mean improvement	24 weeks	12.8 / 13.3	8.0 / 7.2	0.111 / 0.078
	48 weeks	12.0 / 12.4	6.6 / 5.9	0.069 / 0.058
HAQ-DI - mean improvement	48 weeks	0.20 /NA	0.00 / NA	0.044 / NA

† Analysis of co variances using ANCOVA mean changes from baseline.

‡ Mixed model repeated measure analysis, MMRM mean changes from baseline.

NA Data not available.

In general, the adverse events were rated as mild to moderate in the majority of cases and there were no significant safety issues identified for Habeo or the procedure itself (including liposuction and finger injection in the placebo group) during the trial.

After Cytori reviews the complete data set from the STAR trial, Cytori plans to work collaboratively with trial investigators, patient advocates and the regulatory bodies in Cytori's key markets, to evaluate the next steps for Habeo Cell Therapy.

The STAR trial was a prospective, double-blind, randomized, multicenter, parallel-group Phase III pivotal study assessing the safety and efficacy of a single, subcutaneous administration of Habeo Cell Therapy (40 million cells per subject) into the fingers of patients with hand dysfunction due to scleroderma. The subjects were randomized 1:1 to receive either Habeo Cell Therapy or placebo. Investigators conducted final assessments at 48 weeks. The primary study endpoint was improvement in the Cochin Hand Function Score, a self-reported measure of hand function, which was assessed at 24 and 48 weeks. The Cochin score is based on 18 questions relating to hand function; each question is graded on a 0–5 scale, with a total score of 90 points reflecting maximal disability. The Health Assessment Questionnaire-Disability Index (HAQ-DI), a measure of functional disability and a secondary

endpoint in the STAR trial, consists of questions pertaining to activities of daily living graded on a 0–3 scale (with 3 representing “unable to perform”); the HAQ-DI also includes several visual analog scales (VAS) for different body systems. The Raynaud’s Phenomenon condition score, a secondary endpoint in the STAR trial, is a patient reported outcome measure asking the patients how much difficulty they had with their Raynaud’s symptoms over the past 24 hours graded on a scale of 0 – 10 with 0 being no difficulty and 10 being extreme difficulty.

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Cautionary Statement Regarding Forward-Looking Statements

This report includes forward-looking statements regarding events, trends and business prospects, which may affect Cytori’s future operating results and financial position. Such statements, include, but are not limited to, statements regarding Cytori’s plans to evaluate the STAR data in consultation with various internal and external resources, experts and the FDA; Cytori’s conduct of its STAR trial, and possible future clinical trials of Habeo Cell Therapy; the ability to fully characterize the efficacy and safety profile of Habeo Cell Therapy through further study and the potential to yield additional insights into its clinical utility; and the ability of Cytori Cell Therapy™ to provide benefits across multiple disease states and be made available to the physician and patient at the point-of-care through Cytori’s proprietary technologies and products. These statements are subject to risks and uncertainties that could cause Cytori’s actual results and financial position to differ materially. Some of these risks and uncertainties include: risks in the conduct of Cytori’s STAR trial and future clinical trials (including risks in the collection and results of clinical data); risks associated with the conduct of investigator-initiated trials using our cellular therapeutics; risks associated with potential benefits of Cytori’s products (including any potential benefits of Habeo Cell Therapy identified in the STAR trial); risks associated with development of Cytori’s clinical pipeline, including the possibility that Cytori may determine that there may not be a viable continued development path for Habeo Cell Therapy; final clinical outcomes (including the risk that top-line data may not accurately reflect the complete results of a particular study or trial); regulatory risks and uncertainties, including the risk that FDA and other regulatory authorities may not approve Habeo Cell Therapy, or that any marketing approvals, if granted, may have significant limitations on their use; risks related to reimbursement (including failure to achieve desired pricing for Habeo Cell Therapy); risks related to dependence on third party performance; the risk that Habeo Cell Therapy may never be successfully commercialized, or receive anticipated levels of commercial acceptance; Cytori’s ability to raise additional funding that it may need to continue to pursue its commercial and business development plans; 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 report to reflect events, trends or circumstances after the date of this communication.

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[1] Nguyen C, Bérezné A, Mestre-Stanislas, et al. Changes over time and responsiveness of the Cochin Hand Function Scale and Mouth Handicap in Systemic Sclerosis Scale in patients with systemic sclerosis: a prospective observational Study. American Journal of Physical Medicine & Rehabilitation. 2016;95(12):e189-e197.

[2] Pope J. Measures of systemic sclerosis (scleroderma): Health Assessment Questionnaire (HAQ) and Scleroderma HAQ (SHAQ), Physician- and Patient-Rated Global Assessments, Symptom Burden Index (SBI), University of California, Los Angeles Scleroderma Clinical Trials Consortium Gastrointestinal Scale (UCLA SCTC GIT) 2.0, Baseline Dyspnea Index (BDI) and Transition Dyspnea Index (TDI) (Mahler’s Index), Cambridge Pulmonary Hypertension Outcome Review (CAMPHOR), and Raynaud’s Condition Score (RCS). Arthritis Care & Research. ol. 2011;63(S11):S98 –S111. doi 10.1002/acr.20598.

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: July 24, 2017

By: /s/ Tiago Girao
Tiago Girao
VP Finance and Chief Financial Officer