#### 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): August 10, 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 (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)

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))

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).

Emerging growth company  $\Box$ 

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.

## Item 2.02 Results of Operations and Financial Condition

On August 10, 2017, Cytori Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2017. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information disclosed under this Item 2.02 in this report, including 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.

## Item 9.01 Financial Statements and Exhibits

# (d) Exhibits

<u>Exhibit No.</u>	Description
99.1	Cytori Therapeutics, Inc. Press Release, dated August 10, 2017

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: August 10, 2017

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

<u>Exhibit No.</u>	Description
99.1	Cytori Therapeutics, Inc. Press Release, dated August 10, 2017



#### CYTORI THERAPEUTICS CONTACT

Tiago Girao

+1.858.458.0900

ir@cytori.com

# Cytori Reports Second Quarter 2017 Business and Financial Results

SAN DIEGO, August 10, 2017—<u>Cytori Therapeutics</u> (NASDAQ: CYTX) ("Cytori" or the "Company") today announced its second quarter 2017 financial results and provided updates on its corporate activity and clinical development.

Second quarter 2017 net loss was \$6.0 million, or \$0.19 per share. Operating cash burn for the quarter was approximately \$5.0 million. Cytori ended the quarter with approximately \$9.0 million of cash and cash equivalents.

#### Selected Key Recent Highlights:

- STAR trial top-line preliminary data announced. Despite missing primary and secondary endpoints, data showed clinically meaningful improvements in more severely affected patients with diffuse cutaneous scleroderma.
- American Medical Association approved new category III CPT codes describing Cytori's scleroderma therapy.
- BARDA executed a \$13.4 million contract option to fund the RELIEF burn trial.
- Received U.S. FDA IDE approval for RELIEF, a thermal burn pilot trial application related to ongoing BARDA contract.

#### Q2 2017 Financial Performance

- Q2 2017 and year-to-date operating cash burn was \$5.0 million and \$9.9 million, compared to \$5.7 million and \$10.7 million for the same periods in 2016, respectively.
- Q2 2017 and year-to-date total revenues were \$1.5 million and \$3.1 million, compared to \$2.8 million and \$5.7 million for the same periods in 2016, respectively.
- Cash and debt principal balances at June 30, 2017 were approximately \$9.0 million and \$14.2 million, respectively.
- Q2 2017 net loss was \$6.0 million or \$0.19 per share, compared to \$6.4 million or \$0.43 per share for Q2 2016.
- Year-to-date adjusted net loss was \$11.9 million, or \$0.44 per share, and excludes a \$1.7 million non-cash charge for in-process research and development expense from the Azaya Therapeutics asset acquisition, compared to \$11.7 million or \$0.84 per share for the same period in 2016.

• Year-to-date GAAP net loss was \$13.6 million or \$0.50 per share, compared to \$11.7 million or \$0.84 per share for the same period in 2016. "Based on ongoing analysis of our STAR trial data and observed clinically meaningful improvements in the diffuse cutaneous subgroup, we intend to meet with the US FDA as soon as possible for a post-trial meeting to chart next steps. It is important that our Habeo<sup>TM</sup> product ultimately be made available for these patients." said Dr. Marc Hedrick, President and CEO of Cytori. "In addition, manufacturing validation for our ATI-0918 nanoparticle doxorubicin oncology product is on schedule for filing for EMA submission mid next year and other key trials continue to enroll, ideally completing enrollment of both, Scleradec-II and ADRESU by year end."

#### **Selected Key Anticipated Milestones:**

- Complete analysis of STAR full dataset and subsequent meeting with FDA to determine next steps for Habeo clinical development for scleroderma hand dysfunction (Q3).
- Begin enrollment of BARDA's funded RELIEF burn trial (Q4).
- Complete manufacturing activities required for submission of an MAA to the EMA for our recently acquired nanoparticle doxorubicin (Q4).



# 2017 Financial Guidance - Updated

The Company expects full year 2017 operating cash burn to be higher than 2016, primarily due to the development of assets acquired from Azaya Therapeutics.

• Updated operating cash burn forecasted to be within a range of \$20 million to \$23 million, a reduction from previously guided range of \$26 million to \$29 million.

#### Management Conference Call Webcast

Cytori will host a management conference call at 5:30 p.m. Eastern Time today to further discuss its progress. The webcast will be available live and by replay two hours after the call and may be accessed under "Webcasts" in the <u>Investor Relations section</u> of Cytori's website. If you are unable to access the webcast, you may dial in to the call at +1.877.402.3914, Conference ID:67113805.

#### About Cytori

Cytori is a therapeutics company developing regenerative and oncologic therapies from its proprietary cell therapy and nanoparticle platforms for a variety of medical conditions. Data from preclinical studies and clinical trials suggest that Cytori Cell Therapy<sup>™</sup> acts principally by improving blood flow, modulating the immune system, and facilitating wound repair. As a result, Cytori Cell Therapy<sup>™</sup> 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. Cytori Nanomedicine<sup>™</sup> is developing encapsulated therapies for regenerative medicine and oncologic indications using technology that allows Cytori to use the benefits of its encapsulation platform to develop novel therapeutic strategies and reformulate other drugs to optimize their clinical properties. For more information, visit <u>www.cytori.com</u>.

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

This press release includes forward-looking statements that involve known and unknown risks and uncertainties. All statements, other than historical facts are forward looking statements. Such statements, including, without limitation, statements regarding anticipated commercial launch of our Habeo™ therapy and ATI-0918 drug candidate (and timing thereof); completion of manufacturing activities necessary to submit an MAA to the EMA for our ATI-0918 drug candidate; our strategy for addressing our capital requirements through various activities, including operational efficiencies, revenue growth and accessing the capital markets; receipt of feedback from, and related discussions with, BARDA regarding our future contractual relationship with BARDA (and proposed BARDA funding of our thermal burn pilot trial); and our expected 2017 cash burn and reasons for the anticipated cash burn; are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks include clinical, pre-clinical and regulatory uncertainties, such as those associated with conduct and completion of the proposed thermal burn trial, as well as the Company's anticipated submission of data to the EMA from the previously completed bioequivalency trial for ATI-0918. Specifically, the Company faces risks in the collection and results of the STAR and thermal burn trials, including enrollment risks, the risks that clinical data from one or more of these clinical trials will fail to demonstrate safety or efficacy of our product candidates, and risks that insufficiently positive clinical data will adversely affect government funding, regulatory approval pathways and commercial prospects for our cell therapy (e.g., Habeo), and nanomedicines product candidates. We also face risks that investigator-initiated trials using our Cytori Cell Therapy fail to fully enroll or otherwise are conducted in a manner that ultimately is injurious to our business. We also face the risk that we will be unable to time successfully manufacture our ATI-0918 drug candidate in time to meet our projected timeline for submission of an MAA to the EMA, or at all. We also face risks regarding execution of our managed access program (MAP) strategy in Europe, the Middle East and Africa (EMEA), including risks relating to our efforts to ethically direct prospective scleroderma patients into our MAP program. Some of these risks also include risks relating to regulatory challenges the Company faces (including the U.S., EU, China, Japan and its other key geographies) due to a number of factors including novelty of the Company's technology and product offerings, changes in and /or evolution of regulatory approaches to cellular therapeutics like the Company's in its key geographies, and similar matters. The Company also faces risks relating to achievement of the Company's financial goals (including balancing capital requirements and meeting projected 2017 operating cash burn guidance). It is possible that the Company could face unexpected revenue shortfalls, expense increases or other occurrences that adversely affect our cash burn and cash management strategies. Further the Company face risks pertaining to dependence on third party performance and approvals (including performance of investigator-initiated trials, outcome of BARDA's review of the Company's proposed burn wound trial pursuant to its contract with BARDA, and outcome of the EMA's review of our ATI-0918 MAA); performance and acceptance of the Company's products in clinical studies/trials and in the marketplace (including commercial acceptance of the Company's products in Japan and other markets where are products are commercially available, and similar risks); material changes in the marketplace that could adversely impact revenue projections (including changes in market perceptions of the Company's products, and introduction of competitive products); unexpected costs and expenses that could adversely impact liquidity and shorten the Company's current liquidity projections (which could in turn require the Company to seek additional debt or equity capital sooner than currently anticipated); the Company's reliance on key personnel; the Company's ability to identify and develop new programs or assets to expand the Company's clinical pipeline; the right of the U.S.





government (BARDA) to cut or terminate further support of the thermal burn injury program (including any decision by BARDA not to proceed with our proposed thermal burn trial, assuming FDA approval of the Company's IDE submission); the Company's abilities to capitalize on its internal restructuring and achieve break-even or profitability (or to continue to reduce our operating losses); and other risks and uncertainties described under the "Risk Factors" in Cytori's Securities and Exchange Commission Filings, included in the Company's annual and quarterly reports.

There may be events in the future that the Company is unable to predict, or over which it has no control, and its business, financial condition, results of operations and prospects may change in the future. The Company assumes no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made unless the Company has an obligation under U.S. Federal securities laws to do so.



## CYTORI THERAPEUTICS, INC. CONSOLIDATED CONDENSED BALANCE SHEETS (UNAUDITED) (in thousands, except share and par value data)

	As	of June 30, 2017	As of December 31, 2016		
Assets					
Current assets:					
Cash and cash equivalents	\$	9,028	\$	12,560	
Accounts receivable, net of reserves of \$167 in both 2017 and 2016,					
respectively		807		1,242	
Restricted cash		429		350	
Inventories, net		4,243		3,725	
Other current assets		1,116		870	
Total current assets		15,623		18,747	
Property and equipment, net		3,387		1,157	
Other assets		1,712		2,336	
Intangibles, net		7,832		8,447	
Goodwill		3,922		3,922	
Total assets	\$	32,476	\$	34,609	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	6,485	\$	5,872	
Current portion of long-term obligations, net of discount		6,744		6,629	
Total current liabilities		13,229		12,501	
Deferred revenues		110		97	
Long-term deferred rent and other		110		37 17	
Long-term obligations, net of discount, less current portion		7,771		11,008	
Total liabilities	<u></u>	21,246		23,623	
Total fiabilities		21,240		23,023	
Commitments and contingencies					
Stockholders' equity:					
Series A 3.6% convertible preferred stock, \$0.001 par value; 5,000,000 shares					
authorized; 13,500 shares issued; no shares outstanding in 2017 and 2016				_	
Common stock, \$0.001 par value; 75,000,000 shares authorized; 33,328,401 and					
21,707,890 shares issued and outstanding in 2017 and 2016, respectively		33		22	
Additional paid-in capital		402,670		388,769	
Accumulated other comprehensive income		1,183		1,258	
Accumulated deficit		(392,656)		(379,063)	
Total stockholders' equity		11,230		10,986	
Total liabilities and stockholders' equity		32,476	\$	34,609	





## CYTORI THERAPEUTICS, INC. CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED) (in thousands, except share and per share data)

	F	For the Three Months Ended June 30,			For the Six Month			
	+	2017	-	2016	-	2017	-	2016
Product revenues	\$	969	\$	1,126	\$	1,560	\$	2,459
Cost of product revenues		401		503		811		971
Amortization of intangible assets		306		82		612		181
Gross profit		262		541		137		1,307
Development revenues:								
Government contracts and other		531		1,699		1,549		3,284
		531		1,699	_	1,549		3,284
Operating expenses:			_					
Research and development		2,992		5,247		6,281		9,374
Sales and marketing		1,263		889		2,202		1,924
General and administrative		2,119		2,328		4,227		4,614
In process research and development acquired from Azaya Therapeutics				_		1,686		
Total operating expenses		6,374		8,464		14,396		15,912
Operating loss		(5,581)		(6,224)		(12,710)		(11,321)
Other income (expense):								
Interest income		7		2		18		4
Interest expense		(538)		(645)		(1,129)		(1,302)
Other income, net		63		462		228		876
Total other expense		(468)		(181)	_	(883)		(422)
Net loss	\$	(6,049)	\$	(6,405)	\$	(13,593)	\$	(11,743)
Basic and diluted net loss per share	\$	(0.19)	\$	(0.43)	\$	(0.50)	\$	(0.84)
Basic and diluted weighted average shares used in calculating net loss per share		31,250,872		14,778,616		26,993,619		13,932,496
Comprehensive loss:								
Net loss	\$	(6,049)	\$	(6,405)	\$	(13,593)	\$	(11,743)
Other comprehensive loss – foreign currency translation adjustments		(15)		(130)		(75)		(379)
Comprehensive loss	\$	(6,064)	\$	(6,535)	\$	(13,668)	\$	(12,122)

6



## CYTORI THERAPEUTICS, INC. CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED) (in thousands)

	For the Six Months Ended June 30,				
		2017	2016		
Cash flows from operating activities:					
Net loss	\$	(13,593)	\$	(11,743)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		1,052		574	
Amortization of deferred financing costs and debt discount		418		468	
In process research and development acquired from Azaya Therapeutics		1,686		—	
Joint Venture acquisition obligation accretion		—		24	
Provision for expired inventory		340		26	
Stock-based compensation expense		410		645	
Loss on asset disposal		19		2	
Increases (decreases) in cash caused by changes in operating assets and liabilities:					
Accounts receivable		409		66	
Inventories		159		(380)	
Other current assets		(736)		137	
Other assets		43		34	
Accounts payable and accrued expenses		(194)		(431)	
Deferred revenues		13		1	
Long-term deferred rent		119		(158)	
Net cash used in operating activities		(9,855)		(10,735)	
Cash flows from investing activities:					
Purchases of property and equipment		(95)		(105)	
Purchase of long-lived assets part of Azaya Therapeutics' acquisition		(1,201)		_	
Change in restricted cash		(79)		_	
Net cash used in investing activities		(1,375)		(105)	
Cash flows from financing activities:					
Principal payments on long-term obligations		(3,540)			
Joint Venture purchase payments		_		(1,774)	
Proceeds from sale of common stock, net		11,225		18,179	
Net cash provided by financing activities		7,685		16,405	
Effect of exchange rate changes on cash and cash equivalents		13		139	
Net (decrease) increase in cash and cash equivalents		(3,532)		5,704	
Cash and cash equivalents at beginning of period		12,560		14,338	
Cash and cash equivalents at end of period	\$	9,028	\$	20.042	
Suba and cuch equivalents at end of period	Ψ	5,020	Ψ	20,042	

7