# 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): May 11, 2017

# CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation)

Emerging growth company  $\square$ 

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)

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.  $\Box$ 

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 2.02 Results of Operations and Financial Condition

On May 11, 2017, Cytori Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 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

Exhibit No.	<u>Description</u>
99.1	Cytori Therapeutics, Inc. Press Release, dated May 11, 2017

# **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: May 11, 2017 By: /s/ Tiago Girao Tiago Girao

VP Finance and Chief Financial Officer

## **Exhibit Index**

Exhibit No.	<u>Description</u>
99.1	Cytori Therapeutics, Inc. Press Release, dated May 11, 2017



#### CYTORI THERAPEUTICS CONTACT

Tiago Girao

+1.858.458.0900

ir@cytori.com

# Cytori Reports First Quarter 2017 Business and Financial Results

SAN DIEGO, May 11, 2017—<u>Cytori Therapeutics</u> (NASDAQ: CYTX) ("Cytori" or the "Company") today announced its first quarter 2017 financial results and provided updates on its corporate activity and clinical development.

First quarter 2017 adjusted net loss was \$5.9 million, or \$0.26 per share, and excludes a \$1.7 million non-cash charge for in process research and development expense from the Azaya Therapeutics asset acquisition. Q1 2017 GAAP net loss was \$7.5 million, or \$0.33 per share. Operating cash burn for the quarter was approximately \$4.8 million. Cytori ended the quarter with approximately \$6.3 million of cash and cash equivalents, or approximately \$15 million pro-forma at March 31, 2017, when considering \$8.7 million in net cash proceeds since March 31, 2017 from the issuance of shares under Cytori's underwritten public offering that closed on April 17, 2017.

#### **Selected Key Recent Highlights:**

- Received U.S. FDA approval for thermal burn IDE pilot trial application related to ongoing BARDA contract.
- Received U.S. FDA orphan drug designation for cryopreserved or centrally processed Habeo<sup>TM</sup> for treatment of hand manifestations of systemic scleroderma.
- Received U.S. Small Business Designation and related fee reductions.

#### **Q1 2017 Financial Performance**

- Q1 2017 operating cash burn was \$4.8 million, compared to \$5.1 million for Q1 2016.
- Q1 2017 total revenues were \$1.6 million, compared to \$2.9 million in Q1 2016.
- Cash and debt principal balances at March 31, 2017 were approximately \$6.3 million and \$15.9 million, respectively.
- Q1 2017 adjusted net loss was \$5.9 million or \$0.26 per share, compared to a net loss of \$5.3 million or \$0.41 per share for Q1 2016.
- Q1 2017 GAAP net loss was \$7.5 million or \$0.33 per share, compared to a net loss of \$5.3 million or \$0.41 per share for Q1 2016.

"Our areas of primary focus is on stockholder value creation through bringing two valuable late stage products to market," said Dr. Marc Hedrick, President and CEO of Cytori. "Specifically, our U.S. pivotal STAR trial for Habeo<sup>TM</sup> Cell Therapy for scleroderma will report top line data in Q3. Also, we currently project completing bulk manufacturing of our nanoparticle doxorubicin oncology product for testing and validation purposes by year end. In parallel, our marketing team is preparing for initial commercial launch of our scleroderma and oncologic products with the goal of obtaining regulatory approvals in the late 2018 and 2019, respectively. Until then, we will carefully manage our capital resources as we have in prior quarters."

# **Selected Key Anticipated Milestones:**

- · Complete contracting discussions with BARDA regarding their potential funding of our thermal burn trial (Q2)
- Report of 48-week US pivotal/phase III trial data for scleroderma hand dysfunction and preparation for US PMA filing (Q3)
- Complete manufacturing activities required for submission of an MAA to the EMA for our recently acquired nanoparticle doxorubicin (Q4)



#### 2017 Financial Guidance - Reiterated

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, as well as costs to be incurred in preparation of anticipated Habeo<sup>TM</sup> launch and the Company's expansion of its development program for secondary Raynaud's Phenomenon.

• Operating cash burn forecasted to be within a 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: 15172159.

#### **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>TM</sup> acts principally by improving blood flow, modulating the immune system, and facilitating wound repair. As a result, Cytori Cell Therapy<sup>TM</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>TM</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 <a href="https://www.cytori.com">www.cytori.com</a>.

#### **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<sup>TM</sup> therapy and ATI-0918 drug candidate (and timing thereof); our receipt and disclosure of STAR clinical trial data; 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 Company-sponsored STAR trial and 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 March 31, 2017		As of December 31, 2016	
Assets					
Current assets:					
Cash and cash equivalents	\$	6,255	\$	12,560	
Accounts receivable, net of reserves of \$167 in both 2017 and 2016,					
respectively		873		1,242	
Restricted cash		350		350	
Inventories, net		4,107		3,725	
Other current assets		500		870	
Total current assets		12,085		18,747	
Property and equipment, net		3,611		1,157	
Other assets		2,008		2,336	
Intangibles, net		8,145		8,447	
Goodwill		3,922		3,922	
Total assets	\$	29,771	\$	34,609	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	6,196	\$	5,872	
Current portion of long-term obligations, net of discount		6,686		6,629	
Total current liabilities		12,882		12,501	
Deferred revenues		109		97	
Long-term deferred rent and other		17		17	
Long-term obligations, net of discount, less current portion		9,400		11,008	
Total liabilities		22,408		23,623	
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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; 23,767,423 and					
21,707,890 shares issued and outstanding in 2017 and 2016, respectively		24		22	
Additional paid-in capital		392,748		388,769	
Accumulated other comprehensive income		1,198		1,258	
Accumulated deficit		(386,607)		(379,063)	
Total stockholders' equity		7,363		10,986	
Total liabilities and stockholders' equity	\$	29,771	\$	34,609	



# CYTORI THERAPEUTICS, INC. CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

(in thousands, except share and per share data)

		For the Three Months Ended March 31,		
		2017		2016
Product revenues	\$	591	\$	1,333
Cost of product revenues (excluding below amortization of intangible assets)		410		468
Amortization of intangible assets		306		99
Gross (loss) profit		(125)		766
Development revenues:				
Government contracts and other		1,018		1,585
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Operating expenses:				
Research and development		3,289		4,127
Sales and marketing		939		1,035
General and administrative		2,108		2,286
In process research and development acquired from Azaya Therapeutics		1,686		_
Total operating expenses		8,022		7,448
Operating loss		(7,129)		(5,097)
Other income (expense):				
Interest income		11		2
Interest expense		(591)		(657)
Other income, net		165		413
Total other expense		(415)		(242)
Net loss	\$	(7,544)	\$	(5,339)
Basic and diluted net loss per share	\$	(0.33)	\$	(0.41)
Basic and diluted weighted average shares used in calculating net loss per share		22,736,366		13,086,376
Comprehensive loss:				
Net loss	\$	(7,544)	\$	(5,339)
Other comprehensive loss – foreign currency translation				
adjustments		(60)		(249)
Comprehensive loss	\$	(7,604)	\$	(5,588)
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# CYTORI THERAPEUTICS, INC. CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED) (in thousands)

	Fe	or the Three Mont	ns Ende	ed March 31,	
		2017		2016	
Cash flows from operating activities:					
Net loss	\$	(7,544)	\$	(5,339)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		442		291	
Amortization of deferred financing costs and debt discount		219		232	
In process research and development acquired from Azaya Therapeutics		1,686		_	
Joint Venture acquisition obligation accretion		_		17	
Provision for expired inventory		340		_	
Stock-based compensation expense		199		317	
Loss on asset disposal		2		2	
Increases (decreases) in cash caused by changes in operating assets and liabilities:					
Accounts receivable		335		155	
Inventories		7		(206)	
Other current assets		(65)		(408)	
Other assets		24		(211)	
Accounts payable and accrued expenses		(484)		176	
Deferred revenues		12		(4)	
Long-term deferred rent		<u> </u>		(80)	
Net cash used in operating activities		(4,827)		(5,058)	
Cash flows from investing activities:					
Purchases of property and equipment		(5)		(69)	
Purchase of long-lived assets part of Azaya Therapeutics acquisition		(1,158)		_	
Net cash used in investing activities		(1,163)		(69)	
Cash flows from financing activities:					
Principal payments on long-term obligations		(1,770)		_	
Joint Venture purchase payments				(500)	
Proceeds from sale of common stock, net		1,435		562	
Net cash (used in) provided by financing activities		(335)		62	
Effect of exchange rate changes on cash and cash equivalents		20		85	
Net decrease in cash and cash equivalents		(6,305)		(4,980)	
Cash and cash equivalents at beginning of period		12,560		14,338	
Cash and cash equivalents at end of period	\$	6,255	\$	9,358	
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