#### **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): March 12, 2015

# **CYTORI THERAPEUTICS, INC.** (Exact name of registrant as specified in its charter)

001-34375

33-0827593

**Delaware** 

(State or Other Jurisdiction of Incorporation	on) (Commission File Number)	(I.R.S. Employer Identification Number)
	<b>3020 Callan Road, San Diego, California 92121</b> (Address of principal executive offices, with zip code)	
	(858) 458-0900 (Registrant's telephone number, including area code)	
	<b>n/a</b> (Former name or former address, if changed since last repo	ort)
Check the appropriate box below if the following provisions ( see General Instruction	Form 8-K filing is intended to simultaneously satisfy the filing A.2. below):	ng obligation of the registrant under any of the
☐ Written communications pursuan	t to Rule 425 under the Securities Act (17 CFR 230.425)	
☐ Soliciting material pursuant to R	ule 14a-12 under the Exchange Act (17 CFR 240.14a-12)	
□ Pre-commencement communicat	ions pursuant to Rule 14d-2(b) under the Exchange Act (17 C	CFR 240.14d-2(b))
☐ Pre-commencement communicat	ions pursuant to Rule 13e-4(c) under the Exchange Act (17 C	FR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition

On March 12, 2015, Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2014. 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. Description

99.1 Cytori Therapeutics, Inc. Press Release, dated March 12, 2015 \*

\* 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.

# **SIGNATURES**

Date: March 12, 2015

Pursuant to the requirements of the	Securities Exchange Act of 193	4, the Registrant has duly	y caused this report to be sig	gned on its behalf by the
undersigned hereunto duly authorized.				

# CYTORI THERAPEUTICS, INC.

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



#### CYTORI THERAPEUTICS CONTACT

Shawn Richardson +1.858.875.5279 ir@cytori.com

#### Cytori Reports Fourth Quarter and Full Year 2014 Business and Financial Results

SAN DIEGO, March 12, 2015—Cytori Therapeutics (NASDAQ: CYTX) today announced its fourth quarter and year end 2014 business and financial results.

By virtue of a widespread cost reduction initiatives implemented in 2014, Cytori achieved substantial impact in tapering operating cash burn. Q4 operating cash burn decreased to \$4.9 million, down from \$7.2 million in Q3 2014, and \$9.5 million a year ago in Q4 2013. We will continue to work to drive down expenses and increase operating efficiencies, and expect to deliver year-over-year operating cash burn savings of approximately \$10 million from 2013 to 2015. Specifically, the expected operating cash burn in 2015 will be approximately \$25 million for the year, down from \$35 million in 2013. 2014 cost reduction efforts have included eliminating and consolidating certain commercial and development activities and containing outside professional services. Going forward, additional cost reductions will be derived primarily from changes to our fixed costs and physical locations. These efforts will be complemented by diligently working with Cytori's lenders to restructure and extend debt obligations.

Cytori achieved total revenues for the year and fourth quarter ended December 31, 2014 of \$7.6 million and \$3.8 million, respectively, compared to \$12.2 million and \$3.5 million, respectively, for the same periods in 2013. Total net loss allocable to common stock holders was \$38.5 million in 2014 compared with \$26.2 million in 2013. Cytori ended the year with \$14.6 million of cash and cash equivalents.

In addition, Cytori received today written notification from the Nasdaq Stock Market LLC that it has regained full compliance with the Nasdaq Stock Market Listing Rules concerning the Company's closing bid price, and previously received written notification indicating the Company regained compliance with the Nasdaq Stock Market Listing Rule regarding the market value of listed securities. The Company is pleased that each of the Nasdaq Stock Market compliance issues we previously reported in the latter part of 2014 have been resolved.

#### 2014 Highlights:

2014 was a year of significant restructuring and refocusing of clinical programs, expense management, and sales and marketing activities and working to increase revenue opportunities through partnerships, and licensing our non-core activities. Below are some highlights from 2014 and the beginning of 2015.

- Refocused strategy and corporate restructuring May' 14
- Published Phase I/II clinical data for scleroderma Aug' 14
- Received BARDA approval for a \$12M contract option and affirmed an \$8.3M conditional option to support thermal burn injury program Aug' 14
- Received FDA IDE approval for US knee osteoarthritis trial (ACT-OA trial) Sept' 14
- Extended principal payment deferral on our current debt obligation by 5 months Oct'14
- Resolved ATHENA trial hold Oct' 14
- Received FDA IDE conditional approval for US scleroderma pivotal trial (STAR trial) Dec' 14
- Increased the August contract option with BARDA to \$14M to accelerate thermal burn injury program-Dec' 14
- Received FDA IDE full approval for US STAR trial—Jan' 15
- Enrolled the first patient in US ACT-OA trial Feb' 15
- Received positive EMA (European Medicines Agency) opinion on orphan drug status for Cytori Cell Therapy (ECCS-50) Feb' 15
- Received FDA approval of STAR trial site expansion to 20 sites Feb' 15
- Expanded global patent portfolio to a total of 75 patents, with 45 applications pending

"The company, quite deliberately, pivoted in 2014 in terms of clinical and operating focus," said Dr. Marc H. Hedrick, President and CEO of Cytori Therapeutics. "We have initiated two new clinical programs and moved them into late stage trials here in the U.S. In parallel, we have reduced our operating burn substantially by focusing only on those activities that are best positioned in our view of improving shareholder value in the nearer term."

#### **Financial Performance and Guidance**

#### **2014 Financial Performance**

- Cash and debt balances at December 31, 2014 of approximately \$14.6 million and \$25.4 million, respectively.
- Q4 and full-year 2014 operating cash burn of \$4.9 million and \$30.3 million, respectively, compared to \$9.5 million and \$34.6 million for the same periods in 2013.
- Q4 and full-year 2014 product revenue of \$2.5 million and \$5.0 million, respectively, compared to \$2.7 million and \$7.1 million for the same periods in 2013.
- Q4 and full-year 2014 contribution (profit/loss) from our sales and marketing organization, excluding share based compensation, of a profit of \$69 thousand and a loss of \$3.8 million, respectively, compared to a loss of \$0.8 million and a loss of \$4.5 million for the same periods in 2013.

- Q4 and full-year 2014 contract revenue of \$1.3 million and \$2.6 million, respectively, compared to \$0.8 million and \$3.3 million for the same periods in 2013.
- Q4 and full-year 2014 net loss allocable to common stock holders was \$6.9 million (or \$0.08 per share) and \$38.5 million (or \$0.48 per share), respectively, compared to \$10 million (or \$0.14 per share) and \$26.2 million (or \$0.39 per share) for the same periods in 2013.

#### Full-year 2015 Guidance

- Estimation of 2015 operating cash burn of approximately \$25 million.
- Full-year 2015 product revenue expected to be within a range from \$5 million and \$8 million depending on developments in China, Japan and Europe.
- Full-year 2015 contribution (profit/loss) from our sales and marketing organization, excluding share based compensation, expected to be essentially breakeven with a forecasted profit ranging from \$100 thousand and \$300 thousand.
- Full-year 2015 contract revenue expected to be within a range from \$6 million and \$8 million.

#### **Scleroderma**

In August 2014, data from Scleradec I, a pilot trial using Cytori Cell Therapy to treat disabling hand manifestations of scleroderma, were published in the *Annals of Rheumatic Diseases*. In the open label, 12 patient trial, data suggested that the treatment with Cytori Cell Therapy (ECCS-50) led to a concordant improvement in a number of clinical measures consistent with a disease modifying effect of the therapeutic. Based on the promising clinical outcomes from Scleradec I, Cytori will support a follow up confirmatory trial in France, Scleradec II, which will be a multicenter, randomized, double-blind, and placebo controlled trial of a single dose of ECCS-50 or placebo in 40 patients.

Based on the Scleradec I data, in December 2014, the FDA gave conditional approval to Cytori to commence a phase III pivotal trial in scleroderma, the STAR trial. This conditional approval was finalized in January 2015. In the next several months, we will begin enrollment of our 80 patient, randomized, double-blind, controlled STAR trial, which is approved for up to 20 sites.

Scleroderma is a rare autoimmune disorder. It is a systemic disease that affects many major organs, but commonly causes changes in the skin and hands due to skin fibrosis and destructive changes in blood vessels, resulting in disability, diminished mobility, and pain. There are 50,000 - 75,000 scleroderma patients in the US, and over 90% of them struggle with hand dysfunction. Scleroderma is considered an orphan indication, due to its prevalence, and using premium orphan pricing assumptions, the US market opportunity for an effective therapy is in excess of \$1 Billion.

#### Osteoarthritis of the Knee

In February 2015, Cytori began enrolling patients in its Phase IIB ACT-OA Trial, approved by the FDA in September 2014. This trial is a 90 patient, randomized, double-blind, placebo controlled, with up to 15 sites in the US. The trial will evaluate 2 separate doses of ECCO-50 therapy (low dose and high dose) in treating osteoarthritis of the knee. The study's primary endpoint will be the pain on walking (KOOS) at 12 weeks. Data is expected in 2016.

Osteoarthritis of the knee is a disease of the entire joint, involving the cartilage, joint lining, ligaments, and underlying bone. The breakdown of tissues leads to pain and joint stiffness. It is the most common form of arthritis with 13.9 % of adults over 25 years suffering the disease in the US, or an estimated 26.9 million US adults in 2005. It is a disease of high prevalence and a market opportunity in excess of \$3 Billion.

#### **Primary 2015 Operating Objectives:**

- Chinese FDA Class-I clearance followed by an opening product order from our partner Lorem Vascular
- EMA final opinion on orphan drug status for Cytori's scleroderma therapeutic, ECCS-50
- Initiate enrollment of US scleroderma STAR trial
- Publish SCLERADEC-I 12 month data and initiate enrollment of French SCLERADEC-II trial
- Complete enrollment of US ACT-OA trial
- Begin enrollment of MHLW funded Japanese stress urinary incontinence trial
- BARDA funded research progress presented at American Burn Association meeting
- ATHENA 6 and 12 month trial data available
- Complete core development activities for the next generation Celution System

#### Management Conference Call Webcast and Shareholder Letter Information

Cytori will host a management conference call at 5:30 p.m. Eastern Time today to further discuss the Company's progress. The <u>webcast</u> 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: 4453849.

#### **About Cytori**

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 $^{TM}$  acts principally by improving blood flow, modulating the immune system, and facilitating wound repair. As a result, Cytori Cell Therapy $^{TM}$  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. For more information: visit www.cytori.com.

#### **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, including statements regarding our expected \$10 million cash burn savings year over in 2015, when compared to 2013, our expected 2015 product revenue of \$5 million to \$8 million depending on developments in China, Japan and Europe, our expected breakeven forecast for our sales and marketing organization of \$100 thousand to \$300 thousand, our expected 2015 contract revenue in the range from \$6 million to \$8 million, our expected data in 2016 from the ACT-OA Trial, and our expectation to initiate the STAR trial within the next several months are forward looking statements. Such statements are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks include the level of future interest in our products by Japan research institutions, performance of our Japan distribution network, clinical, pre-clinical and regulatory uncertainties, such as those associated with the ACT-OA Trial and STAR clinical trials, including risks in the collection and results of clinical data, final clinical outcomes, dependence on third party performance, performance and acceptance of our products in the marketplace, unexpected costs and expenses, our reliance on key personnel, the right of the Federal Government to cut or terminate further support of the thermal burn injury program, and other risks and uncertainties described under the "Risk Factors" in Cytori's Securities and Exchange Commission Filings, included in our annual and quarterly reports.

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

### CYTORI THERAPEUTICS, INC. CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	As of December 31,	
	2014	2013
Assets		
Current assets:	¢ 14.633.000	¢ 15 500 000
Cash and cash equivalents	\$ 14,622,000	\$ 15,506,000
Accounts receivable, net of reserves of \$1,523,000 and of \$1,445,000 in 2014 and 2013,	1 2 42 000	4.150.000
respectively	1,243,000	4,152,000
Inventories, net	4,829,000	3,694,000
Other current assets	992,000	1,225,000
Total current assets	21,686,000	24,577,000
Property and equipment, net	1,583,000	1,054,000
Restricted cash and cash equivalents	350,000	350,000
Other assets	1,763,000	2,812,000
Intangibles, net	9,415,000	9,345,000
Goodwill	3,922,000	3,922,000
Total assets	\$ 38,719,000	\$ 42,060,000
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,546,000	\$ 6,077,000
Current portion of long-term obligations, net of discount	7,363,000	3,191,000
Termination fee obligation	_	400,000
Puregraft divestiture obligation	_	547,000
Joint Venture purchase obligation	3,008,000	4,691,000
Total current liabilities	15,917,000	14,906,000
Warrant liability	9,793,000	_
Deferred revenues	112,000	212,000
Long-term deferred rent	558,000	710,000
Long-term obligations, net of discount, less current portion	18,041,000	23,100,000
Total liabilities	44,421,000	38,928,000
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 and 5,311 outstanding in 2014, and no shares issued and outstanding in 2013	_	_
Common stock, \$0.001 par value; 145,000,000 shares authorized; 99,348,377 and 71,305,375		
shares issued and outstanding in 2014 and 2013, respectively	99,000	71,000
Additional paid-in capital	331,772,000	303,710,000
Accumulated other comprehensive income	700,000	256,000
Accumulated deficit	(338,273,000)	(300,905,000)
Total stockholders' (deficit) equity	(5,702,000)	3,132,000
Total liabilities and stockholders' (deficit) equity	\$ 38,719,000	\$ 42,060,000
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# CYTORI THERAPEUTICS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS & COMPREHENSIVE LOSS (UNAUDITED)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2014	2013	2014	2013
Product revenues	\$ 2,469,000	\$ 2,706,000	\$ 4,953,000	\$ 7,122,000
Cost of product revenues	1,416,000	1,126,000	2,940,000	3,421,000
Gross profit	1,053,000	1,580,000	2,013,000	3,701,000
Development revenues:  Development, related party  Development			_	638,000 1,179,000
Government contract and other	1,301,000	754,000	2,645,000	3,257,000
	1,301,000	754,000	2,645,000	5,074,000
Operating expenses: Research and development Sales and marketing General and administrative Change in fair value of warrants Change in fair value of option liability	2,999,000 1,074,000 2,831,000 (235,000)	5,072,000 2,573,000 3,807,000 —	15,105,000 6,406,000 15,953,000 (369,000)	17,065,000 9,026,000 16,031,000 (418,000) (2,250,000)
Total operating expenses	6,669,000	11,452,000	37,095,000	39,454,000
Operating loss	(4,315,000)	(9,118,000)	(32,437,000)	(30,679,000)
Other income (expense): Gain (loss) on asset disposal Loss on debt extinguishment	57,000 —	_	42,000 —	(257,000) (708,000)
Interest income	2,000	2,000	6,000	4,000
Interest expense Other income (expense), net	(1,086,000) (413,000)	(941,000) (45,000)	(4,371,000) (608,000)	(3,396,000) (438,000)
Gain on Puregraft divestiture	(115,000)	61,000	— (000,000) —	4,453,000
Gain on previously held equity interest in Joint Venture	_	_	_	4,892,000
Equity loss from investment in Joint Venture				(48,000)
Total other income (expense) Net loss	(1,440,000) (5,755,000)	(923,000) (10,041,000)	(4,931,000) (37,368,000)	4,502,000 (26,177,000)
Beneficial conversion feature for convertible preferred stock	(1,169,000)		(1,169,000)	
Net loss allocable to common stock holders	\$ (6,924,000)	\$ (10,041,000)	\$ (38,537,000)	\$ (26,177,000)
Basic and diluted net loss per share allocable to common stock holders	\$ (0.08)	\$ (0.14)	\$ (0.48)	\$ (0.39)
Basic and diluted weighted average shares used in calculating net loss per share allocable to common stockholders	91,925,991	69,662,038	80,830,698	67,781,364
Comprehensive loss: Net loss	\$ (5,755,000)	\$ (10,041,000)	\$ (37,368,000)	\$ (26,177,000)
Other comprehensive income – foreign currency translation adjustments	243,000	398,000	444,000	256,000
Comprehensive loss	\$ (5,512,000)	\$ (9,643,000)	\$ (36,924,000)	\$ (25,921,000)

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

	For the Years Ended December 31,		
	2014	2013	
Cash flows from operating activities:			
Net loss	\$ (37,368,000)	\$ (26,177,000)	
Adjustments to reconcile net loss to net cash used in operating activities:	, , ,	, , ,	
Depreciation and amortization	779,000	1,630,000	
Amortization of deferred financing costs and debt discount	1,220,000	893,000	
Joint venture acquisition obligation accretion	579,000	204,000	
Provision for doubtful accounts	1,084,000	1,141,000	
Provision for expired enzymes	313,000	_	
Change in fair value of warrants	(369,000)	(418,000)	
Change in fair value of option liability		(2,250,000)	
Stock-based compensation	3,101,000	3,608,000	
Equity loss from investment in joint venture	_	48,000	
Loss on asset disposal	(33,000)	257,000	
Gain on previously held equity interest in Joint Venture	_	(4,892,000)	
Gain on sale of assets	_	(4,453,000)	
Loss on debt extinguishment	_	708,000	
Increases (decreases) in cash caused by changes in operating assets and liabilities:			
Accounts receivable	2,057,000	(1,209,000)	
Inventories	(815,000)	(459,000)	
Other current assets	510,000	(24,000)	
Other assets	11,000	(854,000)	
Accounts payable and accrued expenses	(1,147,000)	(409,000)	
Deferred revenues, related party		(638,000)	
Deferred revenues	(100,000)	(1,223,000)	
Long-term deferred rent	(152,000)	(46,000)	
Net cash used in operating activities	(30,330,000)	(34,563,000)	
Cash flows from investing activities:			
Purchases of property and equipment	(764,000)	(519,000)	
Expenditures for intellectual property	(255,000)	(515,000)	
Proceeds from sale of assets	76,000	5,000,000	
License agreement termination fee	(400,000)	(800,000)	
Cash acquired in purchase of joint venture	_	5,000	
Net cash provided by (used in) investing activities	(1,343,000)	3,686,000	
Cash flows from financing activities:			
Principal payments on long-term debt obligations	(1,962,000)	(22,304,000)	
Proceeds from long-term obligations	_	27,000,000	
Debt issuance costs and loan fees	_	(1,744,000)	
Joint venture purchase payments	(2,262,000)	(221,000)	
Proceeds from exercise of employee stock options and warrants and stock purchase plan	4,066,000	225,000	
Proceeds from issuance of common stock	19,086,000	18,000,000	
Proceeds from issuance of preferred stock	13,500,000		
Costs from sale of common stock	(425,000)	(184,000)	
Costs from sale of preferred stock	(1,129,000)	— (10 1,000) —	
Net cash provided by financing activities	30,874,000	20,772,000	
Net cash provided by financing activities	30,874,000	20,772,000	
Effect of exchange rate changes on cash and cash equivalents	(85,000)	(106,000)	
Net decrease in cash and cash equivalents	(884,000)	(10,211,000)	
Cash and cash equivalents at beginning of year	15,506,000	25,717,000	
Cash and cash equivalents at end of year	\$ 14,622,000	\$ 15,506,000	