



Cytori Reports Third Quarter 2017 Business and Financial Results

November 9, 2017

SAN DIEGO, Nov. 09, 2017 (GLOBE NEWSWIRE) -- [Cytori Therapeutics](#) (NASDAQ:CYTX) ("Cytori" or the "Company") today announced its third quarter 2017 financial results and provided updates on its corporate activity and clinical development.

Third quarter 2017 net loss was \$4.8 million, or \$0.14 per share. Operating cash burn for the quarter was approximately \$4.0 million. Cytori ended the quarter with approximately \$4.8 million of cash and cash equivalents.

Selected Key Recent Highlights:

- U.S. STAR scleroderma clinical trial data accepted for presentation at Systemic Sclerosis World Congress in February 2018.
- BARDA executed a \$13.4 million contract option to fund the U.S. RELIEF burn clinical trial.
- Received U.S. FDA IDE approval for RELIEF, a thermal burn pilot trial related to ongoing BARDA contract.

Q3 2017 Financial Performance

- Q3 2017 and year-to-date operating cash burn was \$4.0 million and \$13.9 million, compared to \$4.6 million and \$15.4 million for the same periods in 2016, respectively.
- Q3 2017 and year-to-date total revenues were \$1.8 million and \$4.9 million, compared to \$2.6 million and \$8.4 million for the same periods in 2016, respectively.
- Cash and debt principal balances at September 30, 2017 were approximately \$4.8 million and \$13.0 million, respectively.
- Q3 2017 net loss was \$4.8 million or \$0.14 per share, compared to \$5.4 million or \$0.26 per share for Q3 2016.
- Year-to-date adjusted net loss was \$16.7 million, or \$0.57 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 \$17.1 million or \$1.06 per share for the same period in 2016.
- Year-to-date GAAP net loss was \$18.4 million or \$0.62 per share, compared to \$17.1 million or \$1.06 per share for the same period in 2016.

"Based on the completed analysis of our STAR trial data, including the strong safety profile, clinically meaningful improvements in the diffuse scleroderma subgroup and the lack of approved treatments with this orphan condition, we intend to meet with the U.S. FDA as soon as possible to chart next steps," said Dr. Marc Hedrick, President and CEO of Cytori. "Simultaneously, manufacturing validation for our recently acquired liposomal doxorubicin chemotherapy drug candidate, ATI-0918, a generic version of Caelyx[®], is ongoing and on track for submitting an application to the European Medicines Agency next year while other key cell therapy trials, specifically SCLERADEC-II and ADRESU for scleroderma and stress urinary incontinence, respectively, march toward full enrollment."

Selected Key Near-Term Milestones:

- Pursue meeting with U.S. FDA to determine next steps required to obtain Habeo[™] Cell Therapy regulatory approval for scleroderma-associated hand dysfunction.
- Begin enrollment of BARDA's funded U.S. RELIEF burn clinical trial.
- Complete ATI-0918 manufacturing and regulatory activities required to prepare an application for the EMA.
- Complete enrollment of SCLERADEC-II and ADRESU clinical trials in France and Japan, respectively.

2017 Financial Guidance - Updated

The Company expects full year 2017 operating cash burn to be lower than 2016, primarily due to the restructuring announced in September 2017.

- Updated operating cash burn forecasted to be within a range of \$17 million to \$19 million, a reduction from previously guided range of \$20 million to \$23 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 [Investor Relations section](#) 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: 5289756.

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[™] acts principally by improving blood flow, modulating the immune system, and facilitating wound repair. As a result, Cytori Cell Therapy[™] 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™ 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 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 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 scleroderma and RELIEF 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 September 30, 2017	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,783	\$ 12,560
Accounts receivable, net of reserves of \$167 in both 2017 and 2016, respectively	230	1,242
Restricted cash	429	350
Inventories, net	3,508	3,725
Other current assets	892	870
Total current assets	9,842	18,747
Property and equipment, net	3,308	1,157
Other assets	1,854	2,336

Intangibles, net	7,520	8,447
Goodwill	3,922	3,922
Total assets	<u>\$ 26,446</u>	<u>\$ 34,609</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,907	\$ 5,872
Current portion of long-term obligations, net of discount	13,497	6,629
Total current liabilities	18,404	12,501
Deferred revenues	103	97
Long-term deferred rent and other	120	17
Long-term obligations, net of discount, less current portion		11,008
Total liabilities	18,627	23,623
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; 34,716,318 and 21,707,890 shares issued and outstanding in 2017 and 2016, respectively	35	22
Additional paid-in capital	404,047	388,769
Accumulated other comprehensive income	1,199	1,258
Accumulated deficit	(397,462)	(379,063)
Total stockholders' equity	7,819	10,986
Total liabilities and stockholders' equity	<u>\$ 26,446</u>	<u>\$ 34,609</u>

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

	<u>For the Three Months Ended</u> <u>September 30,</u>		<u>For the Nine Months Ended</u> <u>September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Product revenues	\$ 467	\$ 731	\$ 2,027	\$ 3,190
Cost of product revenues	181	561	992	1,533
Amortization of intangible assets	306	57	919	237
Gross (loss) profit	<u>(20)</u>	<u>113</u>	<u>116</u>	<u>1,420</u>
Development revenues:				
Government contracts and other	1,306	1,879	2,856	5,163
	<u>1,306</u>	<u>1,879</u>	<u>2,856</u>	<u>5,163</u>
Operating expenses:				
Research and development	3,004	3,960	9,284	13,334
Sales and marketing	840	818	3,043	2,742
General and administrative	1,785	2,011	6,012	6,623
In process research and development acquired from Azaya Therapeutics	—	—	1,686	—
Total operating expenses	<u>5,629</u>	<u>6,789</u>	<u>20,025</u>	<u>22,699</u>

Operating loss	<u>(4,343)</u>	<u>(4,797)</u>	<u>(17,053)</u>	<u>(16,116)</u>
Other income (expense):				
Interest income	5	4	24	8
Interest expense	(474)	(645)	(1,603)	(1,947)
Other income, net	<u>5</u>	<u>54</u>	<u>233</u>	<u>928</u>
Total other expense	<u>(464)</u>	<u>(587)</u>	<u>(1,346)</u>	<u>(1,011)</u>
Net loss	<u>\$ (4,807)</u>	<u>\$ (5,384)</u>	<u>\$ (18,399)</u>	<u>\$ (17,127)</u>
Basic and diluted net loss per share	\$ (0.14)	\$ (0.26)	\$ (0.62)	\$ (1.06)
Basic and diluted weighted average shares used in calculating net loss per share	34,490,828	20,493,840	29,564,032	16,147,042
Comprehensive loss:				
Net loss	\$ (4,807)	\$ (5,384)	\$ (18,399)	\$ (17,127)
Other comprehensive loss – foreign currency translation adjustments	<u>16</u>	<u>58</u>	<u>(59)</u>	<u>(321)</u>
Comprehensive loss	<u>\$ (4,791)</u>	<u>\$ (5,326)</u>	<u>\$ (18,458)</u>	<u>\$ (17,448)</u>

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

**For the Nine Months Ended
September 30,**

	<u>2017</u>	<u>2016</u>
Cash flows from operating activities:		
Net loss	\$ (18,399)	\$ (17,127)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,618	794
Amortization of deferred financing costs and debt discount	580	714
In process research and development acquired from Azaya Therapeutics	1,686	—
Joint Venture acquisition obligation accretion	—	24
Provision for expired inventory	413	26
Stock-based compensation expense	588	925
Loss on asset disposal	9	2
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	991	91
Inventories	457	190
Other current assets	(284)	205
Other assets	74	32
Accounts payable and accrued expenses	(1,746)	(1,013)
Deferred revenues	6	(8)
Long-term deferred rent	103	(227)
Net cash used in operating activities	<u>(13,904)</u>	<u>(15,372)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(271)	(110)
Proceeds from sale of assets	10	—
Purchase of long-lived assets part of Azaya Therapeutics' acquisition	(1,201)	—
Change in restricted cash	(79)	—
Net cash used in investing activities	<u>(1,541)</u>	<u>(110)</u>

Cash flows from financing activities:

Principal payments on long-term obligations	(4,720)	—
Joint Venture purchase payments	—	(1,774)
Proceeds from sale of common stock, net	12,377	17,702
Net cash provided by financing activities	<u>7,657</u>	<u>15,928</u>
Effect of exchange rate changes on cash and cash equivalents	11	140
Net (decrease) increase in cash and cash equivalents	<u>(7,777)</u>	<u>586</u>
Cash and cash equivalents at beginning of period	12,560	14,338
Cash and cash equivalents at end of period	<u>\$ 4,783</u>	<u>\$ 14,924</u>

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Source: Cytori Therapeutics Inc