



Cytori Reports Fourth Quarter and Full Year 2016 Business and Financial Results

March 23, 2017

SAN DIEGO, March 23, 2017 (GLOBE NEWSWIRE) -- [Cytori Therapeutics](#) (NASDAQ:CYTX) ("Cytori" or the "Company") today announced its fourth quarter and year-end 2016 financial results and provided updates on its corporate activity and clinical development.

Fourth quarter and full year 2016 net loss allocable to common stockholders was \$4.9 million, or \$0.24 per share, and \$22.0 million, or \$1.28 per share, respectively. Operating cash burn for the fourth quarter and full year 2016 was approximately \$4.2 million and \$19.5 million, respectively. Cytori ended the year with approximately \$12.6 million of cash and cash equivalents.

Selected Key Recent Highlights:

- Completed enrollment of U.S. STAR pivotal/phase III trial for scleroderma hand dysfunction.
- Completed acquisition of Azaya Therapeutics assets, and initiated nanomedicine development programs.
- Reported 24 month publication of SCLERADEC-I reporting sustained benefit at 24 months across multiple endpoints in patients with scleroderma hand dysfunction.
- Received U.S. FDA orphan drug designation for cryopreserved or centrally processed Habeo™ for treatment of hand manifestations of systemic scleroderma.
- Received U.S. Small Business Designation and related fee reductions.

Q4 and year-end 2016 Financial Performance

- Q4 2016 and year-end operating cash burn was \$4.2 million and \$19.5 million, compared to \$4.5 million and \$20.5 million for the same periods in 2015, respectively.
- Q4 2016 and year-end total revenues were \$3.0 million and \$11.4 million, compared to \$3.4 million and \$11.7 million for the same periods in 2015, respectively.
- Cash and debt principal balances at December 31, 2016 were approximately \$12.6 million and \$17.7 million, respectively.
- Q4 2016 net loss allocable to common stockholders was \$4.9 million or \$0.24 per share, compared to a net loss of \$2.8 million or \$0.25 per share (or a net loss of \$5.4 million and \$0.50 per share when excluding a non-cash credit charge of \$2.7 million related to the change in fair value of warrant liabilities) for the same period in 2015.
- 2016 net loss allocable to common stockholders was \$22.0 million or \$1.28 per share, compared to \$19.4 million or \$2.07 per share (or a net loss of \$26.4 million or \$2.81 per share, which excludes a non-cash charge of \$7.7 million related to the change in fair value of warrant liabilities and a beneficial conversion feature charge for convertible preferred stock of \$0.7 million) for the same period in 2015.

"Our corporate priority and fundamental driver of stockholder value remains the focused and expeditious development of our late stage clinical pipeline and related commercial preparatory activities. In 2016, we continued our focus on operational efficiency and maintaining momentum in our clinical development programs, nonetheless we reduced our net losses by 20%" said Tiago Girao, VP of Finance and CFO of Cytori. "In 2017, we will continue to make appropriate preparations for commercial launch of Habeo™ in anticipation of receipt of STAR trial data, and we also intend to complete the manufacturing activities necessary to submit a marketing authorisation application (MAA) for our recently acquired nanoparticle doxorubicin, ATI-0918, to the European Medicines Agency (EMA). We will address ongoing capital requirements through targeted activities, including, but not limited to, further operational efficiency measures, tighter working capital management, increased revenue, accessing the capital markets as appropriate, and an intense focus on only those activities that we believe will maximize stockholder value creation, such as business development opportunities."

Selected Key Anticipated Milestones:

- Receive feedback from U.S. FDA regarding thermal burn IDE trial application (Q2)
- 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

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™ 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 [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: 9218454.

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; 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 the FDA on our thermal burn IDE, 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-supported, investigator-initiated ADRESU trial. Specifically, the Company faces risks in the collection and results of the STAR and ADRESU trials, including the risks that clinical data from one or more of these clinical trials will fail to demonstrate safety or efficacy of our cellular therapeutics, and risks that insufficiently positive clinical data will adversely affect government funding, regulatory approval pathways and commercial prospects for Habeo, ECCI-50, DCCT-10 and the Company's other potential cell therapy products. 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 FDA 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 December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,560	\$ 14,338

Accounts receivable, net of reserves of \$167 and \$797 in 2016 and 2015, respectively	1,242	1,052
Restricted cash	350	—
Inventories, net	3,725	4,298
Other current assets	870	1,555
Total current assets	<u>18,747</u>	<u>21,243</u>
Property and equipment, net	1,157	1,631
Restricted cash	—	350
Other assets	2,336	1,521
Intangibles, net	8,447	9,031
Goodwill	3,922	3,922
Total assets	<u>\$ 34,609</u>	<u>\$ 37,698</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,872	\$ 6,687
Current portion of long-term obligations, net of discount	6,629	—
Joint venture purchase obligation	—	1,750
Total current liabilities	<u>12,501</u>	<u>8,437</u>
Deferred revenues	97	105
Long-term deferred rent and other	17	269
Long-term obligations, net of discount, less current portion	11,008	16,681
Total liabilities	<u>23,623</u>	<u>25,492</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 13,500 shares issued; no shares outstanding in 2016 and 2015	—	—
Common stock, \$0.001 par value; 75,000,000 shares authorized; 21,707,890 and 13,003,893 shares issued and outstanding in 2016 and 2015, respectively	22	13
Additional paid-in capital	388,769	368,214
Accumulated other comprehensive income	1,258	996
Accumulated deficit	(379,063)	(357,017)
Total stockholders' equity	<u>10,986</u>	<u>12,206</u>
Total liabilities and stockholders' equity	<u>\$ 34,609</u>	<u>\$ 37,698</u>

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

	For the Three Months		For the Twelve Months	
	Ended December 31,		Ended December 31,	
	2016	2015	2016	2015
Product revenues	\$ 1,466	\$ 1,556	\$ 4,656	\$ 4,838
Cost of product revenues	945	791	2,715	3,186
Gross profit	<u>521</u>	<u>765</u>	<u>1,941</u>	<u>1,652</u>

Development revenues:				
Government contracts and other	1,561	1,820	6,724	6,821
	<u>1,561</u>	<u>1,820</u>	<u>6,724</u>	<u>6,821</u>
Operating expenses:				
Research and development	2,862	4,629	16,197	19,000
Sales and marketing	869	603	3,611	2,662
General and administrative	1,939	2,104	8,563	9,765
Change in fair value of warrant liabilities	—	(2,680)	—	(7,668)
Total operating expenses	<u>5,670</u>	<u>4,656</u>	<u>28,371</u>	<u>23,759</u>
Operating loss	<u>(3,588)</u>	<u>(2,071)</u>	<u>(19,706)</u>	<u>(15,286)</u>
Other income (expense):				
Loss on debt extinguishment	—	—	—	(260)
Interest income	13	3	19	9
Interest expense	(644)	(702)	(2,592)	(3,379)
Other income (loss), net	(699)	14	233	172
Total other expense	<u>(1,330)</u>	<u>(685)</u>	<u>(2,340)</u>	<u>(3,458)</u>
Net loss	<u>\$ (4,918)</u>	<u>\$ (2,756)</u>	<u>\$ (22,046)</u>	<u>\$ (18,744)</u>
Beneficial conversion feature for convertible preferred stock	—	—	—	(661)
Net loss allocable to common stockholders	<u>\$ (4,918)</u>	<u>\$ (2,756)</u>	<u>\$ (22,046)</u>	<u>\$ (19,405)</u>
Basic and diluted net loss per share allocable to common stockholders				
	<u>\$ (0.24)</u>	<u>\$ (0.25)</u>	<u>\$ (1.28)</u>	<u>\$ (2.07)</u>
Basic and diluted weighted average shares used in calculating net loss per share allocable to common stockholders				
	20,685,307	10,894,552	17,290,933	9,386,488
Comprehensive loss:				
Net loss	(4,918)	(2,756)	(22,046)	(18,744)
Other comprehensive income (loss) – foreign currency translation adjustments	583	(65)	262	296
Comprehensive loss	<u>\$ (4,335)</u>	<u>\$ (2,821)</u>	<u>\$ (21,784)</u>	<u>\$ (18,448)</u>

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

**For the Years Ended
December 31,**

2016 2015

Cash flows from operating activities:

Net loss	\$ (22,046)	\$ (18,744)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,182	1,093
Amortization of deferred financing costs and debt discount	954	979
Joint Venture acquisition obligation accretion	24	365
Provision for doubtful accounts	—	(105)
Provision for expired inventory	172	—

Change in fair value of warrants	—	(7,668)
Share-based compensation expense	1,080	2,041
(Gain) loss on asset disposal	(127)	8
Loss on debt extinguishment	—	260
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(179)	328
Inventories	471	490
Other current assets	633	(637)
Other assets	(764)	363
Accounts payable and accrued expenses	(673)	1,045
Deferred revenues	(8)	3
Long-term deferred rent	(252)	(289)
Net cash used in operating activities	<u>(19,533)</u>	<u>(20,468)</u>

Cash flows from investing activities:

Purchases of property and equipment	(67)	(611)
Expenditures for intellectual property	—	(13)
Proceeds from sale of assets	131	11
Net cash provided by (used in) investing activities	<u>64</u>	<u>(613)</u>

Cash flows from financing activities:

Principal payments on long-term obligations	—	(25,032)
Proceeds from long-term obligations	—	17,700
Debt issuance costs and loan fees	—	(1,854)
Joint Venture purchase payments	(1,774)	(1,623)
Proceeds from exercise of employee stock options and warrants	—	4,997
Proceeds from sale of common stock	21,467	29,054
Costs from sale of common stock	(2,084)	(2,370)
Dividends paid on preferred stock	—	(75)
Net cash provided by financing activities	<u>17,609</u>	<u>20,797</u>
Effect of exchange rate changes on cash and cash equivalents	82	—
Net decrease in cash and cash equivalents	(1,778)	(284)
Cash and cash equivalents at beginning of period	<u>14,338</u>	<u>14,622</u>
Cash and cash equivalents at end of period	<u>\$ 12,560</u>	<u>\$ 14,338</u>

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Source: Cytori Therapeutics