



Cytori Reports Q2 2018 Business and Financial Results

August 14, 2018

SAN DIEGO, Aug. 14, 2018 (GLOBE NEWSWIRE) -- [Cytori Therapeutics](#) (NASDAQ: CYTX) ("Cytori" or the "Company") today announced Q2 2018 financial results and provided updates on corporate activities.

Q2 2018 net loss was \$3.7 million, or \$0.59 per share. Operating cash burn for Q2 was approximately \$2.7 million. Cytori ended Q2 with approximately \$3.1 million of cash and cash equivalents, or approximately \$8.8 million pro-forma at June 30, 2018, when considering \$5.7 million in net cash proceeds received from a public rights offering which closed on July 25, 2018.

Cytori is developing for manufacture its lead chemotherapeutic drug, ATI-0918, a generic version of pegylated liposomal doxorubicin hydrochloride, with the goal of demonstrating bioequivalence to the European reference drug. Our Nanomedicine team in San Antonio, Texas continues to complete activities in support of a Marketing Authorization Application (MAA) to be filed with the European Medicines Agency (EMA) next year. The Company also continues to engage potential commercial partners for ATI-0918 in Europe, Middle East, North Africa, North America, and Asia Pacific. Furthermore, for Cytori's ATI-1123 chemotherapy drug product candidate, an albumin-stabilized pegylated liposomal docetaxel, the Company has requested an orphan drug designation from FDA for small cell lung cell cancer and is evaluating the FDA's 505(b)(2) new drug application (NDA) pathway in the U.S. which may offer accelerated and lower cost development.

Our Cell Therapy team is awaiting data readouts from clinical trials in scleroderma and urinary incontinence and is actively conducting a clinical trial in thermal burns. 6 month data from the 40 patient, French SCLERADEC II clinical trial (scleroderma) is expected before the end of 2018 and 1 year data from the 45 patient, Japanese ADRESU clinical trial (urinary incontinence) is expected in early 2019. Finally, U.S. FDA has approved a protocol amendment for the RELIEF thermal burn injury trial sponsored by BARDA intended to facilitate enrollment. Cytori completed a successful In-Process Review meeting with BARDA this past June. Thus far, Cytori and BARDA have initiated 2 of 8-10 anticipated U.S. clinical sites.

In Japan, Cytori continues to see favorable growth trends in the use of its commercially approved cell therapy products in the aesthetic and orthopedic markets. The Company remains on track to see continued double digit year over year growth in consumable utilization.

"Our primary corporate objective is to file for European market approval for ATI-0918, our lead oncology drug product. We have also expanded the development of our pipeline drug, ATI-1123, in the U.S. and we are priming it for phase II evaluation." said Dr. Marc Hedrick, President and Chief Executive Officer of Cytori. "We are also pleased with the quarter-over-quarter and year-over-year results of our commercial Cell Therapy efforts in Japan that are primarily focused on consumable utilization. This provides a growing business and infrastructure in anticipation of the SCLERADEC-II and ADRESU trials, in 2018 and 2019, respectively."

Q2 2018 and year-to-date Financial Performance

- Q2 2018 and year-to-date operating cash burn was \$2.7 million and \$6.8 million, compared to \$5.0 million and \$9.9 million for the same periods in 2017, respectively.
- Q2 2018 and year-to-date total revenues were \$1.6 million and \$3.2 million, compared to \$1.5 million and \$3.1 million for the same periods in 2017, respectively.
- Q2 2018 and year-to-date consumable utilization in Japan grew by over 70% and 60%, when comparing to the same periods in 2017, respectively.
- Cash and debt principal balances at June 30, 2018 were approximately \$3.1 million and \$13.0 million, respectively.
- Q2 2018 net loss was \$3.7 million or \$0.59 per share, compared to a net loss of \$6.0 million or \$1.94 per share for Q2 2017.
- Year-to-date net loss was \$8.1 million or \$1.32 per share, compare to an adjusted net loss of \$13.6 million or \$5.04 per share for the same period in 2017, respectively.

Selected Key Anticipated Milestones:

- Complete ATI-0918 development and manufacturing required to prepare and file a MAA with the EMA.
- Receive Orphan Drug Designation and 505(b)(2) pathway feedback from the U.S. FDA for ATI-1123.
- Enroll burn patients in BARDA-funded U.S. RELIEF clinical trial.
- Report 3 and 6 month French SCLERADEC II clinical trial data for scleroderma hand dysfunction.
- Report 1 year Japanese ADRESU clinical trial data for post-surgical male stress urinary incontinence.

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: 4075028.

About Cytori

Cytori is developing, manufacturing, and commercializing nanoparticle-delivered oncology drugs and autologous adipose-derived regenerative cell

(ADRC) therapies within its Nanomedicine™ and Cell Therapy™ franchises, respectively. Cytori Nanomedicine™ is focused on the liposomal encapsulation of anti-neoplastic chemotherapy agents, which may enable the effective delivery of the agents to target sites while reducing systemic toxicity. The Cytori Nanomedicine™ product pipeline consists of ATI-0918 pegylated liposomal doxorubicin hydrochloride for breast cancer, ovarian cancer, multiple myeloma, and Kaposi's sarcoma, a complex/hybrid generic drug, and ATI-1123 patented albumin-stabilized pegylated liposomal docetaxel for multiple solid tumors. Cytori Cell Therapy™, prepared within several hours with the proprietary Celution® System and administered to the patient the same day, has been shown in preclinical and clinical studies to act 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. 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 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; 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 RELIEF 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. 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. 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. 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); 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, 2018	As of December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,079	\$ 9,550
Accounts receivable, net of reserves of \$185 in 2018 and \$167 in 2017	399	145
Restricted cash	40	675
Inventories, net	3,007	3,183
Other current assets	837	1,311
Total current assets	7,362	14,864
Property and equipment, net	2,763	3,052
Other assets	2,048	2,570
Intangibles, net	6,582	7,207
Goodwill	3,922	3,922

Total assets	\$ 22,677	\$ 31,615
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,780	\$ 4,790
Term loan obligations, net of discount	13,836	13,624
Total current liabilities	17,616	18,414
Deferred revenues	217	94
Long-term deferred rent and other	93	107
Total liabilities	17,926	18,615
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 23,500 shares issued; 1,186 and 2,431 shares outstanding in 2018 and 2017, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 6,176,054 and 5,782,573 shares issued and outstanding in 2018 and 2017, respectively	62	58
Additional paid-in capital	413,269	413,304
Accumulated other comprehensive income	1,237	1,387
Accumulated deficit	(409,817)	(401,749)
Total stockholders' equity	4,751	13,000
Total liabilities and stockholders' equity	\$ 22,677	\$ 31,615

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 Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Product revenues	\$ 660	\$ 969	\$ 1,391	\$ 1,560
Cost of product revenues	324	401	596	811
Amortization of intangible assets	306	306	613	612
Gross profit	30	262	182	137
Development revenues:				
Government contracts and other	899	531	1,816	1,549
	899	531	1,816	1,549
Operating expenses:				
Research and development	1,951	2,992	4,451	6,281
Sales and marketing	525	1,263	1,202	2,202
General and administrative	1,469	2,119	3,714	4,227

In process research and development acquired from Azaya Therapeutics	—	—	—	1,686
Total operating expenses	<u>3,945</u>	<u>6,374</u>	<u>9,367</u>	<u>14,396</u>
Operating loss	<u>(3,016)</u>	<u>(5,581)</u>	<u>(7,369)</u>	<u>(12,710)</u>
Other income (expense):				
Interest income	5	7	19	18
Interest expense	(444)	(538)	(866)	(1,129)
Other income (expense), net	<u>(204)</u>	<u>63</u>	<u>148</u>	<u>228</u>
Total other expense	<u>(643)</u>	<u>(468)</u>	<u>(699)</u>	<u>(883)</u>
Net loss	<u>\$ (3,659)</u>	<u>\$ (6,049)</u>	<u>\$ (8,068)</u>	<u>\$ (13,593)</u>
Basic and diluted net loss per share				
	(0.59)	\$ (1.94)	(1.32)	(5.04)
Basic and diluted weighted average shares used in calculating net loss per share				
	6,166,459	3,125,087	6,092,125	2,699,362
Comprehensive loss:				
Net loss	\$ (3,659)	\$ (6,049)	\$ (8,068)	\$ (13,593)
Other comprehensive loss – foreign currency translation adjustments	131	(15)	(150)	(75)
Comprehensive loss	<u>\$ (3,528)</u>	<u>\$ (6,064)</u>	<u>\$ (8,218)</u>	<u>\$ (13,668)</u>

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

**For the Six Months Ended
June 30,**

	<u>2018</u>	<u>2017</u>
Cash flows from operating activities:		
Net loss	\$ (8,068)	\$ (13,593)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	975	1,052
Amortization of deferred financing costs and debt discount	212	418
In process research and development acquired from Azaya Therapeutics	—	1,686
Provision for excess inventory	398	340
Share-based compensation expense	239	410
Loss on asset disposal	20	19
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(274)	409
Inventories	371	159

Other current assets	344	(736)
Other assets	(1)	43
Accounts payable and accrued expenses	(1,165)	(194)
Deferred revenues	123	13
Long-term deferred rent	(14)	119
Net cash used in operating activities	<u>(6,840)</u>	<u>(9,855)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(78)	(95)
Purchase of long-lived assets part of Azaya Therapeutics' acquisition	—	(1,201)
Net cash used in investing activities	<u>(78)</u>	<u>(1,296)</u>
Cash flows from financing activities:		
Principal payments on long-term obligations	—	(3,540)
Proceeds from sale of common stock, net	(200)	11,225
Net cash (used in) provided by financing activities	<u>(200)</u>	<u>7,685</u>
Effect of exchange rate changes on cash and cash equivalents	12	13
Net decrease in cash and cash equivalents	(7,106)	(3,453)
Cash, cash equivalents, and restricted cash at beginning of period	10,225	12,910
	\$	
Cash, cash equivalents, and restricted cash at end of period	<u>3,119</u>	<u>\$ 9,457</u>

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Source: Cytori Therapeutics Inc.