



Cytori Reports Q3 2018 Business and Financial Results

November 14, 2018

SAN DIEGO, Nov. 14, 2018 (GLOBE NEWSWIRE) -- [Cytori Therapeutics](#) (NASDAQ: CYTX) ("Cytori" or the "Company") today announced Q3 2018 financial results and provided updates on corporate activities.

Q3 2018 net loss was \$2.3 million, or \$0.27 per share. Operating cash burn for Q3 was approximately \$2.6 million. Cytori ended Q3 with approximately \$6.8 million of cash and cash equivalents.

Cytori is developing its lead chemotherapy drug, ATI-0918, a generic version of pegylated liposomal doxorubicin hydrochloride, with the goal of submitting a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) next year. We previously completed a bioequivalence study against the European reference drug and are in the process of completing manufacturing-related activities to support the MAA.

The Company also continues to evaluate potential commercial partnering opportunities for ATI-0918 with a focus on Europe, which has a current estimated market size of over \$120 million.

Cytori is also developing another chemotherapy drug, ATI-1123, a patented, albumin-stabilized pegylated liposomal docetaxel. The Company recently received an orphan drug designation from the U.S. FDA for small cell lung cancer and intends to pursue FDA's 505(b)(2) new drug application (NDA) pathway in the U.S. which may offer accelerated and lower cost development.

In the first half of 2019, Cytori expects a 1-year data readout from the 45 patient, multi-center, potential pivotal clinical trial in stress urinary incontinence conducted in Japan called ADRESU.

Later in 2018, Cytori expects a 6-month data readout from the 40 patient, French SCLERADEC II clinical trial in scleroderma patients.

Cytori is actively conducting the U.S. Phase I RELIEF trial in thermal burn injury trial sponsored by BARDA. Cytori completed a successful In-Process Review meeting with BARDA this past June.

Commercially, Cytori is focusing its efforts in Japan and continues to see favorable growth trends in the use of its cell therapy products approved under the Regenerative Medicine Law in the aesthetic and orthopedic markets. The Company remains on track to see continued double digit year-over-year growth in Celution® System consumable utilization.

Finally, Cytori recently received the first \$1.0 million royalty milestone from Bimini Technologies, LLC (Bimini). In 2013, Cytori divested the Puregraft® product line that includes periodic royalty payments of up to \$10.0 million and certain other economic benefits based on Bimini achieving gross profits milestones.

"A key corporate objective is to complete manufacturing support activities and seek European marketing authorization for ATI-0918, our lead oncology drug product. Furthermore, we have recently expanded development activities for the ATI-1123 phase II oncology program and its potential 505(b)(2) acceptability," said Dr. Marc Hedrick, President and Chief Executive Officer of Cytori. "In cell therapy, we are focused on continued revenue growth based on positive quarter-over-quarter and year-over-year consumable utilization trends. In the meantime, we are awaiting pivotal clinical data from our Japanese stress urinary incontinence trial."

Q3 2018 and year-to-date Financial Performance

- Q3 2018 and year-to-date operating cash burn was \$2.6 million and \$9.5 million, compared to \$4.0 million and \$13.9 million for the same periods in 2017, respectively.
- Q3 2018 and year-to-date product revenues were \$0.9 million and \$2.2 million, compared to \$0.5 million and \$2.0 million for the same periods in 2017, respectively.
- Q3 2018 and year-to-date contract revenues were \$0.5 million and \$2.3 million, compared to \$1.3 million and \$2.9 million for the same periods in 2017, respectively.
- Q3 2018 and year-to-date consumable utilization in Japan grew by approximate 90% and 70%, when comparing to the same periods in 2017, respectively.
- Cash and debt principal balances at September 30, 2018 were approximately \$6.8 million and \$13.0 million, respectively.
- Q3 2018 adjusted net loss was \$4.0 million or \$0.45 per share, compared to a net loss of \$4.8 million or \$1.39 per share for the same period in 2017. The adjusted net loss excludes a non-cash beneficial conversion feature (a non gaap measure) related to the issuance of our Series C convertible preferred shares in the third quarter of 2018 of \$2.5 million, as well as a credit of \$1.7 million related to a change in fair value of warrant liability (a non gaap measure). Q3 2018 net loss allocable to common stockholders was \$4.8 million, or \$0.55 per share.
- Year-to-date 2018 adjusted net loss was \$12.1 million or \$1.73 per share, compared to \$18.4 million or \$6.22 per share for the same period in 2017. The adjusted net loss excludes a non-cash beneficial conversion feature (a non gaap measure) related to the issuance of our Series C convertible preferred shares in the third quarter of 2018 of \$2.5 million, as well as a credit of \$1.7 million related to a change in fair value of warrant liability (a non gaap measure). Year-to-date 2018 net loss allocable to common stockholders was \$12.9 million, or \$1.85 per share.

Selected Key Anticipated Milestones:

- Complete ATI-0918 development and manufacturing required to prepare and file a MAA with the EMA.
- Seek FDA 505(b)(2) pathway applicability for ATI-1123 product.
- Obtain Japan MHLW Class III approval for Celution® System consumables.
- Report 1-year Japanese ADRESU pivotal clinical trial data for post-surgical male stress urinary incontinence.
- Enrollment update in the BARDA-funded U.S. RELIEF clinical trial.
- Report French investigator initiated SCLERADEC II clinical trial data in scleroderma hand dysfunction.

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: 9699923.

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 September 30, 2018	As of December 31, 2017
Assets		
Current assets:		

Cash and cash equivalents	\$	6,806	\$	9,550
Accounts receivable, net of reserves of \$185 in 2018 and \$167 in 2017		440		145
Restricted cash		40		675
Inventories, net		2,814		3,183
Other current assets		654		1,311
Total current assets		<u>10,754</u>		<u>14,864</u>
Property and equipment, net		2,648		3,052
Other assets		1,938		2,570
Intangibles, net		6,270		7,207
Goodwill		3,922		3,922
Total assets	\$	<u>25,532</u>	\$	<u>31,615</u>
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	3,645	\$	4,790
Term loan obligations, net of discount		14,007		13,624
Total current liabilities		<u>17,652</u>		<u>18,414</u>
Deferred revenues		187		94
Long-term deferred rent and other		83		107
Warrant liability		1,472		—
Total liabilities		<u>19,394</u>		<u>18,615</u>
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 23,500 shares issued; 4,624 and 2,431 shares outstanding in 2018 and 2017, respectively		—		—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 11,691,293 and 5,782,573 shares issued and outstanding in 2018 and 2017, respectively		67		58
Additional paid-in capital		417,036		413,304
Accumulated other comprehensive income		1,182		1,387
Accumulated deficit		(412,147)		(401,749)
Total stockholders' equity		<u>6,138</u>		<u>13,000</u>
Total liabilities and stockholders' equity	\$	<u>25,532</u>	\$	<u>31,615</u>

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

For the Three Months

For the Nine Months

	Ended September 30,		Ended September 30,	
	2018	2017	2018	2017
Product revenues	\$ 858	\$ 467	\$ 2,249	\$ 2,027
Cost of product revenues	322	181	918	992
Amortization of intangible assets	306	306	919	919
Gross profit (loss)	230	(20)	412	116
Development revenues:				
Government contracts and other	454	1,306	2,270	2,856
	454	1,306	2,270	2,856
Operating expenses:				
Research and development	1,916	3,004	6,366	9,284
Sales and marketing	453	840	1,656	3,043
General and administrative	1,486	1,785	5,199	6,012
Change in fair value of warrants	(1,676)	—	(1,676)	—
In process research and development acquired from Azaya Therapeutics	—	—	—	1,686
Total operating expenses	2,179	5,629	11,545	20,025
Operating loss	(1,495)	(4,343)	(8,863)	(17,053)
Other income (expense):				
Interest income	11	5	30	24
Interest expense	(512)	(474)	(1,379)	(1,603)
Other income (expense), net	9	5	157	233
Issuance costs of warrants	(343)	—	(343)	—
Total other expense	(835)	(464)	(1,535)	(1,346)
Net loss	\$ (2,330)	\$ (4,807)	\$ (10,398)	\$ (18,399)
Beneficial conversion feature for convertible preferred stock	(2,487)	\$ —	(2,487)	\$ —
Net loss allocable to common stockholders	\$ (4,817)	\$ (4,807)	\$ (12,885)	\$ (18,399)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.55)	\$ (1.39)	\$ (1.85)	\$ (6.22)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	8,716,194	3,449,083	6,972,615	2,956,403
Comprehensive loss:				
Net loss	\$ (2,330)	\$ (4,807)	\$ (10,398)	\$ (18,399)
Other comprehensive loss – foreign currency translation adjustments	(55)	16	(205)	(59)
Comprehensive loss	\$ (2,385)	\$ (4,791)	\$ (10,603)	\$ (18,458)

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

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

	2018	2017
Cash flows from operating activities:		
Net loss	\$ (10,398)	\$ (18,399)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,465	1,618
Amortization of deferred financing costs and debt discount	383	580
In process research and development acquired from Azaya Therapeutics	—	1,686
Provision for excess inventory	433	413
Issuance costs of warrants	343	—
Change in fair value of warrants	(1,676)	—
Share-based compensation expense	325	588
Loss on asset disposal	23	9
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(316)	991
Inventories	615	457
Other current assets	514	(284)
Other assets	7	74
Accounts payable and accrued expenses	(1,274)	(1,746)
Deferred revenues	93	6
Long-term deferred rent	(24)	103
Net cash used in operating activities	(9,487)	(13,904)
Cash flows from investing activities:		
Purchases of property and equipment	(128)	(271)
Proceeds from sale of assets	—	10
Purchase of long-lived assets part of Azaya Therapeutics' acquisition	—	(1,201)
Net cash used in investing activities	(128)	(1,462)
Cash flows from financing activities:		
Principal payments on long-term obligations	—	(4,720)
Proceeds from sale of common and preferred stock, net	6,246	12,377
Net cash provided by financing activities	6,246	7,657
Effect of exchange rate changes on cash and cash equivalents	(10)	11
Net decrease in cash and cash equivalents	(3,379)	(7,698)
Cash, cash equivalents, and restricted cash at beginning of period	10,225	12,910
Cash, cash equivalents, and restricted cash at end of period	\$ 6,846	\$ 5,212

Tiago Girao
+1.858.458.0900
ir@cytori.com

Source: Cytori Therapeutics Inc.