Cytori Reports Second Quarter 2016 Business and Financial Results

August 4, 2016

SAN DIEGO--(BUSINESS WIRE)-- Cytori Therapeutics (NASDAQ: CYTX) ("Cytori" or the "Company") today announced its second quarter financial results and provided updates on its corporate activity and clinical development.

Second quarter 2016 net loss allocable to common stockholders was $6.4 million and $0.43 per share. Cytori continues to tightly manage its operating cash burn, spending approximately $5.7 million in the second quarter 2016. Cytori ended the second quarter of 2016 with $20 million of cash and cash equivalents.

"In the first half of the year, our team has advanced our development pipeline in the U.S. in multiple indications, most notably completing enrollment in our Phase 3 trial in scleroderma. Additionally, investigator-initiated studies are progressing in Europe and Japan, and we have continued to lay a sound foundation for early clinical adoption and profitable revenue growth in Japan and Europe, which can provide near-term revenue and importantly build longer-term strategic value," said Dr. Marc H. Hedrick, President and Chief Executive Officer for Cytori. "Corporate milestones over the next twelve months include the first readout from our US phase III scleroderma trial in mid-2017, the initiation of an externally funded clinical trial in burn patients later this year, treatment of the first scleroderma patients as part of our compassionate use program, and Japanese revenue growth."

Select Recent Highlights:

- Enrollment completion of US STAR phase III trial for scleroderma hand dysfunction
- Report of 48-week US pilot/phase IIb ACT-OA trial preliminary topline data
- Limited regulatory approval received by a Cytori customer regarding use of Cytori® Cell Therapy™ for osteoarthritis of the knee at its clinics in Japan
- Completion of rights offering for gross proceeds of $17.1 million
- Broad orphan drug designation granted by European Commission, and small or medium-size enterprise (SME) status granted by European Medicines Agency

Q2 and Year-to-date 2016 Financial Performance

- Q2 2016 and year-to-date operating cash burn of $5.6 million and $10.7 million, compared to $4.8 million and $9.8 million for the same periods in 2015, respectively.
- Cash and debt principal balances at June 30, 2016 of approximately $20 million and $17.7 million, respectively.
- Q2 2016 and year-to-date total revenues of $2.8 million and $5.7 million, compared to $3.5 million and $5.8 million for the same periods in 2015, respectively.
- Q2 2016 net loss allocable to common stockholders of $6.4 million or $0.43 per share, compared to a net income of $4.5 million or $0.45 per share (or a net loss of $8.7 million and $0.94 per share when excluding a non-cash credit charge of $13.1 million related to the change in fair value of warrant liabilities) for the same period in 2015.
- Year-to-date net loss allocable to common stockholders of $11.7 million or $0.84 per share, compared to $18.2 million or $2.22 per share (or a net loss of $15.2 million or $1.86 per share, which excludes a non-cash charge of $2.3 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.

"We reduced our net losses by over 25% from Q2'15 to Q2'16, despite substantial development progress that includes completion of enrollment in our U.S. Phase III scleroderma trial," said Tiago Girao, VP of Finance and CFO of Cytori Therapeutics. "Our current projections indicate that the net proceeds from our Q2 financing activities coupled with ongoing downward pressure on expenses coupled with revenue growth, will provide liquidity for at least the next 12 months of operations."

Summary of ACT-OA trial and topline 48-week results:

The ACT-OA trial was a randomized double blind phase II trial comparing a single administration of either low or high doses of ECCO-50 autologous cellular therapeutic placed into the intraarticular space of one knee in 94 patients with knee osteoarthritis of moderate severity. This pilot trial was designed to establish safety, feasibility and explore a number of efficacy endpoints for a more definitive trial with appropriate statistical powering. Topline results concluded:

- Intraarticular application of a single dose of ECCO-50 is feasible in an outpatient day-surgery setting; no serious adverse events were reported related to the fat harvest, cell injection or to the cell therapy.

- Consistent trends observed in most secondary endpoints at 12, 24 and 48 weeks in the target knee of the treated group relative to placebo control group; as reported in Q1, 12 week primary endpoint of single pain on walking question did not achieve statistical significance.
- Consistent trends observed in all 6 pre-specified MRI Osteoarthritis Knee Score (MOAKS) classification scores suggesting decrease in target knee joint pathologic features at 48 weeks for the treated group relative to placebo control group.

“The safety and feasibility goal of this first trial in OA was substantially achieved,” said Dr. Mark Marino, Cytori Senior Vice President of Clinical Affairs. “Additionally, even though this first randomized controlled trial was not statistically powered to test for a specific therapeutic hypothesis, it showed evidence of a potential cell effect including in the joint imaging data. Further analysis is ongoing on specific patient subsets and in-depth anatomic assessment of the MRI data.”

Anticipated Forthcoming Milestones:

- Clarity for European Union Conditional Market Approval in scleroderma hand dysfunction
- File IDE and obtain approval for burn wound therapy trial related to contract with BARDA (anticipated in 2016)
- Report of 48-week US pivotal/phase III trial data for scleroderma hand dysfunction

2016 Reiterated Financial Guidance

- Operating cash burn within a range of $18 million to $20 million
- Total revenues (product and contract) within a range of $12 million to $14 million

Management Conference Call Webcast

Cytori will host a management conference call at 5:30 p.m. Eastern Time today to further discuss the Company's 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: 54687177.

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™ 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. 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 having at least 12 months’ liquidity (based upon expected expense containment and revenue growth), potential prolonged symptomatic improvement in the target knee of the treated patient group relative to placebo control group in the Company’s ACT-OA trial, evidence of a potential cell effect (including in the joint imaging data), status of SCLERADEC II enrollment, status of the Company’s efforts regarding a proposed burn wound trial, anticipated receipt and disclosure of 48-week STAR data, and reiterated financial guidance (projected operating cash burn and total revenues), 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 the ACT-OA, STAR, SCLERADEC-I, SCLERADEC-II and possible BARDA wound trial (including risks relating to failure to achieve full enrollment of SCLERADEC II or other Company-sponsored/supported trials, risks in the collection and results of ACT-OA, STAR, SCLERADEC II and other clinical data and related final clinical outcomes), as well as achievement of financial goals (including 2016 operating cash burn and 2016 total revenues), dependence on third party performance and approvals (including performance of investigator-initiated trials, and outcome of FDA review of our proposed burn wound trial pursuant to our contract with BARDA), performance and acceptance of our products in clinical studies/trials and in the marketplace, material changes in the marketplace that could adversely impact revenue projections (including changes in market perceptions of our products, and introduction of competitive products), unexpected costs and expenses that could adversely impact liquidity and shorten our current liquidity projections (which could in turn require us to seek additional debt or equity capital within the next 12 months), our reliance on key personnel, the right of the Federal Government to cut or terminate further support of the thermal burn injury program (including any decision by BARDA not to proceed with a wound trial in 2016), our abilities to capitalize on our 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 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 CONDENSED BALANCE SHEETS
(UNAUDITED)

	As of June 30, 2016	As of December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 20,042,000	$ 14,338,000
Accounts receivable, net of reserves of $785,000 and $797,000 in 2016 and 2015, respectively	911,000	1,052,000
Inventories, net	4,534,000	4,298,000
Other current assets	1,263,000	1,555,000
Total current assets	26,750,000	21,243,000
Property and equipment, net	1,380,000	1,631,000
Restricted cash and cash equivalents	350,000	350,000
Other assets	1,449,000	1,521,000
Intangibles, net	8,829,000	9,031,000
Goodwill	3,922,000	3,922,000
Total assets	$ 42,680,000	$ 37,698,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,585,000	$ 6,687,000
Current portion of long-term obligations, net of discount	3,494,000	—
Joint venture purchase obligation	—	1,750,000
Total current liabilities	10,079,000	8,437,000
Deferred revenues	106,000	105,000
Long-term deferred rent and other	111,000	269,000
Long-term obligations, net of discount, less current portion	13,663,000	16,681,000
Total liabilities	23,959,000	25,492,000
Commitments and contingencies		
Stockholders' equity (deficit):		
Series A 3.6% convertible 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; 20,492,601 and 13,003,893 shares issued and outstanding in 2016 and 2015, respectively	20,000	13,000
Additional paid-in capital	386,845,000	368,214,000
Accumulated other comprehensive income	617,000	996,000
Accumulated deficit	(368,761,000)	(357,017,000)
Total stockholders' equity	18,721,000	12,206,000
Total liabilities and stockholders' equity	$ 42,680,000	$ 37,698,000

CYTORI THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
Product revenues	$ 1,126,000	$ 1,614,000	$ 2,459,000	$ 2,516,000
Cost of product revenues	585,000	1,296,000	1,152,000	1,894,000

Gross profit	541,000	318,000	1,307,000	622,000
Development revenues:				
Government contracts and other	1,699,000	1,847,000	3,284,000	3,291,000
	1,699,000	1,847,000	3,284,000	3,291,000
Operating expenses:				
Research and development	5,247,000	6,048,000	9,374,000	10,012,000
Sales and marketing	889,000	654,000	1,924,000	1,493,000
General and administrative	2,328,000	2,793,000	4,614,000	5,292,000
Change in fair value of warrant liabilities	—	(13,122,000)	—	2,322,000
Total operating expenses	8,464,000	(3,627,000)	15,912,000	19,119,000
Operating (loss) income	(6,224,000)	5,792,000	(11,321,000)	(15,206,000)
Other income (expense):				
Income (loss) on asset disposal	—	(1,000)	2,000	8,000
Loss on debt extinguishment	—	(260,000)	—	(260,000)
Interest income	2,000	3,000	4,000	3,000
Interest expense	(645,000)	(936,000)	(1,302,000)	(2,007,000)
Other income (expense), net	462,000	(148,000)	874,000	(47,000)
Total other expense	(181,000)	(1,342,000)	(422,000)	(2,303,000)
Net (loss) income	$ (6,405,000)	$ 4,450,000	$(11,743,000)	$(17,509,000)
Beneficial conversion feature for convertible preferred stock	—	—	—	(661,000)
Net (loss) income allocable to common stockholders	$ (6,405,000)	$ 4,450,000	$(11,743,000)	$(18,170,000)
Net income (loss) per share allocable to common stockholders				
Basic	$ (0.43)	$ 0.48	$ (0.84)	$ (2.22)
Diluted	$ (0.43)	$ 0.45	$ (0.84)	$ (2.22)
Weighted average shares used in calculating net income (loss) per share allocable to common stockholders				
Basic	14,778,616	9,266,141	13,932,496	8,179,403
Diluted	14,778,616	9,824,538	13,932,496	8,179,403
Comprehensive (loss) income:				
Net (loss) income	$ (6,405,000)	$ 4,450,000	$(11,743,000)	$(17,509,000)
Other comprehensive (loss) income – foreign currency translation adjustments	(130,000)	215,000	(379,000)	251,000
Comprehensive (loss) income	$ (6,535,000)	$ 4,665,000	$(12,122,000)	$(17,258,000)

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

	For the Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (11,743,000)	$ (17,509,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	574,000	510,000
Amortization of deferred financing costs and debt discount	468,000	500,000
Joint Venture acquisition obligation accretion	24,000	307,000
Provision for expired inventory	26,000	—
Change in fair value of warrants	—	2,322,000
Stock-based compensation expense	645,000	1,146,000

Loss on asset disposal	2,000	—
Loss on debt extinguishment	—	260,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	66,000	544,000
Inventories	(380,000)	730,000
Other current assets	137,000	(106,000)
Other assets	34,000	407,000
Accounts payable and accrued expenses	(431,000)	1,089,000
Deferred revenues	1,000	151,000
Long-term deferred rent	(158,000)	(139,000)
Net cash used in operating activities	(10,735,000)	(9,788,000)
Cash flows from investing activities:		
Purchases of property and equipment	(105,000)	(497,000)
Expenditures for intellectual property	—	(13,000)
Net cash used in investing activities	(105,000)	(510,000)
Cash flows from financing activities:		
Principal payments on long-term obligations	—	(25,032,000)
Proceeds from long-term obligations	—	17,700,000
Debt issuance costs and loan fees	—	(1,854,000)
Joint Venture purchase payments	(1,774,000)	(1,123,000)
Proceeds from exercise of employee stock options and warrants	—	4,986,000
Proceeds from sale of common stock, net	18,179,000	24,930,000
Dividends paid on preferred stock	—	(75,000)
Net cash provided by financing activities	16,405,000	19,532,000
Effect of exchange rate changes on cash and cash equivalents	139,000	(14,000)
Net increase in cash and cash equivalents	5,704,000	9,220,000
Cash and cash equivalents at beginning of period	14,338,000	14,622,000
Cash and cash equivalents at end of period	$ 20,042,000	$ 23,842,000

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Source: Cytori Therapeutics

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