

## Cytori Therapeutics (CYTX - \$ 1.69)

Healthcare/Biotechnology

### 2Q14: ATHENA Study Could Potentially Resume in 2015 with Developments in Japan as Greater Focus

Ticker: **CYTX**  
Rating: **Buy**  
Price Target: **\$ 8.00**

Yesterday after market close, CYTX reported 2Q14 financial results with a net loss of (\$10.5MM), slightly better than Laidlaw (\$11.8MM) and the Street estimate of (\$11.9MM). Net loss per share equaled (\$0.15) vs. (\$0.15) and (\$0.17) for Laidlaw and the Street, respectively. CYTX ended the 2Q14 with cash of \$12.8MM and \$2.0MM A/R, sufficient for operations into late 2014, in our opinion.

#### Trading Data:

Last Price (08/11/2014)	\$ 1.69
52-Week High (11/5/2013)	\$ 3.93
52-Week Low (8/6/2014)	\$ 1.46
Market Cap. (MM)	\$ 134
Shares Out. (MM)	80

- Stoppage of patient recruitment of the ATHENA study could just be a hiccup.** Management provided greater details on the recent patient recruitment hold of the ATHENA study, suggesting that cerebrovascular events might not be caused by the cell therapy or device used, but might due to the combination of factors mainly associated with vulnerability of patients who were under the surgical procedure but might not been managed appropriately. Although it cannot be fully confirmed, the long procedures, coupled with possibly inadequate hydration, potential insufficient medication, and other factors could increase the propensity developing adverse effects. Among the three patients with stroke like events, CYTX identified two who were in the treatment and one from placebo group after the company partially unblinded a small portion of patients. The company is actively developing solutions by “tightening up” the clinical protocol via optimizing medical management, possibly resuming patient enrollment in early 1Q15, according to our estimate. CYTX suggested that potential changes should not affect the validity of the data to be analyzed going forward and should not incur any statistical penalties. If this timeline can be implemented, we estimate patient enrollment could complete in 2015 with data readout ~2 quarters after.
- Upcoming priorities.** CEO Marc Hedrick indicated that upcoming priorities include: 1) strengthening the balance sheet and managing costs; 2) prioritizing operations in Japan; and 3) focus on operational activities, such as expanding additional pipeline development in a cost-effective manner; finalizing the next generation device; and expanding collaborations with various governments.
- Action.** We reiterate Buy rating and our \$8 target price. Our valuation is based on our peer comparison valuation methodology and by our risk-adjusted cash flow sum-of-the-parts analysis.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-14E</b>	-0.14A	-0.15A	-0.11	-0.12	-0.53	NM
<b>FY-13A</b>	-0.11	-0.05	-0.08	-0.14	-0.39	NM
<b>FY-12A</b>	-0.16	-0.13	-0.19	-0.06	-0.55	NM
<b>FY-11A</b>	-0.23	-0.10	-0.15	-0.12	-0.61	NM

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Source: Company data & Laidlaw & Company estimates

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- **CFO will leave shortly.** CFO Mark Saad will leave CYTX for a new position in another biotech company. The company is scheduled to bring in a new CFO who is familiar with CYTX operations since one of his prior positions was an auditor for CYTX from KPMG.
- Management indicated that more details about the BARDA contract would likely be available later this month once the company formally signs the contract.
- The company believes that the next generation of Celution system, which may be completed in 1H15, could provide substantial upside to the overall ADRC development. Given that the next generation system is much smaller in size and less costly, the commercial model could possibly move from a more “capital equipment”-driven purchase decision to more of a repeat purchase consumable model. As such, it not only could be more appealing to the BARDA expectations but also could be more attractive commercially.

**Figure 1 Estimated and reported 2Q14 results**

<b>Table 1:2Q14 Estimates and Reported Results</b>			
<b>(\$ MM)</b>	<b>Laidlaw Estimate</b>	<b>Actual</b>	<b>Consensus</b>
<b>Total revenue</b>	<b>\$2.6</b>	<b>\$1.3</b>	<b>\$2.4</b>
<b>Total op. profit (loss)</b>	<b>(\$9.7)</b>	<b>(\$10.7)</b>	
R&D	\$5.8	\$4.7	
SG&A	\$5.5	\$6.5	
<b>EPS</b>	<b>(\$0.15)</b>	<b>(\$0.15)</b>	<b>(\$0.17)</b>
Net income (loss)	(\$11.1)	(\$11.8)	(\$11.9)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing
Celution	No-option chronic myocardial ischemia	CE Mark expansion for intravascular use based on PRECISE outcomes	2014
		Potentially re-start patient recruitment of the ATHENA clinical study	1Q15
		Potential completion of patient recruitment of the ATHENA clinical study	2015
		Potential releases data of ATHENA clinical study	2015
	Thermal burns	Potentially to report details of contract from BARDA	3Q14
	Hamstring injury	Potential commence an exploratorr study (n=10)	2014
		Potential to improvisation of new law in Japan	Late '14
		Potential submission to SFDA in China	Late '14
		Potential approval in China	2015
		Product revenue growth	Quarterly report

Source: Laidlaw & Company estimates and company presentation.

## Major Risks

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**Clinical risks of clinical study failure could have a major impact on CYTX share value.** Despite an encouraging PRECISE study outcome, which potentially bodes well for a positive outlook of future studies, it remains too early to project the possible success of the ongoing ATHENA, the upcoming ATHENA II and the potential future pivotal studies. Given that the substantial upside potential for CYTX shares is currently based on the success of ADRCs in no-option chronic myocardial ischemia PMA, a failed study outcome or/and an unsuccessful approval application would have a significant negative impact on CYTX share value. In addition, given the primary endpoint of the two more advanced clinical studies (Baxter and Mesoblast/Teva) are different from that of ATHENA and ATHENA II, additional data potentially are needed to support ADRCs to fulfill the possible pivotal studies requirements.

**Commercial success of the Celution system is less predictable.** Although the Celution system has been available in the market for several years, with approval as a tool and indication claim expansions in ex-U.S. markets, the revenue has been modest. It might be difficult to project, with greater precision, future Celution system sales growth from China, Japan, Europe and other markets. It is also difficult to predict whether or when China might grant the approval of the Celution system (our projection of 2014). Should the development in China be less successful than expected, and sales from other regions do not meet investor expectations, CYTX share value could be negatively impacted.

**Other possible bone marrow based cell therapies could potentially outperform ADRCs Celution system.** Although ADRCs possess advantages over other cell therapies, in our opinion, it is difficult to predict whether they can outperform other bone marrow based cell therapies in clinical performance. From the development timeline and resource prospective and given several major competitors, such as Baxter and Mesoblast/Teva are already in more advanced stages of development, and with greater resources than Cytori, the development and potential regulatory and commercial success of Cytori's program could be further impacted negatively by the advancements of competitors' programs.

**Lack of sufficient cash could impede corporate development.** With additional financial needs to support clinical studies and other operating expenses going forward, the company might have to raise additional capital via either financial market or non-dilutive sources to advance its pipeline development. Given it is possible that costs for the pivotal studies for ADRCs in no-option CMI could be very substantial due to sizeable studies, the company might much prefer to find non-dilutive financial sources for moving the program forward. It is possible by raising capital at a less favorable term; CYTX's share price could decline.

**Risks from international exposure.** A substantial portion of Cytori's current revenues are derived from sales outside the U.S., especially from the European and Asia-Pacific regions. As such, the company is exposed to potential risks of currency fluctuations, as well as pricing controls, regulatory requirements and reimbursement practices that differ from that of the U.S.

**Limited trading liquidity limits shareholder options.** Given CYTX shares only entered the public market recently; daily trading volume and name recognition are relatively low. With relatively illiquid trading volume, shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

Figure 1: Income Statement

Cytori Therapeutics, Inc. – Income Statement								
('000 \$)	2012	2013	1Q14	2Q14	3Q14E	4Q14E	2014E	2015E
Sales to related party	9							
Sales to third parties	8,708	7,122	1,031	935	1,000	1,401	4,367	5,896
<b>Product revenues</b>	<b>8,709</b>	<b>7,122</b>	<b>1,031</b>	<b>935</b>	<b>1,000</b>	<b>1,401</b>	<b>4,367</b>	<b>5,896</b>
BARDA revenue	360	3,257	403	359	2,844	2,844	6,451	11,378
Development, related party	2,882	638	-	-	-	-	0	0
Development	2,529	1,179	-	-	-	-	0	0
Research grant and other	21	0	-	-	-	-	0	0
<b>Development revenues</b>	<b>5,792</b>	<b>5,074</b>	<b>403</b>	<b>356</b>	<b>2,844</b>	<b>2,844</b>	<b>6,451</b>	<b>11,378</b>
<b>Total Revenue</b>	<b>14,501</b>	<b>12,196</b>	<b>1,434</b>	<b>1,291</b>	<b>3,845</b>	<b>4,245</b>	<b>10,818</b>	<b>17,273</b>
Cost of product revenues	4,000	3,421	421	766	410	574	2,171	2,417
Gross profit	4,709	3,701	610	169	590	826	2,196	3,478
Research and development	13,628	17,065	4,292	4,674	4,767	4,863	18,596	24,175
Sales and marketing	9,488	9,026	1,928	1,934	1,963	2,042	7,867	8,260
General and administrative	15,672	16,031	4,340	4,602	4,510	4,533	17,984	19,064
Change in fair value of warrant liability	(209)	(418)	0	0	0	0	0	0
Change in fair value of option liability	340	(2,250)	0	0	0	0	0	0
<b>Operating expense</b>	<b>38,919</b>	<b>39,454</b>	<b>10,560</b>	<b>11,210</b>	<b>11,240</b>	<b>11,437</b>	<b>44,447</b>	<b>51,499</b>
<b>Operating income</b>	<b>(28,418)</b>	<b>(30,679)</b>	<b>(9,547)</b>	<b>(10,685)</b>	<b>(7,806)</b>	<b>(7,766)</b>	<b>(35,801)</b>	<b>(36,642)</b>
Interest income	4	4	2	1	1	1	5	5
Interest expense	(3,386)	(3,396)	(941)	(1,085)	(1,094)	(1,094)	(4,214)	(4,256)
Other income (expense), net	(314)	(438)	86	(58)	250	(250)	28	28
Gain on Puregraft divestiture		4,453	-	-	-	-	0	0
Equity loss from investment in joint venture	(165)	4,844	0	0	0	-	0	0
Total other income (expense)	(3,861)	4,502	(853)	(1,143)	(843)	(1,343)	(4,181)	(4,223)
<b>Income (loss) before taxes</b>	<b>(32,279)</b>	<b>(26,177)</b>	<b>(10,400)</b>	<b>(11,828)</b>	<b>(8,649)</b>	<b>(9,109)</b>	<b>(39,982)</b>	<b>(40,866)</b>
Income tax expense	-	-	-	-	-	-	-	-
<b>Net income</b>	<b>(32,279)</b>	<b>(26,177)</b>	<b>(10,400)</b>	<b>(11,828)</b>	<b>(8,649)</b>	<b>(9,109)</b>	<b>(39,982)</b>	<b>(40,866)</b>
<b>Net income attributable to common shareholders</b>	<b>(\$32,279)</b>	<b>(\$25,921)</b>	<b>(\$10,450)</b>	<b>(\$11,828)</b>	<b>(\$8,649)</b>	<b>(\$9,109)</b>	<b>(\$39,982)</b>	<b>(\$40,866)</b>
Net Earnings (Losses) Per Share—Basic	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.11)	(\$0.12)	(\$0.53)	(\$0.50)
Net Earnings (Losses) Per Share—Diluted	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.11)	(\$0.12)	(\$0.53)	(\$0.50)
Shares outstanding—basic	58,614	67,781	74,102	76,683	76,783	76,883	76,113	81,113
Shares outstanding—diluted	58,614	67,781	74,102	76,683	76,783	76,883	76,113	81,113
<b>Margin Analysis (% of Sales/Revenue)</b>								
COGS	46%	48%	41%	82%	41%	41%	42%	41%
R&D	94%	140%	299%	362%	124%	115%	172%	140%
S&M	109%	127%	134%	150%	51%	48%	180%	140%
G&A	108%	131%	303%	356%	117%	107%	166%	110%
Operating Income (loss)	-196%	-252%	-666%	-828%	-203%	-183%	-331%	-212%
Pretax	-223%	-215%	-725%	-916%	-225%	-215%	-370%	-237%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-223%	-215%	-725%	-916%	-225%	-215%	-370%	-237%
<b>Financial Indicator Growth Analysis (YoY%)</b>								
Product revenues	9%	-18%	-26%	-34%	-38%	-48%	-39%	35%
BARDA revenue	N.A.	805%	-27%	-58%	160%	277%	98%	76%
Total Revenue	45%	-16%	-80%	-91%	2%	87%	-11%	60%
Cost of goods sold	4%	-14%	N.A.	-81%	-33%	-49%	-37%	11%
R&D expenses	25%	25%	15%	13%	16%	-4%	9%	30%
Sales and marketing	-30%	-5%	-15%	-20%	10%	-21%	-13%	5%
G&A	6%	2%	13%	14%	4%	19%	12%	6%
Operating expense	9%	1%	8%	40%	10%	0%	13%	16%
Operating Incomes (Losses)	-3%	8%	42%	68%	-8%	-15%	17%	2%
Pretax Income	-1%	-19%	36%	268%	64%	-9%	53%	2%
Net Income	-1%	-19%	36%	268%	64%	-9%	53%	2%
EPS - Basic	-9%	-29%	23%	231%	41%	-14%	34%	-4%
EPS - Diluted	-9%	-29%	23%	231%	41%	-14%	34%	-4%
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Source: Bloomberg LP; Company reports; Laidlaw &amp; Company estimates.

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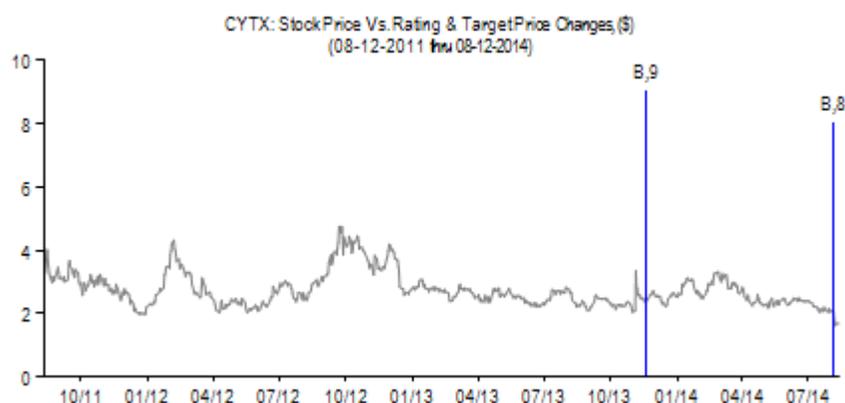
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#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/19/2013	Buy (B)	2.33

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
11/19/2013	9.00	2.33
08/06/2014	8.00	1.79

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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	94.74%	31.58%	10.53%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	5.26%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Mesoblast (MBLY: NR)  
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