

Cytori Therapeutics (CYTX - \$ 2.10)

ATHENA I and II Trial on Clinical Hold Due to Cerebrovascular Events

Yesterday after market close, CYTX reported that the ATHENA and ATHENA II trials were placed on clinical hold and stopped patient enrollment due to a safety review of reported cerebrovascular events. As such, CYTX indicated that the ATHENA I trial will not complete patient enrollment by year-end 2014 as planned.

- Details.** The major reason for the clinical hold is that three patients have experienced symptoms of stroke. Among them, symptoms of two patients were fully resolved within a short period of time, while the third patient has had substantial resolution of symptoms. Such events had not been seen in previously cardiovascular trials. Although it is difficult to speculate the exact reason at the moment, patients enrolled in the ATHENA studies are with severe cardiovascular conditions and potentially with greater co-morbidities. Further, surgical procedure and patient management in Europe (where prior studies were conducted in small number of sites) could be different from those in the U.S. (ATHENA studies are at multiple centers). The company plans to discuss these issues with trial investigating physicians, external experts, and the FDA to potentially find solutions and move the study forward. The specific timeline remains to be determined. Management also indicated that the recently announced NHLBI funded and physician sponsored Phase I study (CELLVAD-ADRC) that evaluates the safety and feasibility of ADRC treatment in end-stage ischemic heart failure patients 60 to 90 days after the placement of LVADs will not be affected.
- Implications.** It is disappointing news given the advancement of the ATHENA studies is one of CYTX share major value drivers. We anticipate greater visibility over the next couple months as the company works through these issues. Other potential value drivers, such as potential China approval (possibly late 2014 or 2015), progress of the BARDA program, additional physician-sponsored clinical studies and improved outlook in Japan remain intact, in our opinion.
- Action.** We reiterate Buy rating but reduce our target price to \$8 from \$9 to reflect the clinical delay of ATHENA studies for ADRCs in no option CMI. 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
FY-14E	-0.14A	-0.15	-0.10	-0.06	-0.45	NM
FY-13A	-0.11	-0.05	-0.08	-0.14	-0.39	NM
FY-12A	-0.16	-0.13	-0.19	-0.06	-0.55	NM
FY-11A	-0.23	-0.10	-0.15	-0.12	-0.61	NM

Source: Company data & Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (08/05/2014)	\$ 2.10
52-Week High (11/5/2013)	\$ 3.93
52-Week Low (11/1/2013)	\$ 2.00
Market Cap. (MM)	\$ 167
Shares Out. (MM)	80

Yale Jen, Ph.D.

Managing Director /
 Senior Biotechnology Analyst
 (212) 953-4978
 yjen@laidlawltd.com

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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
		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 approval in China	Late '14
		Product revenue growth	Quarterly report

Source: Laidlaw & Company estimates and company presentation.

Major Risks

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 perspective 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	2Q14E	3Q14E	4Q14E	2014E	2015E
Sales to related party	9							
Sales to third parties	8,708	7,122	1,031	2,214	1,838	8,676	13,760	18,575
Product revenues	8,709	7,122	1,031	2,214	1,838	8,676	13,760	18,575
BARDA revenue	360	3,257	403	359	3,622	3,622	8,006	14,489
Development, related party	2,882	638	-	-	-	-	0	0
Development	2,529	1,179	-	-	-	-	0	0
Research grant and other	21	0	-	-	-	-	0	0
Development revenues	5,792	5,074	403	359	3,622	3,622	8,006	14,489
Total Revenue	14,501	12,196	1,434	2,573	5,460	12,298	21,766	33,064
Cost of product revenues	4,000	3,421	421	908	754	3,557	5,640	7,616
Gross profit	4,709	3,701	610	1,307	1,084	5,119	8,120	10,959
Research and development	13,628	17,065	4,292	5,794	5,910	6,028	22,025	28,632
Sales and marketing	9,488	9,026	1,928	1,967	1,996	2,076	7,967	8,365
General and administrative	15,672	16,031	4,340	3,575	3,504	3,521	14,941	15,837
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
Operating expense	38,919	39,454	10,560	11,336	11,410	11,626	44,932	52,834
Operating income	(28,418)	(30,679)	(9,547)	(9,671)	(6,703)	(2,885)	(28,805)	(27,386)
Interest income	4	4	2	1	1	1	5	5
Interest expense	(3,386)	(3,396)	(941)	(1,094)	(1,094)	(1,094)	(4,223)	(4,265)
Other income (expense), net	(314)	(438)	86	(300)	250	(250)	(214)	(214)
Gain on Puregraft divestiture		4,453	-	-	-	-	0	0
Equity loss from investment in joint venture	(165)	4,844	0	0	-	-	0	0
Total other income (expense)	(3,861)	4,502	(853)	(1,393)	(843)	(1,343)	(4,432)	(4,474)
Income (loss) before taxes	(32,279)	(26,177)	(10,400)	(11,064)	(7,546)	(4,228)	(33,237)	(31,860)
Income tax expense	-	-	-	-	-	-	-	-
Net income	(32,279)	(26,177)	(10,400)	(11,064)	(7,546)	(4,228)	(33,237)	(31,860)
Net income attributable to common shareholders	(\$32,279)	(\$25,921)	(\$10,450)	(\$11,064)	(\$7,546)	(\$4,228)	(\$33,237)	(\$31,860)
Net Earnings (Losses) Per Share—Basic	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.10)	(\$0.06)	(\$0.45)	(\$0.40)
Net Earnings (Losses) Per Share—Diluted	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.10)	(\$0.06)	(\$0.45)	(\$0.40)
Shares outstanding—basic	58,614	67,781	74,102	74,202	74,302	74,402	74,252	79,252
Shares outstanding—diluted	58,614	67,781	74,102	74,202	74,302	74,402	74,252	79,252
Margin Analysis (% of Sales/Revenue)								
COGS	46%	48%	41%	41%	41%	41%	42%	41%
R&D	94%	140%	299%	225%	108%	49%	101%	87%
S&M	109%	127%	134%	76%	37%	17%	58%	45%
G&A	108%	131%	303%	139%	64%	29%	69%	48%
Operating Income (loss)	-196%	-252%	-666%	-376%	-123%	-23%	-132%	-83%
Pretax	-223%	-215%	-725%	-430%	-138%	-34%	-153%	-96%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-223%	-215%	-725%	-430%	-138%	-34%	-153%	-96%
Financial Indicator Growth Analysis (YoY%)								
Product revenues	9%	-18%	-26%	57%	14%	221%	93%	35%
BARDA revenue	N.A.	805%	-27%	-58%	231%	380%	146%	81%
Total Revenue	45%	-16%	-80%	-82%	45%	442%	78%	52%
Cost of goods sold	4%	-14%	N.A.	-77%	24%	216%	65%	35%
R&D expenses	25%	25%	15%	40%	43%	19%	29%	30%
Sales and marketing	-30%	-5%	-15%	-18%	12%	-19%	-12%	5%
G&A	6%	2%	13%	-12%	-19%	-8%	-7%	6%
Operating expense	9%	1%	8%	41%	11%	2%	14%	18%
Operating Incomes (Losses)	-3%	8%	42%	52%	-21%	-68%	-6%	-5%
Pretax Income	-1%	-19%	36%	245%	44%	-58%	27%	-4%
Net Income	-1%	-19%	36%	245%	44%	-58%	27%	-4%
EPS - Basic	-9%	-29%	23%	220%	27%	-59%	14%	-10%
EPS - Diluted	-9%	-29%	23%	220%	27%	-59%	14%	-10%
Yale Jen, Ph.D. 212-953-4978								

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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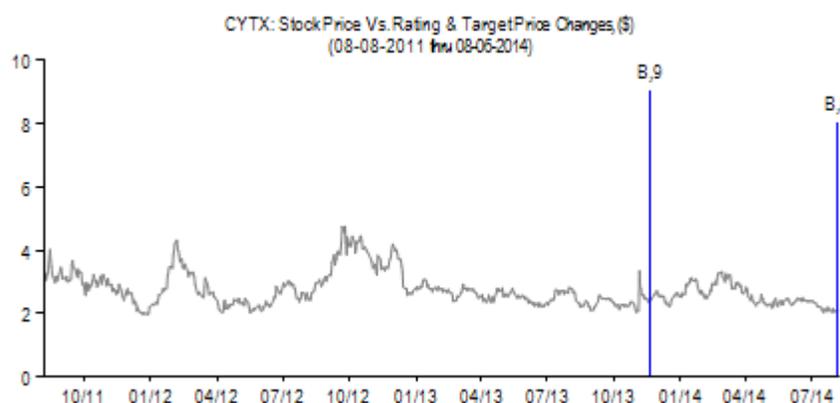
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Rating and Price Target Change History



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	2.10*

* Previous Close 8/5/2014

Source: Laidlaw & Company

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	94.44%	33.33%	11.11%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.56%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Mesoblast (MBLY: NR)
Teva (TEVA: NR)

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