

Cytori Therapeutics (CYTX - \$ 2.26)

BARDA IPR Meeting Date Scheduled on June 10, 2014

CYTX reported this morning that BARDA has scheduled an in-process review (IPR) meeting on June 10, 2014 to review the company's further development of the next-generation Celution System in thermal burn injury under the terms of Contract Option 1.

- Details.** The determination to award the second funding for advancing Celution System in thermal burn injury development is by BARDA's satisfaction that the company has successfully accomplished the prior Phase I proof-of-concept developments. Key objectives of the Phase I studies include: 1) validation of core design elements of the next generation Celution System; 2) demonstration that Cytori's therapeutic cell population can be obtained from patients with burn injury; and 3) demonstration of cell therapy efficacy in a preclinical thermal burn model with concomitant radiation exposure. If the IPR meeting review outcome is favorable. Cytori and BARDA will further fine-tune the statement of work and business proposal and proceed to funding and execution. The potential funding for Option 1 could reach \$32.6MM.
- Implications.** In addition to the ongoing ATHENA studies and potential topline data releases in 1Q15 and beyond, the BARDA decision is a very important near-term catalyst for CYTX shares. Should the company receive the funding and successfully complete the studies under Option 1 to further advance the Celution System in thermal burn injury, CYTX is eligible for an Option 2 funding possibly in late 2015 or early 2016, which is potentially worth up to \$45.5MM. In addition, an Option 3 exists which enable BARDA, under the agency's discretion, to commercially acquire the next-generation Celution System as part of the bio-defense preparation. Option 3 could worth up to \$23.4MM and the company intends to pursue it late this year or in 2015.
- Action.** We reiterate our Buy rating and our \$9 target price based on our peer comparison valuation methodology and by our risk-adjusted cash flow sum-of-the-parts analysis. Our recommendation is based on Celution revenue growth and an encouraging outlook for ADRCs in no option CMI.

Healthcare/Biotechnology

Ticker: **CYTX**
Rating: **Buy**
Price Target: **\$ 9.00**

Trading Data:

Last Price (05/05/2014)	\$ 2.26
52-Week High (11/5/2013)	\$ 3.93
52-Week Low (11/1/2013)	\$ 2.00
Market Cap. (MM)	\$ 171
Shares Out. (MM)	75

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.13	-0.11	-0.11	-0.06	-0.42	NM
FY-13AA	-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

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Source: Company data & Laidlaw & Company estimates

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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	2 /3Q14
		Potential releases data of ATHENA clinical study	4Q14
		Potential completion of patient recruitment of the ATHENA II clinical study	1Q15
		Potential releases data of ATHENA II clinical study	2H15
		Potential commence a pivotal study	2015
	Thermal burns	Potentially to conduct an in-process review (IPR) meeting with BARDA	June 10, '14
		Potentially to receive a contract from BARDA	2Q14
	Hamstring injury	Potential commence an exploratorrr 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	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E
Sales to related party	9							
Sales to third parties	8,708	7,122	3,166	2,501	2,076	9,552	17,295	23,348
Product revenues	8,709	7,122	3,166	2,501	2,076	9,552	17,295	23,348
BARDA revenue	360	3,257	490	4,667	4,667	4,667	14,490	18,667
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	490	4,667	4,667	4,667	14,490	18,667
Total Revenue	14,501	12,196	3,656	7,168	6,743	14,219	31,785	42,015
Cost of product revenues	4,000	3,421	1,298	1,025	851	3,916	7,091	9,573
Gross profit	4,709	3,701	1,868	1,476	1,225	5,636	10,204	13,776
Research and development	13,628	17,065	4,717	6,604	6,736	6,871	24,927	32,405
Sales and marketing	9,488	9,026	2,599	2,651	2,690	2,798	10,738	11,275
General and administrative	15,672	16,031	3,883	3,922	3,844	3,863	15,511	16,442
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	11,199	13,176	13,270	13,531	51,176	60,122
Operating income	(28,418)	(30,679)	(8,841)	(7,034)	(7,378)	(3,229)	(26,482)	(27,680)
Interest income	4	4	1	1	1	1	4	4
Interest expense	(3,386)	(3,396)	(1,094)	(1,094)	(1,094)	(1,094)	(4,376)	(4,420)
Other income (expense), net	(314)	(438)	350	(300)	250	(250)	50	50
Gain on Puregraft divestiture		4,453	-	-	-	-	0	0
Equity loss from investment in joint venture	(165)	4,844	0	-	-	-	0	0
Total other income (expense)	(3,861)	4,502	(743)	(1,393)	(843)	(1,343)	(4,322)	(4,366)
Income (loss) before taxes	(32,279)	(26,177)	(9,584)	(8,427)	(8,221)	(4,572)	(30,804)	(32,046)
Income tax expense	-	-	-	-	-	-	-	-
Net income	(32,279)	(26,177)	(9,584)	(8,427)	(8,221)	(4,572)	(30,804)	(32,046)
Net income attributable to common shareholders	(\$32,279)	(\$25,921)	(\$9,584)	(\$8,427)	(\$8,221)	(\$4,572)	(\$30,804)	(\$32,046)
Net Earnings (Losses) Per Share—Basic	(\$0.55)	(\$0.39)	(\$0.13)	(\$0.11)	(\$0.11)	(\$0.06)	(\$0.42)	(\$0.41)
Net Earnings (Losses) Per Share—Diluted	(\$0.55)	(\$0.39)	(\$0.13)	(\$0.11)	(\$0.11)	(\$0.06)	(\$0.42)	(\$0.41)
Shares outstanding—basic	58,614	67,781	73,762	73,862	73,962	74,062	73,912	78,912
Shares outstanding—diluted	58,614	67,781	73,762	73,862	73,962	74,062	73,912	78,912
Margin Analysis (% of Sales/Revenue)								
COGS	46%	48%	41%	41%	41%	41%	42%	41%
R&D	94%	140%	129%	92%	100%	48%	78%	77%
S&M	109%	127%	71%	37%	40%	20%	62%	48%
G&A	108%	131%	106%	55%	57%	27%	49%	39%
Operating Income (loss)	-196%	-252%	-242%	-98%	-109%	-23%	-83%	-66%
Pretax	-223%	-215%	-262%	-118%	-122%	-32%	-97%	-76%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-223%	-215%	-262%	-118%	-122%	-32%	-97%	-76%
Financial Indicator Growth Analysis (YoY%)								
Product revenues	9%	-18%	127%	78%	28%	253%	143%	35%
BARDA revenue	N.A.	805%	-11%	443%	326%	519%	345%	29%
Total Revenue	45%	-16%	-50%	-51%	79%	527%	161%	32%
Cost of goods sold	4%	-14%	N.A.	-74%	40%	248%	107%	35%
R&D expenses	25%	25%	27%	59%	63%	35%	46%	30%
Sales and marketing	-30%	-5%	15%	10%	51%	9%	19%	5%
G&A	6%	2%	1%	-3%	-11%	1%	-3%	6%
Operating expense	9%	1%	15%	64%	30%	18%	30%	17%
Operating Incomes (Losses)	-3%	8%	31%	11%	-13%	-65%	-14%	5%
Pretax Income	-1%	-19%	25%	162%	56%	-54%	18%	4%
Net Income	-1%	-19%	25%	162%	56%	-54%	18%	4%
EPS - Basic	-9%	-29%	14%	145%	39%	-55%	6%	-3%
EPS - Diluted	-9%	-29%	14%	145%	39%	-55%	6%	-3%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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

Date	Target Price (\$)	Closing Price, (\$)
11/19/2013	9.00	2.33

Source: Laidlaw & Company

Created by: Blue-Compass.net

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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.	81.25%	31.25%	12.50%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.25%	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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