

Cytori Therapeutics (CYTX - \$ 1.64)

BARDA Contract Worth \$12.1MM Plus Additional \$8.3MM After FDA Approval of IDE Trial

This morning, CYTX provided details of its Option 1 BARDA contract, which includes the current pre-clinical study extension of ~\$12.1MM; and additional funding of \$8.3MM if FDA approved an Investigational Device Exemption (IDE) for clinical study.

- Details.** CYTX announced this morning details of the BARDA Option 1 contract. The \$12.1MM portion of the funding is to support: 1) additional R&D activities required to enable a pilot clinical trial in thermal burn, specifically, potentially to gain an approval by the FDA for an IDE; and 2) up to 2 years of preclinical studies in other burn-related areas that could lead to broadening of the utility of ADRC therapy to more general burn centers and in wound healing. The \$8.3MM funding is to cover costs associated with the clinical trial. In addition, the initially proposed possible funding of \$45MM (Option 2) and \$23MM (Option 3) for pivotal clinical trials and additional work in thermal burn complicated by radiation exposure remains intact.
- Implications.** The announcement of the actual BARDA's Option 1 portion of the funding affords the visibility of the company's development path in thermal burn over the next two years. Although the figure is smaller than the "up to \$32.6MM" suggested a while ago, we believe the current potential \$20.4MM funding reflects the actual expenditure needed to accomplish the current goals. Further, additional pre-clinical studies potentially broaden the scope beyond thermal burn, and could be an upside if successful. In addition, we believe the success of the next generation Celution system would be critical to move the development forward as it may afford a smaller and more cost-effective system, instead of the current research-driven designed version. We estimate the completion of the next generation Celution could be achieved in early 2015.
- Action.** We have adjusted our P&L model slightly to reflect the just announced funding revenue from BARDA, and reiterate our Buy rating and \$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. Our recommendation is based on Celution revenue growth and an encouraging outlook for ADRCs in no option CMI.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.14A	-0.15A	-0.13	-0.14	-0.56	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:	\$ 8.00

Trading Data:

Last Price (08/19/2014)	\$ 1.64
52-Week High (11/5/2013)	\$ 3.93
52-Week Low (8/6/2014)	\$ 1.46
Market Cap. (MM)	\$ 131
Shares Out. (MM)	80

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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
		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
	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

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	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
Product revenues	8,709	7,122	1,031	935	1,000	1,401	4,367	5,896
BARDA revenue	360	3,257	403	359	1,344	1,344	3,451	8,144
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	356	1,344	1,344	3,451	8,144
Total Revenue	14,501	12,196	1,434	1,291	2,345	2,745	7,818	14,040
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
Operating expense	38,919	39,454	10,560	11,210	11,240	11,437	44,447	51,499
Operating income	(28,418)	(30,679)	(9,547)	(10,685)	(9,306)	(9,266)	(38,801)	(39,876)
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)
Income (loss) before taxes	(32,279)	(26,177)	(10,400)	(11,828)	(10,149)	(10,609)	(42,982)	(44,099)
Income tax expense	-	-	-	-	-	-	-	-
Net income	(32,279)	(26,177)	(10,400)	(11,828)	(10,149)	(10,609)	(42,982)	(44,099)
Net income attributable to common shareholders	(\$32,279)	(\$25,921)	(\$10,450)	(\$11,828)	(\$10,149)	(\$10,609)	(\$42,982)	(\$44,099)
Net Earnings (Losses) Per Share—Basic	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.13)	(\$0.14)	(\$0.56)	(\$0.54)
Net Earnings (Losses) Per Share—Diluted	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.13)	(\$0.14)	(\$0.56)	(\$0.54)
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
Margin Analysis (% of Sales/Revenue)								
COGS	46%	48%	41%	82%	41%	41%	42%	41%
R&D	94%	140%	299%	362%	203%	177%	238%	172%
S&M	109%	127%	134%	150%	84%	74%	180%	140%
G&A	108%	131%	303%	356%	192%	165%	230%	136%
Operating Income (loss)	-196%	-252%	-666%	-828%	-397%	-338%	-496%	-284%
Pretax	-223%	-215%	-725%	-916%	-433%	-386%	-550%	-314%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-223%	-215%	-725%	-916%	-433%	-386%	-550%	-314%
Financial Indicator Growth Analysis (YoY%)								
Product revenues	9%	-18%	-26%	-34%	-38%	-48%	-39%	35%
BARDA revenue	N.A.	805%	-27%	-58%	23%	78%	6%	136%
Total Revenue	45%	-16%	-80%	-91%	-38%	21%	-36%	80%
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%	10%	2%	26%	3%
Pretax Income	-1%	-19%	36%	268%	93%	6%	64%	3%
Net Income	-1%	-19%	36%	268%	93%	6%	64%	3%
EPS - Basic	-9%	-29%	23%	231%	66%	0%	44%	-4%
EPS - Diluted	-9%	-29%	23%	231%	66%	0%	44%	-4%

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

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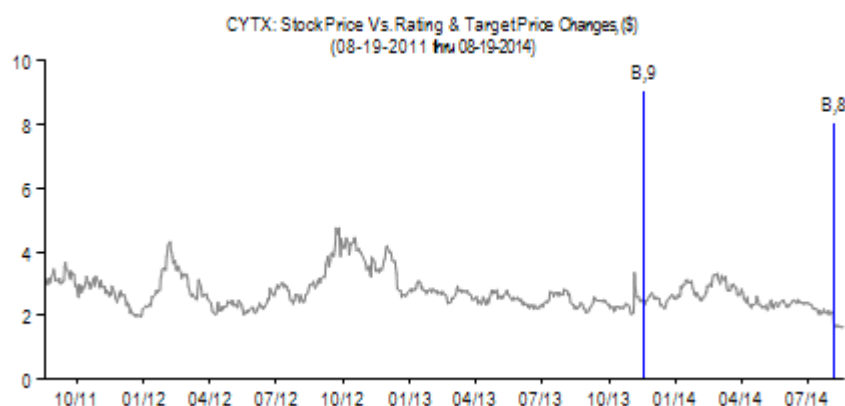
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Source: Laidlaw & Company

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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
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.	94.74%	31.58%	10.53%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.26%	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)
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