

## Cytori Therapeutics (CYTX - \$ 2.49)

### 1Q14 – BARDA Decision is the Near-Term Major Catalyst

Yesterday after market close, CYTX reported 1Q14 financial results with a net loss of (\$10.5MM), slightly worse than Laidlaw (\$9.6MM) and in-line with the Street estimate of (\$10.4MM). Net loss per share equaled (\$0.14) vs. (\$0.13) and (\$0.14) for Laidlaw and the Street, respectively. CYTX ended the 1Q14 with cash of \$12.8MM and \$3.6MM A/R, sufficient for operations into late 2014, in our opinion.

- **Next phase BARDA contract decision in late 2Q14.** With the completion of the first phase study for thermal burns and the IPR meeting scheduled on June 10, 2014, a decision by BARDA for granting the next Option I contract potentially worth up to \$32.6MM could be made in late 2Q14. A positive outcome would be a major catalyst for CYTX shares, in our view.
- **Update on ATHENA trial developments.** CYTX updated on ATHENA Phase II clinical study as 8/10 approved sites have initiated patient enrollment. Based on the current recruitment pace of 0.5 patient/site/month, management estimated potential patient recruitment completion (n=45) in 4Q14 with topline data possibly in mid- or 3Q15. Patient recruitment of the ATHENA II study is limited to one site currently and is expected to accelerate once patient recruitment of the ATHENA trial is completed. The ATHENA II study is expected to include 12 sites.
- **Ex-U.S. Celution commercialization continues.** Partner Lorem Vascular has already started to purchase Celution for commercialization in Southeast Asian markets in 4Q13. If potential approval in China occurs in late 2014, we believe more substantial sales growth might start in 2015.
- **Additional clinical developments.** Some Celution users are conducting clinical studies in different indications and, if successful, could provide incremental upside for Celution commercialization in new indications going forward.
- **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.

### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-14E</b>	-0.14A	-0.09	-0.09	-0.04	-0.36	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

Source: Company data & Laidlaw & Company estimates

Healthcare/Biotechnology

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

### Trading Data:

Last Price (05/12/2014)	\$ 2.49
52-Week High (11/5/2013)	\$ 3.93
52-Week Low (11/1/2013)	\$ 2.00
Market Cap. (MM)	\$ 188
Shares Out. (MM)	75

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- Although 1Q14 product revenue was lower than our and consensus estimates, we believe part of the reason is it has taken a longer time to recognize product shipments (\$3.6MM) that occurred in 4Q13 to customers, mainly in Japan. As such, we have modeled additional revenue recognition of the remaining \$3.6MM revenue in 2Q14.
- Some Celution users are conducting clinical studies in different indications, which include: 1) stress urinary incontinence in Japan (with n=11 and additional added patients after recent publication); 2) anterior cruciate ligament (ACL) repair in Spain (with n=20 and patient recruitment completion expected in 2H14); and 3) scleroderma related sclerodactyly in France (with n=12 and data are submitted for publication). If successful, the positive data could provide incremental upside for Celution commercialization in new indications going forward. If so, CYTX can identify a path for commercialization, and could also provide more support on selected developments.
- Cytori indicated that the company expects to raise additional cash (~\$25MM) in the near term to meet both operating and debt obligations potentially from financial and strategic sources.

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

<b>Table 1:1Q14 Estimates and Reported Results</b>			
<b>(\$ MM)</b>	<b>Laidlaw Estimate</b>	<b>Actual</b>	<b>Consensus</b>
<b>Total revenue</b>	<b>\$3.7</b>	<b>\$1.4</b>	<b>\$2.9</b>
<b>Total op. profit (loss)</b>	<b>(\$8.8)</b>	<b>(\$9.5)</b>	
R&D	\$4.7	\$4.3	
SG&A	\$6.5	\$6.3	
<b>EPS</b>	<b>(\$0.13)</b>	<b>(\$0.14)</b>	<b>(\$0.14)</b>
Net income (loss)	(\$9.6)	(\$10.5)	(\$10.4)

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
		Potential completion of patient recruitment of the ATHENA clinical study	4Q14
		Potential releases data of ATHENA clinical study	1H15
		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	2Q / 3Q14
	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

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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 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
<b>Product revenues</b>	<b>8,709</b>	<b>7,122</b>	<b>1,031</b>	<b>2,214</b>	<b>1,838</b>	<b>8,676</b>	<b>13,760</b>	<b>18,575</b>
BARDA revenue	360	3,257	403	4,667	4,667	4,667	14,403	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
<b>Development revenues</b>	<b>5,792</b>	<b>5,074</b>	<b>403</b>	<b>4,667</b>	<b>4,667</b>	<b>4,667</b>	<b>14,403</b>	<b>18,667</b>
<b>Total Revenue</b>	<b>14,501</b>	<b>12,196</b>	<b>1,434</b>	<b>6,881</b>	<b>6,505</b>	<b>13,343</b>	<b>28,163</b>	<b>37,242</b>
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
<b>Operating expense</b>	<b>38,919</b>	<b>39,454</b>	<b>10,560</b>	<b>11,336</b>	<b>11,410</b>	<b>11,626</b>	<b>44,932</b>	<b>52,834</b>
<b>Operating income</b>	<b>(28,418)</b>	<b>(30,679)</b>	<b>(9,547)</b>	<b>(5,363)</b>	<b>(5,659)</b>	<b>(1,840)</b>	<b>(22,409)</b>	<b>(23,208)</b>
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)
<b>Income (loss) before taxes</b>	<b>(32,279)</b>	<b>(26,177)</b>	<b>(10,400)</b>	<b>(6,756)</b>	<b>(6,502)</b>	<b>(3,183)</b>	<b>(26,841)</b>	<b>(27,682)</b>
Income tax expense	-	-	-	-	-	-	-	-
<b>Net income</b>	<b>(32,279)</b>	<b>(26,177)</b>	<b>(10,400)</b>	<b>(6,756)</b>	<b>(6,502)</b>	<b>(3,183)</b>	<b>(26,841)</b>	<b>(27,682)</b>
<b>Net income attributable to common shareholders</b>	<b>(\$32,279)</b>	<b>(\$25,921)</b>	<b>(\$10,450)</b>	<b>(\$6,756)</b>	<b>(\$6,502)</b>	<b>(\$3,183)</b>	<b>(\$26,841)</b>	<b>(\$27,682)</b>
Net Earnings (Losses) Per Share—Basic	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.09)	(\$0.09)	(\$0.04)	(\$0.36)	(\$0.35)
Net Earnings (Losses) Per Share—Diluted	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.09)	(\$0.09)	(\$0.04)	(\$0.36)	(\$0.35)
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
<b>Margin Analysis (% of Sales/Revenue)</b>								
COGS	46%	48%	41%	41%	41%	41%	42%	41%
R&D	94%	140%	299%	84%	91%	45%	78%	77%
S&M	109%	127%	134%	29%	31%	16%	58%	45%
G&A	108%	131%	303%	52%	54%	26%	53%	43%
Operating Income (loss)	-196%	-252%	-666%	-78%	-87%	-14%	-80%	-62%
Pretax	-223%	-215%	-725%	-98%	-100%	-24%	-95%	-74%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-223%	-215%	-725%	-98%	-100%	-24%	-95%	-74%
<b>Financial Indicator Growth Analysis (YoY%)</b>								
Product revenues	9%	-18%	-26%	57%	14%	221%	93%	35%
BARDA revenue	N.A.	805%	-27%	443%	326%	519%	342%	30%
Total Revenue	45%	-16%	-80%	-53%	73%	489%	131%	32%
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%	-16%	-33%	-80%	-27%	4%
Pretax Income	-1%	-19%	36%	110%	24%	-68%	3%	3%
Net Income	-1%	-19%	36%	110%	24%	-68%	3%	3%
EPS - Basic	-9%	-29%	23%	95%	10%	-69%	-8%	-3%
EPS - Diluted	-9%	-29%	23%	95%	10%	-69%	-8%	-3%

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

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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

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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.	92.86%	35.71%	14.29%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	7.14%	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%

### ADDITIONAL COMPANIES MENTIONED

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

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