

Cytori Therapeutics (CYTX - \$ 1.37)

Celution System Receives Regulatory Clearance in China by the CFDA

This morning, CYTX reported that the Chinese regulatory agency, CFDA, has granted regulatory clearance for the Celution system to the company's exclusive licensee, Lorem Vascular.

- Details.** This morning, CYTX reported that Lorem Vascular, its exclusive licensee in China and several Southeast Asian countries, has received regulatory clearance by the CFDA for the Celution system. Lorem Vascular will start to commercialize the Celution system in China and has begun to consummate partnerships with key hospitals throughout China. As a reminder, CYTX formed the collaboration with Beijing-based Lorem Vascular in 4Q13 for a 30-year exclusive license. According to the deal terms, Lorem Vascular plans to purchase 23 Celution devices and 1,100 Celution consumable sets (in total, they could worth \$5MM in our estimate) upon regulatory approval in China. In addition, Lorem Vascular has committed to purchase a minimum of 50 Celution devices and consumable sets annually for the next three years. Further, CYTX is entitled to receive up to \$500MM in license fees during the 30-year exclusivity period. The license fee is payable after Lorem Vascular has achieved a gross revenue of \$50MM; and CYTX expects to receive a \$10MM payment at each \$50MM revenue growth increment. CYTX is also entitled to 30% royalties on gross profits from Lorem's operations in China, Malaysia, and Hong Kong.
- Implications.** We view the Celution system approval in China as a positive milestone in CYTX's commercial advancement. Given the large, increasingly affluent, and much more health conscious Chinese market, the commercial potential of Celution system for treating vascular and non-vascular indications in this region could be very significant over the long term. The terms of the license fee and royalties to CYTX are favorable, in our view, especially if Lorem can aggressively and successfully market the Celution system in China.
- Action.** We reiterate our Buy rating and \$4 target price to reflect the realignment of CYTX's pipeline development. We are encouraged by the potential of the ECCO-50 treatment modality under a lean and focused operation. Our valuation is based on our peer comparison valuation methodology and by our risk-adjusted cash flow sum-of-the-parts analysis.

Healthcare/Biotechnology

Ticker:	CYTX
Rating:	Buy
Price Target:	\$ 4.00

Trading Data:

Last Price (04/06/2015)	\$ 1.37
52-Week High (4/22/2014)	\$ 2.63
52-Week Low (11/12/2014)	\$ 0.36
Market Cap. (MM)	\$ 156
Shares Out. (MM)	108

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.07	-0.07	-0.06	-0.07	-0.27	NM
FY-14A	-0.14	-0.15	-0.12	-0.08	-0.48	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

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Source: Company data & Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Program	Indication	Event	Timing
ECCO-50	Osteoarthritis	Potentially report exploratory study result	1H16
	Thermal Burn & Radiation Injury	Potential IDE filing approval	Mid-15
	Scleroderma	Start SCLERADEC II trial in France	2015
		Start STAR trial in the U.S.	Mid-15
	Urinary Incontinence	Start Phase III trial in Japan (Nagoya University)	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 earlier clinical 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 STAR pivotal trial that evaluate ECCO-50 as a potential treatment for impaired hand function in scleroderma. Given that the substantial upside potential for CYTX shares is currently based on the success of the STAR, SCLERADEC II and other studies, a failed study outcome or/and an unsuccessful approval application would have a significant negative impact on CYTX share value.

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	3Q14	4Q14	2014	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Sales to related party	9												
Sales to third parties	8,708	7,122	1,031	935	518	2,469	4,953	1,926	1,752	1,577	1,845	7,101	10,296
Product revenues	8,709	7,122	1,031	935	518	2,469	4,953	1,926	1,752	1,577	1,845	7,101	10,296
BARDA revenue	360	3,257	403	359	585	1,301	2,645	1,294	1,294	2,578	2,578	7,744	9,681
Development, related party	2,882	638	-	-	-	-	0	-	-	-	-	0	0
Development	2,529	1,179	-	-	-	-	0	-	-	-	-	0	0
Research grant and other	21	0	-	-	-	-	0	-	-	-	-	0	0
Development revenues	5,792	5,074	403	356	585	1,301	2,645	1,294	1,294	2,578	2,578	7,744	9,681
Total Revenue	14,501	12,196	1,434	1,291	1,103	3,770	7,598	3,220	3,047	4,155	4,423	14,845	19,977
Cost of product revenues	4,000	3,421	421	766	337	1,416	2,940	1,040	911	789	886	3,626	4,427
Gross profit	4,709	3,701	610	169	181	1,053	2,013	886	841	789	960	3,475	5,869
Research and development	13,628	17,065	4,292	4,674	3,140	2,999	15,105	3,299	3,860	4,516	5,013	16,687	18,356
Sales and marketing	9,488	9,026	1,928	1,934	1,471	1,074	6,407	1,128	1,162	1,185	1,197	4,671	4,437
General and administrative	15,672	16,031	4,340	4,602	4,179	2,831	15,952	2,774	2,885	2,943	3,031	11,634	11,401
Change in fair value of warrant liability	(209)	(418)	0	0	(134)	(235)	(369)	(200)	(190)	(190)	(190)	(770)	(770)
Change in fair value of option liability	340	(2,250)	0	0	0	0	0	0	0	0	0	0	0
Operating expense	38,919	39,454	10,560	11,210	8,656	6,669	37,095	7,001	7,717	8,454	9,051	32,222	33,424
Operating income	(28,418)	(30,679)	(9,547)	(10,685)	(7,890)	(4,315)	(32,437)	(4,821)	(5,581)	(5,087)	(5,513)	(21,002)	(17,875)
Interest income	4	4	2	1	1	2	6	2	2	2	2	6	6
Interest expense	(3,386)	(3,396)	(941)	(1,085)	(1,260)	(1,086)	(4,372)	(1,086)	(1,086)	(1,086)	(1,086)	(4,344)	(4,387)
Other income (expense), net	(314)	(438)	86	(58)	(222)	(413)	(607)	(300)	(250)	(100)	(120)	(770)	(770)
Gain on Puregrat divestiture	-	4,453	-	-	-	-	0	-	-	-	-	0	0
Equity loss from investment in joint venture	(165)	4,844	-	-	-	-	0	-	-	-	-	0	0
Total other income (expense)	(3,861)	4,502	(853)	(1,143)	(1,495)	(1,440)	(4,931)	(1,385)	(1,335)	(1,185)	(1,205)	(5,108)	(5,151)
Income (loss) before taxes	(32,279)	(26,177)	(10,400)	(11,828)	(9,385)	(5,755)	(37,368)	(6,205)	(6,915)	(6,272)	(6,718)	(26,110)	(23,026)
Income tax expense	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income	(32,279)	(26,177)	(10,400)	(11,828)	(9,385)	(6,924)	(38,537)	(6,205)	(6,915)	(6,272)	(6,718)	(26,110)	(23,026)
Net income attributable to common shareholders	(32,279)	(25,921)	(\$10,450)	(\$11,828)	(\$9,327)	(\$6,924)	(\$38,537)	(\$6,205)	(\$6,915)	(\$6,272)	(\$6,718)	(\$26,110)	(\$23,026)
Net Earnings (Losses) Per Share—Basic	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.12)	(\$0.08)	(\$0.48)	(\$0.07)	(\$0.07)	(\$0.06)	(\$0.07)	(\$0.27)	(\$0.22)
Net Earnings (Losses) Per Share—Diluted	(\$0.55)	(\$0.39)	(\$0.14)	(\$0.15)	(\$0.12)	(\$0.08)	(\$0.48)	(\$0.07)	(\$0.07)	(\$0.06)	(\$0.07)	(\$0.27)	(\$0.22)
Shares outstanding—basic	58,614	67,781	74,102	76,683	80,430	91,926	80,831	93,926	95,926	97,926	99,926	96,926	103,926
Shares outstanding—diluted	58,614	67,781	74,102	76,683	80,430	91,926	80,831	93,926	95,926	97,926	99,926	96,926	103,926
Margin Analysis (% of Sales/Revenue)													
COGS	46%	48%	41%	82%	65%	57%	59%	54%	52%	50%	48%	51%	43%
R&D	94%	140%	299%	362%	285%	80%	199%	102%	127%	109%	113%	112%	92%
S&M	109%	127%	134%	150%	133%	28%	129%	35%	38%	29%	27%	66%	43%
G&A	108%	131%	303%	356%	379%	75%	210%	86%	95%	71%	69%	78%	57%
Operating Income (loss)	-196%	-252%	-666%	-828%	-715%	-114%	-427%	-150%	-183%	-122%	-125%	-141%	-89%
Pretax	-223%	-215%	-725%	-916%	-851%	-153%	-492%	-193%	-227%	-151%	-152%	-176%	-115%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-223%	-215%	-725%	-916%	-851%	-184%	-507%	-193%	-227%	-151%	-152%	-176%	-115%
Financial Indicator Growth Analysis (YoY%)													
Product revenues	9%	-18%	-26%	-34%	-68%	-9%	-30%	87%	87%	204%	-25%	43%	45%
BARDA revenue	N.A.	805%	-27%	-58%	-47%	73%	-19%	221%	261%	341%	98%	193%	648%
Total Revenue	45%	-16%	-80%	-91%	-71%	66%	-38%	-7%	-75%	190%	243%	95%	520%
Cost of goods sold	4%	-14%	N.A.	-81%	-45%	26%	-14%	N.A.	-73%	3%	-37%	23%	326%
R&D expenses	25%	25%	15%	13%	-24%	-41%	-11%	-23%	-17%	44%	67%	10%	10%
Sales and marketing	-30%	-5%	-15%	-20%	-18%	-58%	-29%	-42%	-40%	-19%	11%	-27%	-5%
G&A	6%	2%	13%	14%	-4%	-26%	0%	-36%	-37%	-30%	7%	-27%	-2%
Operating expense	9%	1%	8%	40%	-15%	-42%	-6%	-34%	-31%	-2%	36%	-13%	377%
Operating Incomes (Losses)	-3%	8%	42%	68%	-7%	-53%	6%	-50%	-48%	-36%	28%	-35%	271%
Pretax Income	-1%	-19%	36%	268%	78%	-43%	43%	-40%	-42%	-33%	17%	-30%	271%
Net Income	-1%	-19%	36%	268%	78%	-31%	47%	-40%	-42%	-33%	-3%	-32%	271%
EPS - Basic	-9%	-29%	23%	231%	46%	-46%	21%	-53%	-53%	-45%	-11%	-43%	235%
EPS - Diluted	-9%	-29%	23%	231%	46%	-46%	21%	-53%	-53%	-45%	-11%	-43%	235%

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

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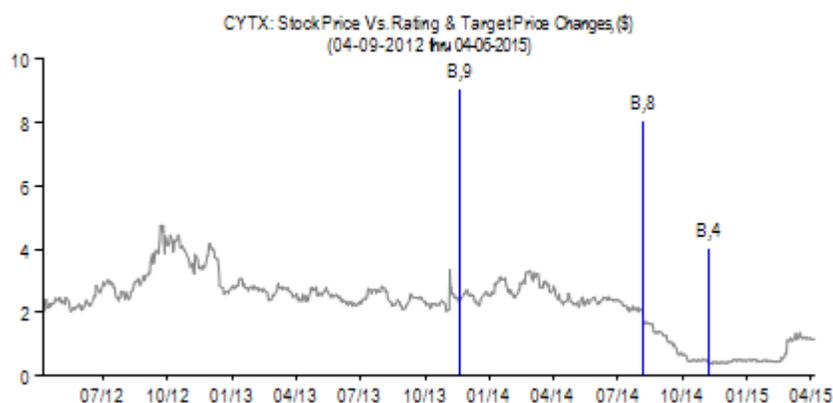
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3 Year Rating Change History

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
11/07/2014	4.00	0.43

Source: Laidlaw & Company

Created by: Blue-Compass.net

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Buy (B)	Expected to outperform the sector average over 12 months.	68.18%	31.82%	9.09%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.55%	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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Baxter (BAX: Not Rated)
Mesoblast (MBLTY: Not Rated)
Teva (TEVA: Not Rated)

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