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EQUITY RESEARCH
Company Report

December 10, 2014

Cytori Therapeutics (CYTX - $ 0.52)

Healthcare/Biotechnology

Conditional Approval by the FDA to Conduct Clinical Trial for Impaired Hand Function in Scleroderma

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

CYTX reported this morning that the FDA has granted conditional approval for an Investigational Device Exemption (IDE) for a pivotal clinical trial (STAR) evaluating the Celution System as a potential treatment for impaired hand and finger function in scleroderma.

- **Details.** The STAR study is a randomized, double blind, placebo-controlled, 80-patient pivotal clinical trial (up to 12 U.S. clinical sites). Patients are expected to receive a single administration of adipose-derived regenerative cells (ADRC) for the evaluation of safety and efficacy. The primary endpoint is Cochin Hand Function Scale measured six months after the initial treatment. After completing 12 months of follow up, patients of the placebo group could crossover to the treatment group. CYTX expects to provide more details on the study next January during the JPM healthcare conference. Patient enrollment is expected to start in 2015. According to CYTX, scleroderma affecting the hand and fingers is a rare autoimmune disease with approximately 50,000 patients in the U.S. Pathological manifestations of the disorder include chronic pain, blood flow changes and severe dysfunction, with mainly palliative symptom treatments available.
- **Implications.** The advancement of ADRC in scleroderma affecting hand and fingers in the U.S. is one of the major CYTX initiatives, in our view; for placing more clinical developments in indications that could be more cost-effective and potentially reach Phase II results more rapidly. The encouraging results from an earlier open-label pilot trial (SCLERADEC-I) demonstrating ADRC provided an average of 50% improvement across four endpoints at six months might bode well for potential success of STAR trial. Should the STAR trial outcome be positive, CYTX could apply for premarket authorization (PMA) of the Celution System in the U.S. A second French-based scleroderma Phase II study (SCLERADEC II with n=40) will also start in 2015. Further, we also view the two recent Japanese regenerative medicine laws could potentially provide a tailwind for expanding Celution System revenue longer term. Under the law, Celution System is under Class I device regulations as the lowest risk category (Tier 3). As such, it could streamline approval and boost clinical use of ADRC.
- **Action.** We reiterate our Buy rating and $4 target price to reflect the realignment of CYTX's pipeline development. We remain encouraged by the potential of the ADRC treatment modality under a lean and focused operation by new management. Our valuation is based on our peer comparison valuation methodology and by our risk-adjusted cash flow sum-of-the-parts analysis.

Trading Data:

Last Price (12/10/2014)	$ 0.52
52–Week High (2/21/2014)	$ 3.47
52–Week Low (11/12/2014)	$ 0.36
Market Cap. (MM)	$ 48
Shares Out. (MM)	92

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.14A	-0.15A	-0.12A	-0.08	-0.49	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

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Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing
Celution	No-option chronic myocardial ischemia	Potentially report ATHENA clinical study results (n=31) and decision on next step	**1Q15**
		Potential completion of next generation Celution system	**Mid-15**
	Osteoarthritis	Potentially commence an exploratorr study	**1Q15**
		Potentially report exploratorr 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.	**2015**
	Urinary Incontinence	Start Phase III trial in Japan (Nagoya University)	**2015**
		Potential to improvisation of new law in Japan	**Late '14**
	China commercialization	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.

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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 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.

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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.

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Figure 1: Income Statement

Cytori Therapeutics, Inc. – Income Statement

('000 $)	2012	2013	1Q14	2Q14	3Q14	4Q14E	2014E	2015E
Sales to related party	9							
Sales to third parties	8,708	7,122	1,031	935	518	1,865	4,349	5,871
Product revenues	8,709	7,122	1,031	935	518	1,865	4,349	5,871
BARDA revenue	360	3,257	403	359	585	1,344	2,691	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	585	1,344	2,691	8,144
Total Revenue	**14,501**	**12,196**	**1,434**	**1,291**	**1,103**	**3,209**	**7,040**	**14,015**
Cost of product revenues	4,000	3,421	421	766	337	765	2,289	2,407
Gross profit	4,709	3,701	610	169	181	1,100	2,060	3,464
Research and development	13,628	17,065	4,292	4,674	3,140	2,763	14,869	16,356
Sales and marketing	9,488	9,026	1,928	1,934	1,471	1,192	6,525	6,198
General and administrative	15,672	16,031	4,340	4,602	4,179	3,845	16,966	16,626
Change in fair value of warrant liability	(209)	(418)	0	0	(134)	0	(134)	0
Change in fair value of option liability	340	(2,250)	0	0	0	0	0	0
Operaing expense	38,919	39,454	10,560	11,210	8,656	7,799	38,225	39,181
Operating income	(28,418)	(30,679)	(9,547)	(10,685)	(7,890)	(5,355)	(33,474)	(27,573)
Interest income	4	4	2	1	1	1	5	5
Interest expense	(3,386)	(3,396)	(941)	(1,085)	(1,260)	(1,094)	(4,380)	(4,424)
Other income (expense), net	(314)	(438)	86	(58)	(222)	(250)	(444)	(444)
Gain on Puregraft divestiture		4,453	-	-	-	-	0	0
Equity loss from investment in joint venture	(165)	4,844	0	0	0	0	0	0
Total other income (expense)	(3,861)	4,502	(853)	(1,143)	(1,495)	(1,343)	(4,819)	(4,863)
Income (loss) before taxes	(32,279)	(26,177)	(10,400)	(11,828)	(9,385)	(6,698)	(38,293)	(32,435)
Income tax expense	-	-	-				-	-
Net income	(32,279)	(26,177)	(10,400)	(11,828)	(9,385)	(6,698)	(38,293)	(32,435)
Net income attributable to common shareholders	($32,279)	($25,921)	($10,450)	($11,828)	($9,327)	($6,698)	($38,293)	($32,435)
Net Earnings (Losses) Per Share—Basic	($0.55)	($0.39)	($0.14)	($0.15)	($0.12)	($0.08)	($0.49)	($0.37)
Net Earnings (Losses) Per Share—Diluted	($0.55)	($0.39)	($0.14)	($0.15)	($0.12)	($0.08)	($0.49)	($0.37)
Shares outstanding—basic	58,614	67,781	74,102	76,683	80,430	81,230	78,111	88,230
Shares outstanding—diluted	58,614	67,781	74,102	76,683	80,430	81,230	78,111	88,230
Margin Analysis (% of Sales/Revenue)								
COGS	46%	48%	41%	82%	41%	41%	42%	41%
R&D	94%	140%	299%	362%	285%	86%	211%	117%
S&M	109%	127%	134%	150%	133%	37%	150%	106%
G&A	108%	131%	303%	356%	379%	120%	241%	119%
Operating Income (loss)	-196%	-252%	-666%	-828%	-715%	-167%	-475%	-197%
Pretax	-223%	-215%	-725%	-916%	-851%	-209%	-544%	-231%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-223%	-215%	-725%	-916%	-851%	-209%	-544%	-231%
Financial Indicator Growth Analysis (YoY%)								
Product revenues	9%	-18%	-26%	-34%	-68%	-31%	-39%	35%
BARDA revenue	N.A.	805%	-27%	-58%	-47%	78%	-17%	203%
Total Revenue	45%	-16%	-80%	-91%	-71%	42%	-42%	99%
Cost of goods sold	4%	-14%	N.A.	-81%	-45%	-32%	-33%	5%
R&D expenses	25%	25%	15%	13%	-24%	-46%	-13%	10%
Sales and marketing	-30%	-5%	-15%	-20%	-18%	-54%	-28%	-5%
G&A	6%	2%	13%	14%	-4%	1%	6%	-2%
Operaing expense	9%	1%	8%	40%	-15%	-32%	-3%	2%
Operating Incomes (Losses)	-3%	8%	42%	68%	-7%	-41%	9%	-18%
Pretax Income	-1%	-19%	36%	268%	78%	-33%	46%	-15%
Net Income	-1%	-19%	36%	268%	78%	-33%	46%	-15%
EPS - Basic	-9%	-29%	23%	231%	46%	-40%	25%	-25%
EPS - Diluted	-9%	-29%	23%	231%	46%	-40%	25%	-25%

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

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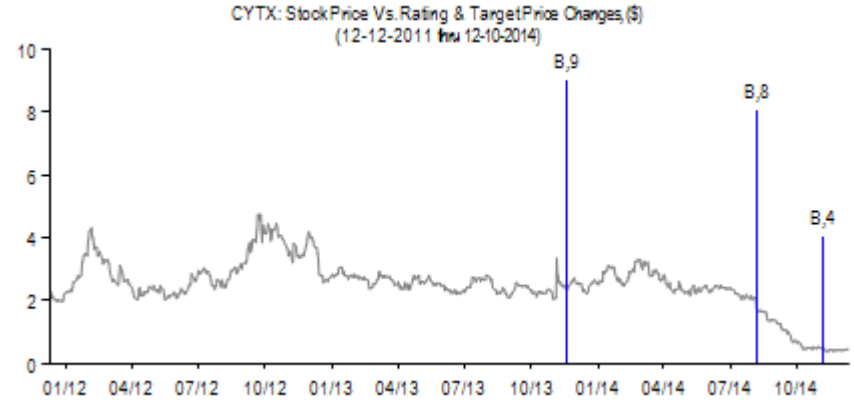
Rating and Price Target Change History



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	1.79
11/07/2014	4.00	0.43

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
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.	80.95%	33.33%	9.52%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.76%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Baxter (BAX: Not Rated)
Mesoblast (MBLTY: Not Rated)
Teva (TEVA: Not Rated)

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