

Cytori Therapeutics (CYTX - \$ 0.50)

3Q14: Major Strategic Changes in Pipeline Development and Sales Restructuring Continue

Yesterday after market close, CYTX reported 3Q14 financial results with a net loss of (\$9.3MM) vs. Laidlaw (\$10MM) and the Street estimate of (\$5.6MM). Net loss per share equaled (\$0.12) vs. (\$0.13) and (\$0.09) for Laidlaw and the Street, respectively. CYTX currently has cash of ~\$20MM (pro-forma) including net proceeds of \$12.5MM from a recent offering, sufficient for operations into late 2015, in our opinion.

- **ATHENA study readout in 1Q15.** As part of the re-alignment effort, the company plans to stop patient enrollment of both ATHENA studies and analyze the un-blinded six month data from a total of 31 patients (28 of study I and 3 of II) to determine the next steps. Given the six month post-treatment follow-up of the 31st patient will be reached in November, we estimate data reporting could be in 1Q15.
- **Re-alignment in pipeline developments.** CYTX is placing more ADRC clinical developments in indications that could be more cost-effective and potentially reach Phase II results more rapidly. Cytori will start a Phase II a/b trial in patients with osteoarthritis affecting the knees to be called ACT-OA. Patient enrollment will begin in early 2015 with results expected in 2016. Estimated costs of the trial are \$3.5MM. Two investigator/government sponsored clinical studies could also start in 2015: 1) A French Phase II study (SCLERADEC II with n=40) to evaluate ADRC in disabling hand manifestations of scleroderma with Cochin Hand Function Scale as the primary endpoint; and 2) A Japanese pivotal trial in male urinary incontinence patients due to post radical prostatectomy for prostate cancer. If successful, investigators intend to seek regulatory claims for this indication and reimbursement in Japan. For the BARDA project, if the next generation Celution system (CYX2) were to receive IDE approval (possibly in mid-2015), CYTX could be eligible for the additional \$8.3MM funding.
- **Greater cost control on marketing and sales to improve bottom line.** The focus will be on conducting less costly sales to improve margins going forward.
- **Action.** We reiterate our Buy rating and change our target price to \$4 from \$8 to reflect modest risks during the realignment of CYTX's pipeline development. We remain encouraged by the potential of 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.

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

Healthcare/Biotechnology

Ticker: **CYTX**
Rating: **Buy**
Price Target: ↓ lower **\$ 4.00**

Trading Data:

Last Price (11/06/2014)	\$ 0.50
52-Week High (2/21/2014)	\$ 3.47
52-Week Low (10/10/2014)	\$ 0.46
Market Cap. (MM)	\$ 40
Shares Out. (MM)	80

Yale Jen, Ph.D.

Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

- The Phase II a/b trial to evaluate ADRC in patients with osteoarthritis affecting the knees, to be called ACT-OA, is a randomized, double-blind, placebo controlled, 90-patient clinical study. Patients will be followed post-treatment for one year. Patients will be equally randomized into three groups: high dose, low dose and placebo. The study will be conducted in 15 sites and patient expects to receive one injection. Total estimated costs are approximately \$3.5MM. The study is expected to begin enrollment in early 2015 with top-line results potentially available in 2016. Objectives of the study include safety and several efficacy endpoints, like symptom relief, function and activity level.
- The French SCLERADEC II study is a multicenter, randomized, double-blind, 40-patient and placebo controlled trial of a single dose of ADRCs or placebo. Patients received placebos are eligible for crossover into treatment. The primary endpoint is Cochin Hand Function Scale. The study is scheduled to start in 2015 with top-line results potentially available in 2016. The estimated costs for CYTX are approximately \$0.5MM.

Figure 1 Estimated and reported 3Q14 results

Table 1:3Q14 Estimates and Reported Results			
(\$ MM)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$2.4	\$1.1	\$2.8
Total op. profit (loss)	(\$9.1)	(\$7.9)	(\$5.3)
R&D	\$4.8	\$3.1	
SG&A	\$6.3	\$5.7	
EPS	(\$0.13)	(\$0.12)	(\$0.09)
Net income (loss)	(\$10.0)	(\$9.3)	(\$5.6)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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
	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.

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	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
Operating 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%
Operating 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%
Yale Jen, Ph.D. 212-953-4978								

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

DISCLOSURES:**ANALYST CERTIFICATION**

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

Additional information available upon request.

† Laidlaw & Company has received compensation from the subject company for brokerage services in the past 12 months.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION**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	0.50*

* Previous Close 11/6/2014



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.	95.24%	33.33%	14.29%
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

NuVasive, Inc. (NUVA – Not Rated)
Baxter (BAX: Not Rated)
Mesoblast (MBLY: Not Rated)
Teva (TEVA: Not Rated)

ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices, market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at www.LaidlawLtd.com, or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

© 2014 Laidlaw & Co. (UK), Ltd.

NOTES: