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EQUITY RESEARCH
Company Report

March 4, 2015

# Cytori Therapeutics (CYTX - $ 1.10)

*Healthcare/Biotechnology*

## 2015 Financial Guidance

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

This morning, CYTX provided preliminary financial results for 2014 and financial guidance for 2015.

- **Details.** The highlights of this morning's announcement include: for 2014, 1) cash and debt at year-end was ~$14.6MM and $25MM, respectively; 2) 4Q14 and full-year cash burn was ~$4.9MM and $30.3MM; respectively; 3) 4Q14 and full-year product revenue was ~$2.5MM and $5.0MM, respectively; 4) 4Q14 and full-year profit/loss from sales and marketing organization, excluding share based compensation, was ~$44K and ~($3.9MM), respectively; 5) 4Q14 and full-year contract revenue was ~$1.3MM and $2.6MM, respectively. Guidance for 2015 included: 1) operating cash burn of ~$25MM; 2) product revenue of $5MM – $8MM; 3) contract revenue of $6MM – $8MM; and 4) full-year profit/loss from sales and marketing organization, excluding share based compensation, could reach $100K – $300K.
- **Implications.** We view the financial guidance very helpful for investors to better understand the revenue growth trajectory and the company's operations in 2015. We believe CYTX's product revenue growth outlook is becoming more positive. This follows passage and implementation of amendments in Japan of the Japanese Pharmaceutical Affairs Law (J-PAL) to the Pharmaceuticals and Medical Devices Act. On the pipeline development front, the major focus in 2015, in our opinion, is the commencement of the STAR pivotal trial to evaluate ECCO-50 as a potential treatment for impaired hand function in scleroderma. The trial received approval from the FDA in early January to begin the study. The FDA recently approved the expansion of clinical trial sites from 12 to 20. We view this as a positive since it 1) could increase the pace of the clinical study; and 2) could increase the exposure and familiarity to physicians and patients with ECCO-50 as treatment for impaired hand function in scleroderma. We also expect a similar trial in Europe to start in 2015. Further, the Committee for Orphan Medicinal Products (COMP) of the EMEA recently issued a positive opinion on the orphan drug designation application of ECCS-50 for treatment of scleroderma.
- **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.

**Trading Data:**

| | |
|---|---|
| Last Price (03/04/2015) | $ 1.10 |
| 52–Week High (3/6/2014) | $ 3.33 |
| 52–Week Low (11/12/2014) | $ 0.36 |
| Market Cap. (MM) | $ 103 |
| 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 2015 and beyond

| Program | Indication | Event | Timing |
|---|---|---|---|
| ECCO-50 | Osteoarthritis | 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** |
| | China commercialization | 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 | 2,512 | 4,996 | 7,494 |
| **Product revenues** | 8,709 | 7,122 | 1,031 | 935 | 518 | 2,512 | 4,996 | 7,494 |
| BARDA revenue | 360 | 3,257 | 403 | 359 | 585 | 1,305 | 2,652 | 7,944 |
| 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 | 1,305 | 2,652 | 7,944 |
| **Total Revenue** | **14,501** | **12,196** | **1,434** | **1,291** | **1,103** | **3,817** | **7,648** | **15,438** |
| Cost of product revenues | 4,000 | 3,421 | 421 | 766 | 337 | 1,030 | 2,554 | 3,073 |
| Gross profit | 4,709 | 3,701 | 610 | 169 | 181 | 1,482 | 2,442 | 4,421 |
| 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) | (5,012) | (33,131) | (26,815) |
| 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) | (6,355) | (37,950) | (31,678) |
| Income tax expense | - | - | - | | | | - | - |
| **Net income** | (32,279) | (26,177) | (10,400) | (11,828) | (9,385) | (6,355) | (37,950) | (31,678) |
| **Net income attributable to common shareholders** | ($32,279) | ($25,921) | ($10,450) | ($11,828) | ($9,327) | ($6,355) | ($37,950) | ($31,678) |
| Net Earnings (Losses) Per Share—Basic | ($0.55) | ($0.39) | ($0.14) | ($0.15) | ($0.12) | ($0.08) | ($0.49) | ($0.36) |
| Net Earnings (Losses) Per Share—Diluted | ($0.55) | ($0.39) | ($0.14) | ($0.15) | ($0.12) | ($0.08) | ($0.49) | ($0.36) |
| 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% | 65% | 41% | 42% | 41% |
| R&D | 94% | 140% | 299% | 362% | 285% | 72% | 194% | 106% |
| S&M | 109% | 127% | 134% | 150% | 133% | 31% | 131% | 83% |
| G&A | 108% | 131% | 303% | 356% | 379% | 101% | 222% | 108% |
| Operating Income (loss) | -196% | -252% | -666% | -828% | -715% | -131% | -433% | -174% |
| Pretax | -223% | -215% | -725% | -916% | -851% | -167% | -496% | -205% |
| Tax Rate | NA | NA | NA | NA | NA | NA | NA | NA |
| Net Income | -223% | -215% | -725% | -916% | -851% | -167% | -496% | -205% |
| **Financial Indicator Growth Analysis (YoY%)** | | | | | | | | |
| Product revenues | 9% | -18% | -26% | -34% | -68% | -7% | -30% | 50% |
| BARDA revenue | N.A. | 805% | -27% | -58% | -47% | 73% | -19% | 200% |
| Total Revenue | 45% | -16% | -80% | -91% | -71% | 68% | -37% | 102% |
| Cost of goods sold | 4% | -14% | N.A. | -81% | -45% | -9% | -25% | 20% |
| 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% | -45% | 8% | -19% |
| Pretax Income | -1% | -19% | 36% | 268% | 78% | -37% | 45% | -17% |
| Net Income | -1% | -19% | 36% | 268% | 78% | -37% | 45% | -17% |
| EPS - Basic | -9% | -29% | 23% | 231% | 46% | -43% | 24% | -26% |
| EPS - Diluted | -9% | -29% | 23% | 231% | 46% | -43% | 24% | -26% |

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



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***Additional information available upon request.***

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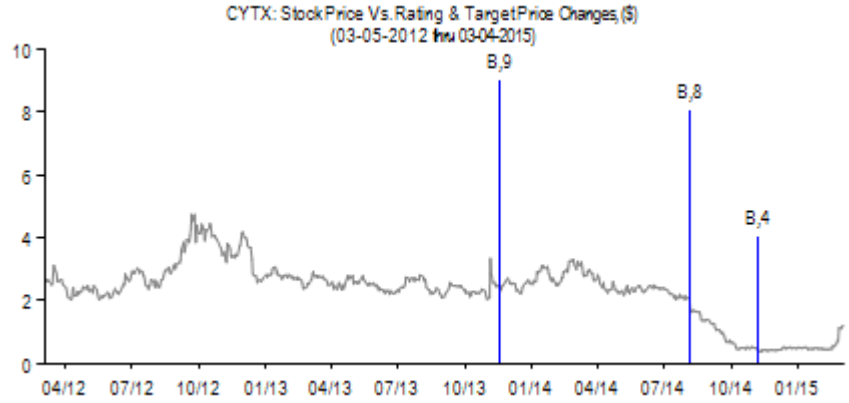


*3 Year Rating Change History*

| 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**

| 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. | 81.82% | 36.36% | 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% |

## ADDITIONAL COMPANIES MENTIONED

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

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