

Cara Therapeutics (CARA - \$7.11)

Clinical Hold Lift Undermined by Changes in Dosing Regimen.

CARA recently announced the Removal of the FDA Clinical Hold on I.V. CR845 for the treatment of postoperative pain and that patient recruitment is expected to resume in May. As a reminder, on 2/25/16, the program was placed on clinical hold due to elevated serum sodium levels in 4 patients in the 5µg/kg treatment arm- even though all 4 resolved to normal sodium levels within 24 hours with 2 of the 4 apparently seemed to be in an elevated condition due to protocol violations. The resolution was at the earlier end of our estimate, but it remains a concern that CARA eliminated the 5µg/kg and 2µg/kg arms and is going forward with the 0.5µg/kg and 1µg/kg arms, which raises the question if efficacy will be hindered at the lower doses. That said, we still believe the data should prove to be positive and we still see CARA as undervalued at these levels. We maintain our Buy rating and \$17 price target.

- **Resolving the clinical hold a nice positive, but two arms dropped.** The quickness with which the clinical hold was resolved is a nice positive but by dropping the 5.0µg/kg and 2.0µg/kg arms it does raise some potential concerns about efficacy. That said, we still think that the 1µg/kg dose should be sufficient since the company was able to not only review safety but also efficacy in the clinical hold.
- **With the hold resolved we're on to the next catalysts.** In-line with guidance CARA expects that the trial will restart in mid-2016. We project top-line data in 1H17, which seems in-line. We still expect the start of Phase 2b oral hip/knee OA trial and the IV CR945 Phase 3 pruritus trial to start in mid 2016 with potential data in 2017. See our "Clinical development trial timelines" chart later in this report for more details.
- **Maintain Buy rating, \$17 price target.** We value CARA on a sum-of-the-parts basis with CR845 for post-op pain at \$7/share, for pruritus at \$5/share, for OA pain at \$2.5/share, and cash (end '16) and technology at \$2.5/share.

Healthcare/Biotechnology

Ticker: **CARA**
Rating: **Buy**
Price Target: **\$17.00**

Trading Data:

Last Price (04/21/2016)	\$7.11
52-Week High (08/13/2015)	\$23.61
52-Week Low (02/26/2016)	\$4.26
Market Cap. (MM)	\$193.8
Shares Out. (MM)	27.25

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	(0.38)	(0.38)	(0.34)	(0.35)	(1.45)	NA
FY-16E	(0.34)	(0.36)	(0.40)	(0.41)	(1.50)	NA
FY-15A	(0.21)	(0.25)	(0.23)	(0.35)	(1.05)	NA
FY-14A	(0.22)	(0.16)	(0.28)	(0.18)	(0.85)	NA

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Source: Company data and Laidlaw & Company estimates

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Figure 1: Valuation

Sum-of-the-parts value: CARA		
Segment	Valuation (000's)	Per share value
CR845 - IV post-op pain	\$207,239	\$7.0
CR845 - oral OA pain	\$72,112	\$2.5
CR845 - IV uremic pruritus	\$95,317	\$3.5
CR845 - oral general pruritus	\$38,279	\$1.5
Cash (end '16) & tech value	\$70,498	\$2.5
SUM	\$483,446	\$17
Shares out '16E (000)		29,490

Source: Laidlaw Estimates

Figure 3: Quarterly Income Statement

CARA Therapeutics										
Quarterly income statement										
(\$000 except per share)	2014A				2014A Year	2015A				2015A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
Revenues										
License & milestones		\$302			\$302			\$1,710		\$1,710
Collaborative revenues	\$178	658	\$1,125	\$914	2,875	\$489	\$874	730	\$750	2,843
Total Revenue	\$178	\$960	\$1,125	\$914	\$3,177	\$489	\$874	\$2,440		\$3,803
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	178	960	1,125	914	3,177	489	874	2,440	-	3,803
Research and development	2,201	3,200	6,208	3,459	15,068	3,385	4,684	5,584	7,568	21,221
General and administrative	1,398	1,472	1,250	1,791	6,181	1,822	1,922	1,865	2,161	7,770
Total operating expenses	3,599	4,672	7,458	5,250	21,249	5,207	6,606	7,449	9,729	28,991
Income (loss) from Operations	(3,421)	(3,712)	(6,333)	(4,336)	(18,072)	(4,718)	(5,732)	(5,009)	(9,729)	(25,188)
Interest income (expense), net	22	56	26	22	126	14	13	22	52	101
Other (exp) gain, net										
Income (loss) before taxes	(3,399)	(3,656)	(6,307)	(4,314)	(17,946)	(4,704)	(5,719)	(4,987)	(9,677)	(25,087)
Income tax exp (benefit)	(16)	(11)	(32)	(142)	(201)	(15)	(35)	(200)	(147)	(397)
Net income (Loss)	(3,383)	(3,645)	(6,275)	(4,172)	(17,745)	(4,689)	(5,684)	(4,787)	(9,530)	(24,690)
Net income to common										
Earning per Share (EPS)	(\$0.22)	(\$0.16)	(\$0.28)	(\$0.18)	(\$0.85)	(\$0.21)	(\$0.25)	(\$0.19)	(\$0.35)	(\$1.00)
Adj EPS ex-1x & non-cash								(\$0.23)		(\$1.05)
Weighted avg. shares (000)	15,654	22,608	22,713	22,791	20,966	22,808	22,828	25,545	27,240	24,620
Fully diluted shares (000)	16,551	23,686	23,677	24,038	21,988	24,103	24,411	27,087	29,515	26,279

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

Figure 4: Annual Income Statement

CARA Therapeutics								
Annual income statement								
(\$000 except per share)	2014A	2015A	2016E	2017E	2018E	2019E	2020E	Comments
Revenues								
CR845 - IV post-op pain						\$53,329	\$151,475	Clinical hold 1Q16 phase 3 starting 2H16 phase 2b starting 2H16
CR845 - IV Uremic pruritus					-	-	17,938	
CR845 - oral hip/knee OA pain							12,500	
License & milestones	\$302	\$1,710	\$1,000	\$0	-	-	-	
Collaborative revenues	2,875	2,843	3,000	\$3,000	\$3,000	3,000	3,000	
Total Revenue	\$3,177	\$3,803	\$4,000	\$3,000	\$3,000	\$56,329	\$184,913	
Expenses:								
Cost of Revenue (COGS)	-	-	-	-	-	7,999	22,721	
Gross Margin	3,177	3,803	4,000	3,000	3,000	48,330	162,191	
R&D	15,068	21,221	32,500	34,000	37,250	40,500	46,000	
SG&A	6,181	7,770	12,250	13,250	15,500	24,750	56,750	125 reps in 2020
Total op exp	21,249	28,991	44,750	47,250	52,750	65,250	102,750	
Inc/(loss) from Ops	(18,072)	(25,188)	(40,750)	(44,250)	(49,750)	(16,920)	59,441	
Int income (exp), net	126	101	100	100	100	100	100	
Other expenses, net	-	-	-	-	-	-	-	
Inc/(loss) before taxes	(17,946)	(25,087)	(40,650)	(44,150)	(49,650)	(16,820)	59,541	
Income tax exp (benefit)	(201)	(397)	-	-	-	-	2,977	sig. tax loss carryforwards
Net income (Loss)	(\$17,745)	(\$24,690)	(\$40,650)	(\$44,150)	(\$49,650)	(\$16,820)	\$56,564	
Net income to common								
Earning per Share	(\$0.85)	(\$1.00)	(\$1.48)	(\$1.45)	(\$1.55)	(\$0.50)	\$1.50	
Adj EPS ex-1x & non-cash		(\$1.05)	(\$1.50)					
Weighted avg. shares (000)	20,966	24,620	27,490	30,490	31,990	33,490	34,990	
Fully diluted shares (000)	21,988	26,279	29,490	32,490	34,490	36,240	37,740	Raise in 2H17

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

Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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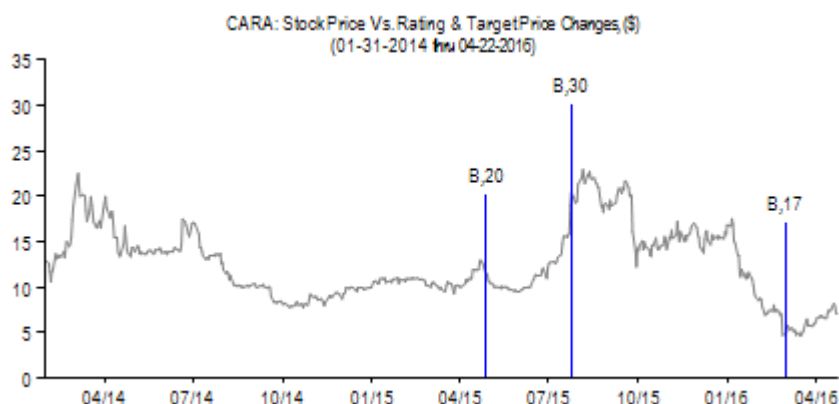
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/28/2015	Buy (B)	11.59

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/28/2015	20.00	11.59
07/24/2015	30.00	20.43
02/29/2016	17.00	4.92

Source: Laidlaw & Company

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			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.	66.67%	27.78%	2.78%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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