

Cara Therapeutics (CARA - \$15.64)

Oral CR-845 one step closer to a potential blockbuster

CARA recently announced positive top-line results from a Phase 2a trial of their oral formulation CR-845 for chronic pain patients with OA of the knee or hip. We believe this single-blind study checks off a crucial box in the development of this novel chronic pain drug. CARA expects to start their Phase 2b trial in 1Q16 with data expected 2H16. In the Phase 2b trial CARA plans to look at the 1mg-5mg dose range (or higher) given the clean safety profile seen in the Phase 2a trial (no drug related SAE's). We see this Phase 2a as an incremental positive, and it sets CARA up well for the next steps in Phase 2b; but there remains a long way to go for the oral version. That said the oral version of CR-845 in both chronic pain and pruritus together represents \$9 of our \$30 PT so getting one step closer to an oral formulation of CR-845 is significant, in our opinion. The next key catalyst for CARA will be the IV pruritus formulation FDA meeting expected in the current Q, and the upcoming IV post-op pain Phase 3 data in mid-2016. Reiterate Buy rating, \$30 PT.

- Positive Phase 2a data sets up the next steps in development.** We see the Phase 2a data as a nice positive for the story with a dose-related mean joint pain score on a numeric rating scale (NRS) decreasing 25% to 34% from baseline throughout the two-week treatment period across the 4 treatment arms (see figure 1 below). This change from baseline is comparable to other drugs used for the treatment of OA pain (see figure 2 below). The Area Under the Curve (AUC) analysis of the overall NRS scores also showed that a significant (p=0.02) reduction for 5.0mg dose vs the other cohorts (see figure 3 below).
- IV to Oral significantly expands the market opportunity.** An oral version of CR-845 opens the potential for CARA to treat the significantly larger ~\$10B US chronic pain market.
- Remarkable Adverse Event (AE) profile a positive.** CARA reported dizziness (7%) and headache (6%) as the most frequent AEs which is vastly better than the nausea, vomiting and constipation seen with opioids or the ulcers & bleeding seen with NSAIDs. CARA notes that there's a real possibility CR-845 could be unscheduled by the DEA, a significant positive.
- Reiterate Buy rating, \$30 price target.** Our price target is based on sum-of-the parts with IV CR845: \$12/share; oral post-op pain: \$4/share; IV uremic pruritus: \$7/share; oral general pruritus: \$5/share, and cash (end' 16) and technology value: \$2/share.

Healthcare/Biotechnology

Ticker:	CARA
Rating:	Buy
Price Target:	\$ 30.00

Trading Data:

Last Price (12/10/2015)	\$15.64
52-Week High (08/13/2015)	\$23.61
52-Week Low (03/26/2015)	\$9.00
Market Cap. (MM)	\$425.8
Shares Out. (MM)	27.23

Earnings Estimates: (per share)

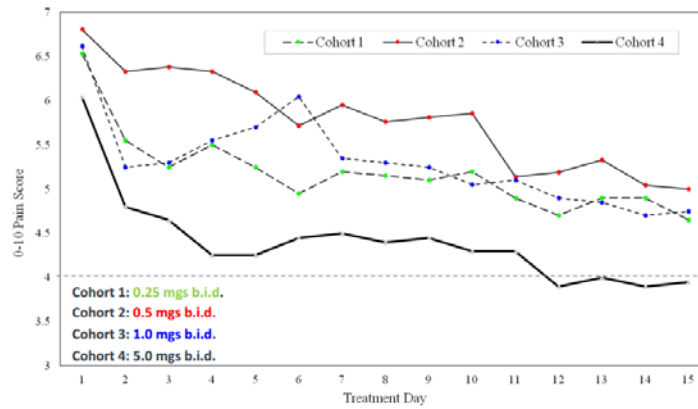
(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	(0.35)	(0.38)	(0.38)	(0.39)	(1.50)	NA
FY-15E	(0.21)A	(0.25)A	(0.23)A	(0.33)	(1.02)	NA
FY-14A	(0.22)	(0.16)	(0.28)	(0.18)	(0.85)	NA
FY-13A	NA	NA	NA	NA	(0.74)	NA

Source: Company data and Laidlaw & Company estimates

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Figure 1: Mean NRS Score by Cohort and Treatment Day - LOCF



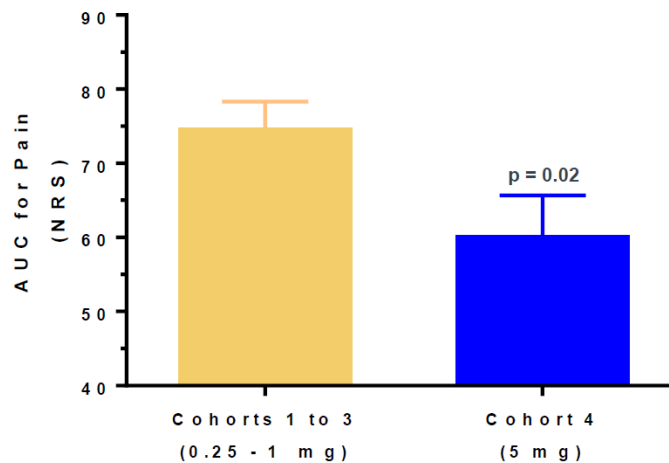
Source: Company Presentation

Figure 2: Comparative Efficacy in NRS Pain in OA Studies

Drug	Time	Change from BL	% Change from BL
Naproxen ¹	2 weeks	-2.5	35%
Celecoxib ¹	2 weeks	-2.5	35%
Duloxetine ² (30mg/day)	2 weeks	-1.6	26%
Oxycodone CR ³	12 weeks	-1.7	26%
CR845 (1mg)	2 weeks	-1.7	26%
CR845 (5mg)	2 weeks	-2.1	34%

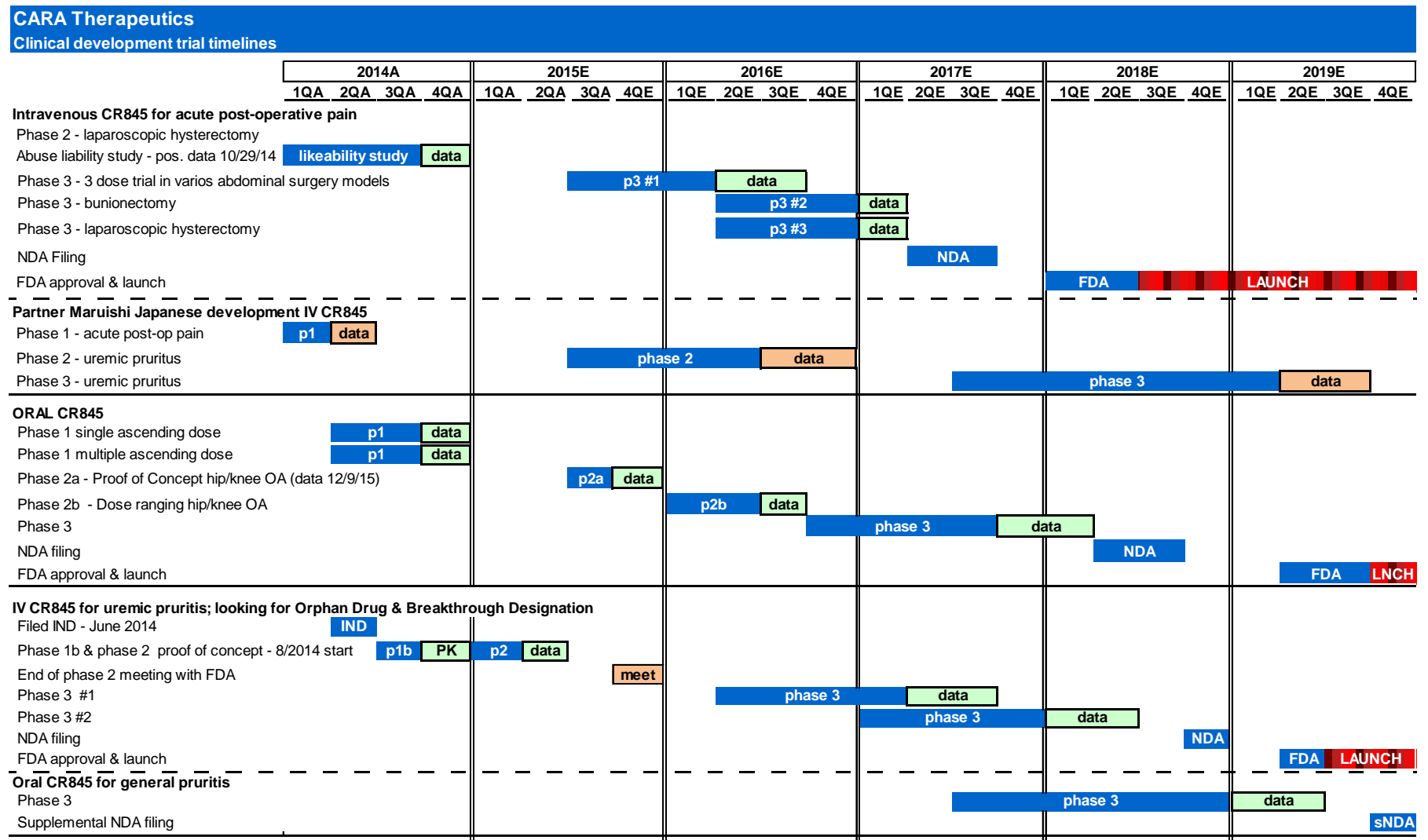
Source: Company Presentation

Figure 3: AUC, Pain NRS, Days 1 to 15



Source: Company presentation

Figure 4: Clinical trials timeline



Source: Company reports and Laidlaw estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 5: Quarterly Income Statement

CARA Therapeutics										
Quarterly income statement										
(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
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	\$750	\$4,553
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	178	960	1,125	914	3,177	489	874	2,440	750	4,553
Research and development	2,201	3,200	6,208	3,459	15,068	3,385	4,684	5,584	7,250	20,903
General and administrative	1,398	1,472	1,250	1,791	6,181	1,822	1,922	1,865	2,000	7,609
Total operating expenses	3,599	4,672	7,458	5,250	21,249	5,207	6,606	7,449	9,250	28,512
Income (loss) from Operations	(3,421)	(3,712)	(6,333)	(4,336)	(18,072)	(4,718)	(5,732)	(5,009)	(8,500)	(23,959)
Interest income (expense), net	22	56	26	22	126	14	13	22	25	74
Other (exp) gain, net										
Income (loss) before taxes	(3,399)	(3,656)	(6,307)	(4,314)	(17,946)	(4,704)	(5,719)	(4,987)	(8,475)	(23,885)
Income tax exp (benefit)	(16)	(11)	(32)	(142)	(201)	(15)	(35)	(200)		
Net income (Loss)	(3,383)	(3,645)	(6,275)	(4,172)	(17,745)	(4,689)	(5,684)	(4,787)	(8,475)	(23,635)
Net income to common										
Earning per Share (EPS)	(\$0.22)	(\$0.16)	(\$0.28)	(\$0.18)	(\$0.85)	(\$0.21)	(\$0.25)	(\$0.19)	(\$0.33)	(\$0.98)
Adj EPS ex-1x & non-cash								(\$0.23)		(\$1.02)
Weighted avg. shares (000)	15,654	22,608	22,713	22,791	20,966	22,808	22,828	25,545	25,595	24,194
Fully diluted shares (000)	16,551	23,686	23,677	24,038	21,988	24,103	24,411	27,087	27,345	25,737

Source: Company reports and Laidlaw estimates

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

Figure 6: Annual Income Statement

CARA Therapeutics							
Annual income statement							
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
Revenues							
CR845 - IV post-op pain					\$27,254	\$149,435	phase 3 started Sept. 2015
CR845 - IV Uremic pruritus					-	53,291	phase 3 starting 1H16
CR845 - oral post-op pain					-	12,500	phase 2b starting 1H16
License & milestones	\$302	\$1,710	\$1,000	\$750	-	-	
Collaborative revenues	2,875	2,843	3,000	\$3,000	3,000	3,000	
Total Revenue	\$3,177	\$4,553	\$4,000	\$3,750	\$30,254	\$218,226	
Expenses:							
Cost of Revenue (COGS)	-	-	-	-	4,088	22,415	
Gross Margin	3,177	4,553	4,000	3,750	26,166	195,811	
R&D	15,068	20,903	32,000	34,000	32,250	61,500	
G&A	6,181	7,609	10,250	11,750	20,000	67,000	
Total op exp	21,249	28,512	42,250	45,750	52,250	128,500	
Inc/(loss) from Ops	(18,072)	(23,959)	(38,250)	(42,000)	(26,084)	67,311	
Int income (exp), net	126	74	100	100	100	100	
Other expenses, net	-	-	-	-	-	-	
Inc/(loss) before taxes	(17,946)	(23,885)	(38,150)	(41,900)	(25,984)	67,411	
Income tax exp (benefit)	(201)	-	-	-	-	1,348	
Net income (Loss)	(\$17,745)	(\$23,635)	(\$38,150)	(\$41,900)	(\$25,984)	\$66,062	
Net income to common							
Earning per Share	(\$0.85)	(\$0.98)	(\$1.48)	(\$1.53)	(\$0.90)	\$2.00	
Adj EPS ex-1x & non-cash		(\$1.02)	(\$1.50)	(\$1.55)			
Weighted avg. shares (000)	20,966	24,194	25,845	27,345	28,845	30,345	
Fully diluted shares (000)	21,988	25,737	27,845	29,345	31,345	33,095	

Source: Company reports and Laidlaw estimates

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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. Dales could run out. 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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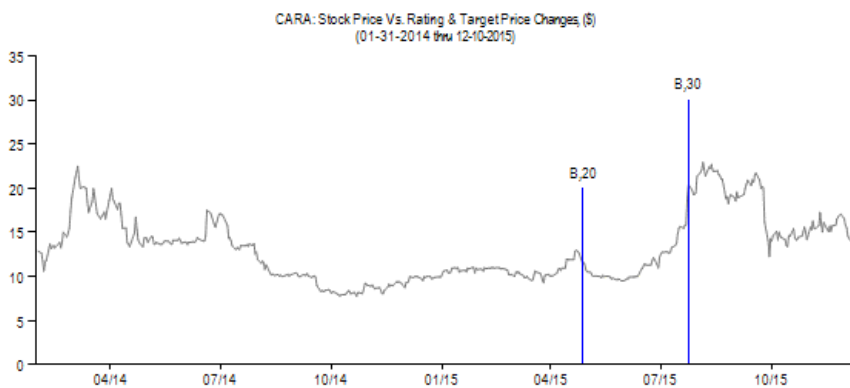
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Additional information available upon request.

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RATINGS INFORMATION

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

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.	64.71%	26.47%	2.94%
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%

ADDITIONAL COMPANIES MENTIONED

Chong Kun Dang (KRX: 185750 – Not Rated)

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