

Cara Therapeutics (CARA - \$4.69)

Resolution of clinical hold, hopefully 2Q16.

We are updating our CARA model following their recently reported 4Q15, which was in line with our expectations with few changes since their late February call on the clinical hold for IV CR845 for post-surgical pain. CARA still isn't an earnings story, but the next few months should prove to be eventful as the company looks to meet with the FDA to lift the clinical hold from IV CR845. CARA continues to note that the hypernatremia (elevated serum sodium levels) in four patients in the 5µg/kg treatment arm caused no serious adverse events (SAEs), yet it's still a mystery why such a benign outcome was pre-specified to trigger a clinical hold. We believe CARA will need at least 30-60 days to meet the FDA and come up with a solution, which pushes out top-line data to 1H17 in our estimation. This increases the timeline & risk profile for CR845, but still yields a value well above current levels, maintain Buy \$17 PT.

- **Next key catalyst remains the clinical hold resolution.** Following the update on the IV CR845 clinical hold, we now project the trial restarting in mid-2016 with top line data 1H17. This anticipates no further safety requests from the FDA, given the lack of SAE's and the rapid resolution of the hypernatremia seen in the trial to date. It also anticipates no additional study changes required by the FDA (given the adaptive trial design) as CARA has noted that they could end up dropping the 5µg/kg arm from the trial.
- **Other indication trials should start in 2016.** We now anticipate the start of Phase 2b oral hip/knee OA trial and the IV CR845 Phase 3 pruritus trial to mid-2H16 start in mid-2016. Data for both expects in 2017. See our "Clinical development trial timelines" chart later in this report for more information.
- **Development risk to CR845 asset goes up following hold.** While CARA has been very clear that there were no SAEs due to the hypernatremia in the IV CR845 trial it raises the question of what other protocol specified stopping rules might delay or potentially halt the program going forward, given the obvious close eye the FDA is keeping on this new chemical entity.
- **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.

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

Source: Company data and Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (03/15/2016)	\$4.69
52-Week High (08/13/2015)	\$23.61
52-Week Low (02/26/2016)	\$4.26
Market Cap. (MM)	\$127.7
Shares Out. (MM)	27.23

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Figure 1: Variance analysis

CARA Therapeutics Quarterly variance analysis										
(000's except per share)	4Q14A	4Q15A	4Q15E	Variance	% Y/Y	FY14A	FY15A	FY15E	Variance	% Y/Y
License & milestones	\$0	\$0	\$0	\$0	NA	\$302	\$1,710	\$1,710	\$0	NA
Collaborative revenues	914	750	750	0	-18%	2,875	2,843	2,843	0	-1%
Total Revenue	\$914	\$0	\$750	(\$750)	-18%	\$3,177	\$3,803	\$4,553	(\$750)	43%
COGS	0	0	0	0	NA	0	0	0	0	NA
Gross Profit	914	0	750	(750)	-18%	3,177	3,803	4,553	(750)	43%
SG&A Expense	1,791	2,161	2,000	161	12%	6,181	7,770	7,609	161	23%
R&D Expense	3,459	7,568	7,250	318	110%	15,068	21,221	20,903	318	39%
Operating Income	(4,336)	(9,729)	(8,500)	(1,229)	96%	(18,072)	(25,188)	(23,959)	(1,229)	33%
Int inc (exp), net	22	52	25	27	14%	126	101	74	27	-41%
Other (op) gain, net	0	0	0	0	NA	0	0	0	0	NA
Pretax Income	(4,314)	(9,677)	(8,475)	(1,202)	96%	(17,946)	(25,087)	(23,885)	(1,202)	33%
Income Tax exp (benefit)	(142)	(147)	0	(147)	-100%	(201)	(397)	0	(397)	-100%
Net income (loss)	(4,172)	(9,530)	(8,475)	(1,055)	103%	(17,745)	(24,690)	(23,635)	(1,055)	33%
1x items & non-cash exp	0	0	0	0	NA	0	(1,163)	(1,163)	0	NA
Adj NI ex-1x/non cash	(4,172)	(9,530)	(8,475)	(1,055)	103%	(17,745)	(25,853)	(24,798)	(1,055)	40%
Weighted avg. shares (000)	22,791	27,240	25,595	1,645	12%	20,966	24,620	24,194	426	15%
Fully diluted shares (000)	24,038	29,515	27,345	2,170	14%	21,988	26,279	25,737	542	17%
Earning per Share (EPS)	(\$0.18)	(\$0.35)	(\$0.33)	(\$0.02)	81%	(\$0.85)	(\$1.00)	(\$0.98)	(\$0.03)	15%
Adj EPS ex-1x & non-cash items							(\$1.05)	(\$1.02)	(\$0.03)	NA

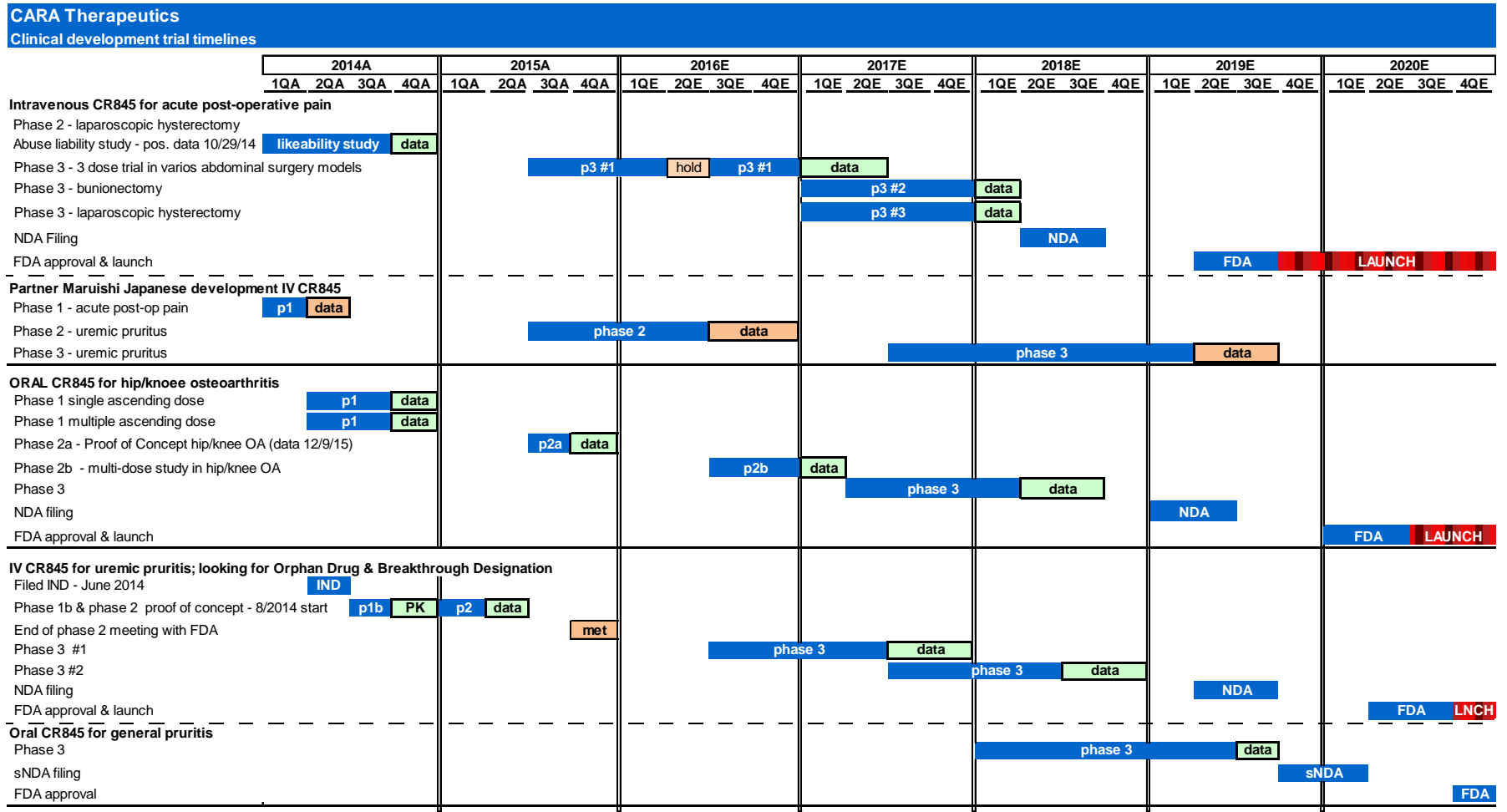
Source: Laidlaw Estimates

Figure 2: 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: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 4: 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 5: 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.

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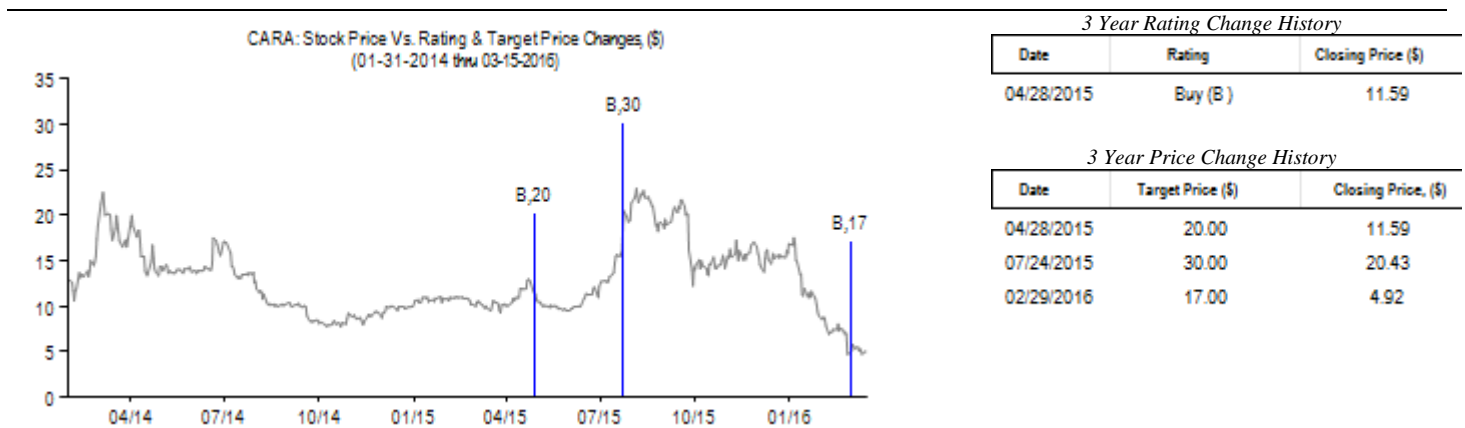
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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
Hold (H)	Expected returns to be 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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