

## Cara Therapeutics (CARA - \$4.76)

### Lowering PT Reflecting Increased Time, Clinical Risk at CARA

We are maintaining our Buy rating on shares of CARA but lowering our price target to \$17 from \$30 following the recent clinical hold of IV CR845. The clinical hold was due to elevated serum sodium levels in four patients in the 5 µg/kg treatment arm. CARA has been quick to point out that all four resolved to normal sodium levels within 24 hours under standard treatment, that two patients were apparently due to protocol violations, and that there were no serious adverse events (SAEs) associated with the elevated sodium levels. While we assume this to be in fact true, it raises the question as to why such a mild, transient, rapidly resolved issue mandates the most serious of trial responses like a full clinical hold. CARA will likely need at least 30 days to meet the FDA to discuss this event and to start to design a solution, and we believe this pushes out top-line data to late 2016 at the earliest (from mid-2016 previously). This also increases the risk profile for IV CR845 and by association the risk profiles for CR845 for OA pain and for psoriasis, in our opinion. While we don't believe the recent sell-off was warranted to the levels CARA is now trading at, we do believe that our current price target reflects our current best estimate of the timeline & risk associated with the CR845 program in light of the recent clinical hold. Maintain Buy, \$17 PT.

- **Clinical hold pushes the timelines out.** We are now modeling in top line IV CR845 data to late 2016 assuming an ~1Q delay until the clinical trial gets re-started. We have also moved out the start of the Phase 2b oral hip/knee OA trial to 2H16 (from 1H16 previously) and the Phase 3 pruritus trial to mid-2016 per management guidance, reflecting a frustrating outward creep in clinical trial timelines. We now model in a late 2019 launch of IV CR845 from a mid-2018 launch previously.
- **Risk to the programs has to go up following hold.** While CARA has been very clear that there were no SAEs due to the elevated sodium levels it raises the question on why the trial was stopped for such a seemingly trivial effect. It also 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, lowering PT to \$17 from \$30.** We value CARA on a sum-of-the-parts basis with IV 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
<b>FY-16E</b>	(0.35)	(0.38)	(0.38)	(0.39)	(1.50)	NA
<b>FY-15E</b>	(0.21)A	(0.25)A	(0.23)A	(0.33)	(1.02)	NA
<b>FY-14A</b>	(0.22)	(0.16)	(0.28)	(0.18)	(0.85)	NA
<b>FY-13A</b>	NA	NA	NA	NA	(0.74)	NA

Source: Company data and Laidlaw & Company estimates

#### Healthcare/Biotechnology

Ticker:	<b>CARA</b>
Rating:	<b>Buy</b>
Price Target:	↓ <b>\$ 17.00</b>

#### Trading Data:

Last Price (02/26/2016)	\$4.76
52-Week High (08/13/2015)	\$23.61
52-Week Low (02/26/2016)	\$4.26
Market Cap. (MM)	\$129.6
Shares Out. (MM)	27.23

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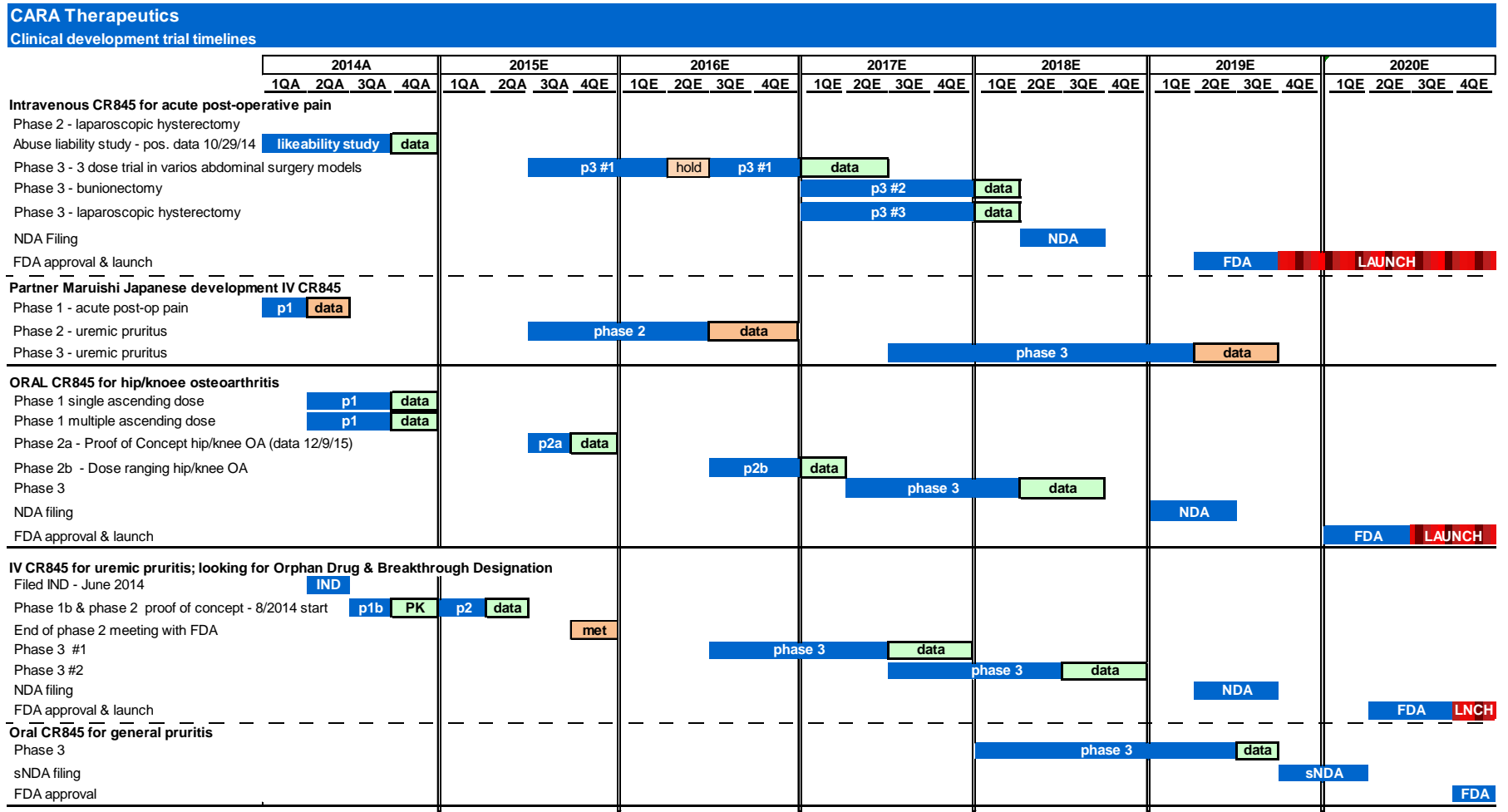
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Figure 1: Valuation

Sum-of-the-parts value: CARA		
Segment	Valuation (000's)	Per share value
CR845 - IV post-op pain	\$189,921	\$7.0
CR845 - oral post-op 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	\$74,777	\$2.5
<b>SUM</b>	<b>\$470,407</b>	<b>\$17</b>
Shares out '16E (000)		27,845

Source: Laidlaw Estimates

Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

<b>CARA Therapeutics</b>										
<b>Quarterly income statement</b>										
(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
<b>Revenues</b>										
License & milestones		\$302			\$302			\$1,710		\$1,710
Collaborative revenues	\$178	658	\$1,125	\$914	2,875	\$489	\$874	730	\$750	2,843
<b>Total Revenue</b>	<b>\$178</b>	<b>\$960</b>	<b>\$1,125</b>	<b>\$914</b>	<b>\$3,177</b>	<b>\$489</b>	<b>\$874</b>	<b>\$2,440</b>	<b>\$750</b>	<b>\$4,553</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
<b>Gross Margin</b>	<b>178</b>	<b>960</b>	<b>1,125</b>	<b>914</b>	<b>3,177</b>	<b>489</b>	<b>874</b>	<b>2,440</b>	<b>750</b>	<b>4,553</b>
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
<b>Income (loss) from Operations</b>	<b>(3,421)</b>	<b>(3,712)</b>	<b>(6,333)</b>	<b>(4,336)</b>	<b>(18,072)</b>	<b>(4,718)</b>	<b>(5,732)</b>	<b>(5,009)</b>	<b>(8,500)</b>	<b>(23,959)</b>
Interest income (expense), net	22	56	26	22	126	14	13	22	25	74
Other (exp) gain, net										
<b>Income (loss) before taxes</b>	<b>(3,399)</b>	<b>(3,656)</b>	<b>(6,307)</b>	<b>(4,314)</b>	<b>(17,946)</b>	<b>(4,704)</b>	<b>(5,719)</b>	<b>(4,987)</b>	<b>(8,475)</b>	<b>(23,885)</b>
Income tax exp (benefit)	(16)	(11)	(32)	(142)	(201)	(15)	(35)	(200)		
<b>Net income (Loss)</b>	<b>(3,383)</b>	<b>(3,645)</b>	<b>(6,275)</b>	<b>(4,172)</b>	<b>(17,745)</b>	<b>(4,689)</b>	<b>(5,684)</b>	<b>(4,787)</b>	<b>(8,475)</b>	<b>(23,635)</b>
<b>Net income to common</b>										
<b>Earning per Share (EPS)</b>	<b>(\$0.22)</b>	<b>(\$0.16)</b>	<b>(\$0.28)</b>	<b>(\$0.18)</b>	<b>(\$0.85)</b>	<b>(\$0.21)</b>	<b>(\$0.25)</b>	<b>(\$0.19)</b>	<b>(\$0.33)</b>	<b>(\$0.98)</b>
<b>Adj EPS ex-1x &amp; non-cash</b>								<b>(\$0.23)</b>		<b>(\$1.02)</b>
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: Bloomberg LP; Company reports; Laidlaw &amp; Company estimates.

Figure 5: Annual Income Statement

CARA Therapeutics								
Annual income statement								
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	2020E	Comments
<b>Revenues</b>								
CR845 - IV post-op pain						\$53,329	\$151,475	Top line 2H16
CR845 - IV Uremic pruritus					-	-	17,938	phase 3 starting 2H16
CR845 - oral hip/knee OA pain					-	-	12,500	phase 2b starting 2H16
License & milestones	\$302	\$1,710	\$1,000	\$750	-	-	-	
Collaborative revenues	2,875	2,843	3,000	\$3,000	\$3,000	3,000	3,000	
<b>Total Revenue</b>	<b>\$3,177</b>	<b>\$4,553</b>	<b>\$4,000</b>	<b>\$3,750</b>	<b>\$3,000</b>	<b>\$56,329</b>	<b>\$184,913</b>	
<b>Expenses:</b>								
Cost of Revenue (COGS)	-	-	-	-	-	7,999	22,721	
<b>Gross Margin</b>	<b>3,177</b>	<b>4,553</b>	<b>4,000</b>	<b>3,750</b>	<b>3,000</b>	<b>48,330</b>	<b>162,191</b>	
R&D	15,068	20,903	32,000	34,000	37,250	40,500	46,000	
SG&A	6,181	7,609	10,250	11,750	11,500	24,000	59,250	125 reps in 2020
Total op exp	21,249	28,512	42,250	45,750	48,750	64,500	105,250	
<b>Inc/(loss) from Ops</b>	<b>(18,072)</b>	<b>(23,959)</b>	<b>(38,250)</b>	<b>(42,000)</b>	<b>(45,750)</b>	<b>(16,170)</b>	<b>56,941</b>	
Int income (exp), net	126	74	100	100	100	100	100	
Other expenses, net	-	-	-	-	-	-	-	
<b>Inc/(loss) before taxes</b>	<b>(17,946)</b>	<b>(23,885)</b>	<b>(38,150)</b>	<b>(41,900)</b>	<b>(45,650)</b>	<b>(16,070)</b>	<b>57,041</b>	
Income tax exp (benefit)	(201)	-	-	-	-	-	2,852	sig. tax loss carryforwards
<b>Net income (Loss)</b>	<b>(\$17,745)</b>	<b>(\$23,635)</b>	<b>(\$38,150)</b>	<b>(\$41,900)</b>	<b>(\$45,650)</b>	<b>(\$16,070)</b>	<b>\$54,189</b>	
<b>Net income to common</b>								
<b>Earning per Share</b>	<b>(\$0.85)</b>	<b>(\$0.98)</b>	<b>(\$1.48)</b>	<b>(\$1.45)</b>	<b>(\$1.50)</b>	<b>(\$0.50)</b>	<b>\$1.50</b>	
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$1.02)</b>	<b>(\$1.50)</b>	<b>(\$1.50)</b>					
Weighted avg. shares (000)	20,966	24,194	25,845	28,845	30,345	31,845	33,345	
Fully diluted shares (000)	21,988	25,737	27,845	30,845	32,845	34,595	36,095	Raise in 2H17

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

## Major Risks

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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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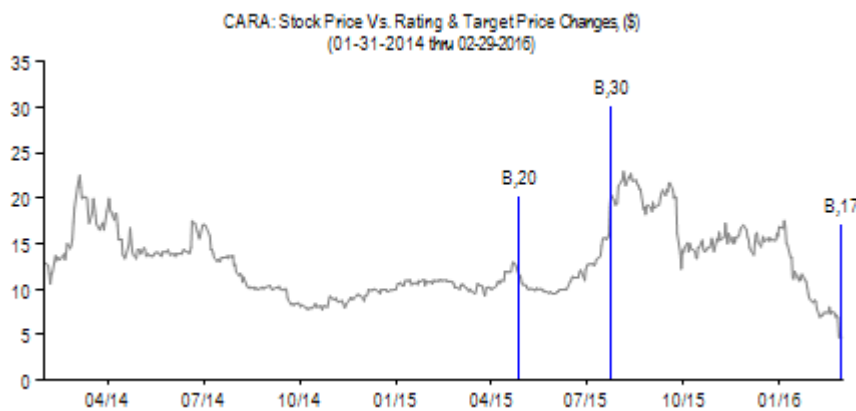
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#### Rating and Price Target Change History



#### 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	4.76*

\* Previous Close 2/26/2016

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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