

Cara Therapeutics (CARA - \$5.56)

Clinical Hold Resolved, Bring on the 2016 Catalysts

CARA recently reported 1Q16 and the main story remains the recently removed Clinical Hold on IV CR845 for postoperative pain. CARA expects to resume patient recruitment this month in a two-arm adaptive trial design with an interim look possible by early 2017. Although CARA dropped the 2µg/kg and 5µg/kg arms due to an abundance of caution, we believe the Clinical Hold was somewhat of a blessing in disguise as it allowed CARA to un-blind the data and examine safety and efficacy of the 1µg/kg dose, leading to the resumption of the trial in just the 1µg/kg dose and a lower 0.5µg/kg dose. CARA expects to start the IV CR845 uremic pruritus (UP) in hemodialysis patients trial in 2Q16 (~1Q ahead of our estimates) and a Phase 2b trial of Oral CR845 in chronic pain in 2H16 (in line with our estimates). We maintain our Buy rating and \$17 price target.

- **Clinical hold and resolution a nice positive.** With the clinical hold resolved and new doses chosen (0.5µg/kg & 1µg/kg) we are pleased to hear that there aren't any other automatic stopping rules in any other trials and that the FDA had not mandated any additional safety looks in both the pain and UP trials. In addition to the un-blinded confirmation that the 1µg/kg seemed both safe and efficacious, the positive results found in UP with this dose should translate well to postoperative pain due to mechanistic similarities.
- **A catalyst filled 2016.** CARA expects IV CR845 for postoperative pain to resume patient recruitment later this month followed by an interim look in early 1Q17 and a potential second Phase 3 trial starting in mid-2017. CARA intends to start the IV CR845 for UP trials in 2Q16, is one quarter ahead of our prior expectations. The Phase 2b for Oral CR 845 in chronic pain is also expected to start in 2H16, and CARA expects to initiate a PK study for oral CR845 for general pruritus in 1H16.
- **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 (05/06/2016)	\$5.56
52-Week High (08/13/2015)	\$23.61
52-Week Low (02/26/2016)	\$4.26
Market Cap. (MM)	\$151.7
Shares Out. (MM)	27.28

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	(0.39)A	(0.36)	(0.40)	(0.41)	(1.58)	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: Variance analysis

CARA Therapeutics					
Quarterly variance analysis					
(000's except per share)	1Q15A	1Q16A	1Q16E	Variance	% Y/Y
License & milestones	\$0	\$0	\$0	\$0	NA
Collaborative revenues	489	7	750	(743)	53%
Total Revenue	\$489	\$7	\$750	(\$743)	53%
COGS	0	0	0	0	NA
Gross Profit	489	7	750	(743)	53%
SG&A Expense	1,822	2,447	2,500	(53)	37%
R&D Expense	3,385	8,546	7,500	1,046	122%
Operating Income	(4,718)	(10,986)	(9,250)	(1,736)	96%
Int inc (exp), net	14	149	25	124	79%
Other (exp) gain, net	0	0	0	0	NA
Pretax Income	(4,704)	(10,837)	(9,225)	(1,612)	96%
Income Tax exp (benefit)	(15)	(145)	0	(145)	-100%
Net income (loss)	(4,689)	(10,692)	(9,225)	(1,467)	97%
1x items & non-cash exp	0	0	0	0	NA
Adj NI ex-1x/non cash	(4,689)	(10,692)	(9,225)	(1,467)	97%
Weighted avg. shares (000)	22,808	27,260	27,340	(81)	20%
Fully diluted shares (000)	24,103	29,260	29,340	(81)	22%
Earning per Share (EPS)	(\$0.21)	(\$0.39)	(\$0.34)	(\$0.05)	64%

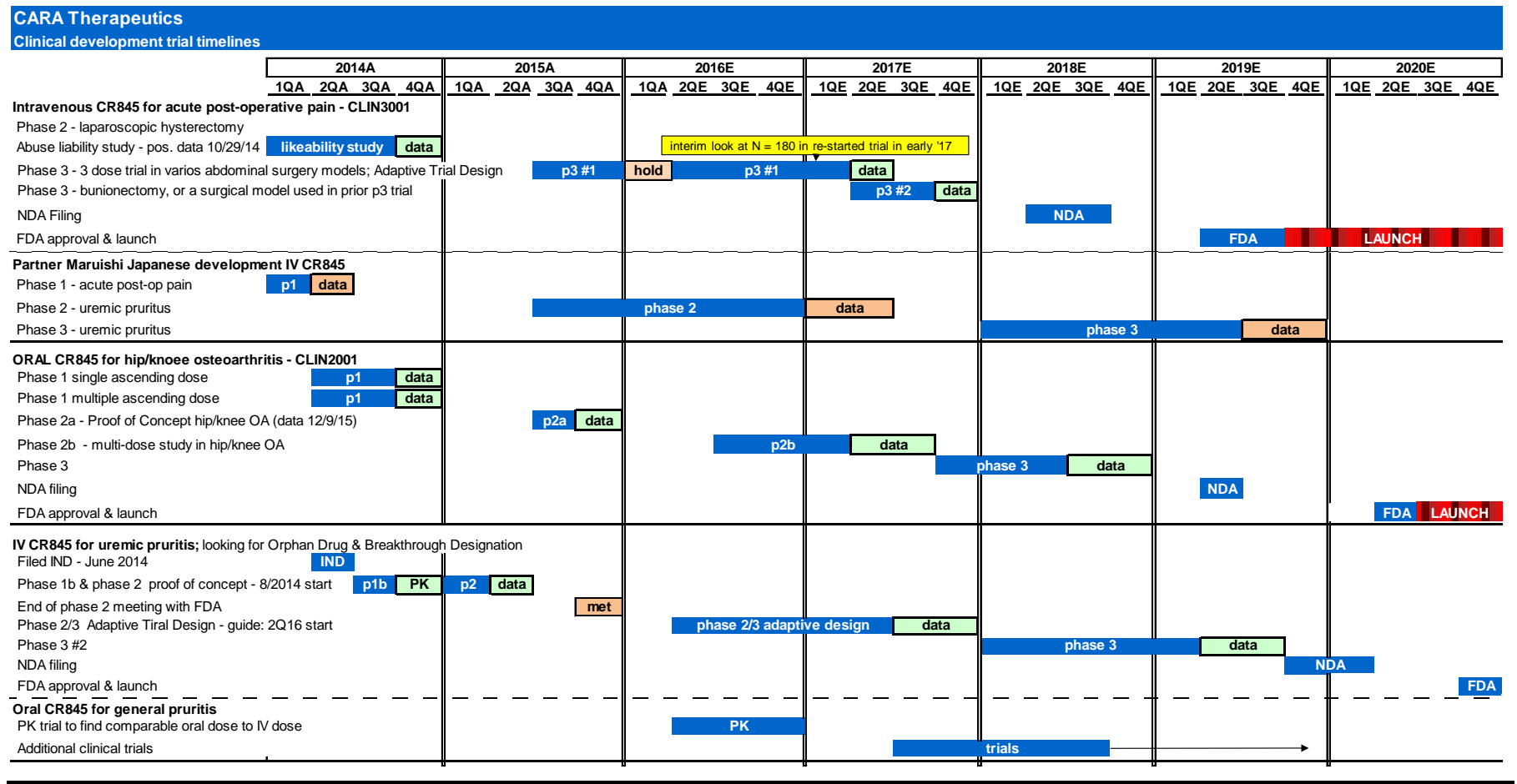
Source: Company reports; Laidlaw & Company estimates

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	\$69,031	\$2.5
SUM	\$481,979	\$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)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
Revenues										
License & milestones			\$1,710		\$1,710			\$1,000		\$1,000
Collaborative revenues	\$489	\$874	730	\$750	2,843	\$7	\$750	750	\$750	2,257
Total Revenue	\$489	\$874	\$2,440		\$3,803	\$7	\$750	\$1,750	\$750	\$3,257
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	489	874	2,440	-	3,803	7	750	1,750	750	3,257
Research and development	3,385	4,684	5,584	7,568	21,221	8,546	8,000	8,500	8,500	33,546
General and administrative	1,822	1,922	1,865	2,161	7,770	2,447	2,750	3,700	3,700	12,597
Total operating expenses	5,207	6,606	7,449	9,729	28,991	10,993	10,750	12,200	12,200	46,143
Income (loss) from Operations	(4,718)	(5,732)	(5,009)	(9,729)	(25,188)	(10,986)	(10,000)	(10,450)	(11,450)	(42,886)
Interest income (expense), net	14	13	22	52	101	149	25	25	25	224
Other (exp) gain, net										
Income (loss) before taxes	(4,704)	(5,719)	(4,987)	(9,677)	(25,087)	(10,837)	(9,975)	(10,425)	(11,425)	(42,662)
Income tax exp (benefit)	(15)	(35)	(200)	(147)	(397)	(145)				
Net income (Loss)	(4,689)	(5,684)	(4,787)	(9,530)	(24,690)	(10,692)	(9,975)	(10,425)	(11,425)	(42,517)
Net income to common										
Earning per Share (EPS)	(\$0.21)	(\$0.25)	(\$0.19)	(\$0.35)	(\$1.00)	(\$0.39)	(\$0.36)	(\$0.38)	(\$0.41)	(\$1.55)
Adj EPS ex-1x & non-cash			(\$0.23)		(\$1.05)			(\$0.40)		(\$1.58)
Weighted avg. shares (000)	22,808	22,828	25,545	27,240	24,620	27,260	27,360	27,460	27,560	27,410
Fully diluted shares (000)	24,103	24,411	27,087	29,515	26,279	29,260	29,360	29,460	29,560	29,410

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

Figure 5: Annual Income Statement

CARA Therapeutics							
Annual income statement							
(\$000 except per share)	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	\$1,710	\$1,000	\$0	-	-	-	
Collaborative revenues	2,843	2,257	\$3,000	\$3,000	3,000	3,000	
Total Revenue	\$3,803	\$3,257	\$3,000	\$3,000	\$56,329	\$184,913	
Expenses:							
Cost of Revenue (COGS)	-	-	-	-	7,999	22,721	
Gross Margin	3,803	3,257	3,000	3,000	48,330	162,191	
R&D	21,221	33,546	34,000	37,200	40,500	46,000	
SG&A	7,770	12,597	13,250	15,500	24,750	56,750	125 reps in 2020
Total op exp	28,991	46,143	47,250	52,700	65,250	102,750	
Inc/(loss) from Ops	(25,188)	(42,886)	(44,250)	(49,700)	(16,920)	59,441	
Int income (exp), net	101	224	100	100	100	100	
Other expenses, net	-	-	-	-	-	-	
Inc/(loss) before taxes	(25,087)	(42,662)	(44,150)	(49,600)	(16,820)	59,541	
Income tax exp (benefit)	(397)	-	-	-	-	2,977	sig. tax loss carryforwards
Net income (Loss)	(\$24,690)	(\$42,517)	(\$44,150)	(\$49,600)	(\$16,820)	\$56,564	
Net income to common							
Earning per Share	(\$1.00)	(\$1.55)	(\$1.45)	(\$1.55)	(\$0.50)	\$1.50	
Adj EPS ex-1x & non-cash	(\$1.05)	(\$1.58)					
Weighted avg. shares (000)	24,620	27,410	30,410	31,910	33,410	34,910	
Fully diluted shares (000)	26,279	29,410	32,410	34,410	36,160	37,660	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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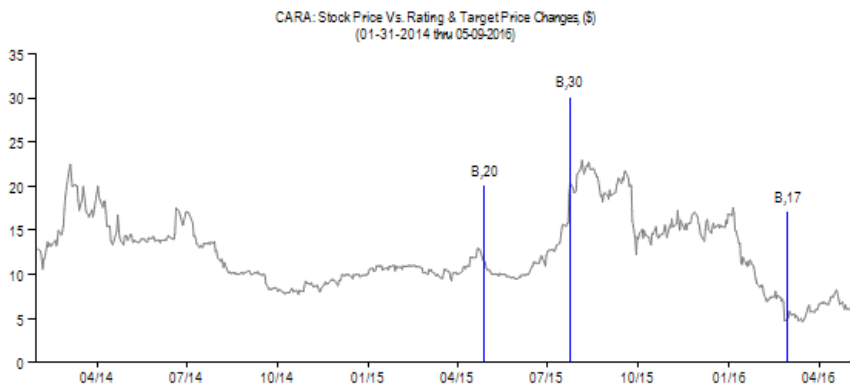
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Rating and Price Target Change History



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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