

Cara Therapeutics (CARA - \$19.14)

With IDMC's Blessings, IV CR845 for Post-Operative Pain Carries On.

This morning before the open, CARA announced the continuation of its Phase 3 trial for IV CR845 in post-operative pain following interim assessment by the Independent Data Monitoring Committee (IDMC). Post this prespecified conditional power analysis, which evaluated safety information (serum sodium levels), CARA will continue to test both doses (1.0ug/kg and 0.5ug/kg) vs. placebo in up to 450 patients. As a reminder, back in 1Q16, this IV CR845 trial in post-operative pain was placed on clinical hold due to cases of hypernatremia, which lead CARA to change their dosing arms from 1, 2, and 5ug/kg, to 0.5 and 1ug/kg. While we see this interim assessment as a net positive, we believe the stock's weakness in the pre-market could have been associated with expectations of efficacy read-through since the IDMC unblinded the data for both safety and efficacy. We recall from the 1Q17 call that the interim look could have triggered an outright stoppage of the trial due to strong efficacy as >65% of the trial was enrolled. We find encouraging that CARA didn't slow their enrollment pace and guided towards trial completion in 4Q17 after which they will initiate a second Phase 3 trial. Data remains the theme this year at CARA and we still expect top-line Phase 2b read-out of oral CR845 for hip/knee osteoarthritis (OA) as well as Phase 1 PK oral CR845 for general pruritus this quarter (within a week). With multiple catalysts still to come, we are reiterating our Buy rating and \$35 price target.

- **IV CR845's Phase 3 clean safety profile, the trial keeps trucking along.** While past IDMC analysis had forced CARA to drop treatment arms, we are encouraged by the clean safety data of both doses (0.5ug/kg and 1.0ug/kg) at >65% enrollment levels.
- **With a week left, 2Q17 is far from over at CARA.** As we are quickly approaching the end of June, we still expect important data on the oral formulation of CR845. Phase 2b data in hip/knee OA pain as well as Phase 1 PK for general pruritus are expected to read out this quarter.
- **Reiterate Buy rating, \$35 price target.** We value CARA on a sum-of-the-parts: IV CR845 for pruritus: \$14/share, IV/oral post-op pain: \$12/share, oral pruritus: \$7/share, and cash (end' 17) and tech: \$2/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	NA	NA	NA	NA	(1.97)	NA
FY-17E	(0.81)A	(0.60)	(0.42)	(0.36)	(2.14)	NA
FY-16A	(0.39)	(0.48)	(0.42)	(0.81)	(2.10)	NA
FY-15A	(0.21)	(0.25)	(0.23)	(0.35)	(1.05)	NA

Healthcare/Biotechnology

Ticker:	CARA
Rating:	Buy
Price Target:	\$35

Trading Data:

Last Price (06/21/2017)	\$19.14
52-Week High (03/19/2017)	\$20.90
52-Week Low (06/27/2016)	\$4.35
Market Cap. (MM)	\$620.9
Shares Out. (MM)	32.5

Analyst

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Source: Company data and Laidlaw & Company estimates

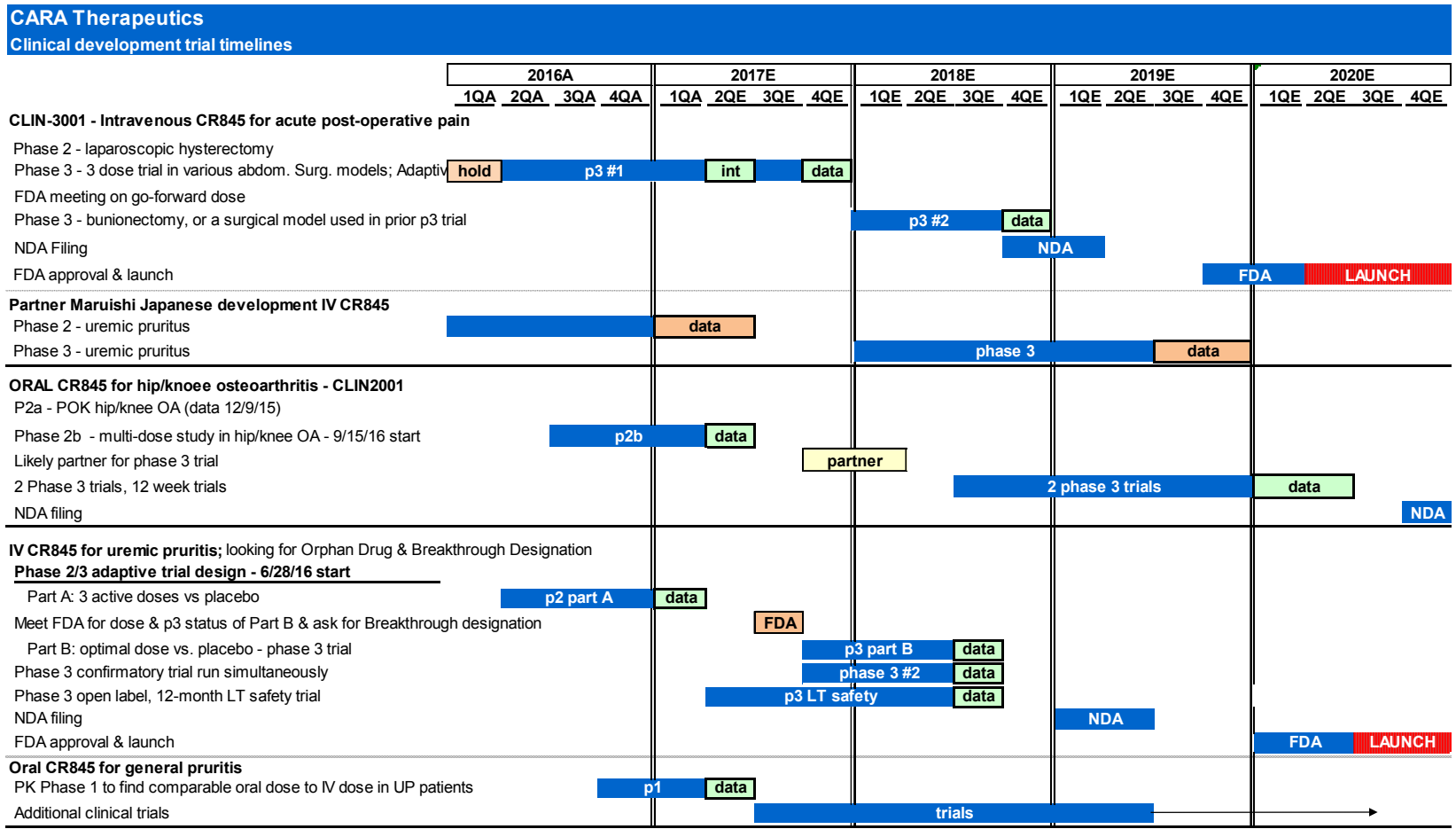
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Figure 1: Valuation

Sum-of-the-parts value: CARA		
Segment	Valuation (000's)	Per share value
CR845 - IV uremic pruritus	\$475,666	\$14
CR845 - IV post-op pain	\$310,093	\$9
CR845 - oral general pruritus	\$235,930	\$7
CR845 - oral OA pain	\$100,094	\$3
Cash (end '17) & tech value	\$54,084	\$2
SUM	\$1,175,867	\$35
Shares out '17E (000)		33,588

Source: Laidlaw Estimates

Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 3: Quarterly Income Statement

CARE Therapeutics										
Quarterly income statement										
(\$000 except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
Revenues										
License & milestones					\$0	\$530				
Collaborative revenues	\$7	\$79			86	\$313	\$750	\$750	\$750	2,563
Total Revenue	\$7	\$79	\$0	\$0	\$86	\$911	\$750	\$750	\$750	\$3,161
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	7	79	-	-	86	911	750	750	750	3,161
Research and development	8,546	10,760	9,671	20,277	49,254	20,836	18,000	12,000	9,750	60,586
General and administrative	2,447	2,645	2,102	2,038	9,232	2,400	2,250	2,750	3,000	10,400
Total operating expenses	10,993	13,405	11,773	22,315	58,486	23,236	20,250	14,750	12,750	70,986
Income (loss) from Operations	(10,986)	(13,326)	(11,773)	(22,315)	(58,400)	(22,325)	(19,500)	(14,000)	(12,000)	(67,825)
Interest income (expense), net	149	172	176	155	652	90	25	25	25	165
Other (exp) gain, net										
Income (loss) before taxes	(10,837)	(13,154)	(11,597)	(22,160)	(57,748)	(22,235)	(19,475)	(13,975)	(11,975)	(67,660)
Income tax exp (benefit)	(145)	(79)	(55)	(189)	(468)	(31)				
Net income (Loss)	(10,692)	(13,075)	(11,542)	(21,971)	(57,280)	(22,204)	(19,475)	(13,975)	(11,975)	(67,629)
Net income to common										
Earning per Share (EPS)	(\$0.39)	(\$0.48)	(\$0.42)	(\$0.81)	(\$2.10)	(\$0.81)	(\$0.60)	(\$0.42)	(\$0.36)	(\$2.14)
Adj EPS ex-1x & non-cash			(\$0.42)		(\$2.10)					
Weighted avg. shares (000)	27,260	27,283	27,283	27,291	27,279	27,300	32,417	33,017	33,617	31,588
Fully diluted shares (000)	29,474	29,540	29,582	30,712	29,827	30,454	34,417	35,017	35,617	33,876

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

Figure 4: Annual Income Statement

CARA Therapeutics						
Annual income statement						
(\$000 except per share)	2016A	2017E	2018E	2019E	2020E	Comments
Revenues						
CR845 - IV post-op pain					\$56,760	Interim data 2Q17
CR845 - IV Uremic pruritus			-	-	17,938	p2 data 1Q17
CR845 - oral hip/knee OA pain			-	-	-	p2b data 2Q17
License & milestones	\$0		-	-	-	Maruishi milestones here
Collaborative revenues	86	\$2,563	\$3,000	\$3,000	3,000	
Total Revenue	\$86	\$3,161	\$3,000	\$3,000	\$77,698	
Expenses:						
Cost of Revenue (COGS)	-	-	-	-	8,514	
Gross Margin	86	3,161	3,000	3,000	69,184	
R&D	49,254	60,586	60,500	58,250	50,500	
SG&A	9,232	10,400	10,750	11,000	30,000	50 reps in 2020
Total op exp	58,486	70,986	71,250	69,250	80,500	
Inc/(loss) from Ops	(58,400)	(67,825)	(68,250)	(66,250)	(11,316)	
Int income (exp), net	652	165	100	100	100	
Other expenses, net	-	-	-	-	-	
Inc/(loss) before taxes	(57,748)	(67,660)	(68,150)	(66,150)	(11,216)	
Income tax exp (benefit)	(468)	-	-	-	-	sig. tax loss carryforwards
Net income (Loss)	(\$57,280)	(\$67,629)	(\$68,150)	(\$66,150)	(\$11,216)	
Net income to common						
Earning per Share	(\$2.10)	(\$2.14)	(\$1.97)	(\$1.78)	(\$0.29)	
Adj EPS ex-1x & non-cash	(\$2.10)					
Weighted avg. shares (000)	27,279	31,588	34,588	37,088	38,588	
Fully diluted shares (000)	29,827	33,876	37,088	39,838	41,338	
Cash position	\$58,276	\$29,084	\$21,066	\$17,399	\$9,092	Additional raises 2017-2019

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.

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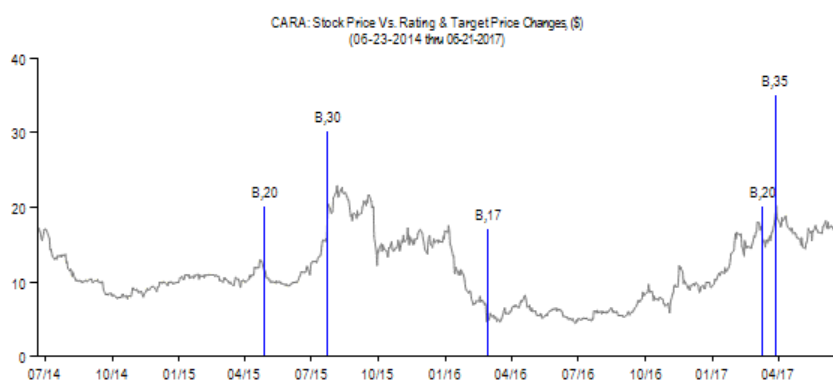
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Rating and Price Target Change History



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
03/10/2017	20.00	15.84
03/28/2017	35.00	19.09

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.	64.44%	31.11%	2.22%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.22%	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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