

Cara Therapeutics (CARA - \$9.02)

Pruritus, an Unmet Medical Need Targeting a Huge Market

We recently held a KOL call with a leading pruritus research specialist on CARA's kappa opioid CR845 and the overall pruritus market. Our KOL sees a tremendous amount of interest in the kappa space for treating pruritus with a clean AE profile. In particular he was impressed with the safety and efficacy of CARA's IV CR845 Phase 2 data for uremic pruritus (UP) from 2Q15, noting that the two week data looked impressive to him for such a small (n=65) patients. He concurs that the Phase 2/3 adaptive trial design appears well constructed, and that it should give a conclusive answer in 2H17 after the Phase 3 optimal dose trial concludes. (See our trial design table later in this report). Our KOL also estimates ~500K UP patients in the US, of which 50%-60% have pruritus, the immediate target for CARA's IV version of CR845. For the larger ~3M non-UP pruritus patients our KOL believes that the oral version will be needed. CARA is anticipating PK data on various doses of the oral version of CR845 in hemodialysis patients in 1Q17, which should inform the bioequivalent oral dose to the IV version. Given the ability to find comparable doses from IV to oral for CR845 in pain indications, our KOL is optimistic that an oral dose for UP will be found as well. With multiple data read-outs anticipated in 1H17 for both IV and oral CR845, we view 2017 as a pivotal year for CARA and we reiterate our Buy rating and our \$17 price target.

- **Phase 2 data should de-risk upcoming Part A Phase 2b in 1Q17.** Our KOL believed that the strong Phase 2 data presages a good chance for a solid signal in the dose-ranging Phase 2b trial. Additionally our KOL sees the change in worst itch score & SKindex-10 as solid, FDA accepted clinical endpoints.
- **Insurance coverage and Reimbursement shouldn't be an issue.** Importantly our KOL is seeing good acceptance by insurers to paying for pruritus treatments. He notes that he hasn't seen one rejection yet for the \$35K-\$40K annual cost of therapy for pruritus medications.
- **Maintain Buy rating, \$17 price target.** We value CARA on a sum-of-the-parts basis with IV post-op pain: \$7/share, IV & oral pruritus: \$5/share, oral OA pain: \$2.5/share, and cash (end '17) and tech value at

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	(0.44)	(0.44)	(0.39)	(0.39)	(1.65)	NA
FY-16E	(0.39)A	(0.48)A	(0.42)A	(0.41)	(1.70)	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

\$2.5/share.

Healthcare/Biotechnology

Ticker: **CARA**
Rating: **Buy**
Price Target: **\$17**

Trading Data:

Last Price (12/13/2016)	\$9.02
52-Week High (01/06/2016)	\$17.69
52-Week Low (02/26/2016)	\$4.26
Market Cap. (MM)	\$246.1
Shares Out. (MM)	27.28

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Figure 1: IV pruritus Phase 2/3 trial design

CLIN3001 - Phase 2/3 IV Uremic Pruritis Adaptive Trial Design	
Aim	Safety & efficacy of oral CR845 in pts with OA of the hip or knee
Design	2 part p2/3 adaptive trial design; Part A: 4 arm, 2wk screen; random/2x blind/placebo over 8 wks; Part B: 2 arm, 2wk screen; random/2x blind/placebo over 12 wks
Dosing	Part A: 3 active dose arms (0.5/1.0/1.5 mcg/kg) administered 3x/week after dialysis for 8 weeks vs placebo; Part B: optimized dose administered 3x/week after dialysis for 12 weeks vs placebo
Endpoints	1': reduction from baseline of weekly mean of daily 24 hr worst itch vs placebo at week 8 (Part A) and week 12 (Part B); 2': SKINDEX 10 & QOL measures
Patients	Part A: N = 160; Part B: N = up to 240
Results	Part A: expected 1H17 (part A started 6/29/16); Part B: expected 2H17 (part B expected to start mid-2017)

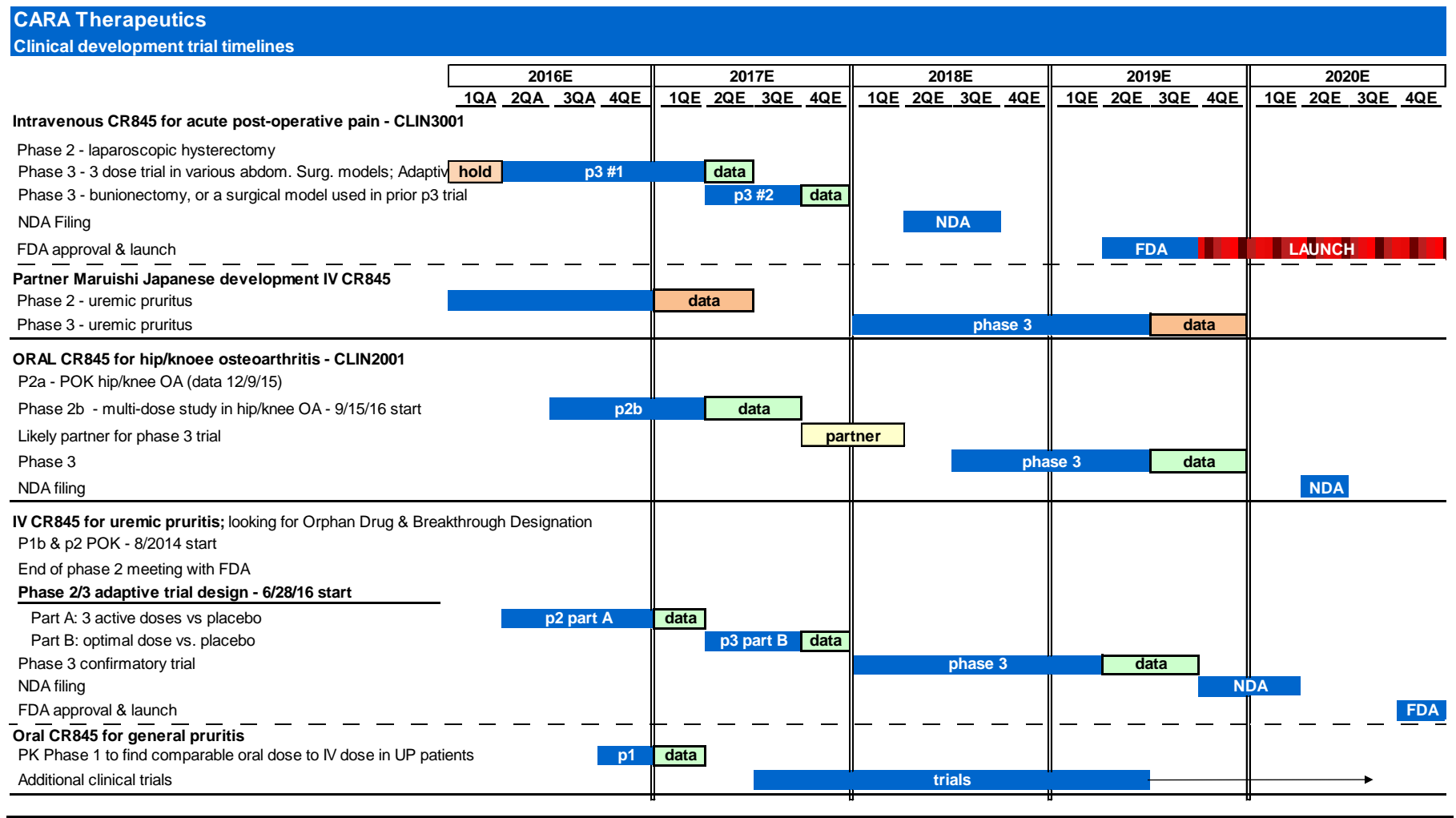
Source: Company reports and Laidlaw Estimates

Figure 2: Valuation

Sum-of-the-parts value: CARA		
Segment	Valuation (000's)	Per share value
CR845 - IV post-op pain	\$236,346	\$7.0
CR845 - oral OA pain	\$83,447	\$2.5
CR845 - IV uremic pruritus	\$126,056	\$3.5
CR845 - oral general pruritus	\$56,788	\$1.5
Cash (end '17) & tech value	\$56,425	\$2.5
SUM	\$559,061	\$17
Shares out '17E (000)		32,233

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	2QA	3QA	4QE	
Revenues										
License & milestones			\$1,710		\$1,710					\$0
Collaborative revenues	\$489	\$874	730	\$750	2,843	\$7	\$79		\$750	836
Total Revenue	\$489	\$874	\$2,440		\$3,803	\$7	\$79	\$0	\$750	\$836
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	489	874	2,440	-	3,803	7	79	-	750	836
Research and development	3,385	4,684	5,584	7,568	21,221	8,546	10,760	9,671	9,500	38,477
General and administrative	1,822	1,922	1,865	2,161	7,770	2,447	2,645	2,102	2,500	9,694
Total operating expenses	5,207	6,606	7,449	9,729	28,991	10,993	13,405	11,773	12,000	48,171
Income (loss) from Operations	(4,718)	(5,732)	(5,009)	(9,729)	(25,188)	(10,986)	(13,326)	(11,773)	(11,250)	(47,335)
Interest income (expense), net	14	13	22	52	101	149	172	176	25	522
Other (exp) gain, net										
Income (loss) before taxes	(4,704)	(5,719)	(4,987)	(9,677)	(25,087)	(10,837)	(13,154)	(11,597)	(11,225)	(46,813)
Income tax exp (benefit)	(15)	(35)	(200)	(147)	(397)	(145)	(79)	(55)		
Net income (Loss)	(4,689)	(5,684)	(4,787)	(9,530)	(24,690)	(10,692)	(13,075)	(11,542)	(11,225)	(46,534)
Net income to common										
Earning per Share (EPS)	(\$0.21)	(\$0.25)	(\$0.19)	(\$0.35)	(\$1.00)	(\$0.39)	(\$0.48)	(\$0.42)	(\$0.41)	(\$1.70)
Adj EPS ex-1x & non-cash			(\$0.23)		(\$1.05)			(\$0.42)		(\$1.70)
Weighted avg. shares (000)	22,808	22,828	25,545	27,240	24,620	27,260	27,283	27,283	27,383	27,302
Fully diluted shares (000)	24,103	24,411	27,087	29,515	26,279	29,474	29,540	29,283	29,383	29,420

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	
CR845 - IV Uremic pruritus				-	-	17,938	phase 3 starting 2H16
CR845 - oral hip/knee OA pain				-	-	-	phase 2b starting 2H16
License & milestones	\$1,710	\$0		-	-	-	
Collaborative revenues	2,843	836	\$3,000	\$3,000	3,000	3,000	
Total Revenue	\$3,803	\$836	\$3,000	\$3,000	\$56,329	\$172,413	
Expenses:							
Cost of Revenue (COGS)	-	-	-	-	7,999	22,721	
Gross Margin	3,803	836	3,000	3,000	48,330	149,691	
R&D	21,221	38,477	39,000	41,000	43,500	46,750	
SG&A	7,770	9,694	14,000	15,250	25,250	57,000	125 reps in 2020
Total op exp	28,991	48,171	53,000	56,250	68,750	103,750	
Inc/(loss) from Ops	(25,188)	(47,335)	(50,000)	(53,250)	(20,420)	45,941	
Int income (exp), net	101	522	100	100	100	100	
Other expenses, net	-	-	-	-	-	-	
Inc/(loss) before taxes	(25,087)	(46,813)	(49,900)	(53,150)	(20,320)	46,041	
Income tax exp (benefit)	(397)	-	-	-	-	2,302	sig. tax loss carryforwards
Net income (Loss)	(\$24,690)	(\$46,534)	(\$49,900)	(\$53,150)	(\$20,320)	\$43,739	
Net income to common							
Earning per Share	(\$1.00)	(\$1.70)	(\$1.65)	(\$1.65)	(\$0.60)	\$1.15	
Adj EPS ex-1x & non-cash	(\$1.05)	(\$1.70)					
Weighted avg. shares (000)	24,620	27,302	30,233	32,233	33,733	35,233	
Fully diluted shares (000)	26,279	29,420	32,233	34,733	36,483	37,983	Raises in 2017 & 2018

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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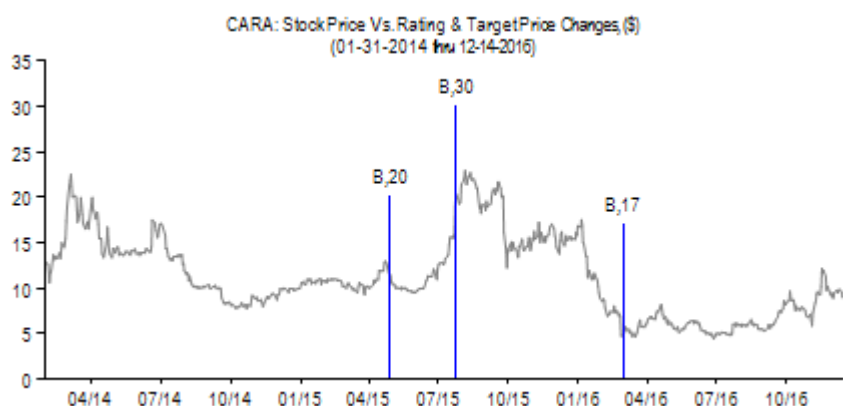
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RATINGS INFORMATION**Rating and Price Target Change History****3 Year Rating Change History**

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
02/29/2016	17.00	4.92

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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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