

Cara Therapeutics (CARA - \$18.99)

Pruritus phase 2 hits significance, huge potential driver for CARA

Yesterday morning CARA reported positive phase 2 trials in uremic pruritus (itching while undergoing dialysis) for their IV CR845 kappa opioid agonist. Given the positive data of yesterday, we are raising our valuation for the pruritus indication as the program risk is now materially diminished with this proof-of-concept phase 2 hitting statistical significance. CARA anticipates meeting the FDA in late 2015 with a 1Q16 start for the phase 3 trial. We believe that the IV version should receive Orphan Designation and could also receive Breakthrough Designation given the unmet medical need amongst dialysis patients. Should the IV dialysis indication get approved, we see a strong likelihood that an oral version for the broader, general pruritus indication could follow in short order. This is a significant market opportunity with approximately 20M sufferers in the US, and could represent a true “blockbuster” product for CARA. We are reiterating our Buy rating and raising our PT from \$20 to \$30 following the de-risking of the pruritus indication.

- **Trial hits on itching intensity primary endpoint.** The primary endpoint was statistically significant at 2 weeks with CR845, which is especially dramatic given the relatively small trial size (n=65). CR845 also hit on the secondary endpoint Skindex-10 score but missed on the secondary endpoint of MOS sleep index. See page 2 for a more complete discussion of the trial results.
- **Timeline moving up from our expectations.** CARA guided to the phase 3 trials starting in 1Q16 with a planned NDA submission in 2017, ahead of our current expectations for a 2Q16 trial start and a 1H18 NDA submission, which is a nice positive. CARA is to meet with the FDA in 2H15/1Q16 for end-of-phase 2 meeting, expects to start p3 in 1H16 with data & filing possibly in 2017. We anticipate a ~300+ person trial and a potentially 6 week dosing schedule. CARA will ask the FDA for orphan & breakthrough designation.
- **Pruritus a real potential blockbuster.** Net, this is a significant positive for CARA as the pruritus indication could be a first-in-class blockbuster for the company if eventually approved for the broader, non-uremic pruritus indication. There are approximately 400K patients in the US that undergo dialysis, ~50% experience pruritus. On a broader scale ~20M Rx's are written annually off label for pruritus, and there are no approved therapies.
- **Reiterate Buy rating, raising price target to \$30.** Our price target is based on sum-of-the parts with IV CR845: \$12/share; oral post-op pain: \$4/share; uremic pruritus: \$7/share; oral general pruritus \$5/share, and cash (end '16) & technology value \$2/share.

Healthcare/Biotechnology

Ticker:	CARA
Rating:	Buy
Price Target:	\$ 30.00

Trading Data:

Last Price (07/23/2015)	\$ 18.99
52-Week High (07/23/2015)	\$18.99
52-Week Low (10/14/2014)	\$7.53
Market Cap. (MM)	\$433.5
Shares Out. (MM)	22.82

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	(0.34)	(0.34)	(0.35)	(0.37)	(1.40)	NA
FY-15E	(0.21)A	(0.18)	(0.32)	(0.34)	(1.05)	NA
FY-14A	(0.22)	(0.16)	(0.28)	(0.18)	(0.85)	NA
FY-13A	NA	NA	NA	NA	(0.74)	NA

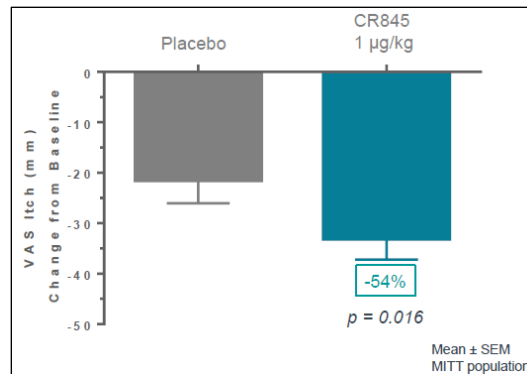
Source: Company data and Laidlaw & Company estimates

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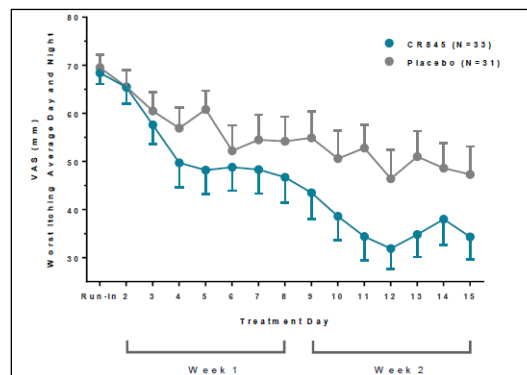
Trial hits on itching intensity primary endpoint. The primary endpoint was statistically significant at 2 weeks with CR845 reporting a 54% greater reduction in worst itch scores from baseline than those receiving placebo (p=0.016). CR845 demonstrated statistical reductions in both daytime (-51%, p=0.03) and nighttime (-75%, p=0.007) worst itch scores compared to placebo. CR845 also hit on the secondary endpoint Skindex-10 score (p=0.031) but missed on the secondary endpoint of MOS sleep index.

Figure 1: Primary Endpoint Itch Intensity



Source: Company presentation.

Figure 2: Itch Intensity over 2 Weeks of Treatment



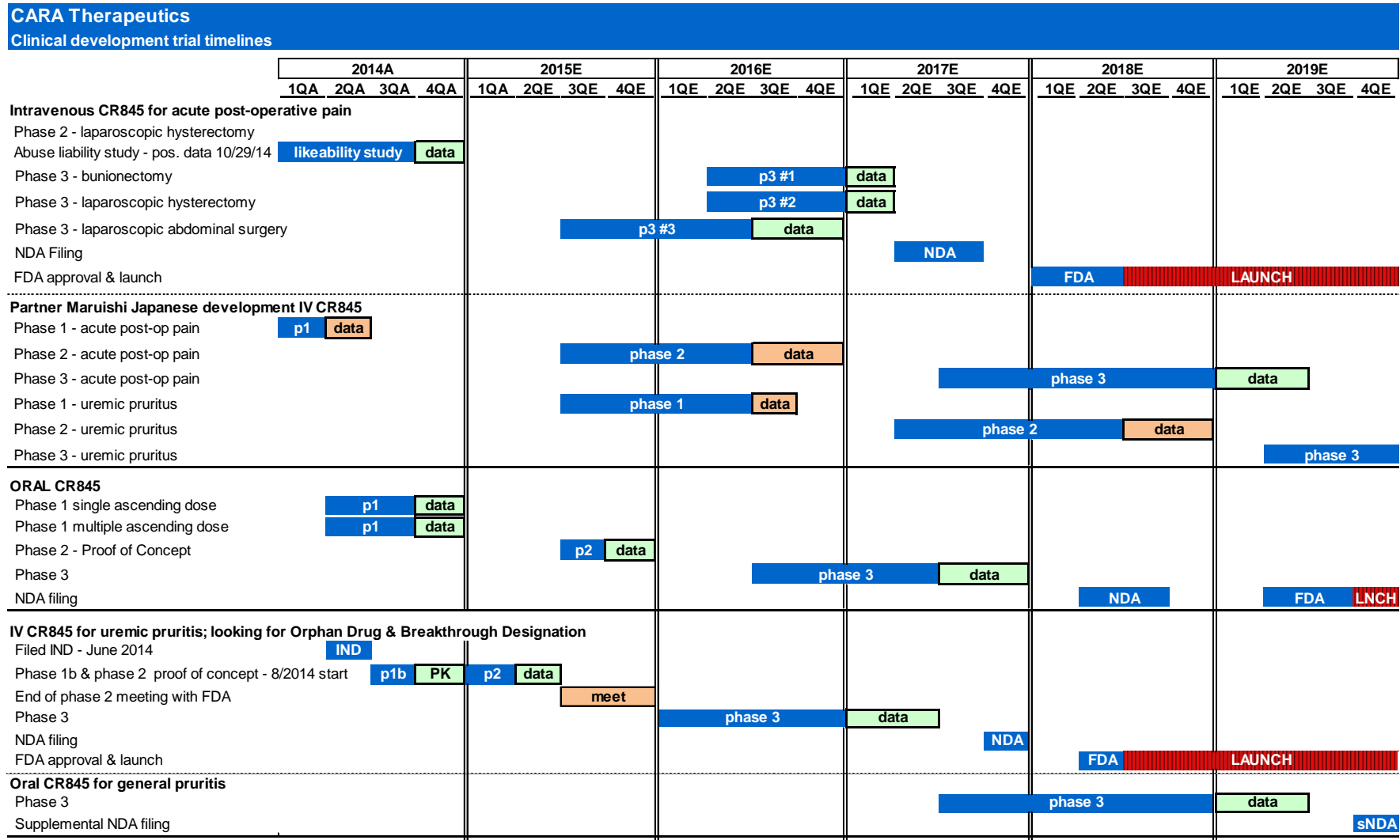
Source: Company presentation.

Figure 3: Valuation

Sum-of-the-parts value: CARA		
Segment	Valuation (000's)	Per share value
CR845 - IV post-op pain	\$391,525	\$12.0
CR845 - oral post-op pain	\$138,559	\$4.0
CR845 - IV uremic pruritus	\$220,422	\$7.0
CR845 - oral general pruritus	\$157,740	\$5.0
Cash (end '16) & tech value	\$73,443	\$2.0
SUM	\$981,688	\$30
Shares out '16E (000)		32,208

Source: Laidlaw & Company estimates.

Figure 4: Clinical trials timeline



Source: Company reports and Laidlaw estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 5: Quarterly Income Statement

CARA Therapeutics										
Quarterly income statement										
(\$000 except per share)	2015E				2015E Year	2016E				2016E Year
	1QA	2QE	3QE	4QE		1QE	2QE	3QE	4QE	
Revenues										
License & milestones										
Collaborative revenues	\$489	\$500	\$500	\$500	\$1,989	\$500	\$500	\$500	\$500	\$2,000
Total Revenue	\$489	\$500	\$500	\$500	\$1,989	\$500	\$500	\$500	\$500	\$2,000
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	489	500	500	500	1,989	500	500	500	500	2,000
Research and development	3,385	3,750	7,750	8,000	22,885	8,000	8,000	8,250	8,500	32,750
General and administrative	1,822	2,000	2,000	2,250	8,072	2,500	2,500	2,500	2,750	10,250
Total operating expenses	5,207	5,750	9,750	10,250	30,957	10,500	10,500	10,750	11,250	43,000
Income (loss) from Operations	(4,718)	(5,250)	(9,250)	(9,750)	(28,968)	(10,000)	(10,000)	(10,250)	(10,750)	(41,000)
Interest income (expense), net	14	25	25	25	89	25	25	25	25	100
Other (exp) gain, net										
Income (loss) before taxes	(4,704)	(5,225)	(9,225)	(9,725)	(28,879)	(9,975)	(9,975)	(10,225)	(10,725)	(40,900)
Income tax exp (benefit)	(15)									
Net income (Loss)	(4,689)	(5,225)	(9,225)	(9,725)	(28,864)	(9,975)	(9,975)	(10,225)	(10,725)	(40,900)
Net income to common										
Earning per Share (EPS)	(\$0.21)	(\$0.18)	(\$0.32)	(\$0.34)	(\$1.05)	(\$0.34)	(\$0.34)	(\$0.35)	(\$0.37)	(\$1.40)
Weighted avg. shares (000)	22,808	28,858	28,908	28,958	27,383	29,058	29,158	29,258	29,358	29,208
Fully diluted shares (000)	25,558	31,608	31,658	31,708	30,133	32,058	32,158	32,258	32,358	32,208

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

Figure 6: Annual Income Statement

CARA Therapeutics							
Annual income statement							
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
Revenues							
CR845 - IV post-op pain					\$27,254	\$205,431	Launch 2H18
CR845 - IV Uremic pruritus					3,170	53,291	Launch 2H18
CR845 - oral post-op pain					-	12,500	Launch 2H19
License & milestones	\$302	-	-	-	-	-	
Collaborative revenues	2,875	\$1,989	\$2,000	\$2,000	2,000	2,000	
Total Revenue	\$3,177	\$1,989	\$2,000	\$2,000	\$32,424	\$273,222	
Expenses:							
Cost of Revenue (COGS)	-	-	-	-	4,088	30,815	
Gross Margin	3,177	1,989	2,000	2,000	28,336	242,407	
R&D	15,068	22,885	32,750	34,500	32,500	40,000	
G&A	6,181	8,072	10,250	10,500	18,500	64,500	
Total op exp	21,249	30,957	43,000	45,000	51,000	104,500	
Inc/(loss) from Ops	(18,072)	(28,968)	(41,000)	(43,000)	(22,664)	137,907	
Int income (exp), net	126	89	100	100	100	100	
Other expenses, net	-	-	-	-	-	-	
Inc/(loss) before taxes	(17,946)	(28,879)	(40,900)	(42,900)	(22,564)	138,007	
Income tax exp (benefit)	(201)	-	-	-	-	2,760	
Net income (Loss)	(\$17,745)	(\$28,864)	(\$40,900)	(\$42,900)	(\$22,564)	\$135,247	
Net income to common							
Earning per Share	(\$0.85)	(\$1.05)	(\$1.40)	(\$1.40)	(\$0.70)	\$3.20	
Weighted avg. shares (000)	20,966	27,383	29,208	30,708	32,208	33,708	
Fully diluted shares (000)	21,988	30,133	32,208	34,208	37,208	42,208	

Source: Company reports and Laidlaw estimates

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

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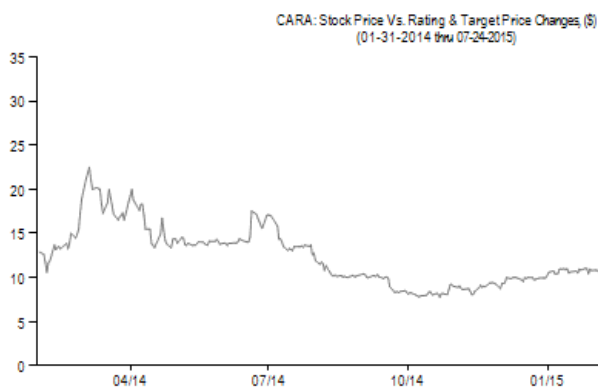
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Rating and Price Target Change History



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	18.99*

* Previous Close 7/23/2015

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	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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