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EQUITY RESEARCH
Company Report

June 8, 2015

Cara Therapeutics (CARA - $ 9.94)

Healthcare/Biotechnology

Kappa opioid targets the next wave in pain management

Ticker:	**CARA**
Rating:	**Buy**
Price Target:	**$ 20.00**

We recently held a KOL call with a leading kappa opioid research specialist on the clinical trial design of CARA's kappa opioid CR845, and the potential clinical utility of kappa opioids for treating pain. Our KOL sees a tremendous amount of interest in the kappa space over the past few years, as novel peripheral treatments are avoiding the CNS SAE's that plagued earlier formulations. In particular CARA seems to be the lead horse in the kappa opioid space, with CR845 starting its first phase 3 trial in 3Q15, with the potential for an NDA filing by mid-2017. With a clean AE profile in its completed phase 2 trials - and a possible improved scheduling - we continue to see CR845 as potentially being a transformative novel compound for pain. We are reiterating our Buy rating and our $20 price target based on a sum-of-the-parts with CR845 IV for post-op pain valued at $12/share, CR845 for uremic pruritus valued at $3.5/share, the oral version of CR845 valued at $2.5/share, and cash (end-'16) and tech valued at $2/share.

Trading Data:

Last Price (06/05/2015)	$ 9.94
52–Week High	$17.77
52–Week Low	$7.53
Market Cap. (MM)	$226.9
Shares Out. (MM)	25.56

- **Kappa receptors increasingly seen as the next generation for treating pain.** Our KOL is seeing a resurgence in interest in the kappa opioid target, which he has been working on since the late 1970's. The ability to avoid the severe hallucinations & depression of earlier formulations while still providing opioid levels of analgesia is sparking significant interest in the kappa receptor.
- **CR845 peripheral action avoids past CNS side effects.** Earlier kappa agonists ran into significant psychosomatic AE's which CR845 avoids by acting peripherally outside the CNS. Our KOL sees this approach as offering a fundamentally novel way of treating pain with a lower AE profile and sees CARA as the most clinically advanced kappa agonist in development.
- **Kappa opioids more likely to be down-scheduled.** While likely still a schedule 2 drug if approved - given the inherent caution at the FDA - our KOL sees a possibility that kappa opioids could be "down-scheduled" following approval. This would likely only occur if the expected lower abuse potential & lower AE's bear out in the post-approval "real-world" setting.
- **CARA clinical trials make sense for approval.** Our KOL noted that hysterectomy & bunionectomy are classic, validated pain targets for FDA approval. There have been some concerns about a potential over enrollment of women in CARA's trials. Our KOL notes that he sees real gender differences in pain perception and a product that could be more targeted towards women would be well received, in his opinion.

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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Oral formulation key for expanding indications. Both our KOL and Laidlaw see the development of an oral formulation for CR845 as a positive for investors as an oral formulation is necessary to expand indications beyond IV post-op pain. We estimate a phase 2 trial for the oral version starting in 3Q15, with data by 4Q15 and confirmatory phase 3 trials starting in 2H16.

Pruritus a major problem with traditional mu opioids. CARA is pursuing a development plan for CR845 in uremic pruritus, with phase 2 data anticipated in late June 2015. While the anti-pruritic effects of kappa agonists were less well known to our KOL, he did note that traditional mu opioids have pruritus as a significant side effect along with the nausea, vomiting, and addiction potential. So should CR845 in fact demonstrate an anti-pruritic effect (which we believe could be likely) this would be a major advance in treating this currently intractable problem. See Figure 2 “Clinical Trials Timeline” on page 4 of this report for our projections of the upcoming clinical trial landscape for CARA.

New preclinical mu-opioid targets could eliminate adverse events altogether. Our KOL’s lab has discovered approximately 30 different proteins generated from the mu opioid receptor that appear to be good targets for further research. This opens the possibility that eventually pain drugs could be developed that eliminate the abuse potential and dependence that characterizes current opioid therapy. Of course, these targets are all in preclinical development, and any human clinical trials remain years away.

Reiterate Buy rating, $20 price target. CARA is a clinical-stage biopharmaceutical company focused on developing and commercializing novel and proprietary chemical entities that selectively target kappa-opioid receptors involved with pain. The lead product candidate is intravenous CR845, an injectable version of a first-in-class kappa-opioid receptor-based peripheral analgesic. It is designed to provide pain relief without stimulating mu-opioid receptors, which trigger many unwanted side effects. CARA has completed two phase II trials investigating IV CR845 in both soft- (laparoscopic hysterectomy) and hard-tissue (bunionectomy) surgeries, successfully demonstrating significant pain relief and a consistent ability to decrease opioid-related adverse events. Currently, CARA is expecting to begin phase III pivotal trials for IV CR845 in 1H15. CARA recently reported positive phase 1a/1b data on the oral tablet formulation of CR845.

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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	$375,756	$12.0
CR845 - uremic pruritus	$116,693	$3.5
CR845 - oral formulation	$82,636	$2.5
Cash (end '16) & tech value	$68,443	$2.0
SUM	**$643,528**	**$20**
Shares out '16E (000)		32,208

Source: Laidlaw & Company estimates.

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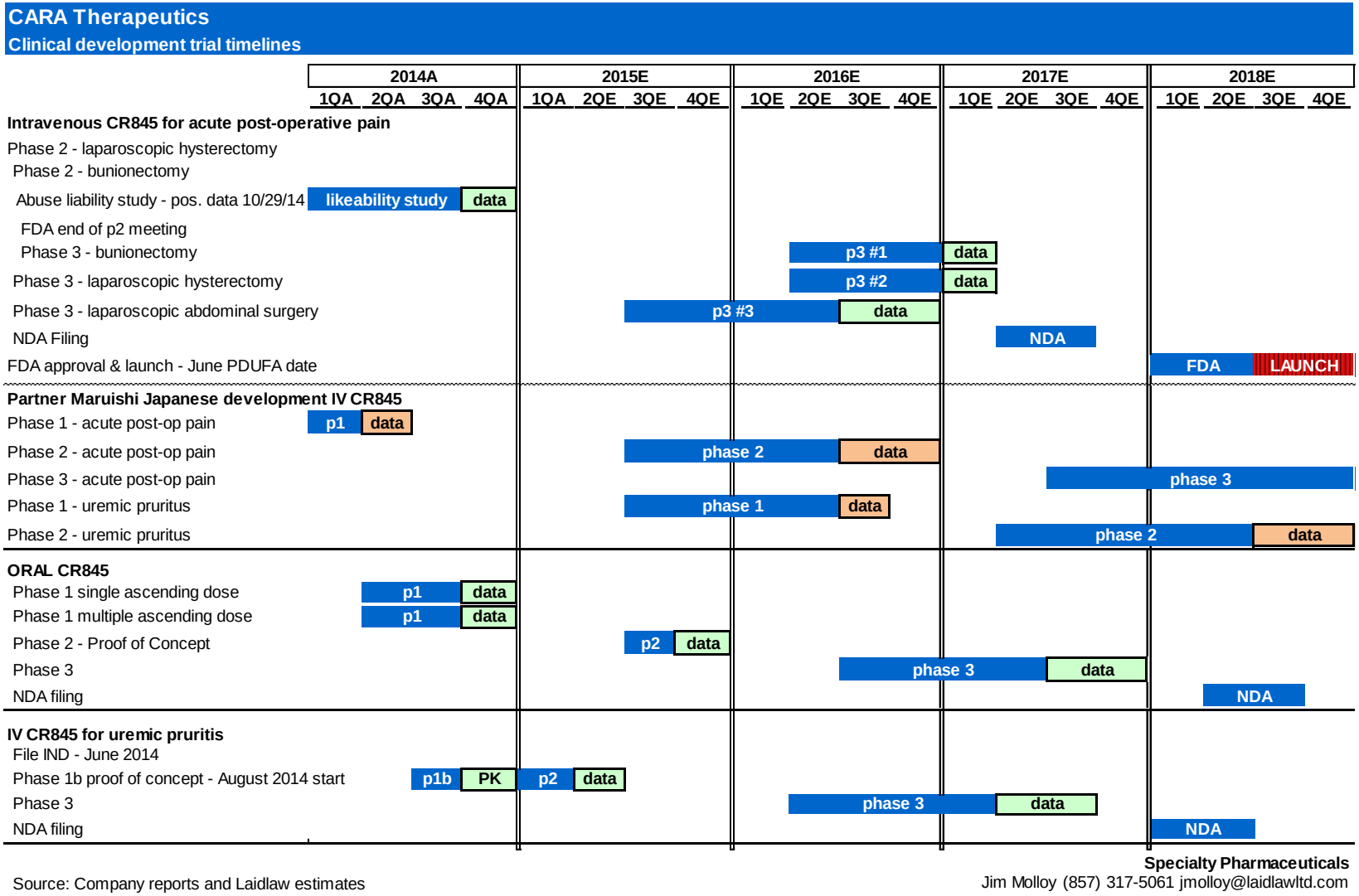
Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

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Figure 3: Quarterly Income Statement

CARA Therapeutics
Quarterly income statement

($000 except per share)	2015E 1QA	2015E 2QE	2015E 3QE	2015E 4QE	2015E Year	2016E 1QE	2016E 2QE	2016E 3QE	2016E 4QE	2016E Year
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.

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Figure 4: Annual Income Statement

CARA Therapeutics
Annual income statement

($000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
Revenues							
CR845 - IV version					$27,254	$205,431	Launch 2H18
CR845 - oral version					-	12,500	Launch 2H19
License & milestones	$302	-	-	-	-	15,000	Launch 2H19
Collaborative revenues	2,875	$1,989	$2,000	$2,000	2,000	2,000	
Total Revenue	**$3,177**	**$1,989**	**$2,000**	**$2,000**	**$29,254**	**$234,931**	
Expenses:							
Cost of Revenue (COGS)	-	-	-	-	4,088	30,815	
Gross Margin	**3,177**	**1,989**	**2,000**	**2,000**	**25,166**	**204,116**	
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	45,750	
Total op exp	21,249	30,957	43,000	45,000	51,000	85,750	
Inc/(loss) from Ops	**(18,072)**	**(28,968)**	**(41,000)**	**(43,000)**	**(25,834)**	**118,366**	
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)**	**(25,734)**	**118,466**	
Income tax exp (benefit)	(201)	-	-	-	-	2,369	
Net income (Loss)	**($17,745)**	**($28,864)**	**($40,900)**	**($42,900)**	**($25,734)**	**$116,097**	
Net income to common							
Earning per Share	**($0.85)**	**($1.05)**	**($1.40)**	**($1.40)**	**($0.80)**	**$2.75**	
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: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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Additional information available upon request.
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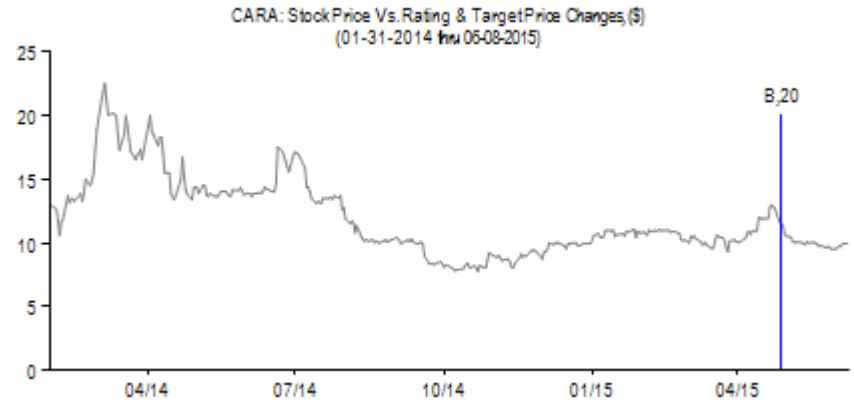
Rating and Price Target Change History



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

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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