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EQUITY RESEARCH
Company Report

July 13, 2017

Cara Therapeutics (CARA - $13.44)

Healthcare/Biotechnology

Ticker:	**CARA**
Rating:	**Buy**
Price Target:	**$30**

Oral CR845 in Pruritus off to a Strong Start, Encouraging Phase 1 PK and Safety Data

Recently, CARA announced summary results from its Phase 1 safety and PK trial of oral CR845 in chronic kidney disease (CKD) patients undergoing hemodialysis. Whether administered daily or post-dialysis 3x/week, all tablets (0.25, 0.5, 1.0, and 2.5mg) showed encouraging safety and bioavailability as drug plasma levels were greater than or equal to those seen in IV CR845 for moderate to severe CKD-associated pruritus (CKD-aP) in hemodialysis patients (see note 3/28/17). In fact, data showed plasma levels of 1.0mg to be similar to those achieved with 1.0ug/kg in IV CR845. We see these results as particularly important since IV CR845 demonstrated efficacy in reduction of itch (NRS), improvement in quality of life (Skindex-10), and obtained Breakthrough Therapy Designation (BTD) for CKD-aP in patients undergoing hemodialysis as well. CARA will use this data to appropriately design their planned Oral CR845 pruritus clinical trials in non-dialysis CKD-aP patients, which they believe should start before YE17. While CARA's stock price took a significant blow following Phase 2b Oral CR845's mixed results in chronic pain patients with OA of the hip or knee announced on 6/29/17 (see 6/30/17 note), we believe the stock is undervalued at these levels. We are also encouraged by this early oral CR845 data in pruritus as this represents a clear unmet medical need. We are reiterating our Buy rating and $30 price target.

- **Oral CR845 for pruritus checks off safety and PK boxes, encouraging IV CR845 plasma levels read-through.** We see strong safety once again at CARA as attesting to their unique peripheral kappa opioid receptor agonist mechanism of action (MOA); and are encouraged by the equal or greater plasma levels as those seen with clinically efficacious IV CR845 for CKD-aP in hemodialysis patients.
- **Busy 2017 isn't quite over at CARA, more data to come.** Already revealed in 2017 are several results, including Phase 2/3 Part A IV CR845 in UP in 1Q17; first Phase 3 interim assessment for IV CR845 in post-op pain in 2Q17; Phase 2b oral CR845 in hip/knee OA in 2Q17 and now Phase 1 PK oral CR845 in their pruritus program, we still expect final data of their first Phase 3 for IV CR845 for post-op pain in 4Q17.
- **Maintain Buy rating, $30 PT.** We value CARA on a sum-of-the-parts: IV CR845 for pruritus: $14/share, IV/oral post-op pain: $11.5/share, oral pruritus: $3/share, and cash (end'17) and tech: $1.5/share.

Trading Data:

Last Price (07/12/2017)	$13.44
52–Week High (06/27/2017)	$28.50
52–Week Low (07/20/2016)	$4.75
Market Cap. (MM)	$436.9
Shares Out. (MM)	32.5

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

Source: Company data and Laidlaw & Company estimates

Analyst

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Figure 1: Clinical Trial Design and Result

CR845 Phase 1 trial of Oral CR845 in Hemodialysis Patients with Chronic Kidney Disease	
Aim	Safety & pharmacokinetic profile of multiple escalating doses
Design	random, placebo controlled. PART A: ascending repeated oral doses 0.25, 0.5, 1.0 and 2.5mg to 4 cohorts of patients (n=47) after each dialysis (ie 3X) over 1 week. PART B: ascending repeated doses 0.25, 0.5 and 1.0mg daily to 3 cohorts of hemodialysis patients (n=36). PART C: final crossover, 1.0 mg oral dose or 1.0ug/kg IV dose (n=7) given after hemodialysis with a 1 week wash-out b/w treatments to det. absolute bioavailability of Oral. PARTS A and B randomized up to n=12/dose group (9 active and 3 placebo). PART C: open-label with n=7 receiving active drug.
Dosing	0.25, 0.5, 1.0 and 2.5mg
Endpoints	Oral bioavailability by plasma concentrations
Safety	TEAEs in CR845 was similar to placebo. All TEAEs were generally mild and comparable to those in p2/3 IV CR845 for pruritus in CKD-aP undergoing dialysis.
Results - 7/12/17	Topline PK showed that plasma levels of CR845 attained after oral doses up to 2.5mg were comparable to or exceeded those achieved with clinically effacacious IV CR845 for treatment of moderate to severe CKD-aP in hemodialysis patients. Absolute oral bioavailability of the 1.0mg tablet was similar in hemodialysis to that obtained in non-CKD patients. Plasma levels of CR845 attained after oral of 1.0mg tablet similar to 1.0ug/kg in IV CR845.

Source: Company and Laidlaw Estimates

Figure 2: 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	$96,835	$3
CR845 - oral OA pain	$88,539	$2.5
Cash (end '17) & tech value	$54,084	$1.5
SUM	**$1,025,217**	**$30**
Shares out '17E (000)		33,876

Source: Laidlaw Estimates

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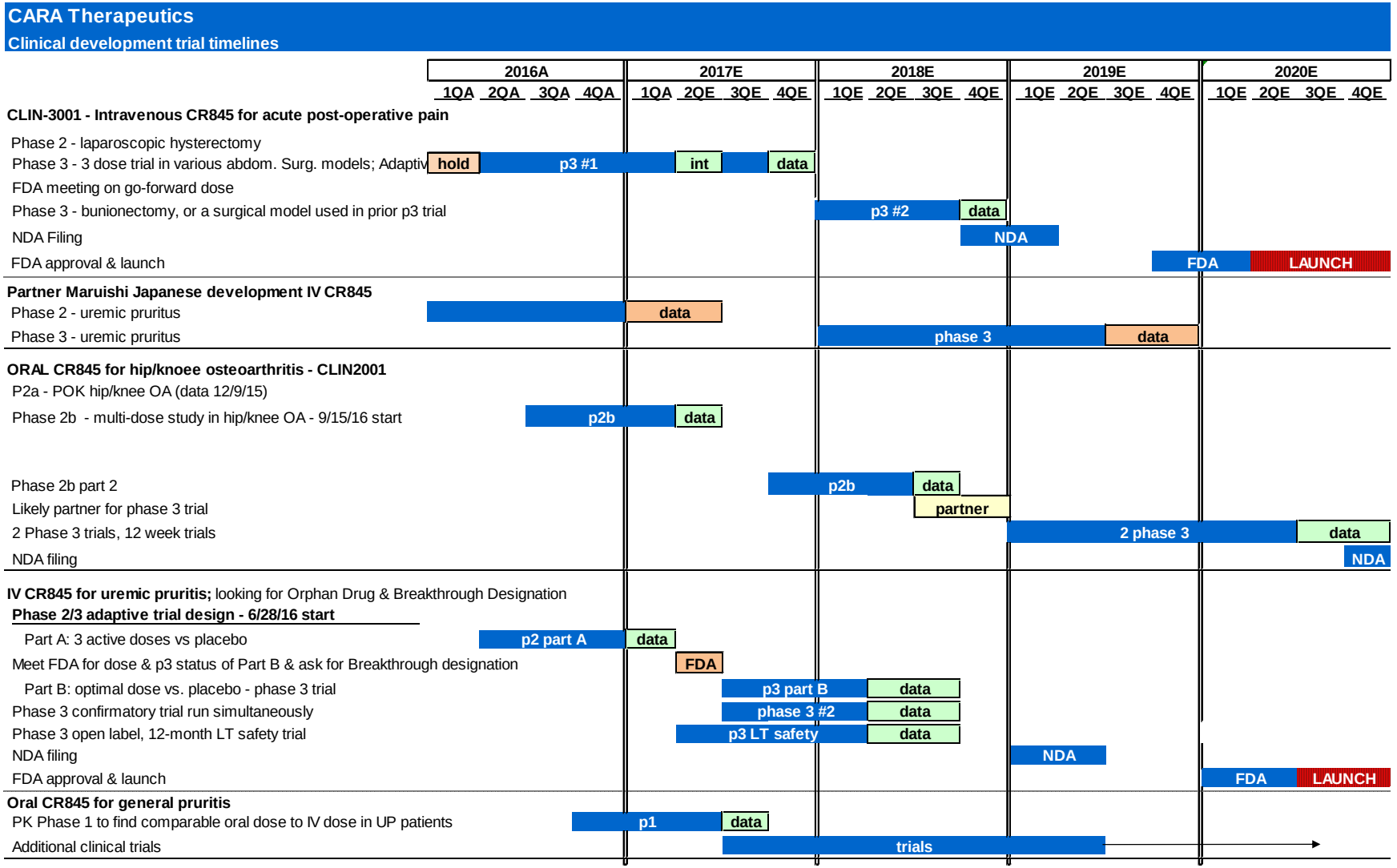
Figure 3: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

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Figure 4: Quarterly Income Statement

CARA Therapeutics
Quarterly income statement

($000 except per share)	2016A 1QA	2016A 2QA	2016A 3QA	2016A 4QA	2016A Year	2017E 1QA	2017E 2QE	2017E 3QE	2017E 4QE	2017E Year
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.

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Figure 5: 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	

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

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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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Additional information available upon request.

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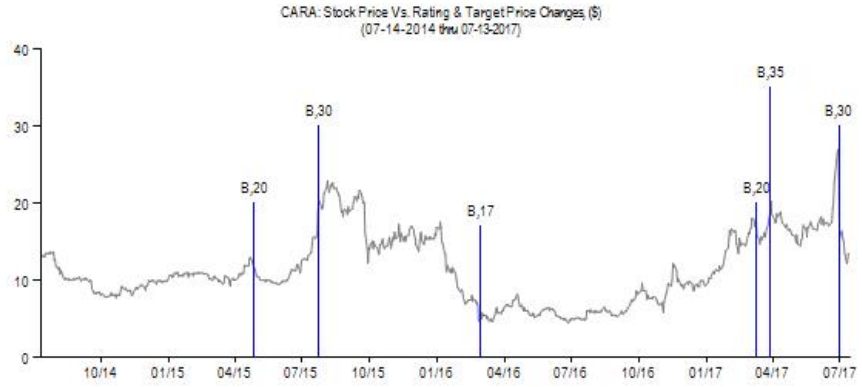
Rating and Price Target Change History



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
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
06/30/2017	30.00	15.39

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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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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