

## Cara Therapeutics (CARA - \$16.80)

Healthcare/Biotechnology

### KOLs on CKD Associated Itch, a Large Unmet Medical Need

We recently attended a KOL breakfast event hosted by CARA and came away incrementally more positive about its IV CR845 program for CKD associated pruritus (CKD-aP). The KOLs (with both academic and clinical backgrounds), emphasized the dearth of options to treat these patients already in deplorable health conditions. As a reminder, on 3/28/17, CARA announced positive data from its Phase 2b trial of IV CR845 for moderate to severe pruritus in dialysis patients as it demonstrated efficacy in reduction of itch (NRS) and improvement in quality of life (Skindex-10) at 8 weeks with p=0.0019 and p=0.0007, respectively. The KOLs were especially encouraged by its ability to significantly improve quality of life as well as its clean AE profile, which attests to CR845's unique peripheral mechanism of action. CARA still plans to meet with the FDA in 3Q17 to establish the plan moving forward. While KOLs have been disappointed many times in past pruritus trials, they saw Phase 2b data as a real positive and are hopeful that IV CR845 will make it across the finish line and alleviate this large growing unmet medical need that is CKD-aP. We still expect data read-outs this quarter for CARA's Phase 3 IV CR845 for post-operative pain, Phase 2b oral CR845 for OA pain as well as Phase 1 PK oral CR845 for general pruritus (blockbuster potential). This is an exciting time for CARA with multiple data points in the near term and we are reiterating our Buy rating and \$35 price target.

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

#### Trading Data:

Last Price (05/16/2017)	\$16.80
52-Week High (03/19/2017)	\$20.90
52-Week Low (06/27/2016)	\$4.35
Market Cap. (MM)	\$546.1
Shares Out. (MM)	32.5

- **KOLs impressed with Phase 2b data, emphasis on quality of life improvement.** As physicians have never had any safe and efficacious approved treatment options for CKD-aP, KOLs were particularly encouraged by the statistically significant improvement in quality of life (Skindex-10) at 8 weeks with p=0.0007. Additionally, 5-D itch score (degree, duration, direction, disability and distribution) and sleep disturbance (MOS) validated Skindex-10 findings.
- **Off to a strong start, data is the theme at CARA in 2017.** After convincing Phase 2b data for IV CR845 in pruritus, we still expect data read-outs this quarter for IV CR845 in post-op pain, oral CR845 in hip/knee OA pain as well as PK Phase 1 for oral CR845 in general pruritus.
- **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
<b>FY-18E</b>	NA	NA	NA	NA	(1.97)	NA
<b>FY-17E</b>	(0.81)A	(0.60)	(0.42)	(0.36)	(2.14)	NA
<b>FY-16A</b>	(0.39)	(0.48)	(0.42)	(0.81)	(2.10)	NA
<b>FY-15A</b>	(0.21)	(0.25)	(0.23)	(0.35)	(1.05)	NA

#### Analyst

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Source: Company data and Laidlaw & Company estimates

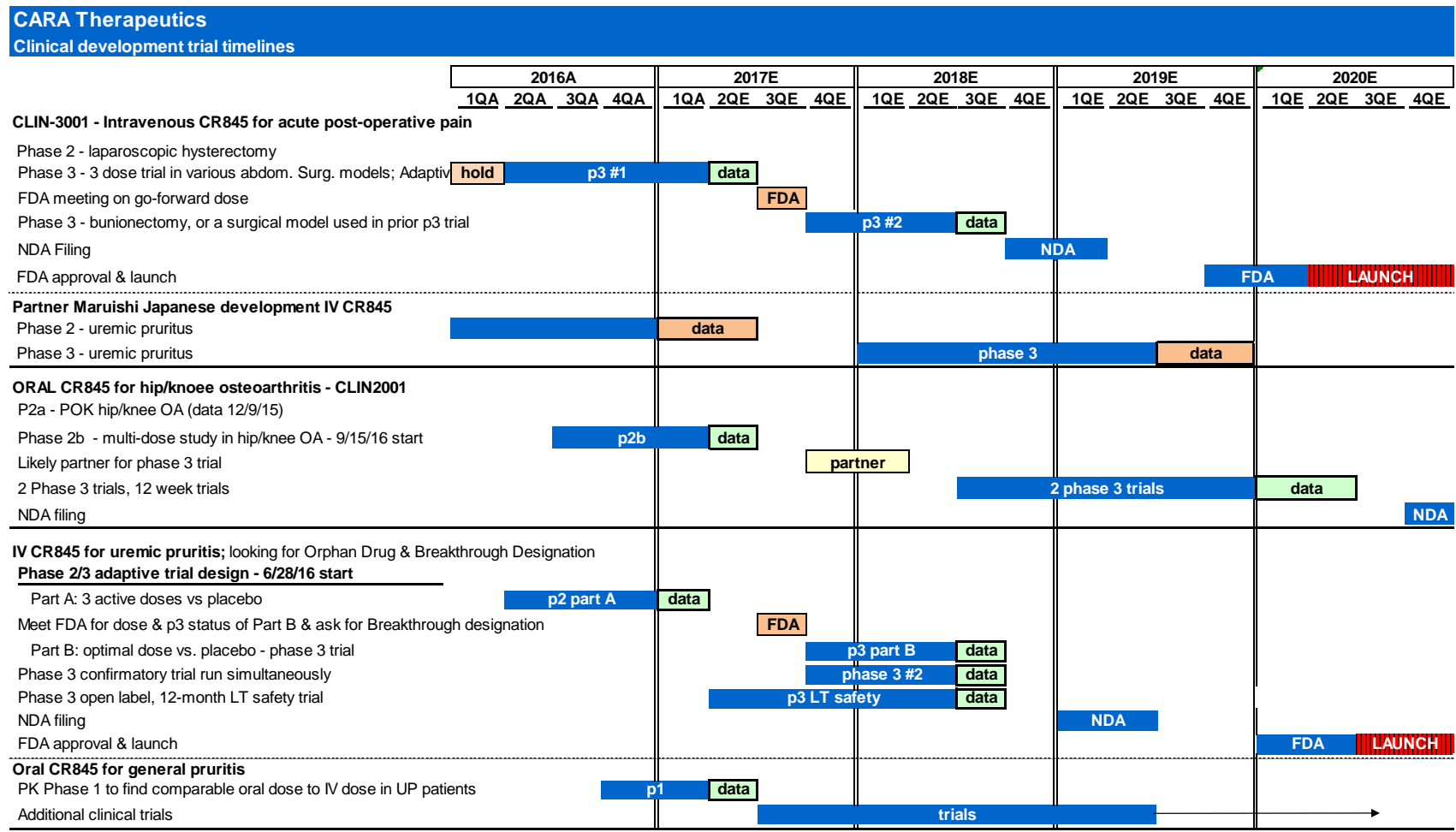
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**Figure 1: Valuation**

<b>Sum-of-the-parts value: CARA</b>		
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
	<b>SUM \$1,175,867</b>	<b>\$35</b>
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

CARA Therapeutics										
Quarterly income statement										
(\$000 except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
<b>Revenues</b>										
License & milestones					\$0	\$530				
Collaborative revenues	\$7	\$79			86	\$313	\$750	\$750	\$750	2,563
<b>Total Revenue</b>	<b>\$7</b>	<b>\$79</b>	<b>\$0</b>	<b>\$0</b>	<b>\$86</b>	<b>\$911</b>	<b>\$750</b>	<b>\$750</b>	<b>\$750</b>	<b>\$3,161</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
<b>Gross Margin</b>	<b>7</b>	<b>79</b>	<b>-</b>	<b>-</b>	<b>86</b>	<b>911</b>	<b>750</b>	<b>750</b>	<b>750</b>	<b>3,161</b>
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
<b>Income (loss) from Operations</b>	<b>(10,986)</b>	<b>(13,326)</b>	<b>(11,773)</b>	<b>(22,315)</b>	<b>(58,400)</b>	<b>(22,325)</b>	<b>(19,500)</b>	<b>(14,000)</b>	<b>(12,000)</b>	<b>(67,825)</b>
Interest income (expense), net	149	172	176	155	652	90	25	25	25	165
Other (exp) gain, net										
<b>Income (loss) before taxes</b>	<b>(10,837)</b>	<b>(13,154)</b>	<b>(11,597)</b>	<b>(22,160)</b>	<b>(57,748)</b>	<b>(22,235)</b>	<b>(19,475)</b>	<b>(13,975)</b>	<b>(11,975)</b>	<b>(67,660)</b>
Income tax exp (benefit)	(145)	(79)	(55)	(189)	(468)	(31)				
<b>Net income (Loss)</b>	<b>(10,692)</b>	<b>(13,075)</b>	<b>(11,542)</b>	<b>(21,971)</b>	<b>(57,280)</b>	<b>(22,204)</b>	<b>(19,475)</b>	<b>(13,975)</b>	<b>(11,975)</b>	<b>(67,629)</b>
<b>Net income to common</b>										
<b>Earning per Share (EPS)</b>	<b>(\$0.39)</b>	<b>(\$0.48)</b>	<b>(\$0.42)</b>	<b>(\$0.81)</b>	<b>(\$2.10)</b>	<b>(\$0.81)</b>	<b>(\$0.60)</b>	<b>(\$0.42)</b>	<b>(\$0.36)</b>	<b>(\$2.14)</b>
<b>Adj EPS ex-1x &amp; non-cash</b>			<b>(\$0.42)</b>		<b>(\$2.10)</b>					
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	29,300	34,417	35,017	35,617	33,588

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

Figure 4: Annual Income Statement

CARA Therapeutics						
Annual income statement						
(\$000 except per share)	2016A	2017E	2018E	2019E	2020E	Comments
<b>Revenues</b>						
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	
<b>Total Revenue</b>	<b>\$86</b>	<b>\$3,161</b>	<b>\$3,000</b>	<b>\$3,000</b>	<b>\$77,698</b>	
<b>Expenses:</b>						
Cost of Revenue (COGS)	-	-	-	-	8,514	
<b>Gross Margin</b>	<b>86</b>	<b>3,161</b>	<b>3,000</b>	<b>3,000</b>	<b>69,184</b>	
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	
<b>Inc/(loss) from Ops</b>	<b>(58,400)</b>	<b>(67,825)</b>	<b>(68,250)</b>	<b>(66,250)</b>	<b>(11,316)</b>	
Int income (exp), net	652	165	100	100	100	
Other expenses, net	-	-	-	-	-	
<b>Inc/(loss) before taxes</b>	<b>(57,748)</b>	<b>(67,660)</b>	<b>(68,150)</b>	<b>(66,150)</b>	<b>(11,216)</b>	
Income tax exp (benefit)	(468)	-	-	-	-	sig. tax loss carryforwards
<b>Net income (Loss)</b>	<b>(\$57,280)</b>	<b>(\$67,629)</b>	<b>(\$68,150)</b>	<b>(\$66,150)</b>	<b>(\$11,216)</b>	
<b>Net income to common</b>						
<b>Earning per Share</b>	<b>(\$2.10)</b>	<b>(\$2.14)</b>	<b>(\$1.97)</b>	<b>(\$1.78)</b>	<b>(\$0.29)</b>	
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$2.10)</b>					
Weighted avg. shares (000)	27,279	31,588	34,588	37,088	38,588	
Fully diluted shares (000)	29,827	33,588	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 &amp; Company estimates.

## Major Risks

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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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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	63.64%	29.55%	2.27%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	2.27%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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