

## Cara Therapeutics (CARA - \$15.88)

### CARA on track with near term catalysts

CARA recently reported 2Q15, beating top and bottom line due to milestone payments from partners Chong Kun Dang Pharmaceuticals (CKD) and Maruishi occurring in the quarter. CARA isn't an earnings story at this point but there are multiple developmental catalysts expected over the coming months. The first Phase 3 trial for IV CR845 for acute post-operative pain was initiated in September and data is expected 1H16; and the Phase 2a trial of oral CR845 for osteoarthritis (OA) should have a data read out this quarter. Finally, CARA expects to meet with the FDA in the fourth quarter to discuss a Phase 3 registration trial for uremic pruritus. With a busy 1H16 ahead we continue to like CARA and we reiterate our Buy rating, \$30 price target.

- **Pruritus getting closer to its blockbuster potential.** The positive Phase 2a data in uremic pruritus is a significant positive for CARA, in our opinion. The pruritus indication could be first-in-class blockbuster (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 general pruritus, with no approved therapies.
- **Important near-term development catalysts abound.** CARA remains on track with initiation of Phase 3 program for I.V. CR845 in acute post-op pain in September. Management also confirmed having fully enrolled their Phase 2a trial for oral CR845 in OA and expects data this quarter. CARA expects to hold an end-of-Phase 2 meeting with the FDA for I.V. CR845 for uremic pruritus this quarter.
- **Top & bottom line beat on milestone payments.** CARA reported 3Q15 a top and bottom line beat mainly due to a \$1.7M milestone from Maruishi for the start of the Phase 2 uremic pruritus trial in Japan.
- **Reiterate Buy rating, \$30 price target.** Our price target is based on sum-of-the parts with IV CR845: \$12/share; oral post-op pain: \$4/share; IV uremic pruritus: \$7/share; oral general pruritus: \$5/share, and cash (end' 16) and technology value: \$2/share.

*Healthcare/Biotechnology*

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

#### Trading Data:

Last Price (11/11/2015)	\$15.88
52-Week High (08/13/2015)	\$23.61
52-Week Low (11/14/2014)	\$7.99
Market Cap. (MM)	\$431.4
Shares Out. (MM)	27.09

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	(0.35)	(0.38)	(0.38)	(0.39)	(1.50)	NA
<b>FY-15E</b>	(0.21)A	(0.25)A	(0.23)A	(0.33)	(1.02)	NA
<b>FY-14A</b>	(0.22)	(0.16)	(0.28)	(0.18)	(0.85)	NA
<b>FY-13A</b>	NA	NA	NA	NA	(0.74)	NA

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Source: Company data and Laidlaw & Company estimates

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Figure 1: Variance analysis

<b>CARA Therapeutics</b>					
<b>Quarterly variance analysis</b>					
(000's except per share)	<b>3Q14A</b>	<b>3Q15A</b>	<b>3Q15E</b>	<b>Variance</b>	<b>% Y/Y</b>
License & milestones	\$0	\$1,710	\$0	\$1,710	NA
Collaborative revenues	1,125	730	500	230	-56%
<b>Total Revenue</b>	<b>\$1,125</b>	<b>\$2,440</b>	<b>\$500</b>	<b>\$1,940</b>	<b>-56%</b>
COGS	0	0	0	0	NA
<b>Gross Profit</b>	<b>1,125</b>	<b>2,440</b>	<b>500</b>	<b>1,940</b>	<b>-56%</b>
SG&A Expense	1,250	1,865	2,500	(635)	100%
R&D Expense	6,208	5,584	6,000	(416)	-3%
<b>Operating Income</b>	<b>(6,333)</b>	<b>(5,009)</b>	<b>(8,000)</b>	<b>2,991</b>	<b>26%</b>
Int inc (exp), net	26	22	25	(3)	-4%
Other (exp) gain, net	0	0	0	0	NA
<b>Pretax Income</b>	<b>(6,307)</b>	<b>(4,987)</b>	<b>(7,975)</b>	<b>2,988</b>	<b>26%</b>
Income Tax exp (benefit)	(32)	(200)	0	(200)	-100%
<b>Net income (loss)</b>	<b>(6,275)</b>	<b>(4,787)</b>	<b>(7,975)</b>	<b>3,188</b>	<b>27%</b>
1x items & non-cash exp	0	(1,163)	0	(1,163)	NA
<b>Adj NI ex-1x/non cash</b>	<b>(6,275)</b>	<b>(5,950)</b>	<b>(7,975)</b>	<b>2,025</b>	<b>27%</b>
Weighted avg. shares (000)	22,713	25,545	27,156	(1,611)	20%
Fully diluted shares (000)	23,677	27,087	28,906	(1,819)	22%
<b>Earning per Share (EPS)</b>	<b>(\$0.28)</b>	<b>(\$0.19)</b>	<b>(\$0.29)</b>	<b>\$0.11</b>	<b>6%</b>
<b>Adj EPS ex-1x &amp; non-cash items</b>		<b>(\$0.23)</b>	<b>(\$0.29)</b>	<b>\$0.06</b>	<b>NA</b>

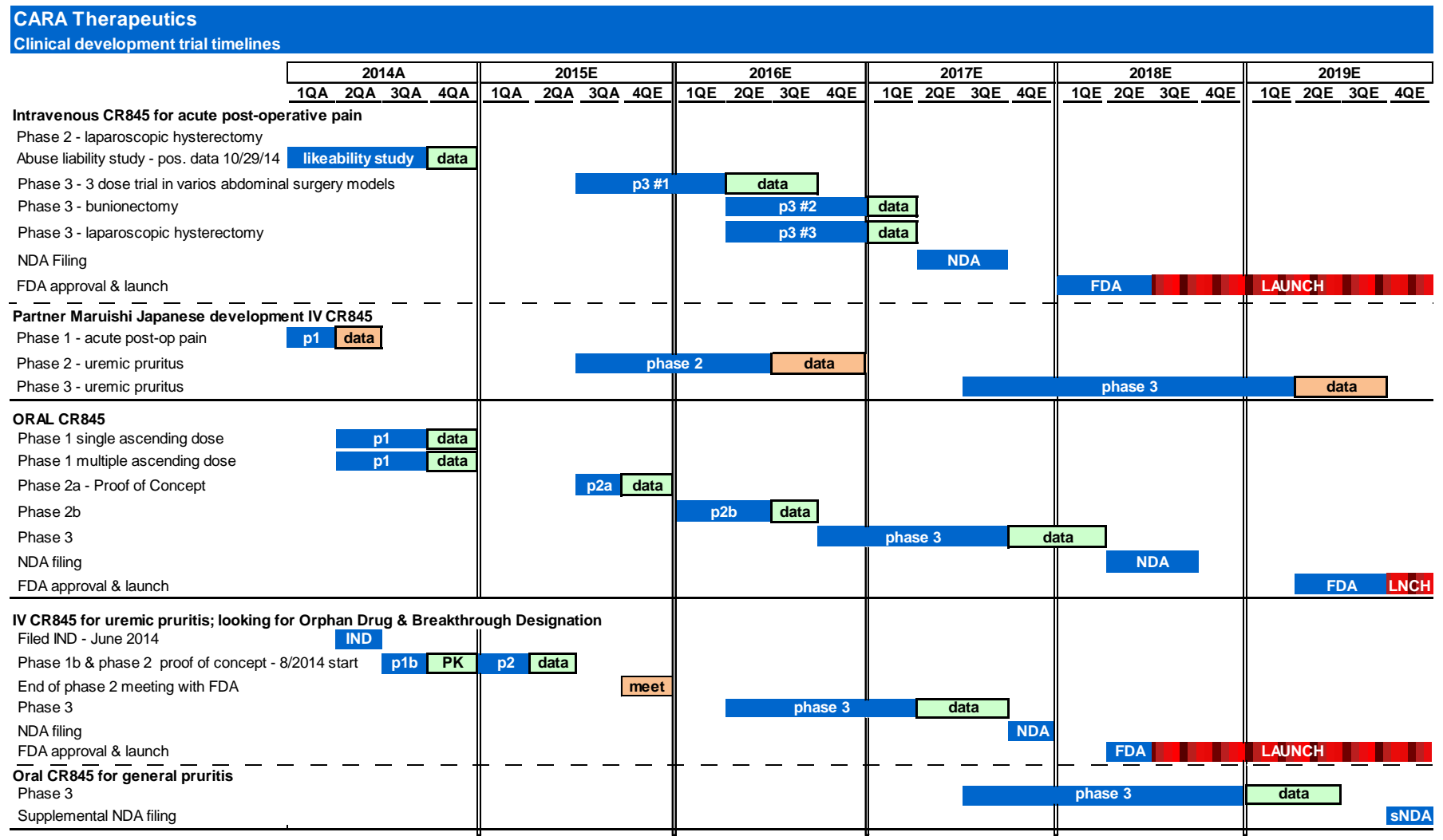
Source: Company presentation, Laidlaw & Company estimates.

Figure 2: Valuation

<b>Sum-of-the-parts value: CARA</b>		
Segment	Valuation (000's)	Per share value
CR845 - IV post-op pain	\$334,203	\$12.0
CR845 - oral post-op pain	\$117,531	\$4.0
CR845 - IV uremic pruritus	\$190,230	\$7.0
CR845 - oral general pruritus	\$132,234	\$5.0
Cash (end '16) & tech value	\$80,217	\$2.0
<b>SUM</b>	<b>\$854,415</b>	<b>\$30</b>
Shares out '16E (000)		27,845

Source: Company presentation, Laidlaw & Company estimates.

Figure 3: Clinical trials timeline



Source: Company reports and Laidlaw estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

<b>CARA Therapeutics</b>										
<b>Quarterly income statement</b>										
(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
<b>Revenues</b>										
License & milestones		\$302			\$302			\$1,710		\$1,710
Collaborative revenues	\$178	658	\$1,125	\$914	2,875	\$489	\$874	730	\$750	2,843
<b>Total Revenue</b>	<b>\$178</b>	<b>\$960</b>	<b>\$1,125</b>	<b>\$914</b>	<b>\$3,177</b>	<b>\$489</b>	<b>\$874</b>	<b>\$2,440</b>	<b>\$750</b>	<b>\$4,553</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
<b>Gross Margin</b>	<b>178</b>	<b>960</b>	<b>1,125</b>	<b>914</b>	<b>3,177</b>	<b>489</b>	<b>874</b>	<b>2,440</b>	<b>750</b>	<b>4,553</b>
Research and development	2,201	3,200	6,208	3,459	15,068	3,385	4,684	5,584	7,250	20,903
General and administrative	1,398	1,472	1,250	1,791	6,181	1,822	1,922	1,865	2,000	7,609
Total operating expenses	3,599	4,672	7,458	5,250	21,249	5,207	6,606	7,449	9,250	28,512
<b>Income (loss) from Operations</b>	<b>(3,421)</b>	<b>(3,712)</b>	<b>(6,333)</b>	<b>(4,336)</b>	<b>(18,072)</b>	<b>(4,718)</b>	<b>(5,732)</b>	<b>(5,009)</b>	<b>(8,500)</b>	<b>(23,959)</b>
Interest income (expense), net	22	56	26	22	126	14	13	22	25	74
Other (exp) gain, net										
<b>Income (loss) before taxes</b>	<b>(3,399)</b>	<b>(3,656)</b>	<b>(6,307)</b>	<b>(4,314)</b>	<b>(17,946)</b>	<b>(4,704)</b>	<b>(5,719)</b>	<b>(4,987)</b>	<b>(8,475)</b>	<b>(23,885)</b>
Income tax exp (benefit)	(16)	(11)	(32)	(142)	(201)	(15)	(35)	(200)		
<b>Net income (Loss)</b>	<b>(3,383)</b>	<b>(3,645)</b>	<b>(6,275)</b>	<b>(4,172)</b>	<b>(17,745)</b>	<b>(4,689)</b>	<b>(5,684)</b>	<b>(4,787)</b>	<b>(8,475)</b>	<b>(23,635)</b>
<b>Net income to common</b>										
<b>Earning per Share (EPS)</b>	<b>(\$0.22)</b>	<b>(\$0.16)</b>	<b>(\$0.28)</b>	<b>(\$0.18)</b>	<b>(\$0.85)</b>	<b>(\$0.21)</b>	<b>(\$0.25)</b>	<b>(\$0.19)</b>	<b>(\$0.33)</b>	<b>(\$0.98)</b>
<b>Adj EPS ex-1x &amp; non-cash</b>								<b>(\$0.23)</b>		<b>(\$1.02)</b>
Weighted avg. shares (000)	15,654	22,608	22,713	22,791	20,966	22,808	22,828	25,545	25,595	24,194
Fully diluted shares (000)	16,551	23,686	23,677	24,038	21,988	24,103	24,411	27,087	27,345	25,737

Source: Company reports and Laidlaw estimates

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

Figure 5: Annual Income Statement

<b>CARA Therapeutics</b>							
<b>Annual income statement</b>							
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
<b>Revenues</b>							
CR845 - IV post-op pain					\$27,254	\$149,435	phase 3 started Sept. 2015
CR845 - IV Uremic pruritus					3,170	53,291	phase 3 starting 1H16
CR845 - oral post-op pain					-	12,500	phase 2b starting 1H16
License & milestones	\$302	\$1,710	\$1,000	\$750	-	-	
Collaborative revenues	2,875	2,843	3,000	\$3,000	3,000	3,000	
<b>Total Revenue</b>	<b>\$3,177</b>	<b>\$4,553</b>	<b>\$4,000</b>	<b>\$3,750</b>	<b>\$33,424</b>	<b>\$218,226</b>	
<b>Expenses:</b>							
Cost of Revenue (COGS)	-	-	-	-	4,088	22,415	
<b>Gross Margin</b>	<b>3,177</b>	<b>4,553</b>	<b>4,000</b>	<b>3,750</b>	<b>29,336</b>	<b>195,811</b>	
R&D	15,068	20,903	32,000	34,000	32,250	61,500	
G&A	6,181	7,609	10,250	11,750	21,750	67,000	
Total op exp	21,249	28,512	42,250	45,750	54,000	128,500	
<b>Inc/(loss) from Ops</b>	<b>(18,072)</b>	<b>(23,959)</b>	<b>(38,250)</b>	<b>(42,000)</b>	<b>(24,664)</b>	<b>67,311</b>	
Int income (exp), net	126	74	100	100	100	100	
Other expenses, net	-	-	-	-	-	-	
<b>Inc/(loss) before taxes</b>	<b>(17,946)</b>	<b>(23,885)</b>	<b>(38,150)</b>	<b>(41,900)</b>	<b>(24,564)</b>	<b>67,411</b>	
Income tax exp (benefit)	(201)	-	-	-	-	1,348	
<b>Net income (Loss)</b>	<b>(\$17,745)</b>	<b>(\$23,635)</b>	<b>(\$38,150)</b>	<b>(\$41,900)</b>	<b>(\$24,564)</b>	<b>\$66,062</b>	
<b>Net income to common</b>							
<b>Earning per Share</b>	<b>(\$0.85)</b>	<b>(\$0.98)</b>	<b>(\$1.48)</b>	<b>(\$1.53)</b>	<b>(\$0.85)</b>	<b>\$2.00</b>	
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$1.02)</b>	<b>(\$1.02)</b>	<b>(\$1.50)</b>	<b>(\$1.55)</b>			
Weighted avg. shares (000)	20,966	24,194	25,845	27,345	28,845	30,345	
Fully diluted shares (000)	21,988	25,737	27,845	29,345	31,345	33,095	

Source: Company reports and Laidlaw estimates

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

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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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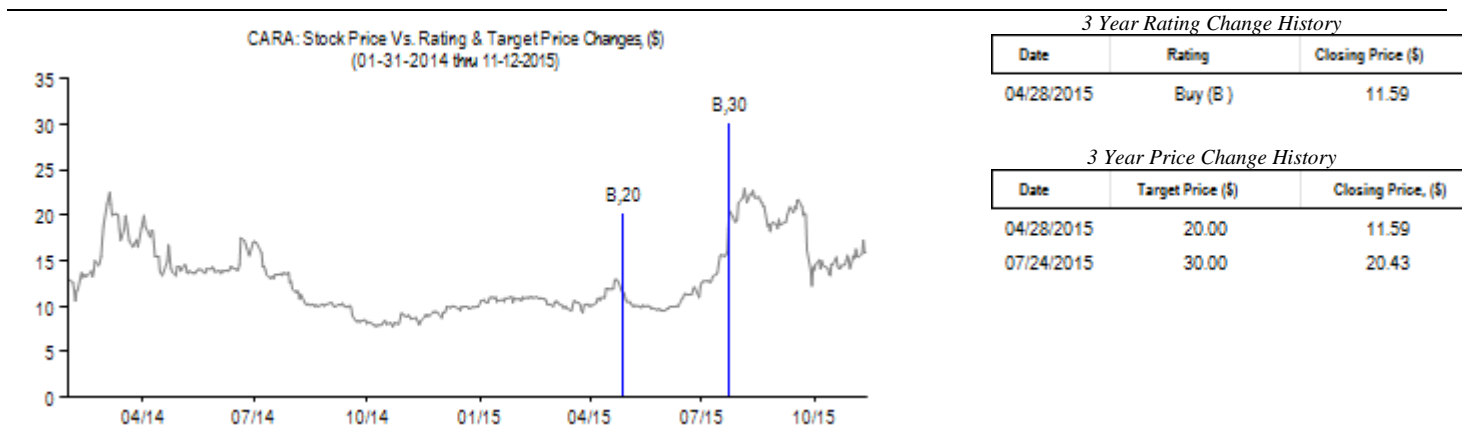
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Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly 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.	71.88%	25.00%	6.25%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.13%	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%

### ADDITIONAL COMPANIES MENTIONED

Chong Kun Dang (KRX: 185750 – Not Rated)

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