

## Cara Therapeutics (CARA - \$22.84)

### IV CR845 BTD for CKD-aP Highlights Potential and Significant Unmet Medical Need.

Before the open, CARA announced that the FDA has granted Breakthrough Therapy Designation (BTD) to IV CR845 for the treatment of moderate to severe uremic pruritus (UP) in chronic kidney disease (CKD) patients undergoing hemodialysis. We believe this attests to the significance of the unmet medical need among CKD patients with UP as well as the strength of part A Phase 2/3 data, which 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. On 5/16/17, we attended a KOL breakfast hosted by CARA discussing IV CR845 for CKD-aP and recall the KOLs' (academic and clinical backgrounds) emphasis on the dearth of options for these patients already in difficult health conditions. Additionally, upon examining CARA's Phase 2/3 data, they were especially encouraged by the significant improvement in quality of life and clean safety profile, which attests to CR845's unique peripheral mechanism of action. While this meeting with the FDA was a little ahead of expectations (very end of 2Q17 vs. expected 3Q17), the outcome is in-line and we continue to like IV-CR845's chances of crossing the finish line. As data is still the theme this year for CARA, we still expect top-line Phase 2b read-out of oral CR845 for hip/knee osteoarthritis (OA) as well as Phase 1 PK oral CR845 for general pruritus this quarter (1 week left). We are reiterating our Buy rating and \$35 price target.

- **BTD for IV CR845 for CKD-aP, another big box checked off.** We are encouraged by the BTD and believe it attests to the significance of the unmet medical need for patients suffering from CKD-aP as well as the strength of the Phase 2/3 data from 1Q17, which significantly hit on both endpoints.
- **More to come at CARA, potentially next week.** While CARA has had a strong 1H17, it is far from over. We expect (next week) topline data for their Phase 2b for OA and p1 PK data for oral CR845 as well as IV CR845 for post-op pain in 4Q17 (great safety to date in interim look).
- **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

#### Healthcare/Biotechnology

Ticker:	<b>CARA</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$35</b>

#### Trading Data:

Last Price (06/23/2017)	\$22.84
52-Week High (06/23/2017)	\$23.55
52-Week Low (06/27/2016)	\$4.35
Market Cap. (MM)	\$746.4
Shares Out. (MM)	32.5

#### Analyst

Francois Brisebois, MSc  
(857)317-5362  
fbrisebois@laidlawltd.com

Source: Company data and Laidlaw & Company estimates

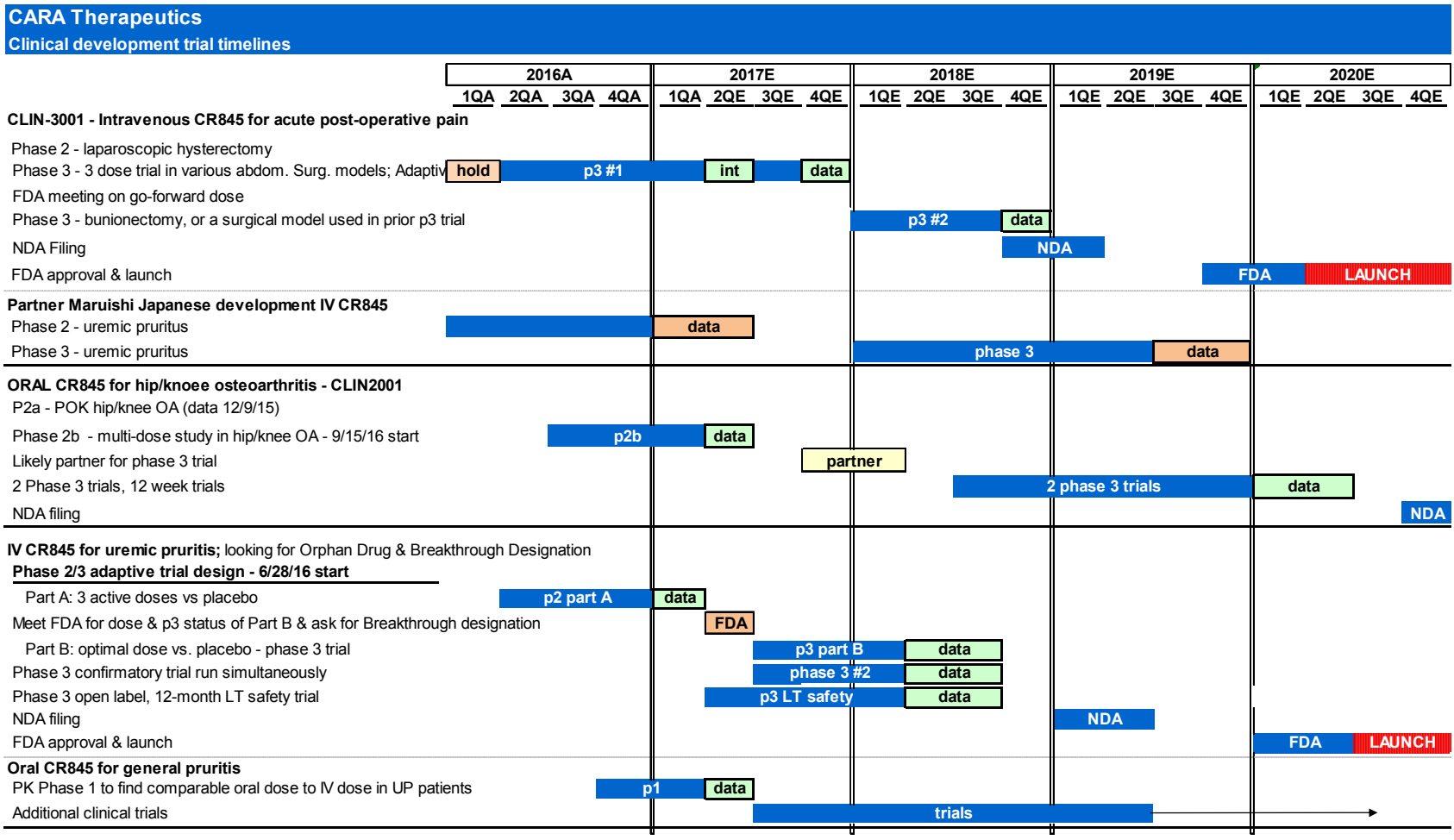
FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

**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</b>	<b>\$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	30,454	34,417	35,017	35,617	33,876

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

Figure 4: Annual Income Statement

<b>CARA Therapeutics</b>						
<b>Annual income statement</b>						
(\$000 except per share)	<b>2016A</b>	<b>2017E</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>	<b>Comments</b>
<b>Revenues</b>						
CR845 - IV post-op pain					\$56,760	Interim data 2Q17 p2 data 1Q17 p2b data 2Q17
CR845 - IV Uremic pruritus			-	-	17,938	
CR845 - oral hip/knee OA pain			-	-	-	
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	50 reps in 2020
SG&A	9,232	10,400	10,750	11,000	30,000	
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	33,876	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

---

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.

## DISCLOSURES:

### ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

### EQUITY DISCLOSURES

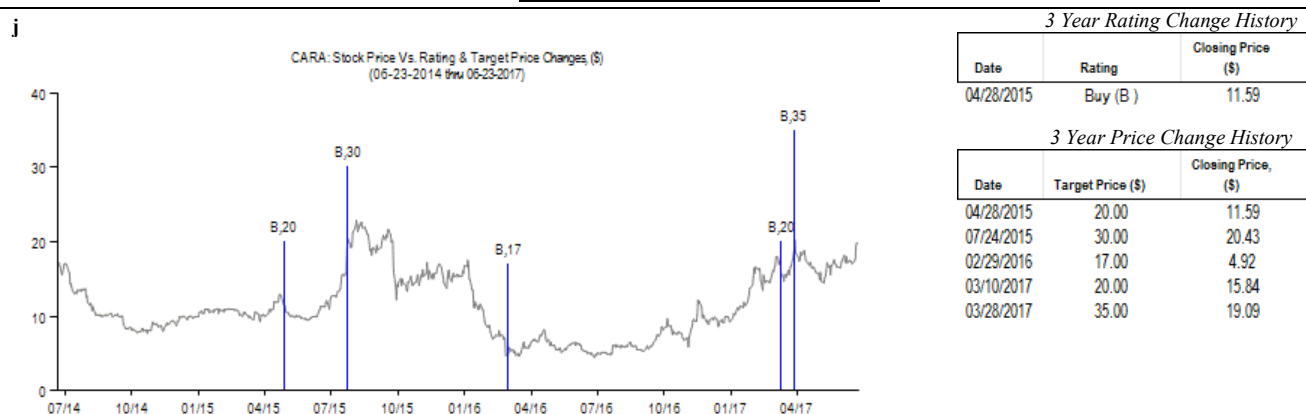
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

#### Additional information available upon request.

# Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

### RATINGS INFORMATION

#### Rating and Price Target Change History



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
<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.	64.44%	31.11%	2.22%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	2.22%	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

### ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices, market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at [www.Laidlawltd.com](http://www.Laidlawltd.com), or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

© 2017 Laidlaw & Co. (UK), Ltd.



**NOTES:**