

Cara Therapeutics (CARA - \$9.95)

Phase 3 registration trials to start 3Q15

Last night after the close CARA reported 1Q15 EPS roughly in-line with our expectations. The biggest change to the story is the rearrangement of the post-surgical pain trials for CR845 with laparoscopic abdominal soft tissue surgery now starting first in 3Q15, with bunionectomy & hysterectomy now delayed to 1H16. While not ideal CARA still expects to wrap up all 3 trials by end-2016 and if they hold to that schedule it should be a wash on timing. The key phase 2 pruritus data remains on-track for late June 2015 data, which could represent the most compelling target market for CR845. We are maintaining our Buy rating, \$20 PT.

- **CARA reports 1Q15 roughly in-line, not an earnings story.** CARA reported a lower 1Q15 EPS loss of (\$0.21) vs Laidlaw at (\$0.36), mostly due to R&D coming in well below our estimates. This is likely due to the push back of the start of the phase 3 trials to 3Q15 (from 2Q15 previously). We had expected the bunionectomy and laparoscopic hysterectomy trials to start in 2Q15, they are now projected to begin in 1H16. The laparoscopic abdominal surgery trial will now be the first of the 3 confirmatory trials. CARA still expects to complete all 3 trials in FY16, in-line with previous guidance.
- **Pruritus data on track for late 2Q15.** This remains perhaps the most compelling opportunity for CARA as there are no approved treatment options for pruritus on the market, and ~13MM off label prescriptions for steroids to ameliorate the condition. While it seems to be a riskier opportunity than post-surgical pain, should CARA report positive p2 data in June for the orphan indication uremic pruritus, they could ask for a breakthrough therapy designation.
- **CARA planning to file CR845 as an unscheduled drug.** A key significant benefit of CR845 is that it does not produce the euphoria typical in mu-opioids, thus having a decreased potential for abuse and addiction. Management plans to file CR845 as an unscheduled drug with no designation, which would make for a significant advantage over current opioid therapies.
- **Oral formulation data 4Q15.** The phase 2 trial for the oral version of CR845 has been pushed out to a 3Q15 start (from 2Q15 previously) but management feels that they should still be able to finish that small phase 2 trial by 4Q15.
- **Maintain Buy rating, \$20 price target.** Our price target is based on a sum-of-the-parts: IV CR845 \$11/share; uremic pruritus: \$3.5/share; oral CR845: \$2.5/share; cash (end '15) & tech value: \$3/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY16E	(0.34)	(0.34)	(0.35)	(0.37)	(1.40)	NA
FY15E	(0.21)A	(0.18)	(0.32)	(0.34)	(1.05)	NA
FY14A	(0.22)	(0.16)	(0.28)	(0.18)	(0.85)	NA
FY13A	NA	NA	NA	NA	(0.74)	NA

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

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

Trading Data:

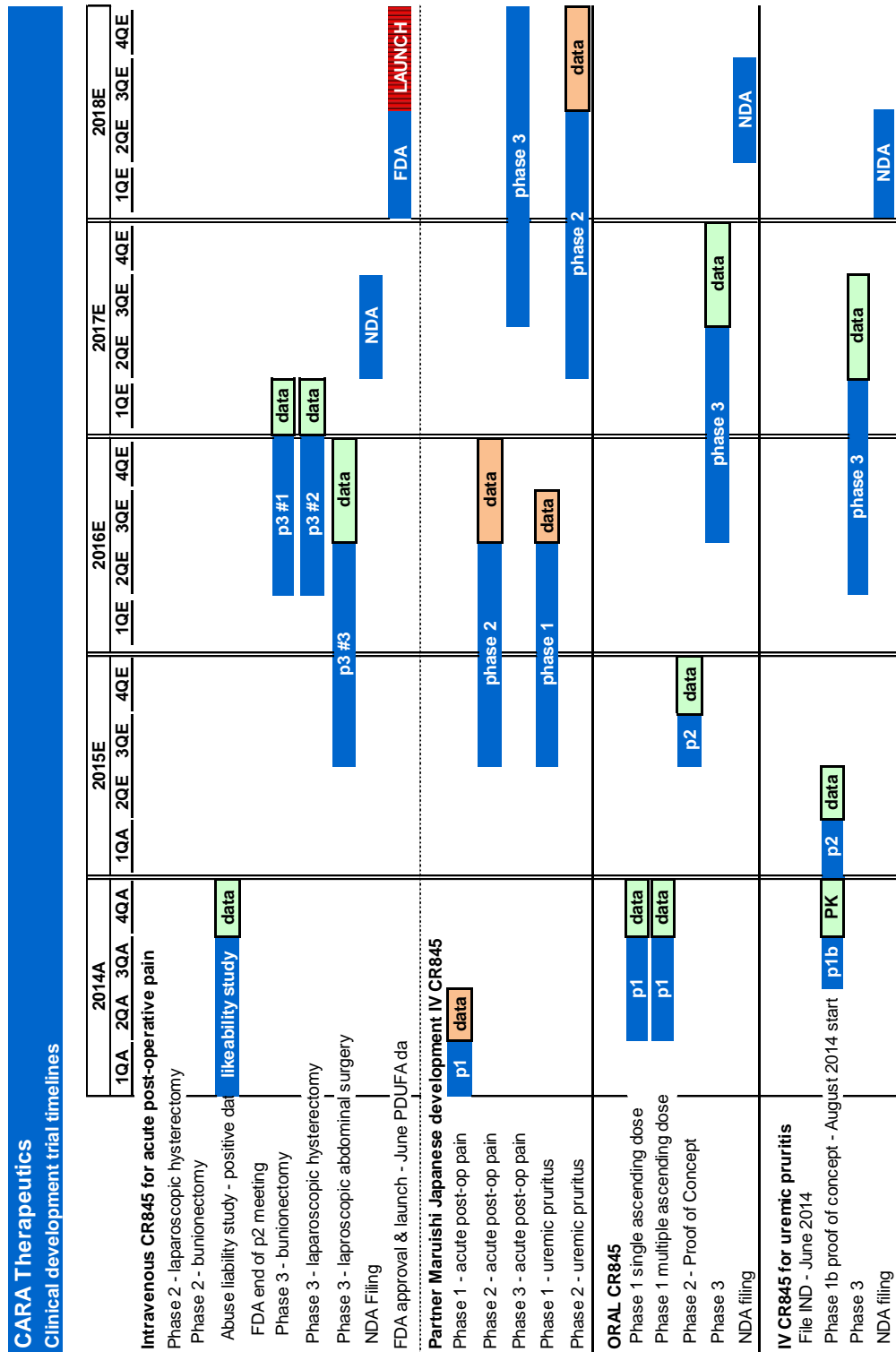
Last Price (05/12/2015)	\$9.95
52-Week High (07/07/2014)	\$17.77
52-Week Low (10/13/2014)	\$7.53
Market Cap. (MM)	\$227.1
Shares Out. (MM)	22.82

Analyst

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Figure 1: Clinical Trial Timelines



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Source: Company reports and Laidlaw estimates

Figure 2: Quarterly Income Statement

CARA Therapeutics										
Quarterly income statement										
(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
Revenues										
License & milestones		\$302			\$302					
Collaborative revenues	\$178	658	\$1,125	\$914	2,875	\$489	\$500	\$500	\$500	\$1,989
Total Revenue	\$178	\$960	\$1,125	\$914	\$3,177	\$489	\$500	\$500	\$500	\$1,989
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	178	960	1,125	914	3,177	489	500	500	500	1,989
Research and development	2,201	3,200	6,208	3,459	15,068	3,385	3,750	7,750	8,000	22,885
General and administrative	1,398	1,472	1,250	1,791	6,181	1,822	2,000	2,000	2,250	8,072
Total operating expenses	3,599	4,672	7,458	5,250	21,249	5,207	5,750	9,750	10,250	30,957
Income (loss) from Operations	(3,421)	(3,712)	(6,333)	(4,336)	(18,072)	(4,718)	(5,250)	(9,250)	(9,750)	(28,968)
Interest income (expense), net	22	56	26	22	126	14	25	25	25	89
Other (exp) gain, net										
Income (loss) before taxes	(3,399)	(3,656)	(6,307)	(4,314)	(17,946)	(4,704)	(5,225)	(9,225)	(9,725)	(28,879)
Income tax exp (benefit)	(16)	(11)	(32)	(142)	(201)	(15)				
Net income (Loss)	(3,383)	(3,645)	(6,275)	(4,172)	(17,745)	(4,689)	(5,225)	(9,225)	(9,725)	(28,864)
Net income to common										
Earning per Share (EPS)	(\$0.22)	(\$0.16)	(\$0.28)	(\$0.18)	(\$0.85)	(\$0.21)	(\$0.18)	(\$0.32)	(\$0.34)	(\$1.05)
Weighted avg. shares (000)	15,654	22,608	22,713	22,791	20,966	22,808	28,858	28,908	28,958	27,383
Fully diluted shares (000)	16,551	23,686	23,677	24,038	21,988	25,558	31,608	31,658	31,708	30,133

Source: Company reports and Laidlaw estimates

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Figure 3: 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: Company reports and Laidlaw estimates

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Source: Company reports; Laidlaw & Company estimates

Major Risks

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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.

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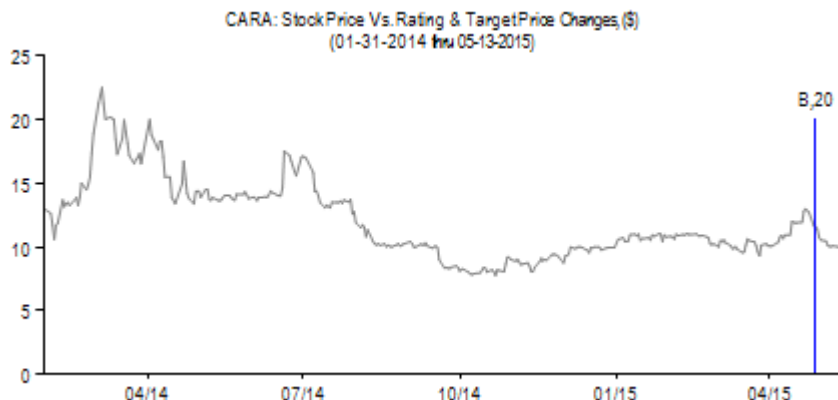
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Rating and Price Target Change History



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.	73.08%	30.77%	7.69%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.85%	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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