

Cara Therapeutics Inc. (CARA)

Overweight

Nothing to Not Like in this Drug Likeability Study

CONCLUSION

Cara announced that the human abuse liability (HAL) study for CR845 has met its primary endpoint with significantly less likability (p-values < 0.0001 for "feeling high" and "overall liking") vs. the Schedule IV comparator pentazocine (Talwin). '845's results were considered equivalent to placebo based on the mixed-model repeated measures analysis, most probably due to the ability of '845 to avoid CNS activity. The results should support a non-scheduled status in our view; however Schedule V is a realistic possibility, but even Schedule IV would give '845 a competitive advantage vs. existing opioids.

- **Overcoming historical hangups for kappas.** Both therapeutic (5 ug) and super-therapeutic doses (15 ug) met the primary endpoint in hallucinogenic-experienced patients, and given the bipolar scale we believe the results speak not only to the abuse liability but, importantly, to the historic CNS kappa activity liabilities seen with previous candidates, and thus provide a measure of platform validation as well. We reiterate our Overweight rating and \$30 price target ahead of expected additional clinical/regulatory validation of '845 in pain, including SAD/MAD data for the oral formulation and an end-of-Phase II meeting with the FDA by YE14.
- **HAL study a key event and outcome.** The company held a conference call this morning to discuss the HAL and future steps. Again, the solid results are likely to support at least a Schedule IV or better status from the DEA. Particularly notable, in our view, may be the differential time course for likability and "feeling high" for I.V. 845 vs. pentazocine (Exhibits 1 and 2). Though the first use for '845 is expected to be I.V. in the hospital setting, future uses may include as an oral formulation in the outpatient setting where scheduling is likely to be more important. That said, scheduling is also important for convenience in delivery and monitoring in the hospital setting, and therefore even Schedule IV would give '845 a competitive advantage vs. existing opioids.

RISKS TO ACHIEVEMENT OF PRICE TARGET

Failure of lead candidate I.V. '845 in pivotal studies, DEA scheduling, or safety signals.

COMPANY DESCRIPTION

Cara develops novel peripherally-restricted candidates for pain indications.

PRICE: US\$8.65

TARGET: US\$30.00

DCF of I.V. CR845 revenues for post-op pain in the U.S.

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Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$30.00
FY14E Rev (mil)	—	US\$1.1
FY15E Rev (mil)	—	US\$0.0
FY14E EPS	—	US\$(0.93)
FY15E EPS	—	US\$(1.64)
52-Week High / Low	US\$23.25 / US\$7.53	
Shares Out (mil)	21.8	
Market Cap. (mil)	US\$188.6	
Avg Daily Vol (ooo)	87	
Book Value/Share	US\$2.70	
Net Cash Per Share	US\$2.80	
Debt to Total Capital	0%	
Div (ann)	NA	
Yield		
Fiscal Year End	Dec	

Price Performance - 1 Year



Source: Bloomberg

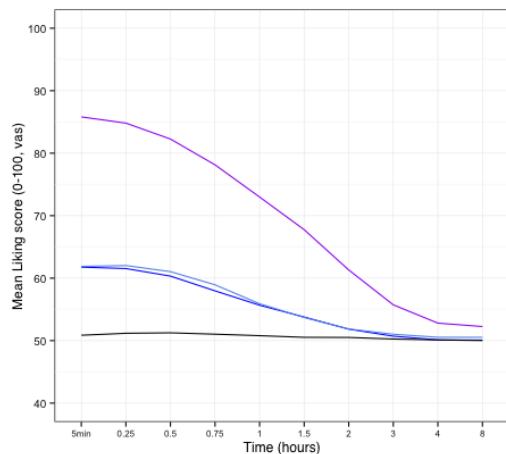
YEAR	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2013A	—	—	—	0.0	12.0	15.7x	—	—	—	(0.49)	(0.74)	NM
2014E	0.2A	1.0A	0.0	0.0	1.1	171.4x	(0.22)A	(0.16)A	(0.24)	(0.31)	(0.93)	NM
2015E	0.0	0.0	0.0	0.0	0.0	NA	(0.38)	(0.41)	(0.42)	(0.43)	(1.64)	NM

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'845 in pain the most near-term focus. Cara is continuing to make progress in pruritus and we expect Phase I proof of concept data by YE in uremic pruritus, however, the most important value driver is likely to be pain. Cara has 2 main pain programs: the I.V. formulation of '845 intended for the acute, post-op setting; and an oral '845 program looking at chronic pain. In addition to the EOP2 event for I.V. '845, we also expect to see single-ascending-dose (SAD), multiple-ascending-dose (MAD, 3 BID doses for safety, 1 TID dose to inform possible post-surgery stepdown use) data (PK, safety and biomarker for kappa activity) for the oral formulation by YE. The company is confident that the new tablet oral formulation is effective in delivery of the drug. Finally, we look for Phase III trial start by mid-2015 and anticipate this will move quickly.

Exhibit 1

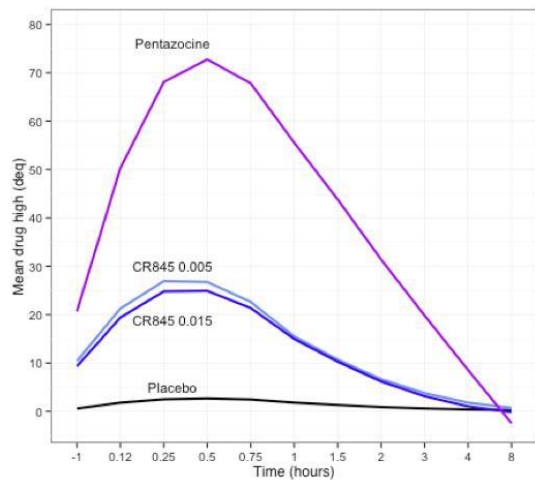
OVERALL LIKING TIME COURSE



Source: company reports

Exhibit 2

“FEELING HIGH” TIME COURSE



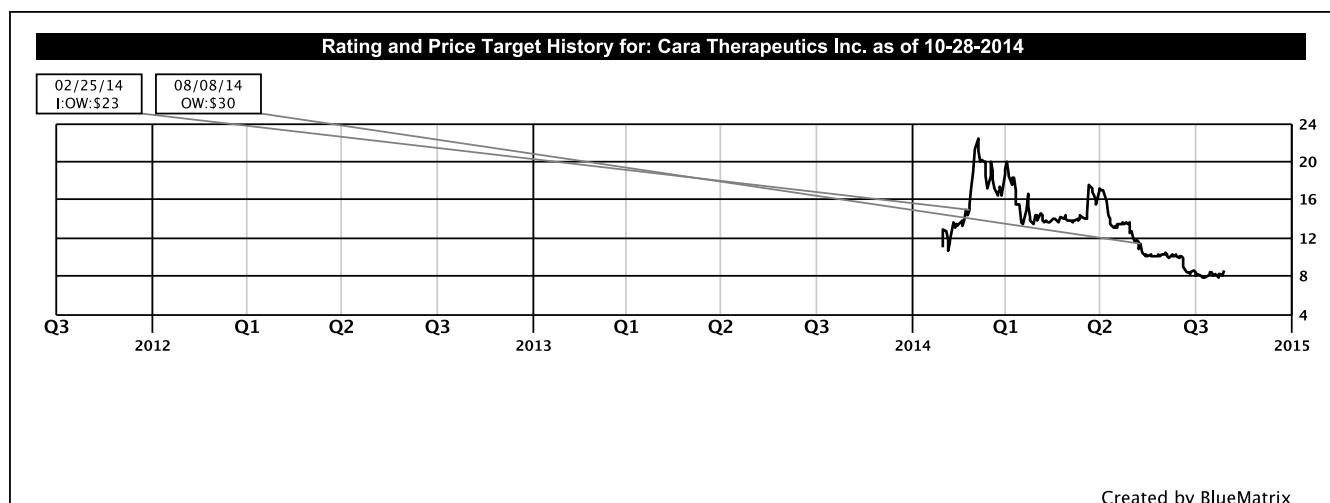
Source: company reports

Cara (\$ in thousands, except per share amounts)	2011	2012	2013	1Q14	2Q14	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E
Income Statement																
Revenue																
License and milestone fees	-	1,190	9,637	-	302	-	-	302	-	-	-	-	-	7,400	6,900	-
% total revenue	-	100%	81%	0%	31%	na	na	27%	na	na	na	na	na	100%	34%	0%
Revenues under collaborative agreements	-	-	2,327	178	658	-	-	836	-	-	-	-	-	-	-	-
% total revenue	-	0%	19%	100%	69%	na	na	73%	na	na	na	na	na	0%	0%	0%
Product sales and royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	13,324	102,320
% total revenue	-	0%	0%	0%	0%	na	na	0%	na	na	na	na	na	0%	66%	100%
Total Revenues	-	1,190	11,964	178	960	-	-	1,138	-	-	-	-	-	7,400	20,224	102,320
Costs & Expenses:																
Cost of product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	4,250	26,311
R&D	7,159	4,597	8,685	2,201	3,200	4,500	6,000	15,901	8,000	9,000	9,450	9,923	36,373	40,059	30,939	30,103
SG&A	2,407	2,829	3,557	1,398	1,472	1,200	1,500	5,570	1,650	1,815	1,997	2,196	7,658	11,504	20,650	24,162
Total Operating Expenses	9,566	7,426	12,242	3,599	4,672	5,700	7,500	21,471	9,650	10,815	11,447	12,119	44,030	51,563	55,839	80,576
Operating Income (loss)	(9,566)	(6,236)	(278)	(3,421)	(3,712)	(5,700)	(7,500)	(20,333)	(9,650)	(10,815)	(11,447)	(12,119)	(44,030)	(44,163)	(35,616)	21,744
Investment income	-	-	-	22	56	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before income taxes	(9,841)	(6,302)	(3,993)	(3,399)	(3,656)	(5,700)	(7,500)	(20,333)	(9,650)	(10,815)	(11,447)	(12,119)	(44,030)	(44,163)	(35,616)	21,744
Income tax (benefit) provision	(35)	(31)	(30)	(16)	(11)	(57)	(75)	(159)	(97)	(108)	(114)	(121)	(440)	(442)	(8,191)	7,610
Tax rate	0	0		0.5%	1.0%	1.0%	1.0%	0.9%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	26.5%	35.0%
Net operating loss offset			3	-	11	57	75	143	97	108	114	121	440	442	8,191	(7,610)
Net income (loss) available to common stockholders	(9,806)	(6,271)	(3,963)	(3,383)	(3,645)	(5,643)	(7,425)	(20,174)	(9,554)	(10,707)	(11,332)	(11,997)	(43,590)	(43,721)	(27,424)	14,134
Net income (loss) to common shareholders - basic	(9,806)	(6,271)	(3,072)	(3,383)	(3,645)	(5,643)	(7,425)	(20,174)	(9,554)	(10,707)	(11,332)	(11,997)	(43,590)	(43,721)	(27,424)	14,134
Net income (loss) to common shareholders - diluted	(9,806)	(6,271)	(3,072)	(3,383)	(3,645)	(5,643)	(7,425)	(20,174)	(9,554)	(10,707)	(11,332)	(11,997)	(43,590)	(43,721)	(27,424)	14,134
Basic Earnings Per Share	(1.21)	(0.75)	(\$0.74)	(\$0.22)	(\$0.16)	(\$0.24)	(\$0.31)	(\$0.93)	(\$0.38)	(\$0.41)	(\$0.42)	(\$0.43)	(\$1.64)	(\$1.32)	(\$0.71)	\$0.33
Diluted Earnings Per Share	(1.21)	(0.75)	(\$0.74)	(\$0.22)	(\$0.16)	(\$0.24)	(\$0.31)	(\$0.93)	(\$0.38)	(\$0.41)	(\$0.42)	(\$0.43)	(\$1.64)	(\$1.32)	(\$0.71)	\$0.28
Basic Shares Outstanding	8,089	8,322	4,133	15,654	22,608	23,287	23,985	24,705	25,446	26,209	26,996	27,805	28,640	33,201	38,489	42,495
Diluted Shares Outstanding	8,089	8,322	4,133	15,654	22,608	23,287	23,985	24,705	25,446	26,209	26,996	27,805	28,640	33,201	38,489	50,994

Proprietary to Piper Jaffray & Co. August 9, 2014
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 Current disclosure information for this company can be found at:
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R: Resuming Coverage
T: Transferring Coverage
D: Discontinuing Coverage
S: Suspending Coverage
OW: Overweight
N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

Distribution of Ratings/IB Services Piper Jaffray				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OW]	374	61.31	94	25.13
HOLD [N]	224	36.72	24	10.71
SELL [UW]	12	1.97	0	0.00

Note: Distribution of Ratings/IB Services shows the number of companies currently in each rating category from which Piper Jaffray and its affiliates received compensation for investment banking services within the past 12 months. FINRA rules require disclosure of which ratings most closely correspond with "buy," "hold," and "sell" recommendations. Piper Jaffray ratings are not the equivalent of buy, hold or sell, but instead represent recommended relative weightings. Nevertheless, Overweight corresponds most closely with buy, Neutral with hold and Underweight with sell. See Stock Rating definitions below.

Analyst Certification — Charles C. Duncan, PhD, Sr. Research Analyst — Roy Buchanan, Ph.D., Research Analyst

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