

Cara Therapeutics Inc. (CARA)

Overweight

Good Cash & Near Term Clinical Milestones Bode Well for 2015

CONCLUSION

Cara reported 3Q results and provided a clinical update, ending the quarter with \$58M in cash, which we continue to expect will fund operations at least into 2016 - management guided to 18 months of burn without licensing milestones which we believe may prove overly conservative. The company's multiple clinical programs remain on track and a number of catalysts before YE or in 1Q15 should maintain investor interest. In our view, Cara's success in the human abuse liability (HAL) study, possibly leading to Schedule IV, V, or even no scheduling, bodes well for I.V. '845 in the post op setting and possibly reads-through to the oral formulation. We reiterate our Overweight rating and \$30 price target on Cara in advance of multiple clinical readouts for its kappa opioid agonist over the next 12 months.

- **The head-line event has been the recent HAL study read-out.** I.V. '845 proved placebo-like on a mixed-model analysis and soundly beat Schedule IV kappa/mu mixed agonist pentazocine on multiple other measures (see our note [here](#)). Management was hesitant to project what the FDA may or may not do with the data and suggestions for scheduling of the oral agent, however, management did point out that the I.V. results likely set the highest bar for the agent. That makes logical sense, I.V. delivery produces the most rapid "rush" with no GI retention and limited 1st-pass metabolism. For the I.V. program, Cara still plans to request an end of Phase II by YE and possibly start Phase IIIs, likely one each of a bunionectomy and laparoscopic hysterectomy surgery study, in early '15.
- **Pruritis visibility is increasing and presents potential upside.** Neither oral '845 or the pruritis opportunity are in our current valuation for Cara. Though both are making progress, we believe the key value driver in the next 12 months is likely I.V. '845. However, we could be surprised by either oral or pruritis. Cara continues to expect top-line safety, PK, and dosing data from the Phase II proof-of-concept study of I.V. '845 in uremic pruritis, with top-line efficacy data in 1H15. The company sees oral '845 as possibly proving effective in chronic pruritis. The Maruishi SAD/MAD studies of I.V. '845 in acute pain and uremic pruritis in Japan are expected to read out around YE.

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\$8.48

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	US\$2.3
FY15E Rev (mil)	—	US\$0.0
FY14E EPS	US\$(0.93)	US\$(0.98)
FY15E EPS	US\$(1.64)	US\$(1.68)
52-Week High / Low	US\$23.25 / US\$7.53	
Shares Out (mil)	22.7	
Market Cap. (mil)	US\$192.5	
Avg Daily Vol (ooo)	105	
Book Value/Share	US\$2.44	
Net Cash Per Share	US\$2.57	
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	16.0x	—	—	—	(0.49)	(0.74)	NM
2014E	0.2A	1.0A	1.1A	0.0	2.3	83.7x	(0.22)A	(0.16)A	(0.29)A	(0.32)	(0.98)	NM
2015E	0.0	0.0	0.0	0.0	0.0	NA	(0.38)	(0.42)	(0.43)	(0.44)	(1.68)	NM

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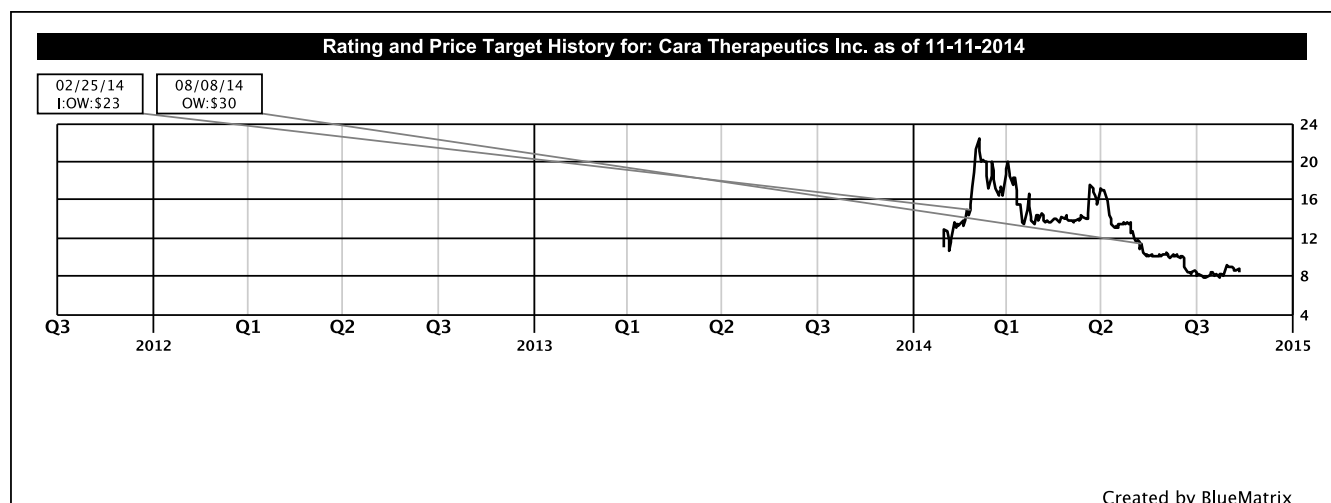
Clinical and regulatory timelines on track. The single and multiple-ascending-dose Phase I studies (150 patient, tablet formulation) for oral '845 remain on track for starting by YE. These studies are intended to provide safety, PK, and biomarker data to inform a Phase II proof of concept study to start in 2015. We believe there is substantial potential for oral '845 not only in acute pain (post-op step down) but possibly also the chronic setting.

Cara (\$ in thousands, except per share amounts)	2011	2012	2013	1Q14	2Q14	3Q14	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%	0%	na	13%	na	na	na	na	na	100%	34%	0%
Revenues under collaborative agreements	-	-	2,327	178	658	1,125	-	1,961	-	-	-	-	-	-	-	-
% total revenue	-	0%	19%	100%	69%	100%	na	87%	na	na	na	na	na	0%	0%	0%
Product sales and royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	13,324	102,320
% total revenue	-	0%	0%	0%	0%	0%	na	0%	na	na	na	na	na	0%	66%	100%
Total Revenues	-	1,190	11,964	178	960	1,125	-	2,263	-	-	-	-	-	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	6,208	6,000	17,609	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	1,520	1,500	5,890	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	7,728	7,500	23,499	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)	(6,603)	(7,500)	(21,236)	(9,650)	(10,815)	(11,447)	(12,119)	(44,030)	(44,163)	(35,616)	21,744
Investment income	-	-	-	22	56	26	-	-	-	-	-	-	-	-	-	-
Income (loss) before income taxes	(9,841)	(6,302)	(3,993)	(3,399)	(3,656)	(6,577)	(7,500)	(21,236)	(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)	(32)	(75)	(134)	(97)	(108)	(114)	(121)	(440)	(442)	(8,191)	7,610
Tax rate	0	0		0.5%	0.3%	0.5%	1.0%	0.6%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	26.5%	35.0%
Net operating loss offset			3	-	11	32	75	118	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)	(6,545)	(7,425)	(21,102)	(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)	(6,545)	(7,425)	(21,102)	(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)	(6,545)	(7,425)	(21,102)	(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)	(\$0.29)	(\$0.32)	(\$0.98)	(\$0.38)	(\$0.42)	(\$0.43)	(\$0.44)	(\$1.68)	(\$1.35)	(\$0.73)	\$0.34
Diluted Earnings Per Share	(1.21)	(0.75)	(\$0.74)	(\$0.22)	(\$0.16)	(\$0.29)	(\$0.32)	(\$0.98)	(\$0.38)	(\$0.42)	(\$0.43)	(\$0.44)	(\$1.68)	(\$1.35)	(\$0.73)	\$0.28
Basic Shares Outstanding	8,089	8,322	4,133	15,654	22,608	22,713	23,394	24,096	24,819	25,564	26,331	27,121	27,934	32,383	37,541	41,449
Diluted Shares Outstanding	8,089	8,322	4,133	15,654	22,608	22,713	23,394	24,096	24,819	25,564	26,331	27,121	27,934	32,383	37,541	49,738

Proprietary to Piper Jaffray & Co. November 13, 2014
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4.3 2.8 2.6
 \$4.1 \$2.7 \$2.4

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D: Discontinuing Coverage
S: Suspending Coverage
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N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

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			Count	Percent
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SELL [UW]	12	1.97	0	0.00

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