

#### Specialty Pharmaceuticals

Price:	\$8.75
Fair Value Estimate:	\$25.00
52-Week Range:	\$7.53 - \$23.25
Market Cap (MM):	\$200
Shr.O/S-Diluted (mm):	22.8
Average Daily Volume:	106,734
Book Value:	\$1.33
Dividend:	NA
Cash/Share:	\$0.68
FCF Yield:	(27.9)%
Debt/Cap:	0%

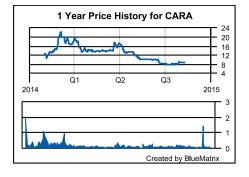
FYE: Dec	2013A	2014E	2015E
EPS:	\$(0.74)A	\$(0.84)E	\$(1.06)E
Prior EPS:		NC	NC
Consensus	NM	-0.84	-1.10
P/E Ratio:	NA	NA	NA

#### Quarterly EPS:

Q1	\$(0.42)A	\$(0.22)A	
Q2	\$(0.38)A	\$(0.16)A	
Q3	\$(0.38)A	\$(0.29)A	
Q4	\$(0.49)A	\$(0.30)E	

## Quarterly Revenue (M):

Q1	\$0A	\$0A	
Q2	\$10A	\$1A	
Q3	\$1A	\$1A	
Q4	\$1A	\$1E	
Year:	\$12A	\$2E	\$0E



November 11, 2014

# Cara Therapeutics Inc.

(CARA) - BUY

# CARA: 3Q Miss on R&D, But More Data by Year End

#### PORTFOLIO MANAGER BRIEF

CARA reported 3Q14 EPS of (\$0.29) below Janney estimate of (\$0.24). The miss was mainly attributed to R&D expense of \$6.2M, which was well above estimates. We anticipate R&D spend to be flat to slightly lower through the end of 2014 due to the conclusion of several clinical trails and then accelerating rapidly into 2015 with the initiation of two large Phase 3 pain trials for IV CR845. Several more clinical data points are anticipated through 4Q14 and 1H15 which should offer some upside potential. Maintain Buy rating, \$25 fair value.

## **ANALYST NOTES**

- Upside Potential Through Year End: Though the major catalysts on CARA start to materialize in 2015 and 2016, there are still several important data points that will read out on 4Q14 and 1H15. Top-line results from the Phase 1 single and ascending dose trials for the tablet formulation in expected in late Nov/early Dec. This is important as it will validate the oral tablet formulation, an important piece of the CARA value proposition. Late in 2014, top-line safety and PK data from Part 1 of the Proof-of-Concept of IV CR845 in dialysis itch should read out with Part 2 efficacy data following in 1H15. Also of note, CARA management is requesting an End of Phase 2 meeting with the FDA in 4Q14 for IV CR845 in acute pain which would allow for the Phase 3 trials to initiate in 1015.
- The Major Catalyst Timeline: With IV CR845 for acute pain set to initiate two Phase 3 trials in 1Q15, we believe that the bunionectomy trial will enroll quickly which means that top-line data could read out in late 2015, with hysterectomy data in mid-2016. Another major catalyst is an expected Phase 2 POC trial for the oral formulation with data in 2H15 followed by the Phase 3 initiation by the end of the year.
- Q3 Financial Review Expect Accelerating R&D Expense in 2015: CARA announced 3Q14 EPS of (\$0.29) compared to Janney estimates of (\$0.24) and consensus of (\$0.22). Though covering the expense of three clinical programs, R&D expense of \$6.2M was above estimates. We have adjusted our 4Q14 expense to reflect a flat to slightly lower spend as these trials transition from ongoing to data analysis. With two large pain trails set to begin in 1Q15, we are also adding additional R&D expense to our 2015 numbers. CARA ended the \$58M in cash which should allow for operations 18 months out which should include the Phase 3 data.
- Maintain Buy rating, \$25 fair value: We value CARA at \$25/share based on a sumof-the-parts with CR845 sales of at \$22.50/share based on a 4x multiple of 2019 US

sales discounted 5 years at 20% to account for the risks remaining in this program. Our remaining \$2.50/share value is based on cash (end 2014) and technology value.

## **INVESTMENT THESIS**

After a quiet 2014, with a significant discount to the name, CARA should light up 4Q14 with data from their clinical progress with CR845. With positive data from their HAL trial, this continues to solidify our thesis that CR845, a novel kappa opioid formulation has the potential to be, if approved a schedule IV or lower opioid, marking a significant advantage against current mu opioid products not only in terms of availability but also safety profile. We see value adds with data from their oral formulation and POC trial in by year end and Phase 3 start in 1Q15.

#### ISSUES TO CONSIDER

Key Issue	Our Position	Timing	Impact
Will the two Phase 3 trials of CR845 be successful?	This is, of course a tough question to answer, and we are going to reserve our judgment until after the End of Phase 2 meeting and we have more clarity on the trial design of both the bunionectomy (hard tissue) and hysterectomy (soft tissue) trials. The closer to the Phase 2 study designs, the more positive we will be.	12-24 Months	+ O -
Where will CR845 fall on the controlled substance schedule?	Though there is the potential for CR845 to be an uncontrolled opioid, we don't believe that the DEA will go for that. Instead, we believe it more likely that CR845 will be a Schedule V, giving it a substantial commercial advantage over other current mu-opioid therapies.	12-24 Months	+ 0 -
How important is the oral formulation?	With the read out of the Phase 1a/1b trials in the oral formulation, this is an important part of the CARA story. To truly be successful with a chronic pain therapy, there must be an oral formulation to act alone or as a step-down to IV. We believe that the PK and safety data will be positive as CARA as done previous work on capsule formulation which should translate into the tablet.	0-3 Months	+ 0 -

## FIVE-YEAR VALUATION

Historical Multiples - Premium to Comps							
Current vs 5 yr Average Historical Premium		5 Yr Historical I	Premium Range	Implied @ Hist Avg			
Metric	Current	Low High		Average	Multiple Price (USD)		
Current Price					\$8.75		
NTM/PE	N/A	N/A	N/A	N/A	N/A		
NTM EV/EBITDA	0.1x	N/A	N/A	N/A	N/A		
NTM EV/FCF	227.7x	227.7x	227.7x	227.7x	N/A		
NTM EV/REV	103.1x	29.1x	103.1x	66.1x	\$15.29		
Price/Book	3.2x	3.0x	7.0x	4.7x	\$12.84		

## EXHIBIT 1:

## CARA Therapeutics Quarterly variance analysis

(000's except per share)	3Q13A	3Q14A	3Q14E	Variance	% Y/Y
License & milestones	\$0	\$0	\$0	\$0	N/A
Collaborative revenues	800	1,125	200	(925)	41%
Total Revenue	\$800	\$1,125	\$200	(\$925)	41%
COGS	0	0	0	0	N/A
Gross Profit	800	1,125	200	(925)	41%
SG&A Expense	847	1,520	1,650	130	79%
R&D Expense	2,607	6,208	4,100	(2,108)	138%
Operating Income	(2,654)	(6,603)	(5,550)	1,053	149%
Interest income (expense), net	(1,034)	26	50	24	-103%
Other (exp) gain, net	0	0	0	0	N/A
Pretax Income	(3,688)	(6,577)	(5,500)	1,077	78%
Income Tax exp (benefit)	(9)	(32)	(10)	22	256%
Net income (loss)	(3,679)	(6,545)	(5,490)	1,055	78%
1x items & non-cash exp	0	0	0	0	N/A
Adj NI ex-1x/non cash	(3,679)	(6,545)	(5,490)	1,055	78%
Weighted avg. shares (000)	38,410	22,713	22,858	145	-41%
Fully diluted shares (000)	38,410	24,213	24,358	145	-37%
Earning per Share (EPS)	(\$0.10)	(\$0.29)	(\$0.24)	\$0.05	201%
Adj EPS ex-1x & non-cash	\$0.00	\$0.00	\$0.00	\$0.00	N/A

Source: Company reports and Janney estimates

## EXHIBIT 2:

CARA Therapeutics										
Quarterly income statement										
		201	3A		2013A		201	4E		2014E
(\$000 except per share)	1QA	2QA	3QA	4QE	<u>Year</u>	1QA	2QA	3QE	4QE	<u>Year</u>
Revenues										
CR845 - IV version CR845 - oral version										
License		\$9,637			\$9,637		\$302	\$0		\$302
Collaborative revenues/ Milestones	\$54	500	\$800	\$973	2,327	178	658	1,125	700	2,661
Total Revenue	\$54	\$10,137	\$800	\$973	\$11,964	\$178	\$960	\$1,125	\$700	\$2,963
Expenses: Cost of Revenue (COGS)										
Gross Margin	54	10,137	800	973	11,964	178	960	1,125	700	2,963
Research and development	1,850	2,250	2,607	1,978	8,685	2,201	3,200	6,208	6,000	17,609
General and administrative	800	810	847	1,059	3,516	1,398	1,472	1,520	1,650	6,040
Total operating expenses	2,650	3,060	3,454	3,037	12,201	3,599	4,672	7,728	7,650	23,649
Income (loss) from Operations	(2,596)	7,077	(2,654)	(2,064)	(237)	(3,421)	(3,712)	(6,603)	(6,950)	(20,686)
Interest income (expense), net Other (exp) gain, net	(1,345)	(1,345)	(1,034)	(32)	(3,756)	22	56	26	50	154
Income (loss) before taxes	(3,941)	5,732	(3,688)	(2,096)	(3,993)	(3,399)	(3,656)	(6,577)	(6,900)	(20,532)
Income tax exp (benefit)	(9)	(9)	(9)	(3)	(30)	(16)	(11)	(32)	(10)	(69)
Net Income (Loss) Preferred stock converstion	(3,932)	5,741	(3,679)	(2,093)	<b>(3,963)</b> 891	(3,383)	(3,645)	(6,545)	(6,890)	(20,463)
Earning per Share (EPS)	(\$0.25)	\$0.37	(\$0.10)	(\$0.49)	(\$0.96)	(\$0.22)	(\$0.16)	(\$0.29)	(\$0.30)	(\$0.98)
Adj EPS ex-1x & non-cash items		(\$0.25)			(\$0.74)		(\$0.14)			(\$0.95)
Weighted avg. shares (000)	15,550	15,550	38,410	4,288	4,133	15,654	22,608	22,713	22,963	20,985
Fully diluted shares (000)						17,404	24,108	24,213	24,463	22,547

Source: Company reports and Janney estimates

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## IMPORTANT DISCLOSURES

## **Research Analyst Certification**

I, Chiara Russo, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

## Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Cara Therapeutics Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Cara Therapeutics Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Cara Therapeutics Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Cara Therapeutics Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

## **Definition of Ratings**

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

## **Price Charts**



## Janney Montgomery Scott Ratings Distribution as of 9/30/14

		_	ib Serv.	/Past 12 Wos.
Rating	Count	Percent	Count	Percent
BUY [B]	169	52.81	24	14.20
NEUTRAL [N]	150	46.88	18	12.00
SELL [S]	1	0.31	0	0

<sup>\*</sup>Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.

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## Other Disclosures

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