

Specialty Pharmaceuticals

Price:	\$8.65
Fair Value Estimate:	\$25.00
52-Week Range:	\$7.53 - \$23.25
Market Cap (MM):	\$195
Shr.O/S-Diluted (mm):	22.6
Average Daily Volume:	86,742
Book Value:	\$1.33
Dividend:	NA
Cash/Share:	\$0.68
FCF Yield:	(28.2)%
Debt/Cap:	0%

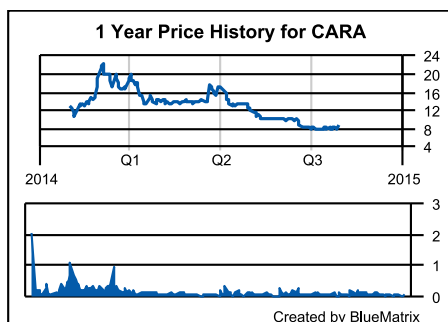
FYE: Dec	2013A	2014E	2015E
EPS:	\$(0.74)A	\$(0.84)E	\$(1.06)E
Prior EPS:		NC	NC
Consensus	NM	-0.83	-1.09
P/E Ratio:	NA	NA	NA

Quarterly EPS:

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

Quarterly Revenue (M):

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



October 29, 2014

## Cara Therapeutics Inc.

(CARA) - BUY

### CARA: HAL Data Opens Door for Schedule V or Unscheduled Opioid

#### PORTFOLIO MANAGER BRIEF

With the release of the Human Abuse Liability (HAL) data, we get a solid look at where CR845 could potentially fall in the DEA Controlled Substance Schedule...and it looks really good, sustaining our investment thesis. As the comparator is Schedule IV pentazocine and CR845 statistically demonstrated "less likability", we believe that CARA can make a compelling argument for CR845 as the first Schedule V or unscheduled kappa-opioid for chronic pain. Maintain Buy rating, \$25 fair value.

#### ANALYST NOTES

- **Positive Human Abuse Liability Data:** The results from the HAL study (Exhibit 1) indicate that not only was the patient population sensitive enough to distinguish between placebo and the active comparator, pentazocine (schedule IV) but more importantly that IV CR845 was statistically "less liked". On a bipolar scale of 1-100 with 50 being "Neither like nor dislike", Placebo rated at 52.4, CR845 (0.005) rated a 65.3, CR845 (0.015) rated at 66.9 and pentazocine came in at 87.6. This demonstrates highly statistically significant lower drug "liking scores" for CR845.
- **Why is the HAL data important?** Being a kappa-opioid receptor agonist, one of the significant benefits over most current acute pain treatments is that CR845 does not produce the euphoria typically seen in mu-opioids like morphine and its derivatives. With this lack of euphoria, there is a decrease in the potential for abuse and addiction. CR845 is "abuse deterrent" simply by virtue of being a kappa-opioid. The HAL data basically quantifies this point. We believe that with this data, CARA can make an argument that if CR845 has a lower likability score than a schedule IV drug then it can potentially be approved as a schedule V or even as an unscheduled opioid. CARA now looks to have an end-of-Phase 2 meeting with the FDA by year end and being Phase 3 trials in 1H15.
- **From HAL to oral to itch, Oh my!:** With the read out of positive HAL results in late October, several more data points are expected to read out in the next two months into 1Q15. The oral formulation should have data from the single and multiple ascending dose Phase 1a/1b trials in November/December as well as results from the Proof-of-Concept Part A data for dialysis itch in November. Data from Part B is expected in 1H15 as well as the initiation of both Phase 3 trials for IV CR845 in soft and hard tissue in 1H15.

- Unexpected Loss of Chief Medical Officer: CARA announced the unexpected death of their Chief Medical Officer, Dr. Robert Medve who had recently joined the company in June of this year. Though only with the company for 5 months, CARA will be under some pressure to fill this vacancy in light of their current clinical schedule.
- Dialysis Itch Opportunity is Compelling: At the recent analyst day, CARA management also laid out some more insight into the uremic pruritus market. 40%-60% of dialysis patients experience moderate to severe UP as well as large patient populations associated with atopic dermatitis/eczema, cholestatic liver disease and others. With the majority of itch treated with generic corticosteroids (~13M patients) with which many are unresponsive, there is the potential for premium pricing within the market which could potentially translate into a \$500M+ market opportunity. That's an itch that should be scratched.

## 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 itch by year end and Phase 3 start in 1Q15.

## ISSUES TO CONSIDER

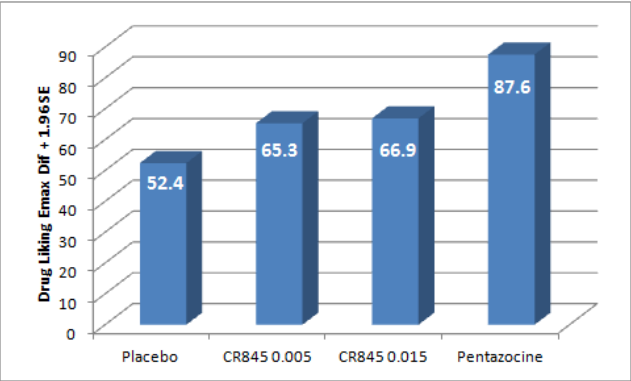
Key Issue	Our Position	Timing	Impact
Will the two Phase 3 trials in CR845 be successful?	This is, of course a tough question to answer and we are going to reserve our judgment until after the End of Phase 2 meeting and we have more clarity on the trial design of both the bunionectomy (hard tissue) and hysterectomy (soft tissue) trials. The closer to the Phase 2 study designs, the more positive we will be.	12-24 Months	<div><div>+</div><div>○</div><div>-</div></div>
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	<div><div>+</div><div>○</div><div>-</div></div>
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	<div><div>+</div><div>○</div><div>-</div></div>

## FIVE-YEAR VALUATION

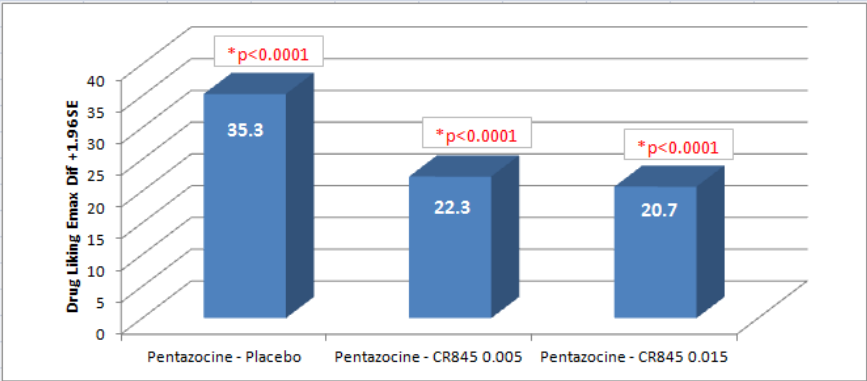
Historical Multiples - Premium to Comps					
Current vs 5 yr Average Historical Premium		5 Yr Historical Premium Range		Implied @ Hist Avg	
Metric	Current	Low	High	Average	Multiple Price (USD)
Current Price					\$8.65
NTM/PE	N/A	N/A	N/A	N/A	N/A
NTM EV/EBITDA	0.1x	N/A	N/A	N/A	N/A
NTM EV/FCF	227.7x	227.7x	227.7x	227.7x	N/A
NTM EV/REV	103.1x	29.1x	103.1x	66.1x	\$14.99
Price/Book	3.2x	2.9x	7.0x	4.5x	\$12.17

**EXHIBIT 1: Human Abuse Liability Results**

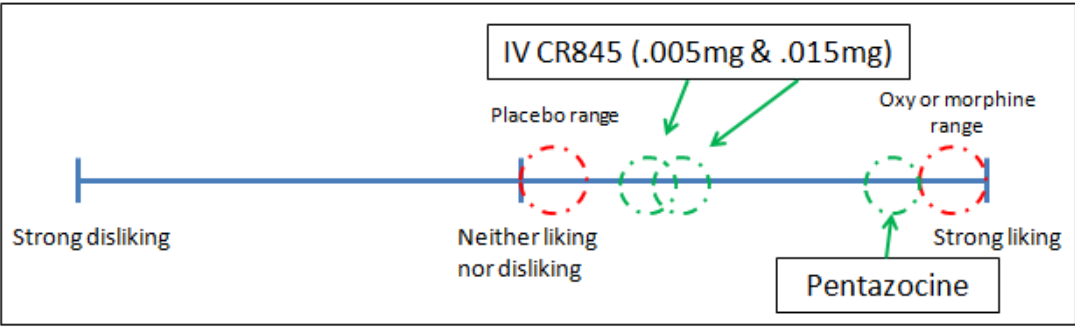
Drug Liking VAS Emax



Differences between Pentazocine and CR845



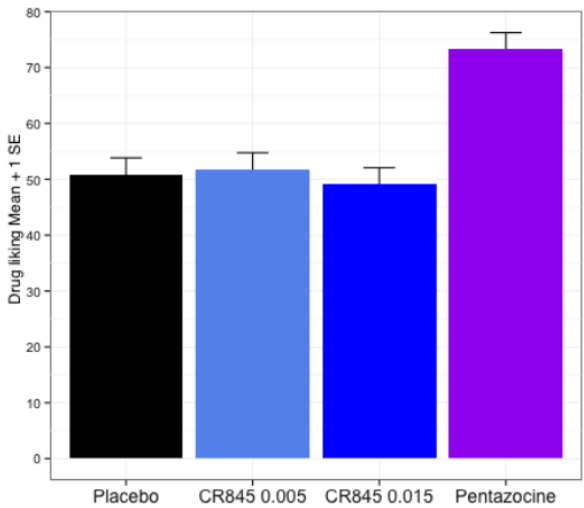
**EXHIBIT 2: Visual Representation of VAS “Drug Liking” Results**



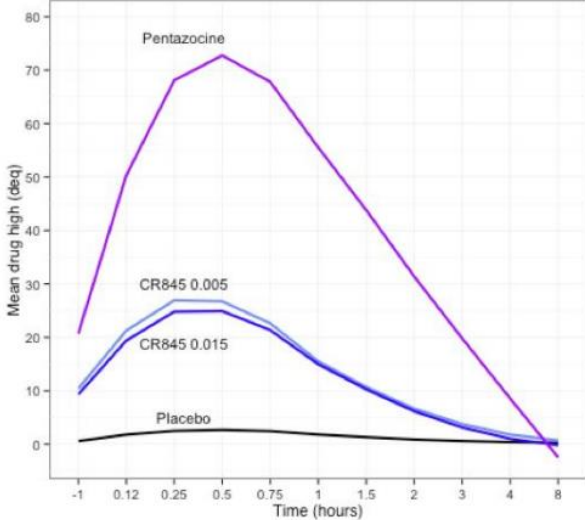
Source: Janney Montgomery Scott estimates

**EXHIBIT 3: Exploratory Endpoints**

Drug Liking over 8 Hour Session



“Feeling High” Exploratory Endpoint



**EXHIBIT 4:** Example of DEA Controlled Substances Schedule

Example of DEA Schedule Drugs*				
Schedule 1	Schedule 2	Schedule 3	Schedule 4	Schedule 5
Heroin	Fentanyl	Testosterone (Androgel)	Zolpidem (Ambien)	Bromodiphenhydramine/Codeine (Ambophen)
LSD	Amphetamine/Dextroamphetamine (Adderall)	Buprenorphine (Buprenex)	Diazepam (Valium)	Codeine/Promethazine
Marijuana	Hydrocodone combos (Vicodin)	Pseudoephedrine	Clonazepam	Atropine/Diphenoxylate
Mescaline	Morphine	Ketamine (Ketalar)	Eszopiclone (Lunesta)	Pregabalin (Lyrica)
MDMA	Oxycodone combos (Percocet)	Benzphetamine	Alprazolam (Xanax)	Codeine/Pheniramine/Phenylephrine/Sodium citrate (Tussirex)
GHB	Hydromorphone	Esterified estrogens/Methyltestosterone	Pentazocine (Talwin)	Lacosamide (Vimpat)
Ecstasy	Dextroamphetamine			
Psilocybin	Methylphenidate (Ritalin, Concerta)			
Mathaqualone				
Khat				
Bath Salts				

\*Not a complete list

## 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.

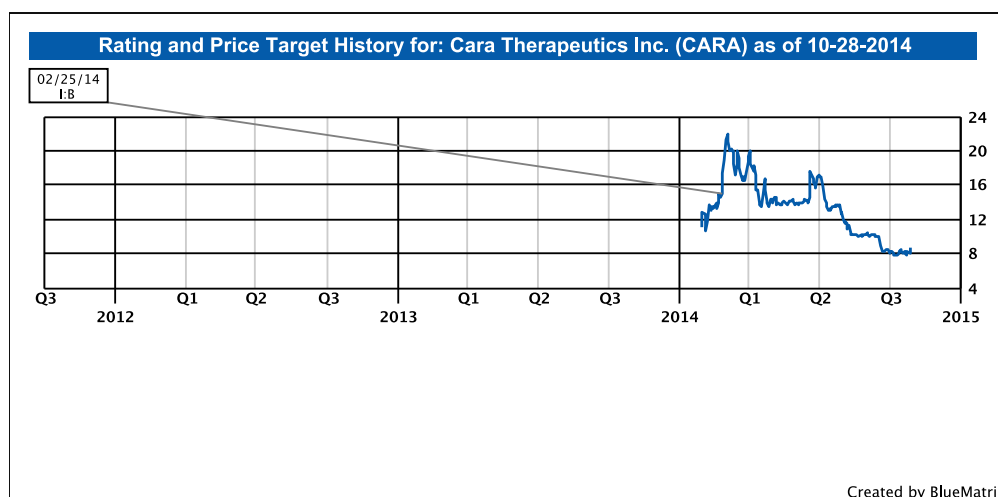
### Definition of Ratings

**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

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
<b>BUY [B]</b>	169	52.81	24	14.20
<b>NEUTRAL [N]</b>	150	46.88	18	12.00
<b>SELL [S]</b>	1	0.31	0	0.00

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

## Other Disclosures

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