



March 9, 2017

Cara Therapeutics Reports Fourth Quarter and Full Year 2016 Financial Results

- Conference call today at 4:30 p.m. ET -

STAMFORD, Conn., March 09, 2017 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (NASDAQ:CARA), a biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors, today announced financial results for the fourth quarter and full year ended December 31, 2016.

"In 2016, we advanced our three late-stage trials in indications of high unmet need where existing therapies are ineffective or are limited by significant side effects and the high potential for abuse," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We look forward to a transformative 2017, as we anticipate sharing efficacy data for CR845 in uremic pruritus, acute postoperative pain and chronic pain."

Fourth Quarter and Recent Business Highlights

- | In September 2016, initiated Phase 2b trial evaluating three doses of oral CR845 in chronic pain patients with osteoarthritis (OA).
- | In October 2016, delivered presentation and hosted industry symposium at the 10th Annual Pain & Migraine Therapeutics Summit and ANESTHESIOLOGY® 2016, respectively, at which the Company discussed CR845 as a novel approach to acute and chronic pain management due to its unlikeliness to lead to physical dependence.
- | In November 2016, announced the completion of enrollment in Part A of an adaptive Phase 2 / 3 trial of I.V. CR845, which was initiated in June 2016 in dialysis patients suffering from moderate-to-severe uremic pruritus (UP), an intractable systemic itch condition in patients with chronic kidney disease (CKD), for which there are no approved therapies in the United States.
- | In November 2016, presented two posters at Kidney Week, the American Society of Nephrology's Annual Meeting, which included positive data from the Company's Phase 2 study of I.V. CR845 in UP.

Expected 2017 Milestones

- | Top-line data expected in the first quarter of 2017 from Part A of the adaptive Phase 2/3 trial of I.V. CR845 in 160 dialysis patients suffering from moderate-to-severe UP.
- | Trial completion expected in the first quarter of 2017, with data readout expected in the second quarter of 2017, from a pharmacokinetic safety trial of multiple doses of Oral CR845 in hemodialysis patients to define bioequivalent tablet strengths to inform the ability to develop an oral tablet formulation for moderate-to-severe UP.
- | Top-line data expected in the second quarter of 2017 from the Phase 2b trial of Oral CR845, for the treatment of pain associated with OA.
- | Interim conditional power analysis expected in the second quarter of 2017 from CLIN-3001, our 450 patient adaptive Phase 3 trial of I.V. CR845 in postoperative pain.
- | Data expected in the second quarter of 2017 from a Phase 1 trial to quantitatively assess any effects of I.V. CR845 on respiratory drive after bolus infusion in healthy volunteers.

Fourth Quarter 2016 Financial Results

Net Loss: The Company reported a net loss of \$22.0 million, or \$0.81 per basic and diluted share, for the fourth quarter of 2016 compared to a net loss of \$9.5 million, or \$0.35 per basic and diluted share, for the same period of 2015.

Revenues: The Company did not recognize any revenues during the fourth quarter of 2016 or 2015.

Research and Development (R&D) Expenses: R&D expenses were \$20.3 million in the fourth quarter of 2016 compared to \$7.6 million in the same period of 2015. The higher R&D expenses in the fourth quarter of 2016 were principally due to a net increase in direct clinical trial costs and an increase in payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were \$2.0 million in the fourth quarter of 2016 compared to \$2.2 million in the same period of 2015. The decrease in the fourth quarter of 2016 was primarily due to a decrease in

franchise tax and amortization expense, which were partially offset by increases in payroll and related costs.

Full Year 2016 Financial Results

Net Loss: The Company reported a net loss of \$57.3 million, or \$2.10 per basic and diluted share, for 2016 compared to a net loss of \$24.7 million, or \$1.00 per basic and diluted share, for 2015.

Revenues: License and milestone fees revenue was \$1.7 million for 2015 (representing \$1.1 million of the \$1.7 million milestone payment earned in September 2015 under the Maruishi Agreement, which was attributable to the previously delivered license, and \$600,000 from the two milestone payments earned by the Company under the CKD Agreement in July and September 2015). No license and milestone fees revenue was recognized in 2016.

Collaborative revenue was \$2.1 million for 2015 (consisting of \$600,000 of the \$1.7 million milestone payment earned in September 2015 under the Maruishi Agreement, which was attributable to the fully delivered R&D services deliverable, and \$1.5 million of revenue that had been deferred upon entry into the Maruishi Agreement). No collaborative revenue was recognized in 2016.

Clinical compound revenue for 2016 and 2015 was \$86,000 and \$0, respectively, from the sale of clinical compound to Maruishi.

Research and Development (R&D) Expenses: R&D expenses were \$49.3 million in 2016 compared to \$21.2 million in 2015. The higher R&D expenses in 2016 were principally due to a net increase in direct clinical trial costs, consultant services in support of clinical trials, and increases in payroll and related costs for R&D personnel and in rent.

General and Administrative (G&A) Expenses: G&A expenses were \$9.2 million in 2016 compared to \$7.8 million in 2015. The increase in 2016 was primarily due to increases in payroll and related costs, rent, amortization, public/investor relations costs, insurance costs and professional fees, including accounting and audit fees.

Other Income: Other income was \$652,000 in 2016 compared to \$101,000 in 2015. The increase in 2016 was primarily due to (1) an increase in interest income and dividends earned on our portfolio of investments, which included marketable securities during the entire year ended December 31, 2016 but only during the last month of the year ended December 31, 2015 and (2) higher interest rates and a higher average balance of cash and cash equivalents and marketable securities in 2016 as a result of our follow-on offering of common stock, which closed in August 2015.

Cash and Cash Equivalents and Marketable Securities Position: At December 31, 2016, cash and cash equivalents and marketable securities totaled \$58.3 million compared to \$106.7 million at December 31, 2015. The decrease in the balance of cash and cash equivalents and marketable securities primarily resulted from cash used in operations of \$47.4 million.

Financial Guidance

Based on timing expectations and projected costs for current clinical development plans, Cara expects that its existing cash and cash equivalents and available-for-sale marketable securities as of December 31, 2016 will be sufficient for the Company to fund its operating expenses and capital expenditure requirements through the end of the first quarter of 2018, without giving effect to any potential milestone payments under existing collaborations.

Conference Call

Cara management will host a conference call today at 4:30 p.m. ET to discuss fourth quarter and full year 2016 financial results and provide a business update.

To participate in the conference call, please dial 855-445-2816 (domestic) or 484-756-4300 (international) and refer to conference ID 70053458. A live webcast of the call can be accessed under "Events and Presentations" in the News & Investors section of the Company's website at www.CaraTherapeutics.com.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors. Cara is developing a novel and proprietary class of product candidates that target the body's peripheral nervous system and have demonstrated initial efficacy in patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated

with currently available pain therapeutics.

Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning the expected timing of the Company's planned clinical trials, the potential results of ongoing and planned clinical trials, future regulatory and development milestones for the Company's product candidates and the Company's expected cash reach. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Cara Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2016 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Cara Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Financial tables follow

CARA THERAPEUTICS, INC. STATEMENTS OF OPERATIONS

(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Year Ended December 31,	
	December 31, 2016	2015	2016	2015
Revenue:				
License and milestone fees	\$ -	\$ -	\$ -	\$ 1,710
Collaborative revenue	-	-	-	2,093
Clinical compound revenue	-	-	86	-
Total revenue	-	-	86	3,803
Operating expenses:				
Research and development	20,277	7,568	49,253	21,221
General and administrative	2,038	2,161	9,233	7,770
Total operating expenses	22,315	9,729	58,486	28,991
Operating loss	(22,315)	(9,729)	(58,400)	(25,188)
Other income	155	52	652	101
Loss before benefit from income taxes	(22,160)	(9,677)	(57,748)	(25,087)
Benefit from income taxes	189	147	468	397
Net loss	<u>\$ (21,971)</u>	<u>\$ (9,530)</u>	<u>\$ (57,280)</u>	<u>\$ (24,690)</u>
Net loss per share :				
Basic and Diluted	\$ (0.81)	\$ (0.35)	\$ (2.10)	\$ (1.00)
Weighted average shares:				
Basic and Diluted	27,290,548	27,240,369	27,279,008	24,620,372

CARA THERAPEUTICS, INC. BALANCE SHEETS

(in thousands)
(unaudited)

	December 31,	
	2016	2015

Assets

Current assets:

Cash and cash equivalents	\$ 12,092	\$ 15,101
Marketable securities	46,184	91,640
Income tax receivable	852	384
Other receivables	87	80
Prepaid expenses	1,530	1,729
Restricted cash, current	700	-
Total current assets	61,445	108,934
Property and equipment, net	1,614	1,263
Restricted cash	769	700
Total assets	<u>\$ 63,828</u>	<u>\$ 110,897</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable and accrued expenses	\$ 11,533	\$ 5,268
Total current liabilities	11,533	5,268

Deferred lease obligation	1,570	585
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Commitments and contingencies

Stockholders' equity:

Preferred stock	-	-
Common stock	27	27
Additional paid-in capital	212,866	209,943
Accumulated deficit	(162,171)	(104,891)
Accumulated other comprehensive income (loss)	3	(35)
Total stockholders' equity	50,725	105,044
Total liabilities and stockholders' equity	<u>\$ 63,828</u>	<u>\$ 110,897</u>

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