Cara Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results

March 15, 2018

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

STAMFORD, Conn., March 15, 2018 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting kappa opioid receptors, today announced financial results for the fourth quarter and full year ended December 31, 2017.

“We are very pleased with the progress we have made with both I.V. and oral KORSUVA across our ongoing clinical programs in pruritus and with CR845/difelikefalin in pain, including the recent initiation of our first pivotal Phase 3 trial of I.V. KORSUVA in hemodialysis patients with chronic kidney disease-associated pruritus (CKD-aP),” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “In 2018, we expect to continue to expand our development programs with KORSUVA for the treatment of other significant unmet pruritus indications, including patients with chronic kidney disease who are not on dialysis, patients with chronic liver disease as well as other dermatological conditions.”

Fourth Quarter and Recent Developments:

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus (CKD-aP): Hemodialysis

- In January 2018, the Company initiated the first pivotal Phase 3 efficacy trial (KALM-1) of KORSUVA (CR845/difelikefalin) injection in the United States for the treatment of CKD-aP in patients undergoing hemodialysis. In addition, the Company is also conducting a 52-week Phase 3 safety study of KORSUVA (CR845/difelikefalin) injection in patients undergoing hemodialysis with CKD-aP.
- In October 2017, the Company completed the End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) and established the Phase 3 program to support a New Drug Application (NDA) for KORSUVA injection for the treatment of moderate-to-severe CKD-aP in hemodialysis patients.
- In November 2017, the Company presented clinical data from the Phase 2b efficacy trial of KORSUVA injection in hemodialysis patients with moderate to severe pruritus at the American Society of Nephrology's Annual Meeting.

Oral KORSUVA: Chronic Kidney Disease-Associated Pruritus (CKD-aP): Non-Hemodialysis

- In October 2017, the Company announced initiation of the Phase 1 pharmacokinetic (PK) and safety trial of Oral KORSUVA tablets in patients with stage III-V CKD who are not on dialysis. Data from the trial will inform the dose selection and design of the planned Phase 2 trial in non-hemodialysis patients with CKD-aP.

Oral KORSUVA: Chronic Liver Disease-Associated Pruritus (CLD-aP)

- In February 2018, the Company announced dosing of the first patient in a Phase 1 PK and safety trial of Oral KORSUVA in patients with CLD. Data from this trial will inform the design/ doses for the planned Phase 2 trial of Oral KORSUVA in patients with moderate-to-severe CLD-aP.

I.V. CR845/Difelikefalin: Acute Post-Operative Pain

- The adaptive Phase 3 trial of I.V. CR845 for the treatment of acute postoperative pain in patients undergoing abdominal surgery is nearing enrollment completion. Data from this trial are expected in the second quarter of 2018.
- In October 2017, the Company presented clinical data on the respiratory effects of I.V. CR845 at ANESTHESIOLOGY® 2017, the American Society of Anesthesiologists' annual meeting.

Oral CR845/Difelikefalin: Chronic Pain

- In November 2017, the Company presented data from its Phase 2b study of Oral CR845 in patients with osteoarthritis of the hip or knee at the American College of Rheumatology ACR/ARHP Annual Meeting.
- The Company does not intend to further develop Oral CR845 for chronic pain on its own and expects to seek partnerships and collaborations with companies with expertise in chronic pain.

Expected 2018 Milestones

- Completion of enrollment and top-line data from the adaptive Phase 2/3 trial of I.V. CR845/difelikefalin for the treatment of acute post-operative pain.

- Initiation of a placebo-controlled Phase 2 trial of Oral KORSUVA in patients with stage III-V CKD who are not on dialysis.
- Initiation of an international Phase 3 trial of KORSUVA injection in hemodialysis patients with CKD-aP.
- Initiation of Phase 2 trial of Oral KORSUVA in patients with CLD-aP.

Upcoming Activities:

The Company expects to make presentations at the following medical conferences through May, 2018:

- National Kidney Foundation Spring Clinical Meeting, April 10-14, 2018
- American Academy of Pain Medicine's Annual Meeting, April 26-29, 2018
- International Investigative Dermatology Meeting, May 16-19, 2018

Fourth Quarter 2017 Financial Results

Net Loss: The Company reported a net loss of $14.2 million, or $0.43 per basic and diluted share, for the fourth quarter of 2017 compared to a net loss of $22.0 million, or $0.81 per basic and diluted share, for the same period of 2016.

Revenues: The Company did not recognize any revenues during the fourth quarter of 2017 or 2016.

Research and Development (R&D) Expenses: R&D expenses were $11.6 million in the fourth quarter of 2017 compared to $20.3 million in the same period of 2016. The lower R&D expenses in the fourth quarter of 2017 were principally due to a net decrease in direct clinical trial costs, which were partially offset by an increase in payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were $3.0 million in the fourth quarter of 2017 compared to $2.0 million in the same period of 2016. The increase in the fourth quarter of 2017 was primarily due to increases in stock-based compensation expense and payroll and related costs.

Other Income: Other income was $368,000 in the fourth quarter of 2017 compared to $155,000 in 2016. The increase in the fourth quarter of 2017 was primarily due to higher dividend and interest income resulting from higher interest rates on a higher average balance in the Company's portfolio of investments.

Full Year 2017 Financial Results

Net Loss: The Company reported a net loss of $58.1 million, or $1.86 per basic and diluted share, for 2017 compared to a net loss of $57.3 million, or $2.10 per basic and diluted share, for 2016.

Revenues: Total revenue in 2017 was $911,000 as compared to $86,000 in 2016. Total revenue consisted of:

1. License and milestone fees revenue of $530,000 in 2017 related to a sub-license fee received from Maruishi Pharmaceuticals in connection with its sub-license agreement with Kissei Pharmaceuticals. No license and milestone fees revenue was recognized in 2016.
2. Collaborative revenue of $313,000 in 2017 related to a sub-license fee received from Maruishi. No collaborative revenue was recognized in 2016.
3. Clinical compound revenue of $68,000 and $86,000 for 2017 and 2016, respectively, for the sale of clinical compound to Maruishi.

Research and Development (R&D) Expenses: R&D expenses were $48.5 million in 2017 compared to $49.3 million in 2016. The lower R&D expenses in 2017 were principally due to a net decrease in direct clinical trial costs and in rent, which were partially offset by increases in stock compensation expense and payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were $11.9 million in 2017 compared to $9.2 million in 2016. The increase in 2017 was primarily due to increases in payroll and related costs, stock-based compensation expense, and public/investor relations costs, which were partially offset by decreases in rent and amortization.

Other Income: Other income was $1.2 million in 2017 compared to $652,000 in 2016. The increase in 2017 was primarily due to higher dividend and interest income resulting from higher interest rates on a higher average balance of the Company's portfolio of investments in the 2017 period.

Cash and Cash Equivalents and Marketable Securities Position: At December 31, 2017, cash and cash equivalents and marketable securities totaled $92.6 million compared to $58.3 million at December 31, 2016. The increase in the balance of cash and cash equivalents and marketable securities primarily resulted from the net proceeds of $86.2 million from the Company's follow-on public offering of common stock in April 2017, from the proceeds of the exercise of stock options and from restricted cash that was reclassified to cash and cash equivalents, partially offset by cash used in operations of $54.8 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, 2017 will be sufficient for the Company to fund its operating expenses and capital expenditure requirements into the first half of 2019, 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 2017 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 2689187. 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 biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors (KORs). Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In Phase 2 trials, KORSUVA injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP) and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Additionally, CR845/difelikefalin has demonstrated initial signs of efficacy in patients with moderate-to-severe pain, without inducing many of the undesirable side effects typically associated with currently available opioid pain therapeutics.

The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product, and its safety and efficacy have not been fully evaluated by any regulatory authority.

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, 2017 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 December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Revenue:				
License and milestone fees	$ -	$ -	$ 530	$ -
Collaborative revenue	-	-	313	-
Clinical compound revenue	-	-	68	86
Total revenue	-	-	911	86
Operating expenses:				
Research and development	11,576	20,277	48,524	49,253
General and administrative	2,995	2,038	11,872	9,233
Total operating expenses	14,571	22,315	60,396	58,486
Operating loss	(14,571)	(22,315)	(59,485)	(58,400)
Other income	368	155	1,156	652
Loss before benefit from income taxes	(14,203)	(22,160)	(58,329)	(57,748)
Benefit from income taxes	26	189	204	468
Net loss	$ (14,177)	$ (21,971)	$ (58,125)	$ (57,280)
Net loss per share :				
Basic and Diluted	$ (0.43)	$ (0.81)	$ (1.86)	$ (2.10)
Weighted average shares:				
Basic and Diluted	32,635,706	27,290,548	31,202,842	27,279,008

CARA THERAPEUTICS, INC.
BALANCE SHEETS

(in thousands)
(unaudited)

	December 31, 2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$ 9,388	$ 12,092
Marketable securities	83,181	46,184
Income tax receivable	731	852
Other receivables	123	87
Prepaid expenses	1,635	1,530
Restricted cash, current	-	700
Total current assets	95,058	61,445
Property and equipment, net	1,177	1,614
Restricted cash	769	769
Total assets	$ 97,004	$ 63,828
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,506	$ 11,533
Total current liabilities	8,506	11,533
Deferred lease obligation	1,718	1,570
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	33	27
Additional paid-in capital	307,158	212,866
Accumulated deficit	(220,341)	(162,171)
Accumulated other comprehensive income (loss)	(70)	3
Total stockholders' equity	86,780	50,725
Total liabilities and stockholders' equity	$ 97,004	$ 63,828

INVESTOR CONTACT:
Michael Schaffzin
Stern Investor Relations, Inc.
212-362-1200
michael@sternir.com

MEDIA CONTACT:
Annie Starr
6 Degrees
973-415-8838
astarr@6degreespr.com

Primary Logo

Source: Cara Therapeutics, Inc.