



Cara Therapeutics Reports First Quarter 2018 Financial Results

May 9, 2018

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

STAMFORD, Conn., May 09, 2018 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors, today announced financial results and operational highlights for the first quarter ended March 31, 2018.

"During the quarter, we were pleased with the progress made in building out our pruritus pipeline, headlined by the initiation of our pivotal U.S. Phase 3 trial of KORSUVA injection in hemodialysis patients with chronic kidney disease-associated pruritus," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We look forward to the continued development of our other pruritus clinical programs, including Oral KORSUVA for the treatment of pruritus in pre-dialysis chronic kidney disease and chronic liver disease patient populations, and will be reporting on the progress of these studies later this year. In addition, we have now completed enrollment in our adaptive Phase 3 trial in acute post-operative pain and expect to announce top-line data later this quarter."

First 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 conducting a 52-week Phase 3 safety study of KORSUVA (CR845/difelikefalin) injection in patients undergoing hemodialysis with CKD-aP.

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

The open label, dose-escalating Phase 1 pharmacokinetic (PK), safety and tolerability trial continues to enroll moderate and severe CKD patients in escalating dose cohorts. Top-line data are expected in the second quarter of 2018.

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

Enrollment is complete in the adaptive Phase 3 trial of I.V. CR845 for the treatment of acute post-operative pain in patients undergoing abdominal surgery. Data from this trial are expected in the second quarter of 2018.

Upcoming Activities

The Company expects to make presentations at the following conferences through June 2018:

- International Investigative Dermatology Meeting, May 16-19, 2018
- Jefferies 2018 Global Healthcare Conference, June 5-8, 2018
- Cantor Dermatology & Aesthetics Summit, June 19, 2018

First Quarter 2018 Financial Results

Net Loss: The Company reported a net loss of \$16.8 million, or \$0.51 per basic and diluted share, for the first quarter of 2018 compared to a net loss of \$22.2 million, or \$0.81 per basic and diluted share, for the same quarter of 2017.

Revenues: The Company did not recognize any revenue during the first quarter of 2018. Total revenue in the first quarter of 2017 was \$911,000, which consisted of:

- (1) License and milestone fees revenue of \$530,000 related to a sub-license fee earned from Maruishi Pharmaceuticals, or Maruishi, in connection with its sub-license agreement with Kissei Pharmaceuticals.
- (2) Collaborative revenue of \$313,000 related to a sub-license fee earned from Maruishi; and
- (3) Clinical compound revenue of \$68,000 from the sale of clinical compound to Maruishi.

Research and Development (R&D) Expenses: R&D expenses were \$13.4 million in the first quarter of 2018 compared to \$20.8 million in the same period of 2017. The lower R&D expenses in 2018 were principally due to a net decrease in direct clinical trial costs, 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 \$3.7 million during the first quarter of 2018 compared to \$2.4 million in the same

period of 2017. The increase in 2018 was primarily due to increases in stock compensation expense and payroll and related costs for G&A personnel.

Other Income: Other income was \$311,000 in the first quarter of 2018 compared to \$90,000 in the same period of 2017. The increase in 2018 was primarily due to higher dividend and interest income resulting from a higher average balance of the Company's portfolio of investments in the 2018 period.

Cash and Cash Equivalents and Marketable Securities Position: At March 31, 2018, cash and cash equivalents and marketable securities totaled \$74.5 million compared to \$92.6 million at December 31, 2017. The decrease in the balance of cash and cash equivalents and marketable securities primarily resulted from cash used in operations of \$18.5 million, partially offset by proceeds of \$0.3 million from the exercise of stock options.

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 March 31, 2018 will be sufficient to fund its operating expenses and capital expenditures 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 first quarter 2018 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 1264618. 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 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.

CONDENSED STATEMENTS OF OPERATIONS

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

(unaudited)

	Three Months Ended March 31,	
	2018	2017
Revenue:		
License and milestone fees	\$ -	\$ 530
Collaborative revenue	-	313
Clinical compound revenue	-	68
Total revenue	-	911
Operating expenses:		
Research and development	13,427	20,836
General and administrative	3,697	2,400

Total operating expenses	17,124		23,236	
Operating loss	(17,124))	(22,325))
Other income	311		90	
Loss before benefit from income taxes	(16,813))	(22,235))
Benefit from income taxes	46		31	
Net loss	\$ (16,767))	\$ (22,204))
Net loss per share :				
Basic and Diluted	\$ (0.51))	\$ (0.81))
Weighted average shares:				
Basic and Diluted	32,681,661		27,299,678	

CARA THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2018		December 31, 2017	
Assets				
Current assets:				
Cash and cash equivalents	\$ 11,877		\$ 9,388	
Marketable securities	62,644		83,181	
Income tax receivable	777		731	
Other receivables	84		123	
Prepaid expenses	3,431		1,635	
Total current assets	78,813		95,058	
Property and equipment, net	1,053		1,177	
Restricted cash	769		769	
Total assets	\$ 80,635		\$ 97,004	
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable and accrued expenses	\$ 6,875		\$ 8,506	
Total current liabilities	6,875		8,506	
Deferred lease obligation	1,657		1,718	
Commitments and contingencies				
Stockholders' equity:				
Preferred stock	-		-	
Common stock	33		33	
Additional paid-in capital	309,292		307,158	
Accumulated deficit	(237,108))	(220,341))
Accumulated other comprehensive loss	(114))	(70))
Total stockholders' equity	72,103		86,780	
Total liabilities and stockholders' equity	\$ 80,635		\$ 97,004	

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Source: Cara Therapeutics, Inc.