Cara Therapeutics Reports Third Quarter 2023 Financial Results

November 13, 2023

– Non-dilutive financing agreement with HealthCare Royalty for up to $40 million expected to extend cash runway into 2025 –

– Key data readouts for all three late-stage oral difelikefalin clinical programs anticipated within current financial runway –

– Topline results from Part A of KIND 1 Phase 3 atopic dermatitis trial expected in December 2023 –

– 3Q23 total revenue of $4.9M including collaborative revenue of $1.9M from the Company's share of profit of KORSUVA ® (difelikefalin) injection –

– Conference call today at 4:30 p.m. EST –

STAMFORD, Conn., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq: CARA), a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus, today announced financial results and operational highlights for the third quarter ended September 30, 2023.

"We are pleased to have closed our non-dilutive financing transaction with HealthCare Royalty, which extends our cash runway into 2025," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "This financing will help us reach key clinical catalysts which we believe will validate the potential of our oral difelikefalin pipeline."

Mr. Posner continued, "We look forward to releasing topline efficacy and safety data from Part A of our KIND 1 atopic dermatitis (AD) trial in December. Our other two late-stage clinical programs for the treatment of pruritus associated with advanced chronic kidney disease (CKD) and notalgia paresthetica (NP) are on track for key data readouts in 2024. We will continue to focus on maintaining a strong balance sheet and delivering on our commitments across our wholly owned pipeline."

3Q23 and Recent Highlights

- Entered into Royalty Interest Purchase and Sale Agreement with HealthCare Royalty (HCRx) for up to $40 million, extending Cara's cash runway into 2025
- Topline efficacy and safety data from Part A of the KIND 1 Phase 3 program in pruritus associated with AD expected in December 2023
- Enrollment on track in the KICK Phase 3 program in pruritus associated with advanced CKD, with topline results expected in 2H24
- Enrollment also on track in the KOURAGE Phase 2/3 program in NP, with readout from Part A targeted in 2H24 and final topline results for the program in 1H26
- Findings from the Neuropathic Itch Patient Survey (NIRVE) were reported in an oral presentation at the EADV Congress 2023
- Centers for Medicare & Medicaid Services issued the CY 2024 End Stage Renal Disease Prospective Payment System final rule
- Helen M. Boudreau was appointed to the Company's Board of Directors and will serve as Chair of the Audit Committee
- Harrison M. Bains retired from the Company's Board of Directors

KORSUVA Injection U.S. Update: 3Q23

In the third quarter of 2023, KORSUVA injection generated net sales of $4.4 million and the Company recorded collaborative revenue of $1.9 million, which represented the Company's share of the profit from sales of KORSUVA injection.

Wholesalers shipped 90,828 vials to dialysis centers during the third quarter of 2023. Vial orders increased 36% quarter to quarter.

In October 2023, the Centers for Medicare & Medicaid Services (CMS) issued a final rule for the End Stage Renal Disease Prospective Payment System (ESRD PPS) for calendar year 2024, which confirmed the TDAPA period for KORSUVA injection until March 31, 2024, and maintained the reimbursement methodology from the June 2023 proposed rule.

Upcoming Meeting Activities

The Company expects to present at the following upcoming investor conferences:

- Stifel Healthcare Conference, November 15, 2023, at 10:55 a.m. EST
- Jefferies London Healthcare Conference, November 16, 2023, at 8:00 a.m. GMT
- Piper Sandler Healthcare Conference, November 29, 2023, at 4:30 p.m. EST

Third Quarter 2023 Financial Results

Cash, cash equivalents and marketable securities at September 30, 2023 totaled $83.3 million compared to $156.7 million at December 31, 2022. The decrease in the balance primarily resulted from $74.7 million of cash used in operating activities.

For the third quarter of 2023, net loss was $28.0 million, or $(0.52) per basic and diluted share, compared to net loss of $23.2 million, or $(0.43) per basic and diluted share, for the same period in 2022.

Revenues: Total revenue was $4.9 million and $10.8 million for the three months ended September 30, 2023 and 2022, respectively. Revenue consisted of:

- $1.9 million and $7.4 million of collaborative revenue related to our share of the profit from CSL Vifor's sales of KORSUVA injection to third parties during the three months ended September 30, 2023 and 2022, respectively. In addition, $0.5 million of collaborative revenue was recognized during the three months ended September 30, 2023. This amount relates to an allocated portion of the regulatory milestone payment we earned in September 2023 from Maruishi Pharmaceuticals Co. Ltd, or Maruishi, for the marketing approval in Japan for KORSUVA injection;
- $1.3 million and $3.4 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor during the three months ended September 30, 2023 and 2022, respectively;
- Approximately $167,000 of royalty revenue related to our royalties on the net sales of Kapruvia in Europe during the three months ended September 30, 2023. There was no royalty revenue during the three months ended September 30, 2022; and
- $0.9 million of license and milestone fees revenue related to the remaining allocated portion of a regulatory milestone payment we earned in September 2023 from Maruishi for the marketing approval in Japan for KORSUVA injection. There was no license and milestone fees revenue during the three months ended September 30, 2022.

Cost of Goods Sold: Cost of goods sold was $1.6 million and $3.1 million during the three months ended September 30, 2023 and 2022, respectively, related to commercial supply revenue for KORSUVA injection sales to CSL Vifor.

Research and Development (R&D) Expenses: R&D expenses were $25.5 million for the three months ended September 30, 2023 compared to $24.7 million in the same period of 2022. The slightly higher R&D expenses in 2023 were primarily due to increases in clinical trial costs related to our three late-stage development programs, partially offset by a decrease in stock-based compensation expense. R&D expenses for the three months ended September 30, 2022 included $5.0 million related to a milestone payment due to Enteris Biopharma, Inc.

General and Administrative (G&A) Expenses: G&A expenses were essentially flat at $6.8 million for the three months ended September 30, 2023 compared to $6.9 million in the same period of 2022.

Other Income, net: Other income, net was approximately $866,000 for the three months ended September 30, 2023 compared to approximately $665,000 in the same period of 2022. The increase in other income, net was primarily due to an increase in interest income resulting from a higher yield on our portfolio of investments during the three months ended September 30, 2023.

Financial Guidance

Cara expects that our current unrestricted cash and cash equivalents and available-for-sale marketable securities, including the proceeds from our recently announced royalty financing and the collaborative revenue from our share of the profit from KORSUVA injection, will be sufficient to fund our currently anticipated operating plan into 2025.

About Cara Therapeutics

Cara Therapeutics is a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company's KORSUVA® (difelikefalin) injection is the first and only FDA-approved treatment for moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. The Company is developing an oral formulation of difelikefalin and has Phase 3 programs ongoing for the treatment of pruritus in patients with advanced chronic kidney disease and atopic dermatitis. In addition, the Company has an ongoing Phase 2/3 program of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica. For more information, visit www.CaraTherapeutics.com and follow the company on X (Twitter), LinkedIn and Instagram.

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 Company's and its partners ongoing commercialization of and ability to successfully commercialize KORSUVA injection and Kapruvia, future revenue and profit share from sales of KORSUVA and Kapruvia, planned future regulatory submissions and potential future regulatory approvals, future product launches, the performance of the Company's commercial partners, including CSL Vifor, expected timing of the initiation, enrollment and data readouts from the Company's planned and ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development milestones for the Company's product candidates, the potential for the Company's product candidates to be alternatives in the therapeutic areas investigated and the potential for oral difelikefalin to address additional pruritic indications, the size and growth of the potential markets for pruritus management, the receipt of potential milestone payments pursuant to the Purchase and Sale Agreement with HealthCare Royalty 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. These risks and uncertainties include the risks inherent in the launch of new products, including that our commercial partners, including CSL Vifor, may not perform as expected, risks inherent in the clinical and regulatory development of pharmaceutical products, and the risks 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 ending December 31, 2022 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2023. 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, except as required by law.

Financial tables follow

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 62,875	$ 63,741
Marketable securities	15,666	81,658
Accounts receivable, net - related party	3,351	3,260
Inventory, net	3,266	2,383
Income tax receivable	697	697
Other receivables	1,682	496
Prepaid expenses	12,658	16,267
Restricted cash	408	408
Total current assets	100,603	168,910
Operating lease right-of-use assets	7,108	1,551
Marketable securities, non-current	4,747	11,350
Property and equipment, net	1,380	426
Restricted cash, non-current	1,500	-
Total assets	$ 115,338	$ 182,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,384	$ 21,540
Operating lease liabilities, current	497	1,918
Total current liabilities	22,881	23,458
Operating lease liabilities, non-current	6,815	-
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	54	53
Additional paid-in capital	738,435	726,630
Accumulated deficit	(652,408)	(566,232)
Accumulated other comprehensive loss	(439)	(1,672)
Total stockholders' equity	85,642	158,779
Total liabilities and stockholders' equity	$ 115,338	$ 182,237

CARA THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				

Collaborative revenue	$ 2,471	$ 7,443	$ 10,631	$ 15,446
Commercial supply revenue	1,252	3,370	5,843	8,160
Royalty revenue	167	-	415	-
License and milestone fees	910	-	910	15,000
Clinical compound revenue	66	-	165	-
Total revenue	4,866	10,813	17,964	38,606
Operating expenses:				
Cost of goods sold	1,558	3,055	5,566	5,136
Research and development	25,451	24,691	80,095	65,869
General and administrative	6,755	6,912	21,191	23,829
Total operating expenses	33,764	34,658	106,852	94,834
Operating loss	(28,898)	(23,845)	(88,888)	(56,228)
Other income, net	866	665	2,712	1,093
Net loss	$ (28,032)	$ (23,180)	$ (86,176)	$ (55,135)
Net loss per share:				
Basic and Diluted	$ (0.52)	$ (0.43)	$ (1.59)	$ (1.03)
Weighted average shares:				
Basic and Diluted	54,235,695	53,726,123	54,038,239	53,616,753

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