Cara Therapeutics Reports First Quarter 2024 Financial Results

May 13, 2024

Topline efficacy and safety results from KOURAGE 1 Part A portion of notalgia paresthetica (NP) pivotal program now expected by the end of 2Q24

STAMFORD, Conn., May 13, 2024 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq: CARA), a development-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 first quarter ended March 31, 2024.

“Our notalgia paresthetica (NP) pivotal clinical program is progressing ahead of schedule and we now expect to report topline efficacy and safety results from KOURAGE 1 Part A by the end of the second quarter of 2024,” said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. “We believe the medical dermatology community’s interest in our clinical program underscores the significant unmet need for an effective and safe anti-pruritic treatment for the sizeable NP patient population. We look forward to rapidly advancing the ongoing Phase 2/3 program of our differentiated asset, oral difelikefalin, in this common but under-explored sensory neuropathy.”

KOURAGE Update

KOURAGE 1 Part A is the dose-finding portion of the Phase 2/3 clinical program evaluating oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with NP. The Company enrolled 214 patients and expects topline efficacy and safety results from KOURAGE 1 Part A by the end of the second quarter of 2024. Part A is not powered for statistical significance. This readout will provide key information, specifically the dose and sample size to initiate the Phase 3 pivotal portion of the program – Part B of KOURAGE 1 and the second study KOURAGE 2. Final topline results from the first pivotal study are expected by the end of 2025 with the second pivotal study results in early 2026.

In March 2024, the Company hosted a virtual event, Meet the NP Experts, featuring a panel of leading dermatologists and key opinion leaders to discuss the unmet need in NP and the potential of oral difelikefalin. A replay of the webcast is available under “Events & Presentations” in the Investors section of the Company’s website, www.CaraTherapeutics.com.

1Q24 KORSUVA Injection U.S. Update

In the first quarter of 2024, KORSUVA® (difelikefalin) injection generated net sales of approximately $1.8 million and the Company recorded collaborative revenue of approximately $800,000, which represented the Company’s share of the profit from sales of KORSUVA injection.

Wholesalers shipped 111,720 vials to dialysis centers during the first quarter of 2024.

On March 31, 2024, the Transitional Drug Add-On Payment Adjustment (TDAPA) period for KORSUVA injection expired. After the TDAPA period, KORSUVA injection is reimbursed through the ESRD PPS bundle.

First Quarter 2024 Financial Results

Cash, cash equivalents and marketable securities at March 31, 2024 totaled $69.8 million compared to $100.8 million at December 31, 2023. The decrease in the balance primarily resulted from $30.5 million of cash used in operating activities.

For the first quarter of 2024, net loss was $30.7 million, or $(0.56) per basic and diluted share, compared to net loss of $26.7 million, or ($0.49) per basic and diluted share, for the same period in 2023.

Revenues: Total revenue was $2.1 million and $6.2 million for the three months ended March 31, 2024 and 2023, respectively. Revenue primarily consisted of:

- $0.8 million and $2.8 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 March 31, 2024 and 2023, respectively.
- $0.6 million and $3.2 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor during the three months ended March 31, 2024 and 2023, respectively.
- $0.6 million of other revenue related to royalty payments earned in conjunction with ex U.S. sales of KORSUVA/Kapruvia under agreements with CSL Vifor and Maruishi Pharmaceuticals Co. Ltd., or Maruishi, during the three months ended March 31, 2024, which were sold under the Purchase and Sale agreement with HCRX Investments Holdco, L.P. and Healthcare Royalty Partners IV, L.P., or the HCR Agreement, and considered non-cash. There was no other revenue during the three months ended March 31, 2023.

Cost of Goods Sold: Cost of goods sold was $0.6 million and $2.6 million for the three months ended March 31, 2024 and 2023, respectively, related to commercial supply revenue for KORSUVA injection sales to CSL Vifor.

Research and Development (R&D) Expenses: R&D expenses were $22.0 million for the three months ended March 31, 2024 compared to $24.3 million in the same period of 2023. The lower R&D expenses in 2024 were primarily due to decreases in stock-based compensation expense, payroll and related costs, travel costs and other related conference costs as well as lower costs associated with the discontinuation of our atopic dermatitis and advanced chronic kidney disease programs, partially offset by increases related to the oral difelikefalin NP program.

General and Administrative (G&A) Expenses: G&A expenses were essentially flat at $6.8 million for the three months ended March 31, 2024 compared to $6.9 million in the same period of 2023.

Restructuring Expenses: Restructuring expenses were $2.4 million for the three months ended March 31, 2024 which were related to our strategic prioritization of NP and the associated workforce reduction in the 2024 period. There were no restructuring expenses recorded during the three months ended March 31, 2023.

Other Income, net: Other income, net was approximately $1.0 million for each of the three months ended March 31, 2024 and 2023.

Non-cash interest expense on liability related to sales of future royalties and milestones: Non-cash interest expense was $2.0 million which represented imputed interest on the carrying value of the liability associated with the HCR Agreement and the amortization of the related issuance costs associated with the HCR Agreement for the three months ended March 31, 2024. There was no non-cash interest expense for the three months ended March 31, 2023.

Financial Guidance

Cara expects that our current unrestricted cash and cash equivalents and available-for-sale marketable securities will be sufficient to fund our currently anticipated operating plan into 2026. Our current operating plan assumes certain costs related to our planned pivotal trials in NP.

About the KOURAGE Phase 2/3 Clinical Program in Notalgia Paresthetica

KOURAGE is a Phase 2/3 clinical program evaluating oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica (NP). The program is comprised of two studies – KOURAGE 1 and KOURAGE 2 – which will likely be double-blind, placebo-controlled, 8-week studies with patients allowed to roll-over into open-label 52-week extensions.

KOURAGE 1 is composed of two parts. The dose-finding portion of KOURAGE 1 (Part A) includes 214 patients who are randomized equally to four arms (0.25 mg BID, 1.0 mg BID, 2.0 mg BID, placebo BID). Part A is not powered for statistical significance.

Part B and KOURAGE 2 will likely be double-blind, placebo-controlled, 8-week studies with patients randomized 1:1 to either difelikefalin or matching placebo. The primary endpoint for both the dose-finding portion of KOURAGE 1 (Part A) and the two pivotal studies Part B and KOURAGE 2 will likely be the proportion of patients with a ≥4-point improvement at Week 8 from baseline in the worst itch numeric rating scale.

About Cara Therapeutics

Cara Therapeutics is a development-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company is developing an oral formulation of difelikefalin, a selective, peripherally acting, non-scheduled kappa opioid receptor agonist, for the treatment of chronic pruritus associated with notalgia paresthetica (NP), a common, underdiagnosed neuropathy affecting the upper back for which there are no FDA-approved therapies. The Company is conducting a Phase 2/3 clinical program in NP with topline results of the dose-finding portion expected by the end of the second quarter of 2024. Cara Therapeutics also developed an IV formulation of difelikefalin, which is approved in the United States, EU, and multiple other countries for the treatment of moderate-to-severe pruritus associated with advanced chronic kidney disease in adults undergoing hemodialysis. The IV formulation is out-licensed worldwide. 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 planned future regulatory submissions and potential future regulatory approvals, future product launches, 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 candidate, the potential for the Company's product candidate to be an alternative in the therapeutic areas investigated, including notalgia paresthetica, the size and growth of the potential markets for pruritus management such as notalgia paresthetica, the commercial potential of the Company's product candidate, and the Company's cash runway. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The 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 ending December 31, 2023 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission, including its Form 10-Q for the quarter ended March 31, 2024. 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.

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 46,996	$ 51,775
Marketable securities	22,777	48,983
Accounts receivable, net - related party	1,718	2,765
Inventory, net	2,741	2,821
Income tax receivable	697	697
Other receivables	506	555
Prepaid expenses	5,790	8,154
Restricted cash	-	408
Total current assets	81,225	116,158
Operating lease right-of-use assets	3,826	4,864
Property and equipment, net	3,548	3,322
Restricted cash, non-current	1,500	1,500
Total assets	$ 90,099	$ 125,844
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,875	$ 25,592
Operating lease liability, current	220	-
Total current liabilities	15,095	25,592
Liability related to sales of future royalties and milestones, net	38,376	37,079
Operating lease liability, non-current	6,825	6,088
Total liabilities	60,296	68,759
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	54	54
Additional paid-in capital	745,381	742,036
Accumulated deficit	(715,441)	(684,745)
Accumulated other comprehensive loss	(191)	(260)
Total stockholders' equity	29,803	57,085
Total liabilities and stockholders' equity	$ 90,099	$ 125,844

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

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Collaborative revenue	$ 788	$ 2,750
Commercial supply revenue	640	3,191
Royalty revenue	-	125
Clinical compound revenue	84	99
Other revenue	623	-
Total revenue	2,135	6,165
Operating expenses:		
Cost of goods sold	620	2,590
Research and development	21,964	24,334
General and administrative	6,816	6,891
Restructuring	2,401	-
Total operating expenses	31,801	33,815
Operating loss	(29,666)	(27,650)
Other income, net	952	985

Non-cash interest expense on liability related to sales of future royalties and milestones	(1,982)	-
Net loss	$ (30,696)	$ (26,665)
Net loss per share:		
Basic and Diluted	$ (0.56)	$ (0.49)
Weighted average shares:		
Basic and Diluted	54,588,090	53,872,038

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