CalciMedica Reports First Quarter 2024 Financial Results and Provides Clinical & Corporate Updates

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Last patient enrolled in CARPO, Phase 2b trial of Auxora™ in acute pancreatitis (AP); topline data expected in 2Q 2024

KOURAGE, Phase 2 trial in severe acute kidney injury (AKI) remains on track to initiate patient enrollment in 2Q 2024 with data expected in 2025

Collaborators from Cedars-Sinai to present abstract on human proteomics data supporting the potential benefits of Auxora in AP at Digestive Disease Week (DDW) 2024

Cash position expected to fund operations into 2H 2025

LA JOLLA, Calif., May 13, 2024 /PRNewswire/ -- CalciMedica Inc. ("CalciMedica") (Nasdaq: CALC), a clinical-stage biopharmaceutical company focused on developing novel calcium release-activated calcium (CRAC) channel inhibition therapies for acute and chronic inflammatory and immunologic illnesses, today reported financial results for the first quarter ended March 31, 2024.

"This past quarter was transformational for CalciMedica. We completed enrollment in our Phase 2b CARPO trial in AP, we received FDA clearance on our IND application and started work on KOURAGE, our Phase 2 trial in patients with severe AKI, and we continued to progress our other programs, with multiple value-creating milestones on the horizon," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "Our progress was further supported by a private placement of up to approximately $54 million including an upfront investment of $20.4 million and a potential additional approximately $33.1 million from accompanying warrants that trigger upon announcement of clinical trial data. We expect our cash, cash equivalents and short-term investments will provide funding into the second half of 2025. We look forward to continuing to advance our programs and to announcing topline data from CARPO later this quarter."

Recent Clinical and Preclinical Updates and Anticipated Milestones:

- **Last patient enrolled in Phase 2b CARPO trial and topline data expected in 2Q24:** In April 2024, CalciMedica enrolled the last patient in CARPO, the Company's randomized, double-blind, placebo-controlled Phase 2b trial of Auxora™ in acute pancreatitis (AP) patients, reaching full target enrollment of 216 patients. Topline data from the trial is expected to be announced later this quarter.

- **Phase 2 KOURAGE trial initiation underway:** In February 2024, CalciMedica received clearance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) for Auxora to be evaluated in a Phase 2 trial in severe acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF), which has been named KOURAGE. CalciMedica expects to enroll the first patient in KOURAGE later this quarter, with data expected in 2025.

- **Abstract accepted for poster presentation at DDW 2024:** CalciMedica collaborator Richard Waldon, Ph.D., of Cedars-Sinai Medical Center will be presenting a poster titled "Serum Proteomics Reveals That the Orai1 Inhibitor Auxora May Provide Benefits in Severe Acute Pancreatitis Similar to Those Seen in COVID-19 Pneumonia" at the upcoming DDW 2024 meeting on Saturday, May 18th from 12:30-1:30 p.m. ET.

- **Preclinical data presented at AKI & CRRT:** In March 2024, CalciMedica collaborator David

Basile, Ph.D., of Indiana University presented data from preclinical studies of Auxora in AKI at the 29th International Acute Kidney Injury and Continuous Renal Replacement Therapy Conference (AKI & CRRT) in San Diego, CA. The results of the studies indicate that Auxora has the ability to hasten the recovery of kidney function and improve survival in rat models of AKI through inhibiting the Orai1 channels on Th17 and endothelial cells.

- **CRSPA study expanded and continuing to enroll in Phase 2 portion of trial:** The CRSPA study in asparaginase-induced pancreatic toxicity (AIPT) has been expanded to additional sites, and the dose used in the initial cohort has been established as the recommended Phase 2 dose and a target total trial enrollment has been set at 24. Data is expected in 2025.

Financial Results for the Three Months Ended March 31, 2024:

- In January 2024, CalciMedica completed a private placement of securities to new and existing investors for up to approximately $54 million in gross proceeds that includes initial upfront funding of $20.4 million and up to an additional approximately $33.1 million upon exercise of accompanying warrants. The upfront net proceeds from the private placement will support the Company's ongoing Phase 2 CARPO trial for Auxora in AP and planned Phase 2 KOURAGE trial for Auxora in AKI.
- As of March 31, 2024, CalciMedica had approximately $25.7 million in cash, cash equivalents and short-term investments, which, based on its current operating plan, CalciMedica expects to be sufficient to fund its operations into the second half of 2025.
- Total loss from operations for the three months ended March 31, 2024, was approximately $5.8 million, which was offset by a gain from the fair value adjustment to the warrant liability of $5.6 million and interest income of $0.3 million.
- With the impact of a $5.6 million non-cash gain from the fair value adjustment of the warrant liability, net income was $0.1 million, or $0.01 per share (basic and diluted) for the three months March 31, 2024.

About CalciMedica
CalciMedica is a clinical-stage biopharmaceutical company focused on developing novel CRAC channel inhibition therapies for inflammatory and immunologic diseases. CalciMedica's proprietary technology targets the inhibition of CRAC channels to modulate the immune response and protect against tissue cell injury, with the potential to provide therapeutic benefits in life-threatening inflammatory and immunologic diseases for which there are currently no approved therapies. CalciMedica's lead product candidate Auxora™, a proprietary, intravenous-formulated CRAC channel inhibitor, has demonstrated positive and consistent clinical results in multiple completed efficacy clinical trials. CalciMedica is currently conducting a Phase 2b trial (called CARPO – NCT04681066) for AP with SIRS, with topline data expected in the second quarter of 2024, as well as supporting the ongoing Phase 1/2 AIPT study (called CRSPA – NCT04195347), with data expected in 2025. CalciMedica plans to initiate patient enrollment its Phase 2 study (called KOURAGE – NCT06374797) in AKI with associated AHRF in the second quarter of 2024 with data expected in 2025. CalciMedica was founded by scientists from Torrey Pines Therapeutics and the Harvard CBR Institute for Biomedical Research, and is headquartered in La Jolla, CA. For more information, please visit www.calcimedica.com.

Forward-Looking Statements
This communication contains forward-looking statements which include, but are not limited to, CalciMedica's expected use of proceeds from the private placement; any additional gross proceeds that may be received by CalciMedica upon exercise, if any, of the accompanying warrants issued in the private placement; CalciMedica's expected cash runway; CalciMedica's business strategy; the potential for multiple value-creating milestones on the horizon; CalciMedica's planned and ongoing clinical trials and the timing, design, expected patient enrollment thereof and the expected timing for the release of data from those trials, including its Phase 2b CARPO trial of Auxora for AP with accompanying SIRS, its ongoing Phase ½ CRSPA trial of Auxora in pediatric patients with AIPT and its planned Phase 2 KOURAGE trial of Auxora in AKI with associated AHRF; the potential benefits of Auxora for the treatment of AP, AIPT and AKI; and the potential of CalciMedica's proprietary technology to provide therapeutic benefits in life-threatening inflammatory and immunologic diseases. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. CalciMedica's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks, and changes in circumstances, including but not limited to risks and uncertainties related to: the impact of fluctuations in global financial markets on CalciMedica's business and the actions it may take in response thereto; CalciMedica's ability to execute its plans and strategies; the ability to obtain and maintain regulatory approval for Auxora; results from clinical trials or preclinical studies may not be indicative of results that may be observed in the future; potential safety and other complications from Auxora; the scope, progress and expansion of developing and commercializing Auxora; the size and growth of the market therefor and the rate and degree of market acceptance thereof; economic, business, competitive, and/or regulatory factors affecting the business of CalciMedica generally; CalciMedica's ability to protect its intellectual property position; and the impact of government laws and regulations. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" in CalciMedica's Annual Report on Form 10-Q for the quarter ended March 31, 2024, being filed with the Securities and Exchange Commission (SEC) later today, and elsewhere in CalciMedica's subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from time to time and available at www.sec.gov. These documents can be accessed on CalciMedica's web page at ir.calcimedica.com/financials-filings/sec-filings. The forward-looking statements contained herein are made as of the date hereof, and CalciMedica undertakes no obligation to update them after this date, except as required by law.

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CALCIMEDICA, INC.
Condensed Consolidated Balance Sheets
(in thousands, except par value and share amounts)
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 6,755	$ 5,530
Short-term investments	18,955	5,708
Prepaid expenses and other current assets	894	367
Total current assets	26,604	11,605
Property and equipment, net	153	167
Other assets	377	413
Total assets	$ 27,134	$ 12,185
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,535	$ 1,419
Accrued clinical trial costs	1,000	1,141
Accrued other	1,752	1,468
Total current liabilities	4,287	4,028
Long-term liabilities		
Warrant liability	5,600	—
Total liabilities	9,887	4,028
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares and no shares authorized at March 31, 2024 and December 31, 2023, respectively; no shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized at March 31, 2024 and December 31, 2023; 10,740,115 and 5,754,505 issued and outstanding at March 31, 2024 and December 31, 2023, respectively	3	1
Additional paid-in capital	163,195	154,218
Accumulated deficit	(145,934)	(146,064)
Accumulated other comprehensive income (loss)	(17)	2
Total stockholders' equity	17,247	8,157
Total liabilities and stockholders' equity	$ 27,134	$ 12,185

CALCIMEDICA, INC.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 2,944	$ 6,491
General and administrative	2,823	15,849
Total operating expenses	5,767	22,340
Loss from operations	(5,767)	(22,340)
Other income (expense)		
Change in fair value of financial instruments	5,590	3,168
Other income (expense), net	307	(116)

Total other income (expense), net	5,897	3,052
Net income (loss)	$ 130	$ (19,288)
Earnings per share		
Basic	$ 0.01	$ (23.43)
Diluted	$ 0.01	$ (23.43)
Shares used in computing earnings per share		
Basic	9,754,517	823,069
Diluted	10,047,415	823,069

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