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

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Positive topline data announced from CARPO, Phase 2b trial of Auxora™ in acute pancreatitis (AP); additional data to be presented at a medical meeting later this year

First patient enrolled in KOURAGE, Phase 2 trial of Auxora™ in severe acute kidney injury (AKI), with data expected in 2025

LA JOLLA, Calif., Aug. 12, 2024 /PRNewswire/ -- CalciMedica Inc. ("CalciMedica or the Company") (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 second quarter ended June 30, 2024.

"CalciMedica continues to progress steadily with the successful execution of multiple milestones across our pipeline. In the second quarter, we completed enrollment in our Phase 2b CARPO trial in patients with AP and subsequently announced positive topline data, which met our primary objective and further support Auxora's potential as an effective treatment for critically ill patients with acute inflammatory disease. We look forward to sharing additional data from this trial later in the year and are also planning to meet with the FDA to discuss the design of a Phase 3 trial," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "In addition, we are excited about KOURAGE, our Phase 2 trial in patients with severe AKI. We are enrolling patients and opening new sites and expect to share topline data from this study in 2025."

Recent Clinical Updates and Anticipated Milestones:

- **Positive topline data announced from Phase 2b CARPO trial:** In June 2024, CalciMedica hosted a conference call to review positive topline data from CARPO, the Company's randomized, double-blind, placebo-controlled Phase 2b trial of Auxora™ in patients with acute pancreatitis (AP) and accompanying systemic inflammatory response syndrome (SIRS). The trial met its primary objective with a statistically significant dose response in median time to solid food tolerance in a pre-specified subgroup of hyper-inflamed patients with AP as well as in reduction of severe organ failure across the full patient population. Full data from the trial are expected in the second half of 2024 and the Company plans to present them at future medical meetings. Further, the Company plans to discuss the full results with the U.S. Food and Drug Administration (FDA) in an end-of-phase 2 meeting and to be in a position to initiate a pivotal trial in AP in 2025.

- **First patient enrolled in Phase 2 KOURAGE trial:** In July 2024, CalciMedica announced that the first patient has been dosed in KOURAGE, the Company's randomized, double-blind, placebo-controlled Phase 2 trial of Auxora™ in patients with severe AKI with associated acute hypoxemic respiratory failure (AHRF). CalciMedica expects to enroll 150 patients with stage 2 and stage 3 AKI who have AHRF and are receiving oxygen either by non-invasive mechanical ventilation, high flow nasal cannula or intermittent mandatory ventilation. Topline data are expected in 2025.

- **CalciMedica added to Russell Microcap® Index:** In July 2024, CalciMedica announced that the Company would be joining the Russell Microcap® Index at the conclusion of the 2024 Russell U.S. Indexes annual reconstitution, which became effective at the open of U.S. equity

markets on July 1, 2024.

- **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 as the dose used in the initial cohort has been established as the recommended Phase 2 dose. CalciMedica expects this trial to enroll approximately 24 patients and data are expected in 2025.

Financial Results for the Three and Six Months Ended June 30, 2024:

- As of June 30, 2024, CalciMedica had approximately $19.1 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 June 30, 2024, was approximately $6.5 million. Total loss from operations for the six months ended June 30, 2024, was approximately $12.3 million.
- Including the impact of a $2.3 million non-cash gain from the fair value adjustment of the warrant liability and $0.3 million of interest income, the net loss for the three months ended June 30, 2024, was approximately $4.0 million, or $0.36 per share (basic and diluted). Including the impact of a $7.9 million non-cash gain from the fair value adjustment of the warrant liability and $0.6 million of interest income, net loss for the six months ended June 30, 2024, was $3.8 million, or $0.37 per share (basic and diluted).

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™ has demonstrated positive and consistent clinical results in multiple completed efficacy clinical trials. CalciMedica has announced topline data for a Phase 2b trial (called CARPO – NCT04681066) in patients with AP with SIRS and completed a Phase 2 trial (called CARDEA – NCT04345614) in patients with COVID pneumonia. The Company is currently conducting a Phase 2 trial (called KOURAGE – NCT06374797) in patients with AKI with associated AHRF with data expected in 2025 and continuing to support the ongoing Phase 1/2 trial (called CRSPA – NCT04195347) in patients with AIPT 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 cash runway; 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 Phase 2 KOURAGE trial of Auxora in AKI with associated AHRF, and its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with AIPT; plans for an end of phase 2 meeting with the FDA for CARPO and to be in a position to initiate a pivotal trial in AP in 2025; the potential benefits of Auxora for the treatment of AP, AKI and AIPT; 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; the impact of government laws and regulations; and CalciMedica's financial position and need for additional capital. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets		
	$	$
Cash and cash equivalents	5,056	5,530
Short-term investments	14,081	5,708
Prepaid expenses and other current assets	1,305	367
Total current assets	20,442	11,605
Property and equipment, net	138	167
Other assets	472	413
	$	$
Total assets	21,052	12,185
Liabilities and Stockholders' Equity		
Current liabilities		
	$	$
Accounts payable	2,144	1,419
Accrued clinical trial costs	829	1,141
Accrued expenses	941	1,468
Total current liabilities	3,914	4,028
Long-term liabilities		
Warrant liability	3,300	—
Total liabilities	7,214	4,028
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares and no shares authorized at June 30, 2024 and December 31, 2023, respectively; no shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized at June 30, 2024 and December 31, 2023; 10,750,156 and 5,754,505 issued and outstanding at June 30, 2024 and December 31, 2023, respectively	3	1
Additional paid-in capital	163,732	154,218
Accumulated deficit	(149,888)	(146,064)
Accumulated other comprehensive income (loss)	(9)	2
Total stockholders' equity	13,838	8,157
	$	$
Total liabilities and stockholders' equity	21,052	12,185

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 4,157	$ 3,814	$ 7,101	$ 10,305
General and administrative	2,372	2,769	5,195	18,618
Total operating expenses	6,529	6,583	12,296	28,923
Loss from operations	(6,529)	(6,583)	(12,296)	(28,923)
Other income				
Change in fair value of financial instruments	2,300	—	7,890	3,168
Other income	275	279	582	163
Total other income	2,575	279	8,472	3,331
Net loss	$ (3,954)	$ (6,304)	$ (3,824)	$ (25,592)
Net loss per share - basic and diluted	$ (0.36)	$ (1.11)	$ (0.37)	$ (7.86)

Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	11,129,053	5,661,933	10,441,785	3,255,868

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