



CalciMedica Reports Third Quarter 2025 Financial Results and Provides Clinical & Corporate Updates

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Enrollment ongoing in Phase 2 KOURAGE trial of Auxora™ in acute kidney injury (AKI) with respiratory failure; data expected in 1H 2026

Positive discussions with FDA on pivotal trial in acute pancreatitis (AP); final trial design expected in 1H 2026

Cash position expected to fund operations into 2H 2026

LA JOLLA, Calif., Nov. 12, 2025 /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 third quarter ended September 30, 2025 and provided clinical and corporate updates.



"Enrollment continues in our Phase 2 KOURAGE trial evaluating Auxora in patients with AKI with respiratory failure, and we look forward to sharing data in the first half of 2026. As we approach this milestone, we are encouraged by AKI animal model data recently shared at ASN and results in PAH animal models published in *JCI Insight*, both of which provide further mechanistic rationale for CRAC channel inhibition as a promising approach for treating AKI," said Rachel Leheny, Ph.D., CEO of CalciMedica. "Additionally, discussions with the FDA have been positive regarding our program in AP. We expect our recently announced collaboration with Telperian and its AI-driven analytics platform will enable us to leverage insights from completed Auxora trials to optimize the design of our pivotal trial in AP, which we expect to finalize in the first half of 2026."

Recent Clinical & Corporate Highlights:

[Clinical Updates & Anticipated Milestones](#)

Acute Kidney Injury (AKI) with Respiratory Failure Program Update

- **Enrollment ongoing in Phase 2 KOURAGE trial:** Enrollment is ongoing in KOURAGE, CalciMedica's randomized, double-blind, placebo-controlled Phase 2 trial of Auxora™ in patients with Stage 2 or Stage 3 AKI with respiratory failure. The Company plans to enroll 150 patients in KOURAGE, with data expected in the first half of 2026.
- **Poster presentation at the American Society of Nephrology (ASN) Kidney Week 2025:** In November 2025, CalciMedica and collaborators from Indiana University School of Medicine, including David P. Basile, Ph.D., Professor of Anatomy, Cell Biology and Physiology, presented a poster titled "[Store-Operated Calcium-Channel Inhibitor Auxora Improves Kidney Function Following Ischemia-Induced AKI in Rats](#)" at ASN Kidney Week 2025. In the study, treatment with Auxora versus placebo significantly reduced Th17 cells in both the kidney and lung, significantly increased glomerular filtration rate (GFR), and decreased renal injury in a rat model of AKI. The findings, particularly the new observations of IL-17 reductions in the lung, provide strong mechanistic support for Auxora as a potential treatment for severe AKI with respiratory failure. The inclusion and exclusion criteria of CalciMedica's Phase 2 KOURAGE study are expected to enrich for patients with elevated IL-17 levels, which have been shown to correlate with mortality and major adverse kidney events in severe AKI.

Acute Pancreatitis (AP) Program Update

- **Positive discussions with the U.S. Food and Drug Administration (FDA) on pivotal**

trial in AP: CalciMedica has had constructive engagement with the FDA regarding the design of a pivotal trial in AP. The Company expects to finalize the pivotal trial design in the first half of 2026. This study is anticipated to be the first pivotal trial in the U.S. for a therapeutic in AP.

- **Announced collaboration with Telperian to leverage AI insights to support the design of pivotal trial design in AP:** In October 2025, CalciMedica and Telperian announced a collaboration to integrate Telperian's advanced AI platform into analyses of data from completed Auxora clinical trials. Insights from this work are expected to help inform the finalization of the design of CalciMedica's pivotal trial in AP and support ongoing regulatory discussions with the FDA.

Preclinical Program Updates

- **Publication in *JCI* Insight:** In November 2025, a manuscript authored by CalciMedica and collaborators titled "[Combination of Orai1 Inhibitor CM5480 with Specific Therapy Mitigates Pulmonary Hypertension and Its Cardiac Dysfunction](#)" was published in *JCI Insight*. The publication describes preclinical data supporting CalciMedica's proprietary CRAC channel inhibitor candidate, CM5480, as a potential first-in-class, differentiated therapy for the treatment of pulmonary arterial hypertension (PAH). In an animal model of PAH, CM5480 restored or improved multiple disease-affected pathways and functions—including heart contraction and cardiac output, gene expression profiles, DNA repair, and metabolism. Treatment with CM5480 also significantly reduced right ventricular dysfunction (RVD) both as a monotherapy and in combination with existing PAH therapies. Beyond PAH, these findings suggest that CRAC channel inhibition may directly improve RVD, which occurs in approximately half of patients with sepsis, the leading cause of AKI. This potential effect provides additional mechanistic support for Auxora as a potential treatment for AKI with respiratory failure.

Financial Results for the Third Quarter Ended September 30, 2025:

Cash Position: Cash, cash equivalents, and short-term investments were \$14.1 million as of September 30, 2025. The Company expects its cash position to be sufficient to fund its current operating plan into the second half of 2026.

R&D Expenses: Research and development expenses were \$3.9 million for the three months ended September 30, 2025, compared to \$3.6 million for the three months ended September 30, 2024. The increase of \$0.3 million was primarily due to an increase in clinical trial and preclinical activities offset by a decrease in consultants and other costs.

G&A Expenses: General and administrative expenses were \$1.8 million for the three months ended September 30, 2025, compared to \$2.2 million for the three months ended September 30, 2024. The decrease of \$0.4 million was primarily due to a decrease in professional services and consultants and other costs.

Other Income (Expense): Other expenses were \$2.2 million for the three months ended September 30, 2025, compared to other income of \$0.1 million for the three months ended September 30, 2024. The increase of \$2.3 million in expenses was primarily due to a non-cash increase in fair value adjustments to the Company's financial instruments.

Net Loss: Net loss was \$7.8 million, or \$0.52 per basic and diluted share, for the three months ended September 30, 2025, compared to \$5.6 million, or \$0.50 per basic and diluted share, for the three months ended September 30, 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™ has demonstrated positive and consistent clinical results in multiple completed efficacy clinical trials and been well-tolerated in over 350 critically ill patients dosed. CalciMedica has announced data for a Phase 2b trial (called CARPO – [NCT04681066](#)) in patients with acute pancreatitis (AP) and accompanying systemic inflammatory response syndrome (SIRS) and for 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 acute kidney injury (AKI) with associated respiratory failure, with data expected in the first half of 2026. 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 updates and the release of data from its Phase 2 KOURAGE trial of Auxora in AKI with associated respiratory failure in the first half of 2026; the positive nature of discussions with the FDA concerning design of a pivotal trial in AP and expectation of a final trial design in first half of 2026; the potential benefits of CalciMedica's collaboration with Telperian, including with respect to the design of CalciMedica's pivotal trial in AP; CalciMedica's

belief that Auxora reduces Th17 cells in both the kidney and lung, increases glomerular filtration rate, and decreases renal injury; the potential regarding preclinical animal studies of Auxora; the potential of CM5480 to provide therapeutic benefits in PAH; and the potential of CalciMedica's proprietary technology to provide therapeutic benefits in acute and chronic 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 September 30, 2025, 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.calcimedita.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)

	September 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	\$ 5,470	\$ 7,935
Short-term investments	8,614	10,734
Prepaid clinical trial expenses	230	748
Other prepaid expenses and current assets	539	248
Total current assets	14,853	19,665
Property and equipment, net	49	119
Other assets	11	10
Total assets	\$ 14,913	\$ 19,794
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 1,133	\$ 1,998
Accrued clinical trial costs	1,523	820
Accrued expenses	1,025	866
Total current liabilities	3,681	3,684
Long-term liabilities		
Promissory note	8,900	—
Warrant liability	2,600	1,700
Total liabilities	15,181	5,384
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit)		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at September 30, 2025 and December 31, 2024, respectively; no shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	—	—
Common stock, \$0.0001 par value; 500,000,000 shares authorized at September 30, 2025 and December 31, 2024, respectively; 14,257,234 and 13,481,917, issued and outstanding at September 30, 2025 and December 31, 2024, respectively	4	4
Additional paid-in capital	178,293	174,166
Accumulated deficit	(178,566)	(159,764)
Accumulated other comprehensive income	1	4
Total stockholders' equity (deficit)	(268)	14,410
Total liabilities and stockholders' equity	\$ 14,913	\$ 19,794

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 3,851	\$ 3,546	\$ 12,127	\$ 10,647
General and administrative	1,767	2,190	6,609	7,385
Total operating expenses	5,618	5,736	18,736	18,032
Loss from operations	(5,618)	(5,736)	(18,736)	(18,032)
Other income (expense):				
Change in fair value of financial instruments	(2,000)	(100)	200	7,790
Interest expense	(326)	—	(1,097)	—
Interest income	140	218	562	800
Other income	—	—	269	—
Total other income (expense)	(2,186)	118	(66)	8,590
Net loss	\$ (7,804)	\$ (5,618)	\$ (18,802)	\$ (9,442)
Net loss per share - basic and diluted	\$ (0.52)	\$ (0.50)	\$ (1.28)	\$ (0.88)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	15,076,456	11,134,964	14,734,641	10,674,531

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