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

November 13, 2024 12:00 PM EST

Additional positive data, including a win ratio analysis, announced from CARPO Phase 2b trial of Auxora™ in acute pancreatitis (AP); Company expects to be in a position to initiate Phase 3 program in 2025

Enrollment ongoing in Phase 2 KOURAGE trial in acute kidney injury (AKI) and in Phase 2 portion of CRSPA trial in asparaginase-induced pancreatic toxicity (AIPT); data from both trials expected in 2025

Following a public offering in October, the Company's cash position is expected to fund current operations into the first half of 2026

LA JOLLA, Calif., Nov. 13, 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 third quarter ended September 30, 2024 and provided clinical and corporate updates.

"These past few months have been very exciting for CalciMedica, punctuated by our announcement of the full data set and win ratio analysis from our Phase 2b CARPO trial in patients with AP, which was presented by Prof. Sutton at the American College of Gastroenterology Annual Meeting last month," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "With its unique dual mechanism of immunomodulation and direct organ tissue protection, we believe Auxora continues to be a promising candidate for treating not only AP patients, but also critically ill patients suffering from other acute inflammatory diseases, such as AKI. We are committed to working closely with the FDA to design a pivotal program for Auxora in AP, and we continue to make progress in KOURAGE, our Phase 2 trial of Auxora in patients with severe AKI, with enrollment ongoing and topline data expected in 2025."

Recent Clinical Updates and Anticipated Milestones:

- **Additional positive data, including a win ratio analysis, announced from Phase 2b CARPO trial:** In October 2024, collaborator Prof. Robert Sutton from the University of Liverpool and Liverpool University Hospitals NHS Foundation Trust and chair of the Steering Committee for the CARPO trial presented late-breaking positive data from CARPO, the Company's randomized, double-blind, placebo-controlled Phase 2b trial of Auxora™ in patients with AP and accompanying systemic inflammatory response syndrome (SIRS), in a plenary presentation at the American College of Gastroenterology (ACG) 2024 Annual Scientific Meeting and in a conference call hosted by CalciMedica later the same day. Key findings include:
  - Auxora demonstrated a statistically significant 100% relative risk reduction (p = 0.0027) in new-onset severe respiratory failure and a 64.2% relative risk reduction (p = 0.0476) in new-onset persistent respiratory failure in the combined high and medium dose Auxora patients compared to the combined low dose Auxora and placebo patients.
  - Analysis of certain key endpoints found a statistically significant stratified win ratio of 1.640 (p = 0.0372) for high dose Auxora patients compared to placebo patients.
  - Clinically meaningful reductions in additional key endpoints, new-onset necrotizing pancreatitis and time to medically indicated discharge, were observed for high dose Auxora patients compared to placebo patients.

The Company is planning an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and expects to be in a position to initiate a Phase 3 program in 2025.

- **Enrollment ongoing in Phase 2 KOURAGE trial:** Enrollment is ongoing in KOURAGE, the Company's randomized, double-blind, placebo-controlled Phase 2 trial of Auxora™ in patients with severe acute kidney injury (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.

- **Enrollment ongoing in Phase 2 portion of CRSPA trial:** Following the establishment of a recommended Phase 2 dose and the expansion of the study to additional sites, enrollment remains ongoing in the Phase 2 portion of the Company's CRSPA study in asparaginase-induced pancreatic toxicity (AIPT). CalciMedica expects this trial to enroll approximately 24 patients and data are expected in 2025.

Financial Results and Corporate Updates:

- As of September 30, 2024, CalciMedica had approximately $14.6 million in cash, cash equivalents and short-term investments.
- On November 1, 2024, the Company completed an underwritten public offering of 2,720,000 shares of its common stock at a price to the public of $3.75 per share. The gross proceeds to the Company from the offering were $10.2 million, with the potential for additional proceeds if the underwriter exercises its option to purchase additional shares.
- The Company's cash, cash equivalents and short-term investments balance as of September 30, 2024, after giving effect to the estimated net proceeds from the offering of approximately $9.1 million, would have been approximately $23.7 million, which is expected to fund current operations into the first half of 2026.
- Total loss from operations for the three and nine months ended September 30, 2024, was approximately $5.7 million and $18.0 million, respectively.
- Net loss for the three and nine months ended September 30, 2024, was approximately $5.6 million and $9.4 million, respectively, or $0.50 and $0.88 net loss per share (basic and diluted), respectively.

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 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 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; the potential for additional proceeds from the underwritten public offering if the underwriter exercises its option to purchase additional shares; 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 September 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.

CalciMedica Contact:

Investors and Media
Argot Partners
Sarah Sutton/Kevin Murphy
calcimedica@argotpartners.com
(212) 600-1902

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

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 9,151	$ 5,530
Short-term investments	5,452	5,708
Prepaid expenses and other current assets	1,083	367
Total current assets	15,686	11,605
Property and equipment, net	130	167
Other assets	396	413
Total assets	$ 16,212	$ 12,185
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,536	$ 1,419
Accrued clinical trial costs	1,103	1,141
Accrued expenses	1,143	1,468
Total current liabilities	3,782	4,028
Long-term liabilities		
Warrant liability	3,400	—
Total liabilities	7,182	4,028
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; no shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized at September 30, 2024 and December 31, 2023; 10,761,917 and 5,754,505 issued and outstanding at September 30, 2024 and December 31, 2023, respectively	3	1
Additional paid-in capital	164,529	154,218
Accumulated deficit	(155,506)	(146,064)
Accumulated other comprehensive income	4	2
Total stockholders' equity	9,030	8,157
Total liabilities and stockholders' equity	$ 16,212	$ 12,185

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 3,546	$ 2,772	$ 10,647	$ 13,077
General and administrative	2,190	2,061	7,385	20,679
Total operating expenses	5,736	4,833	18,032	33,756

Loss from operations	(5,736)	(4,833)	(18,032)	(33,756)
Other income				
Change in fair value of financial instruments	(100)	—	7,790	3,168
Other income	218	214	800	377
Total other income	118	214	8,590	3,545
Net loss	$ (5,618)	$ (4,619)	$ (9,442)	$ (30,211)
Net loss per share - basic and diluted	$ (0.50)	$ (0.82)	$ (0.88)	$ (7.43)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	11,134,964	5,667,343	10,674,531	4,068,526

View original content to download multimedia:https://www.prnewswire.com/news-releases/calcimedica-reports-third-quarter-2024-financial-results-and-provides-clinical--corporate-updates-302303464.html

SOURCE CalciMedica, Inc.