CalciMedica Reports 2023 Financial Results and Provides Clinical & Corporate Updates

March 28, 2024 11:00 AM EDT

Enrollment in CARPO, Phase 2b trial of Auxora™ in acute pancreatitis (AP), on track with topline data expected in 2Q 2024

Auxora granted Investigational New Drug clearance by the FDA for Phase 2 trial in severe acute kidney injury (AKI); KOURAGE initiating in 2Q 2024

CRSPA Phase 1/2 trial of Auxora in asparaginase-induced pancreatic toxicity (AIPT) expanded and progressing to Phase 2 following initial patient cohort results presented at ASH 2023

Following a private placement financing in January, Company's cash position is expected to fund operations into 2H 2025

LA JOLLA, Calif., March 28, 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 year ended December 31, 2023.

"Over the course of 2023 and into this year, we have continued to build upon CalciMedica's clinical and financial strength, which has culminated in several recent achievements and has positioned us to execute on key milestones in 2024 including presenting topline data from our ongoing CARPO trial in acute pancreatitis in the second quarter," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "Importantly, the support from leading life science investors in our recent private placement financing allows us to initiate KOURAGE, our Phase 2 trial of Auxora in severe AKI patients, and to continue to progress other key programs in our pipeline."

Recent Clinical and Preclinical Updates and Anticipated Milestones:

- **Phase 2b CARPO enrollment on track and topline data expected in 2Q:** Enrollment in CARPO, CalciMedica's randomized, double-blind, placebo-controlled Phase 2b trial of Auxora™ in AP patients, is expected to be complete and topline data from the trial to be announced in the second quarter of 2024.

- **IND application for Auxora in AKI approved and 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 AKI with associated acute hypoxemic respiratory failure (AHRF) which has been named KOURAGE. CalciMedica expects to enroll the first patient in KOURAGE in the second quarter of 2024, with data expected in 2025.

- **Data from initial cohort of Phase 1/2 CRSPA study with St. Jude presented at ASH:** In December 2023, CalciMedica's collaborators at St. Jude Children's Research Hospital presented data from the initial cohort of the Phase 1/2 CRSPA study of Auxora in AIPT at the 65th Annual American Society of Hematology Meeting & Exposition (ASH) in San Diego, CA. The data from the initial cohort compared to a historical matched control group showed fewer hospital and ICU days for treated patients. No patients in the CRSPA study required total parenteral nutrition, compared to 68.8% in the historical matched control group, who required 27 days of nutritional support on average. 27% of patients in the matched control group had greater than 30% pancreatic necrosis at 30 days compared to none of the Auxora-treated patients.

- **CRSPA study expanded and continuing to enroll in Phase 2 portion of trial:** The CRSPA study has been expanded to additional sites, 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.

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

2023 Financial Results and Corporate Updates:

- As of December 31, 2023, CalciMedica had $11.2 million in cash, cash equivalents and short-term investments.
- 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. CalciMedica intends to use the upfront net proceeds from the private placement to fund the Company's ongoing Phase 2 clinical trials for Auxora in AP and AKI.
- As of the end of the first quarter of 2024, the Company expects its cash, cash equivalents and short-term investments to be approximately $25.5 million, which, based on its current operating plan, it expects to be sufficient to fund its operations into the second half of 2025.
- Total operating expenses were $38.1 million for the year ended December 31, 2023, which included $16.2 million of one-time charges of which $10.5 million was non-cash, related to accelerated vesting of stock options and severance for employees of Graybug Vision, Inc. at the time of the reverse merger with Graybug.
- Net loss was $34.4 million, or $7.66 per share (basic and diluted) for the year ended December 31, 2023.

About Auxora™
CalciMedica's lead clinical compound, Auxora™, is a potent and selective small molecule inhibitor of Orai1-containing CRAC channels that is being developed for use in patients with acute inflammatory and immunologic illnesses. CRAC channels are found on many cell types, including immune system cells, endothelium cells and pancreatic acinar cells, where aberrant activation of these channels may play a key role in the pathobiology of acute and chronic inflammatory syndromes. Auxora is currently being evaluated in: (i) a Phase 2b trial for acute pancreatitis (AP) with accompanying systemic inflammatory response syndrome (SIRS), called CARPO, (ii) a Phase 2 trial in acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF), called KOURAGE, expected to initiate in the second quarter of 2024 and (iii) an investigator-sponsored Phase 1/2 trial, called CRSPA, being conducted in pediatric patients with asparaginase-induced pancreatic toxicity (AIPT) as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase. There are currently no approved therapies to treat either AP, AKI or AIPT. In previous trials, patients responded well to Auxora regardless of severity or cause of disease. CalciMedica is also exploring the potential of Auxora treatment for other acute indications including acute respiratory distress syndrome.

About CARPO and AP
CARPO is an international, randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish Auxora's dose-response and efficacy in AP with accompanying SIRS. It is expected to enroll 216 patients. AP can be a life-threatening condition where the pancreas becomes inflamed, sometimes leading to pancreatic cell death or necrosis, systemic inflammation, organ failure and death. There are an estimated 275,000 hospitalizations for AP annually in the United States, of which approximately 40% present with SIRS, which can compromise the function of other tissues or organs, especially the lungs. Organ failure is responsible for much of the mortality seen in AP. There is currently no approved therapy for AP. Details of the CARPO trial are available on clinicaltrials.gov (NCT04681066).

About KOURAGE and AKI
KOURAGE is a randomized, double-blind, placebo-controlled study that will evaluate 150 patients with Stage 2 and 3 AKI who have AHRF and are receiving oxygen by non-invasive mechanical ventilation, high flow nasal cannula or intermittent mandatory ventilation (IMV). AKI denotes a sudden reduction in kidney function, or the organ's ability to clean and filter the blood. AKI can result as a complication of other serious illnesses such as sepsis, respiratory infections and failure, acute pancreatitis, trauma, surgery and burns. There are approximately 3.7 million hospitalized with AKI in the United States each year with approximately 1.1 million of these patients advancing to Stage 2 and Stage 3 AKI, over half of whom have associated AHRF. The risk of serious morbidities and mortality is significant for advanced Stage 2 and Stage 3 AKI patients. There are currently no approved therapies for AKI.

About CRSPA and AIPT
CRSPA is an investigator-sponsored Phase 1/2 trial being conducted in pediatric acute lymphoblastic leukemia (ALL) patients with AIPT, which is

acute pancreatitis toxicity caused by the administration of asparaginase (such as Oncaspar and Rylaze). CalciMedica believes that the CRSPA trial has defined an optimal pediatric dose for Auxora in this setting and the trial is currently being expanded to additional sites and is expected to enroll 24 patients. Approximately 3,000 pediatric patients are treated for ALL in the United States each year and treatment with asparaginase triggers the development of AIPT in 7-10% of these patients, with approximately half developing pancreatic necrosis and/or pseudocysts. There are currently no approved therapies for AIPT. Details of the CRSPA trial are available on clinicaltrials.gov (NCT04195347).

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 its Phase 2 study (called KOURAGE) 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, statements regarding CalciMedica's expected cash, cash equivalents and short-term investments as of the end of the first quarter of 2024; CalciMedica's expected use of proceeds from the private placement; CalciMedica's expected cash runway; CalciMedica's business strategy; 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 planned Phase 2 KOURAGE trial of Auxora in AKI with associated AHRF, its ongoing Phase 2b CARPO trial of Auxora for AP with accompanying SIRS and its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with AIPT; the potential benefits of Auxora for the treatment of AKI, AP and AIPT; the estimated patient populations in the United States for AKI, AIPT and AP; the potential of Auxora for the treatment of other acute indications including acute respiratory distress syndrome; 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-K for the year ended December 31, 2023 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.
Consolidated Balance Sheets
(in thousands, except par value and share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 5,530	$ 1,327
Restricted cash	—	149
Short-term investments	5,708	—
Prepaid expenses and other current assets	367	254
Total current assets	11,605	1,730
Property and equipment, net	167	147
Right-of-use asset, net	—	48
Other assets	413	1,424
Total assets	$ 12,185	$ 3,349
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,419	$ 2,866
Accrued clinical trial costs	1,141	1,143

Accrued other	1,468	572
Other current liabilities	—	199
Total current liabilities	4,028	4,780
Long-term liabilities		
Warrant liability	—	2,645
Convertible promissory notes	—	5,157
Total liabilities	4,028	12,582
Commitments and contingencies (Note 9)		
Convertible preferred stock		
Series A convertible preferred stock, $0.001 par value; no shares and 25,751,716 authorized, issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	19,107
Series B convertible preferred stock, $0.001 par value; no shares and 11,235,460 authorized at December 31, 2023 and December 31, 2022, respectively; no shares and 10,667,279 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	8,224
Series C-1 convertible preferred stock, $0.001 par value; no shares and 8,016,886 shares authorized, issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	5,683
Series C-2 convertible preferred stock, $0.001 par value; no shares and 16,291,526 authorized at December 31, 2023 and December 31, 2022, respectively; no shares and 13,504,959 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	9,563
Series D convertible preferred stock, $0.001 par value; no shares and 88,875,077 authorized at December 31, 2023 and December 31, 2022, respectively; no shares and 26,880,040 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	19,494
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value; 10,000,000 shares and no shares authorized at December 31, 2023 and December 31, 2022, respectively; no shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 and 5,694,626 shares authorized at December 31, 2023 and December 31, 2022, respectively; 5,754,505 and 84,165 issued and outstanding at December 31, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	154,218	40,402
Accumulated deficit	(146,064)	(111,707)
Accumulated other comprehensive income (loss)	2	
Total stockholders' equity (deficit)	8,157	(71,304)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 12,185	$ 3,349

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

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 15,859	$ 8,350
General and administrative	22,216	5,843
Total operating expenses	38,075	14,193
Loss from operations	(38,075)	(14,193)
Other income (expense)		
Change in fair value of warrant liability	1,146	3,784
Change in fair value of convertible promissory notes	2,022	2,745
Interest on convertible promissory notes payable	(110)	(132)
Other income (expense), net	660	(28)
Total other income (expense), net	3,718	6,369
Net loss	(34,357)	(7,824)
Deemed distribution to convertible promissory note holders	—	(1,318)
Net loss attributable to common stockholders	$ (34,357)	$ (9,142)
Net loss per share—basic and diluted	$ (7.66)	$ (111.16)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	4,486,258	82,245

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