UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

June 27, 2024 Date of Report (Date of earliest event reported)

CalciMedica, Inc. (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-39538

45-2120079 (IRS Employer Identification No.)

505 Coast Boulevard South, Suite 307 La Jolla, California (Address of principal executive offices)

92037 (Zip Code)

Registrant's telephone number, including area code: (858) 952-5500 $\,$

	(Former nam	Not Applicable e or former address, if changed since last re	port.)
	ck the appropriate box below if the Form 8-K filing is intowing provisions:	ended to simultaneously satisfy the fi	ling obligations of the registrant under any of the
	Written communications pursuant to Rule 425 under the	e Securities Act (17 CFR 230.425)	
	Soliciting material pursuant to Rule 14a-12 under the E	xchange Act (17 CFR 240.14a-12)	
	Pre-commencement communications pursuant to Rule	14d-2(b) under the Exchange Act (17	CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17	CFR 240.13e-4(c))
Seci	urities registered pursuant to Section 12(b) of the Act:		
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered
(Common Stock, \$0.0001 par value per share	CALC	The Nasdaq Capital Market
	cate by check mark whether the registrant is an emerging ster) or Rule 12b-2 of the Securities Exchange Act of 193		905 of the Securities Act of 1933 (§ 230.405 of this
Eme	erging growth company 🗵		
	emerging growth company, indicate by check mark if the or revised financial accounting standards provided pursu		

Item 7.01. Regulation FD Disclosure.

On June 27, 2024, CalciMedica, Inc. (the "Company") issued a press release announcing topline data from the Phase 2b CARPO trial of Auxora in acute pancreatitis ("AP"). A copy of the press release is attached hereto as Exhibit 99.1.

Included as Exhibit 99.2 to this Form 8-K is a slide presentation titled Developing Novel Therapies for Acute Inflammatory and Immunologic Diseases: CARPO Trial Topline Results dated June 27, 2024, that is incorporated herein by reference. The Company intends to utilize this presentation and its contents in various meetings with securities analysts, investors and others, including during a conference call and live webcast with the investment community on June 27, 2024, at 8:30 a.m. Eastern Time.

The information in this Item 7.01, including the attached Exhibits 99.1 and 99.2, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 8.01. Other Events.

On January 27, 2024, the Company announced positive topline data from CARPO, the Company's international, randomized, double-blind, placebo-controlled, dose-ranging Phase 2b trial evaluating Auxora for the treatment of AP with accompanying systemic inflammatory response syndrome ("SIRS").

The Phase 2b CARPO trial intended to establish Auxora's dose-response and efficacy in AP with accompanying SIRS. The trial reached its target enrollment of 216. Patients were randomized into four groups to receive either high 2.0 mg/kg dose (n=53), medium 1.0 mg/kg dose (n=56) or low 0.5 mg/kg dose (n=52) of Auxora or a matched dose of placebo (n=53) intravenously every 24 hours for a total of three doses. Treatment and observation of patients continued for 30 days. Patients were stratified by baseline hematocrit, a biomarker for inflammation severity, so that efficacy in a pre-specified hyper-inflamed sub-group of patients could be evaluated. These patients represented approximately 43% of the patients enrolled (2.0 mg/kg, n=23; 1.0 mg/kg, n=25; 0.5 mg/kg, n=24; and placebo, n=20). Patients were well-matched for all baseline characteristics with the exception that the placebo group had approximately 12% lower proportion of hyper-inflamed patients than the study overall.

Summary Efficacy Data

The Phase 2b CARPO trial met its study objective by showing a dose response for time to solid food tolerance as well as other clinical endpoints. The primary endpoint of median time to solid food tolerance in the pre-specified subgroup of patients with hyper-inflammatory AP showed a statistically significant dose response with placebo patients requiring 4.7 days to tolerate solid food and patients in the high dose group showing a 1.9 day improvement (41.0% relative risk reduction) when compared to placebo, the medium dose group showing a 2.1 day improvement (43.6% relative risk reduction) and the low dose group showing a 1.5 day improvement (31.0% relative risk reduction). In patients without hyper-inflammatory AP, Auxora did not show a measurable benefit due to the patients tolerating solid food relatively quickly in all treatment groups.

Additionally, Auxora demonstrated a statistically significant dose response in reduction of severe organ failure which was defined as respiratory failure requiring invasive mechanical ventilation or 48 hours or more of high-flow nasal canula therapy, renal failure requiring renal replacement therapy, or cardiovascular failure requiring the use of vasopressor or inotropic support for greater than 48 hours. Severe organ failure occurred in 3.8% of high dose patients, 3.6% of medium dose patients, 9.6% of low dose patients, and 9.4% of placebo patients, representing a 59.6% relative risk reduction for the high dose patients when compared to placebo and 61.7% risk reduction for the medium dose patients when compared to placebo.

The median length of hospital stay was 5.0 days for the placebo group while the high dose group showed a reduction in the length of stay of 1.0 day. The mean length of hospital stay was 7.1 days for the placebo group while both the high dose and medium dose patients showed a reduction in the length of stay of 1.2 days and the hyper-inflammatory AP subgroup showed a reduction in the length of stay of 1.5 days for the hyper-inflamed high dose patients and 1.9 days for the hyper-inflamed medium dose patients.

The proportion of patients who remained in the hospital for longer than 21 days was 0% for high dose patients, 1.8% for medium dose patients, 5.8% for low dose patients, and 5.7% for placebo patients. Comparing the combined placebo and low dose patients to the combined high and medium dose patients, this represents an 84.3% relative risk for a prolonged hospital stay.

Summary of Safety Data

Auxora was well-tolerated with 20 treatment-emergent serious adverse events ("TESAEs") reported in the placebo group, 14 in the high dose group, 21 in the medium dose group, and 23 in the low dose group. None of the TESAEs in the high and medium dose groups and only 1 in the low dose group were deemed to be drug-related. There were no related TESAEs in the placebo group. Treatment-emergent adverse events ("TEAEs") led to drug discontinuation in 3 patients in the placebo group, 2 in the high dose group, 2 in the medium dose group, and 2 in the low dose group. TEAEs led to death in 1 patient in the placebo group and 1 patient in the medium dose group. There were no deaths in the high dose or low dose group.

The Company intends to present additional data from the Phase 2b CARPO trial, including results from the analysis of CTs taken at baseline and 30-days post enrollment, at a medical meeting later this year.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements which include but are not limited to statements related to the Company's business strategy; the potential benefits of Auxora for treatment of AP patients and the healthcare system; the dose response for Auxora across multiple endpoints, the target patient population and the likely drug dose for a pivotal trial; the Company'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 plans to present additional data from the Phase 2b CARPO trial of Auxora for AP with accompanying SIRS at a future medical meeting later this year; plans to move forward rapidly with a pivotal trial of Auxora for AP; plans regarding its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with asparaginase-induced pancreatic toxicity ("AIPT") and its planned Phase 2 KOURAGE trial of Auxora in acute kidney injury ("AKI") with associated acute hypoxemic respiratory failure; the potential benefits of Auxora for the treatment of AIPT and AKI; and the potential of the Company'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. The Company'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 the Company's business and the actions it may take in response thereto; the Company'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, including preliminary results, 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 the Company generally; the Company's ability to protect its intellectual property position; the impact of government laws and regulations; and the Company's 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" and elsewhere in the Company's most recent filings with the U.S. Securities and Exchange Commission ("SEC"), including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 and any subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from The forward-looking statements included in this Current Report on Form 8-K are made only as of the date hereof. The Company assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

tem 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number

Number Description

99.1 <u>Press release regarding Phase 2b CARPO Trial Topline Data, dated June 27, 2024.</u>

99.2 <u>Corporate Presentation of the Company, dated June 27, 2024.</u>

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 27, 2024

CalciMedica, Inc.

By: /s/A. Rachel Leheny, Ph.D.
Name: A. Rachel Leheny, Ph.D.
Title: Chief Executive Officer

CalciMedica Announces Positive Topline Data from Phase 2b CARPO Trial of Auxora™ in Acute Pancreatitis (AP)



Primary objective of the trial met with statistically significant dose response with up to 43.6% relative reduction (2.1 day improvement) in median time to solid food tolerance versus placebo in hyper-inflamed patients

Statistically significant dose response with up to 61.7% reduction in severe organ failure in all patients versus placebo

Up to 100% reduction in hospital stays longer than 21 days

Planning End-of-Phase 2 meeting with the FDA in preparation for a pivotal trial Conference call to discuss the CARPO topline results scheduled for 8:30 a.m. ET today

LA JOLLA, Calif., June 27, 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 announced positive topline data from CARPO, the Company's randomized, double-blind, placebo-controlled Phase 2b trial evaluating Auxora™ for the treatment of acute pancreatitis (AP) with accompanying systemic inflammatory response syndrome (SIRS). The trial established a dose response for Auxora across multiple endpoints, identified both the target patient population and the likely drug dose for a pivotal trial, and re-affirmed Auxora's safety profile and tolerability as seen in prior clinical trials.

"With these results, CARPO has added significantly to the body of evidence showing Auxora's potential as an effective treatment for critically ill patients with acute inflammatory disease and warrants advancing our drug in both AP and acute kidney injury," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "We plan to move quickly towards initiating our Phase 3 trial in AP and are eager to engage with the FDA to discuss our trial plans once we have all the data from CARPO. We look forward to unlocking Auxora's potential to treat these patients who have few treatment options."

"There are currently no drugs for the treatment of AP and the CARPO data show a benefit in multiple endpoints, supporting the need for Auxora," said Joseph Miller, M.D., Clinical Associate Professor of Emergency Medicine at Henry Ford Health and Michigan State University and Associate Director Emergency Care Research at Henry Ford Health and a principal investigator in the CARPO trial. "AP is one of the costliest gastrointestinal diseases for hospitals due to prolonged lengths of stay for severe patients. By reducing the occurrence of severe organ failure and extended hospital stays, Auxora may provide significant benefits to patients with AP and to the health care system and should be welcomed by clinicians and hospitals."

The CARPO Trial Topline Results:

The Phase 2b CARPO trial was an international, randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish Auxora's dose-response and efficacy in AP with accompanying SIRS. The trial reached its target enrollment of 216. Patients were randomized into four groups to receive either high 2.0 mg/kg dose (n=53), medium 1.0 mg/kg dose (n=56) or low 0.5 mg/kg dose (n=52) of Auxora or a matched dose of placebo (n=53) intravenously every 24 hours for a total of three doses. Treatment and observation of patients continued for 30 days. Patients were stratified by baseline hematocrit, a biomarker for inflammation severity, so that efficacy in a pre-specified hyper-inflamed sub-group of patients could be evaluated. These patients represented approximately 43% of the patients enrolled (2.0 mg/kg, n=23; 1.0 mg/kg, n=25; 0.5 mg/kg, n=24; and placebo, n=20). Patients were well-matched for all baseline characteristics with the exception that the placebo group had approximately 12% lower proportion of hyper-inflamed patients than the study overall.

Summary of Efficacy Data:

CARPO met its study objective by showing a dose response for time to solid food tolerance as well as other clinical endpoints. The primary endpoint of median time to solid food tolerance in the pre-specified subgroup of patients with hyper-inflammatory acute pancreatitis showed a statistically significant dose response with placebo patients requiring 4.7 days to tolerate solid food and patients in the high dose group showing a 1.9 day improvement (41.0% relative risk reduction) when compared to placebo, the medium dose group a 2.1 day improvement (43.6% relative risk reduction) and the low dose group a 1.5 day improvement (31.0% relative risk reduction). In patients without hyper-inflammatory AP, Auxora did not show a measurable benefit due to the patients tolerating solid food relatively quickly in all treatment groups.

Additionally, Auxora demonstrated a statistically significant dose response in reduction of severe organ failure which was defined as respiratory failure requiring invasive mechanical ventilation or 48 hours or more of high-flow nasal canula therapy, renal failure requiring renal replacement therapy, or cardiovascular failure requiring the use of vasopressor or inotropic support for greater than 48 hours. Severe organ failure occurred in 3.8% of high dose patients, 3.6% of medium dose patients, 9.6% of low dose patients, and 9.4% of placebo patients, representing a 59.6% relative risk reduction for the high dose patients when compared to placebo and 61.7% risk reduction for the medium dose patients when compared to placebo.

The median length of hospital stay was 5.0 days for the placebo group while the high dose group showed a reduction in the length of stay of 1.0 day. The mean length of stay showed a greater benefit: the placebo patients had a mean stay of 7.1 days and both the high dose and medium dose patients had a reduction of 1.2 days. In the patients with hyperinflammatory acute pancreatitis, the reduction was even greater, 1.5 days for the hyper-inflamed high dose patients and 1.9 days for the hyper-inflamed medium dose patients.

The proportion of patients who remained in the hospital for longer than 21 days was 0% for high dose patients, 1.8% for medium dose patients, 5.8% for low dose patients, and 5.7% for placebo patients. Comparing the combined placebo and low dose patients to the combined high and medium dose patients, this represents a 84.3% relative risk for a prolonged hospital stay.

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Auxora was well-tolerated with 20 treatment-emergent serious adverse events (TESAEs) reported in the placebo group, 14 in the high dose group, 21 in the medium dose group, and 23 in the low dose group. None of the TESAEs in the high and medium dose groups and only 1 in the low dose group were deemed to be drug-related. There were no related TESAEs in the placebo group. Treatment-emergent adverse events (TEAEs) led to drug discontinuation in 3 patients in the placebo group, 2 in the high dose group, 2 in the medium dose group, and 2 in the low dose group. TEAEs led to death in 1 patient in the placebo group and 1 in the medium dose group. There were no deaths in the high dose or low dose group.

"Consistent with our prior Phase 2b CARDEA trial in severe and critical COVID pneumonia patients and with our Phase 2a trial in AP patients with SIRS and hypoxemia, CARPO has demonstrated Auxora's potential to treat some of the more severely ill patients with acute inflammatory diseases," said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. "Importantly, we found that Auxora provided patients with clinically meaningful improvements in key outcome measures, while also being well-tolerated. We have identified the target population of patients most likely to benefit from Auxora and determined the likely dose for a pivotal trial. With this information we are more confident in proceeding with a pivotal program in AP. I want to thank the patients who enrolled in the trial as well as the investigators and their study teams for their hard work and contributions to the success of this trial. CARPO has advanced our understanding of AP and brought us closer to a solution for this potentially life-threatening condition for which currently no approved therapy exists."

"CARPO has demonstrated that patients with hyper-inflammation benefit most from Auxora. This is encouraging as we initiate KOURAGE where we have established enrollment criteria that select the acute kidney injury patients who are most likely to be suffering from severe inflammation and where reduction of organ failure is a key metric of efficacy," said Lakhmir Chawla, M.D., Clinical Professor of Medicine at University of California San Diego, Chief Medical Officer at ExThera Medical, Scientific Advisor to CalciMedica, and Chair of the KOURAGE Steering Committee.

CalciMedica intends to present additional data from CARPO, including results from the analysis of CTs taken at baseline and 30-days post enrollment, at a medical meeting later this year.

Conference Call and Webcast Details

Stockholders and other interested parties may participate in the call by following the instructions below. A live webcast of the event can also be accessed in the "Upcoming Events" section of CalciMedica's IR website at https://ir.calcimedica.com/. A replay of the webcast will be available following the completion of the event.

Participant Webcast Link: https://app.webinar.net/jDbvg4E9vPn

Participant Dial-in Numbers: 1-800-836-8184 (US) and 1-646-357-8785 (international)

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, 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 AP

AP, or inflammation of the pancreas, can be a life-threatening condition. Moderate or severe AP sometimes leads 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, a predictor of moderate and severe disease 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, 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 patients hospitalized with AKI in the United States each year with approximately 1.1 million 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 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 completed a Phase 2b trial (called CARPO – NCT04581066) in AP with SIRS and a Phase 2b trial (called CARDEA – NCT04345614) in COVID pneumonia patients, continues to support the ongoing Phase 1/2 AIPT study (called CRSPA – NCT04195347), with data expected in 2025, and has initiated its Phase 2 study (called KOURAGE – NCT06374797) in AKI with associated AHRF 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.

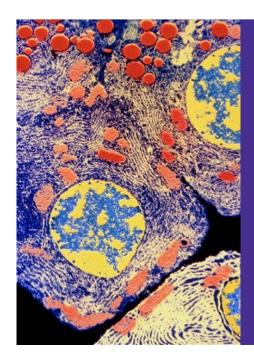
Forward-Looking Statements

This communication contains forward-looking statements which include, but are not limited to, statements related to: CalciMedica's business strategy; the potential benefits of Auxora for treatment of AP patients and the healthcare system; the dose response for Auxora across multiple endpoints, the target patient population and the likely drug dose for a pivotal trial; 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 plans to present additional data from the Phase 2b CARPO trial of Auxora for AP with accompanying SIRS at future medical meeting later this year; plans to move forward rapidly with a pivotal trial of Auxora for AP; plans regarding its ongoing Phase 1/2 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 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, and elsewhere in CalciMedica's subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the Securities and Exchange Commission (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





Developing Novel Therapies for Acute Inflammatory and Immunologic Diseases

CARPO Trial Topline Results

June 27, 2024

Forward-Looking Statements

This presentation contains forward-looking statements which include, but are not limited to, statements regarding CalciMedica's business strategy and clinical development plans; the design and potential benefits of CalciMedica's product candidates; CalciMedica's ongoing and planned clinical trials, including its planned Phase 3 trial of Auxora for acute pancreatitis (AP), pending discussions with the U.S. Food and Drug Administration (FDA), and Auxora being ready for such Phase 3 trial; the timing for CalciMedica's receipt and announcement of data from its clinical trials, including plans to release final data from the Phase 2b CARPO trial later this year; CalciMedica's planned regulatory filings and the timing thereof; and results from the Phase 2b CARPO trial increasing confidence in the KOURAGE trial of Auxora in acute kidney injury (AkI). 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 related to: the impact of fluctuations in global financial markets on CalciMedica's business and the actions it may take in response related to: the impact of gluctuations in global financial markets on CalciMedica's product candidates; 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 need for additional capital. Additional risks and uncertainties that could cause actual outcomes and results to differ materially

These forward-looking statements are based on information available to, and expectations of, CalciMedica of the date of this presentation. CalciMedica disclaims any obligation to update these forward-looking statements, except as may be required by law.



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CARPO Topline Takeaways

- Primary objective was met with a dose response for multiple endpoints
 - Statistically significant for time to solid food tolerance in high hematocrit patients
 - · Statistically significant for severe organ failure in the entire population
- Auxora was well-tolerated
- · Auxora is ready for Phase 3 clinical development
 - Pending discussions with FDA following final data
 - Final data, including CT scan (baseline and 30-day) data, expected to presented at a medical meeting later this year
- · Reduction in severe organ failure increases confidence in our KOURAGE AKI trial
 - Magnitude in reduction similar to what was seen in CARDEA and Phase 2a AP trials



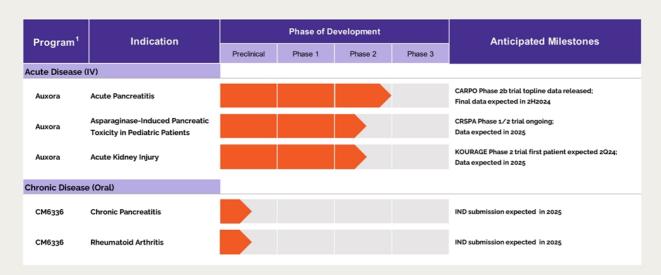
Auxora Clinically Active and Well-Tolerated in Multiple Phase 2 Trials

Population	Trial Size	Results
Pancreas		
Acute Pancreatitis With SIRS (CARPO)	N=216	 Topline results show: Improvement in clinically significant endpoints Statistically significant dose response for time to solid food tolerance in patients with hyper-inflammation Statistically significant dose response in severe organ failure
Acute Pancreatitis Accompanied by SIRS and Hypoxemia	N=21	 Rapid increase in patients tolerating solid diet (potential trial pivotal endpoint) >2-day reduction in hospital stay and 50% reduction SIRS
Asparaginase-Induced Pancreatic Toxicity (CRSPA)	N=9	Trial ongoing, preliminary results show rapid resolution of pain and food tolerance
Lung		
COVID-19 with Respiratory Failure (CARDEA) On LFO ₂ 1 or HFNC ²	N=284 (Part 2) N=30 (Part 1)	 56% statistically significant decrease in mortality at Day 30 33% reduction in ventilation >2-day shorter hospital stay ~40% reduction in reported acute kidney injury Mortality benefit in patients with compromised kidney function (low GFR)
COVID-19 with Respiratory Failure On IMV ³	N=9	Open-label trial with varying doses showing pharmacodynamic response



** CalciMedica 1) LFO₂: Low Flow Oxygen; 2) HFNC: High-Flow Nasal Cannula; 3) IMV: Invasive Mechanical Ventilation

Differentiated Pipeline in Acute and Chronic Inflammatory and Immunologic Diseases

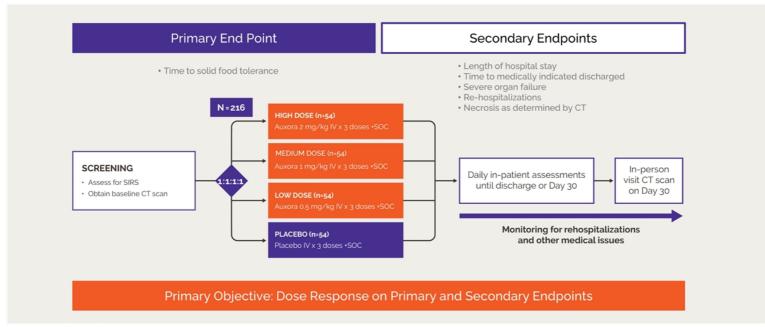


With CARPO results, Auxora is Phase 3 ready pending End-of-Phase 2 Discussion with FDA



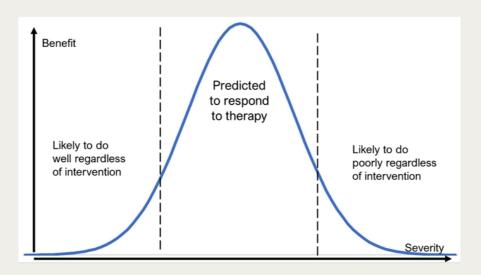
1) All Auxora programs are IV for rapid onset in the acute care setting. CM6336 is intended for chronic oral dosing.

CARPO Phase 2b Clinical Trial in AP





Defining Who to Treat: Patients with Acute Critical Illnesses





Vincent, J. L., Opal, S. M., & Marshall, J. C. (2010). Ten reasons why we should NOT use severity scores as entry criteria for clinical trials or in our treatment decisions. Critical care medicine, 38(1), 283-287.

Enrich CARPO for Patients with Hyperinflammatory Acute Pancreatitis

- CARPO added inclusion criteria to enroll pre-specified subgroup of patients with an elevated hematocrit
- Inclusion criteria in addition to SIRS
 - Hematocrit ≥44% for men or ≥40% for women, established biomarker for inflammation
 - HCT biomarker supported by Phase 2a AP trial results

HCT at Baseline	#Patients	Initial NLR	Max D-dimer ng/mL	Max CRP mg/L	Max IL-6 pg/mL	ICU admission
HCT ≤44%	13	8.41 (5.2, 13.2)	3996(1205, 13235)	195 (86, 343)	108 (41, 442)	2/13 (15%)
HCT >44%	8	19.9 (13.2, 46.7)	4245 (3685, 6205)	380 (248, 395)	391 (245, 849)	6/8 (75%)

- A peripancreatic fluid collection or a pleural effusion on a CECT performed in the 24 hours before Consent or after Consent and before Randomization
- Abdominal examination documenting either abdominal guarding or rebound tenderness



CARPO Baseline Characteristics

	Placebo	2.0 mg/kg	1.0 mg/kg	0.5 mg/kg	Total Auxora	Total
	N=53	N=53	N=56	N=52	N=161	N=214
Age (Median)	42	42	43.5	48.5	43	43
(Min, Max)	20, 78	19, 91	22, 84	23, 85	19, 91	19, 91
Male (%)	33 (62.3)	33 (62.3)	33 (58.9)	32 (61.5)	98 (60.9)	131 (61.2)
Female (%)	20 (37.7)	20 (37.7)	23 (41.1)	20 (38.5)	63 (39.1)	83 (38.8)
HCT (≥44 males, ≥40 females) (% of N)	20 (37.7)	23 (43.4%)	25 (44.6%)	24 (46%)	72 (44.7%)	92 (43.0%)

Note: mITT was 214 patients as 2 enrolled patients did not receive study drug



Time to Solid Food Tolerance

Statistical significance achieved on dose response in patients with hyperinflammatory AP

		Placebo	2.0 mg/kg	1.0 mg/kg	0.5 mg/kg
n= 122 Low Hematocrit	25 th % Median hours 75 th %	n= 33 36.0 62.0 137.0	n= 29* 25.0 65.0 100.0	n= 31 28.0 68.0 353.0	n= 28 19.0 67.0 184.0
n= 92 High Hematocrit	25 th % Median hours 75 th %	n= 20 41.5 113.5 187.0	n= 23* 13.0 67.0 117.0	n= 25 20.0 64.0 113	n= 24 37.0 78.0 187.5

^{*}One hematocrit missing at baseline

Determination of solid food tolerance

- Patient offered a low fat, ≥500-calorie solid meal
- Patient consumes ≥50% of the meal without vomiting or an increase in abdominal pain in the two hours after the meal (as confirmed by clinical trial nurse)



Length of Hospital Stay

		Placebo N=53	2.0 mg/kg N=53	1.0 mg/kg N=56	0.5 mg/kg N=52
LOS mITT	Median days	5.0	4.0	5.0	5.5
LOS mITT	Mean days	7.1	5.9	5.9	7.6
LOS High Hematocrit	Mean days	7.8	6.3	5.7	7.9
22-30 days	n subjects (%)	3 (5.7)	0 (0.0)	1 (1.8)	3 (5.8)



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Severe Organ Failure

Statistical significance achieved on dose response

	Placebo N=53	2.0 mg/kg N=53	1.0 mg/kg N=56	0.5 mg/kg N=52
Severe Respiratory (%)	4/53 (7.5)	2/53 (3.8)	2/56 (3.6)	5/52 (9.6)
Severe Renal (%)	1/53 (1.9)	0/53 (0.0)	1/56 (1.8)	2/52 (3.8)
Severe Cardiovascular (%)	1/53 (1.9)	1/53 (1.9)	1/56 (1.8)	3/52 (5.8)
Any severe organ failure (%)	5/53 (9.4)	2/53 (3.8)	2/56 (3.6)	5/52 (9.6)

Definition of severe organ failure

- Severe respiratory failure defined as those patients receiving invasive mechanical ventilation (IMV) or
 those receiving for ≥ 48 hours use of either high flow nasal cannula (HFNC) or non-invasive mechanical
 ventilation (NIMV) (Use of NIMV for the treatment of obstructive sleep apnea not considered as meeting
 the definition of severe respiratory failure)
- · Severe renal failure defined as the initiation of renal replacement therapy
- Severe cardiovascular failure defined as the use of vasopressor or inotropic support for ≥48 hours



Serious Adverse Event Summary

	Placebo N=53	2.0 mg/kg N=53	1.0 mg/kg N=56	0.5 mg/kg N=52	Total Auxora N=161
Number of TESAEs	20	14	21	23	58
Patients discontinuing study drug due to TESAEs	3	2	2	2	6
Patients with TEAEs leading to death	1	0	1	0	1

TESAE=treatment emergent serious adverse event TEAE=treatment emergent adverse event



Conclusions and Next Steps

- Auxora is ready for Phase 3 clinical development pending FDA discussion
- Primary objective met with a dose response for multiple endpoints
- Auxora well-tolerated
- · Reduction in severe organ failure increases confidence in KOURAGE AKI trial
- Next steps: further analysis of additional data and End-of-Phase 2 meeting with FDA



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