

**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**  
**October 30, 2024**  
**Date of Report (Date of earliest event reported)**

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

<b>Delaware</b> <small>(State or other jurisdiction of incorporation)</small>	<b>001-39538</b> <small>(Commission File Number)</small>	<b>45-2120079</b> <small>(IRS Employer Identification No.)</small>
<b>505 Coast Boulevard South, Suite 307</b> <b>La Jolla, California</b> <small>(Address of principal executive offices)</small>		<b>92037</b> <small>(Zip Code)</small>

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

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange 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))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$0.0001, par value per share	CALC	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On October 30, 2024, CalciMedica, Inc. (the “Company”) issued a press release announcing late-breaking positive data from the Phase 2b CARPO trial of Auxora in acute pancreatitis (“AP”) patients with accompanying systemic inflammatory response syndrome (“SIRS”). 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” dated October 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.

The information in this Item 7.01 of this Current Report on Form 8-K, 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, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be incorporated by reference into any filing we make with the U.S. Securities and Exchange Commission (“SEC”), whether before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 8.01 Other Events**

On October 30, 2024, the Company announced late-breaking positive 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 SIRS. These data demonstrate the potential of Auxora to address the significant disease burden of AP for the estimated 300,000 U.S. patients hospitalized for AP annually, with an estimated 100,000 with accompanying 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. CT scans to evaluate pancreatic inflammation and necrosis were performed at study entry and at 30 days. Patients were stratified by baseline hematocrit, a biomarker for inflammation severity and 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 & Safety Data**

In addition to the topline data previously reported in June 2024, the Phase 2b CARPO trial met its study objective by showing clinically meaningful reductions for observed high and/or medium dose Auxora patients compared to placebo or combined placebo and low dose Auxora patients in additional key endpoints including statistically significant reductions in rates of new-onset severe respiratory failure and new-onset persistent respiratory failure, reductions in new-onset necrotizing pancreatitis, reduced times to medically indicated discharge and reductions in the proportion of patients requiring long hospital stays.

New onset severe respiratory failure, defined as (i) receiving invasive mechanical ventilation or (ii) use of either high-flow nasal cannula or non-invasive mechanical ventilation for 48 hours or longer, occurred in 0% of high dose patients, 0% of medium dose patients, 8.3% of low dose patients, and 8.5% of placebo patients, representing a 100% (p = 0.0027) relative risk reduction when combined high and medium dose patients were compared to combined low dose and placebo patients. New-onset persistent respiratory failure, defined as (i) severe respiratory failure or (ii) not severe respiratory failure but PaO<sub>2</sub> /FiO<sub>2</sub> of 300 or lower for 48 hours or longer and use of low-flow oxygen support, occurred in 8% of high dose patients, 1.9% of medium dose patients, 10.4% of low dose patients, and 17% of placebo patients, representing a 64.2% (p = 0.0476) relative risk reduction when combined high and medium dose patients were compared to combined low dose and placebo patients.

Additionally, new onset necrotizing pancreatitis, measured on day 30 occurred in 29.7% of high dose patients, 40.8% of medium dose patients, 38.6% of low dose patients, and 37.0% of placebo patients, representing a relative risk reduction of approximately 20% for high dose patients compared to placebo patients.

Median time to medically indicated discharge, defined as (i) no clinical evidence of infection necessitating continued hospitalization, (ii) solid food tolerance, and (iii) abdominal pain resolved or controlled with non-opiate medications, was 89.0 hours for high dose patients, 104.5 hours for medium dose patients, 109.5 hours for low dose patients, and 104.0 hours for placebo patients, demonstrating a reduction of 15.0 hours for high dose patients when compared to placebo. Long hospital stays were reduced in combined high and medium dose patients compared to combined low dose and placebo patients, with 18% vs 31% of patients in the hospital longer than 7 days, 5% vs 10% longer than 14 days, and 1% vs 6% longer than 21 days, respectively. There were no high dose patients who stayed in the hospital longer than 21 days.

When key endpoints—all-cause mortality, new-onset severe respiratory failure, new-onset necrotizing pancreatitis, and time to medically indicated discharge—were integrated into a win ratio analysis, the high dose of Auxora outperformed placebo by a similar margin across all endpoints and delivered a stratified win ratio of 1.640 (p = 0.0372).

As in prior Phase 2 trials, Auxora provided patients with clinically meaningful improvement and was well-tolerated. There was a trend of decreasing treatment emergent serious adverse event (“TESAE”) rates with increasing doses of drug. Additionally, there were no drug-related TESAEs or deaths in patients receiving the high dose of Auxora.

#### ***Planned Activities***

Planning for a Phase 3 program of Auxora in patients with AP with accompanying SIRS is ongoing, with the CARPO trial results expected to inform the design and characteristics, pending an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (“FDA”).

#### **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, including its potential to address the significant disease burden of AP; the estimated patient population and demographics of patients with AP; the Company’s target patient population in AP and the likely drug dose for a Phase 3 trial of Auxora for the treatment of AP; 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; plans for an end of Phase 2 meeting with the FDA for CARPO; 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; expected IP protections for Auxora; 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 June 30, 2024 and any subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from time to time.

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.

**Item 9.01 Financial Statements and Exhibits. (d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated October 30, 2024.</a>
99.2	<a href="#">Slide presentation titled “Developing Novel Therapies for Acute Inflammatory and Immunologic Diseases” dated October 2024.</a>
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.

CalciMedica, Inc.

Date: October 30, 2024

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



**CalciMedica to Present Late-Breaking Positive Data, Including a Win Ratio Analysis, from Phase 2b CARPO Trial of Auxora™ in Acute Pancreatitis (AP) at the American College of Gastroenterology (ACG) 2024 Annual Scientific Meeting**

*Statistically significant 100% reduction ( $p = 0.0027$ ) in new-onset severe respiratory failure and 64.2% reduction ( $p = 0.0476$ ) in new-onset persistent respiratory failure in combined high and medium dose Auxora patients versus combined low dose Auxora and placebo patients*

*Statistically significant stratified win ratio of 1.640 ( $p = 0.0372$ ) for high dose Auxora compared to placebo*

*Clinically meaningful reduction observed for high dose Auxora patients compared to placebo in additional key endpoints: new-onset necrotizing pancreatitis and time to medically indicated discharge*

*Conference call and webcast to review full data set from the Ph2b CARPO trial to be held at 12 p.m. ET/ 9 a.m. PT*

LA JOLLA, CA, Oct. 30, 2024 – 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 is announcing late-breaking positive data from the Phase 2b CARPO trial of Auxora™ in acute pancreatitis (AP) with accompanying systemic inflammatory response syndrome (SIRS) at the American College of Gastroenterology (ACG) 2024 Annual Scientific Meeting in Philadelphia, PA and virtually. 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 will deliver a plenary presentation entitled “A Randomized, Double-Blind, Placebo Controlled Dose Ranging Study of Auxora in Patients with Acute Pancreatitis (AP) and Accompanying Systemic Inflammatory Response Syndrome (SIRS) - CARPO.”

“With the data being presented here at ACG, we see that Auxora continues to deliver across key AP endpoints, showing that the drug substantially reduced respiratory failure, necrotizing pancreatitis, and long hospital stays, which may in turn minimize patient mortality and morbidity as well as the economic burden of this disease,” said Prof. Robert Sutton. “The reduction of severe respiratory failure is particularly clinically meaningful as respiratory failure is the main driver of mortality in AP patients. These data demonstrate that Auxora may be an important new tool in a critical illness with no approved therapies, and we are encouraged as we look ahead to the Phase 3 trial of Auxora in AP patients with SIRS.”

“CARPO has delivered results that mirror those from previous Phase 2 trials of Auxora in other acute critical diseases and represents a significant step forward for the development of CRAC channel inhibitors in these diseases,” said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. “The CARPO results highlight Auxora’s unique immunomodulatory action coupled with direct organ tissue protection, most importantly in the lung, and provide an optimistic readthrough to the acute kidney injury, or AKI, setting, where respiratory failure is also a significant cause of mortality. With these data, we are even more encouraged about KOURAGE, our Phase 2 trial in AKI patients with respiratory failure, which we expect to read out next year.”

### CARPO Trial Design

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. CT scans to evaluate pancreatic inflammation and necrosis were performed at study entry and at 30 days. Patients were stratified by baseline hematocrit, a biomarker for inflammation severity, and 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.

### Efficacy & Safety Data Presented at the ACG Annual Scientific Meeting

At ACG, Prof. Sutton will be discussing CARPO endpoints previously reported in June, including median time to solid food tolerance (up to a 50 hour reduction for Auxora patients compared to placebo) and severe organ failure including both respiratory and renal failure (up to 61.7% relative risk reduction for Auxora patients compared to placebo), and presenting new data from additional endpoints. The new data includes an integration of key endpoints of the trial into a win ratio analysis, providing a comprehensive evaluation of Auxora for the treatment of AP with SIRS.

- New-onset severe respiratory failure, defined as (i) receiving invasive mechanical ventilation or (ii) use of either high-flow nasal cannula or non-invasive mechanical ventilation for 48 hours or longer, occurred in 0% of high dose patients, 0% of medium dose patients, 8.3% of low dose patients, and 8.5% of placebo patients, representing a 100% (p = 0.0027) relative risk reduction when combined high and medium dose patients were compared to combined low dose and placebo patients.
- New-onset persistent respiratory failure, defined as (i) severe respiratory failure or (ii) not severe respiratory failure but PaO<sub>2</sub> /FiO<sub>2</sub> of 300 or lower for 48 hours or longer and use of low-flow oxygen support, occurred in 8% of high dose patients, 1.9% of medium dose patients, 10.4% of low dose patients, and 17% of placebo patients, representing a 64.2% (p = 0.0476) relative risk reduction when combined high and medium dose patients were compared to combined low dose and placebo patients.
- New-onset necrotizing pancreatitis, measured on day 30, occurred in 29.7% of high dose patients, 40.8% of medium dose patients, 38.6% of low dose patients, and 37.0% of placebo patients, representing a relative risk reduction of approximately 20% for high dose patients compared to placebo patients.
- Median time to medically indicated discharge, defined as (i) no clinical evidence of infection necessitating continued hospitalization, (ii) solid food tolerance, and (iii) abdominal pain resolved or controlled with non-opiate medications, was 89.0 hours for high dose patients, 104.5 hours for medium dose patients, 109.5 hours for low dose patients, and 104.0 hours for placebo patients, demonstrating a reduction of 15.0 hours for high dose patients when compared to placebo.

- Long hospital stays were reduced in combined high and medium dose patients compared to combined low dose and placebo patients, with 18% vs 31% of patients in the hospital longer than 7 days, 5% vs 10% longer than 14 days, and 1% vs 6% longer than 21 days, respectively. There were no high dose patients who stayed in the hospital longer than 21 days.
- When key endpoints—all-cause mortality, new-onset severe respiratory failure, new-onset necrotizing pancreatitis, and time to medically indicated discharge—were integrated into a win ratio analysis, the high dose of Auxora outperformed placebo by a similar margin across all endpoints and delivered a stratified win ratio of 1.640 (p = 0.0372).

As in prior Phase 2 trials, Auxora provided patients with clinically meaningful improvement and was well-tolerated. There was a trend of decreasing treatment emergent serious adverse event (TESAE) rates with increasing doses of drug. Additionally, there were no drug-related TESAEs or deaths in patients receiving the high dose of Auxora.

“AP is a complex inflammatory syndrome that currently has no approved therapies, leaving a significant unmet medical need for patients and hospital systems,” said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. “With CARPO, we believe we have now identified the most effective dose of Auxora for AP patients and have clarified how best to measure the drug’s benefit to these patients. Given the complexity of issues that these patients experience, we are encouraged that the 2.0 mg/kg Auxora dose delivered a statistically significant 1.640 stratified win ratio compared to placebo. We plan to meet with the FDA to discuss the design of a Phase 3 trial of Auxora in patients with AP with accompanying SIRS.”

The Company will be hosting a conference call and webcast on Wednesday, October 30, 2024 at 12 p.m. ET/ 9 a.m. PT, during which Prof. Robert Sutton will deliver his plenary presentation from the ACG Annual Scientific meeting. To join, follow the instructions below.

**Participant Webcast Link:** <https://app.webinar.net/4EanW4A2PXk>

Click on the webcast link and complete the online registration form.

Upon registering, you will be connected to the online webcast.

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

If prompted by the operator, ask to join the CalciMedica Phase 2b CARPO Full Data Set & Win Ratio call.

#### **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 has demonstrated positive and consistent clinical results in multiple completed efficacy clinical trials, including a Phase 2b trial (called CARPO) in patients with AP with SIRS and a Phase 2 trial (called CARDEA) in patients with



COVID pneumonia. Auxora is currently being evaluated in a Phase 2 trial in acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF), called KOURAGE, and 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 300,000 U.S. patients hospitalized for AP annually, with an estimated 100,000 with accompanying 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](https://clinicaltrials.gov/ct2/show/study/NCT04681066) (NCT04681066).

#### **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](https://clinicaltrials.gov/ct2/show/study/NCT04681066)) in patients with AP with SIRS and completed a Phase 2 trial (called CARDEA – [NCT04345614](https://clinicaltrials.gov/ct2/show/study/NCT04345614)) in patients with COVID pneumonia. The Company is currently conducting a Phase 2 trial (called KOURAGE – [NCT06374797](https://clinicaltrials.gov/ct2/show/study/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](https://clinicaltrials.gov/ct2/show/study/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](http://www.calcimedica.com).

#### **Forward-Looking Statements**

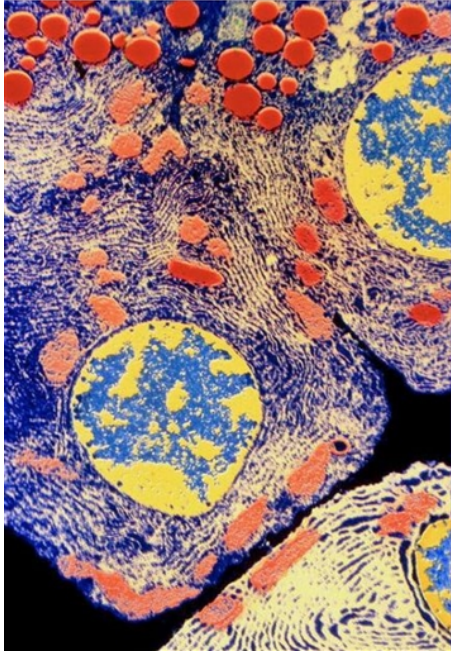
This communication contains forward-looking statements which include, but are not limited to, CalciMedica's business strategy; the potential benefits of Auxora for treatment of AP patients and the healthcare system, including its potential to address the significant disease burden of AP; the estimated patient population and demographics of patients with AP; the Company's target patient population in AP and the likely drug dose of Phase 3 trial of Auxora for the treatment of AP; 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, its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with AIPT and its planned Phase 3 trial of Auxora for AP with accompanying SIRS; plans for an end of Phase 2 meeting with

the FDA for CARPO; the potential benefits of Auxora for the treatment of AP, AKI and AIP; 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, 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 from time to time and available at [www.sec.gov](http://www.sec.gov). These documents can be accessed on CalciMedica's web page at [ir.calci-medica.com/financials-filings/sec-filings](http://ir.calci-medica.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  
[calci-medica@argotpartners.com](mailto:calci-medica@argotpartners.com)  
(212) 600-1902



**Developing Novel Therapies for Acute Inflammatory and Immunologic Diseases**


October 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; expected IP protections; the timing for CalciMedica's receipt and announcement of data from its clinical trials and other clinical milestones; the estimated patient populations and addressable market for CalciMedica's product candidates; and expectations regarding CalciMedica's cash runway. 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 CalciMedica's product candidates; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from 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; expected length of IP protection for CalciMedica's product candidates; the impact of government laws and regulations; and CalciMedica's cash runway 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 most recently filed periodic report, and subsequent periodic reports filed by CalciMedica, under the Securities Exchange Act of 1934, as amended, from time to time and available at [www.sec.gov](http://www.sec.gov). These documents can be accessed on CalciMedica's web page at [calcimedica.com](http://calcimedica.com).

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.

## Investment Highlights

	<b>Proprietary Technology</b>	CRAC channel inhibitors for life-threatening inflammatory diseases with high unmet need
	<b>Compelling Clinical Data</b>	Consistent positive clinical activity and good tolerability in six Phase 2 clinical trials in acute critical illnesses
	<b>Substantial Market Opportunity</b>	-1 million target AKI population and ~100 thousand target AP population represent \$multi-billion U.S. market opportunities with no approved therapies
	<b>Strong IP</b>	Composition of matter (2036), formulation (2038), and methods of use (2036-2041+) worldwide patent protection
	<b>Cash to Fund Clinical Programs</b>	Current cash runway into 2H25 expected to fund operations and completion of the ongoing KOURAGE Phase 2 trial in AKI patients

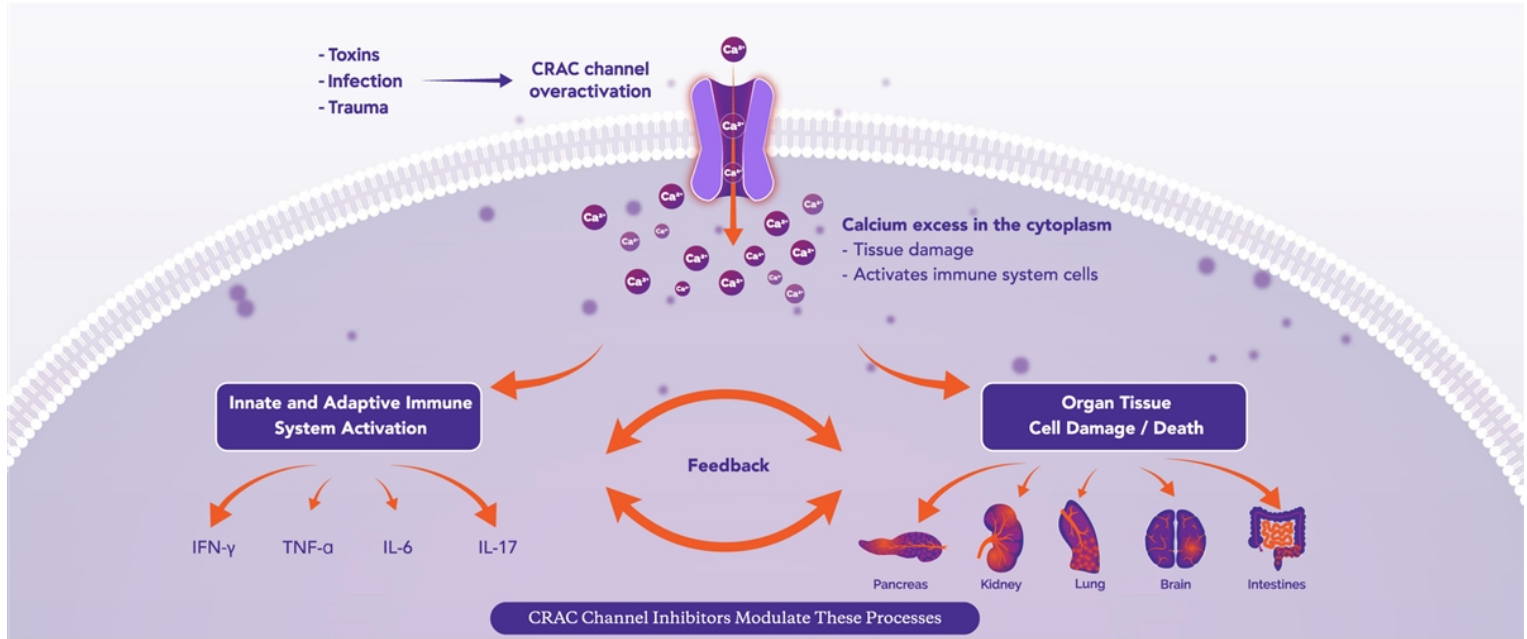
# Differentiated Pipeline in Acute and Chronic Inflammatory and Immunologic Diseases

Program <sup>1</sup>	Indication	Phase of Development				Anticipated Milestones
		Preclinical	Phase 1	Phase 2	Phase 3	
<b>Acute Disease (IV)</b>						
Auxora	Acute Pancreatitis	████████	████████	████████▶	████████	CARPO Phase 2b trial completed and positive data announced; Next step: End-of-Phase 2 Meeting with FDA
Auxora	Asparaginase-Induced Pancreatic Toxicity in Pediatric Patients	████████	████████	████████▶	████████	CRSPA Phase 1/2 trial ongoing; Data expected in 2025
Auxora	Acute Kidney Injury	████████	████████	████████▶	████████	KOURAGE Phase 2 trial ongoing; Data expected in 2025
<b>Chronic Disease (Oral)</b>						
CM6336	Chronic Pancreatitis	████████▶	████████	████████	████████	Potential IND submission in 2025
CM6336	Rheumatoid Arthritis	████████▶	████████	████████	████████	Potential IND submission in 2025

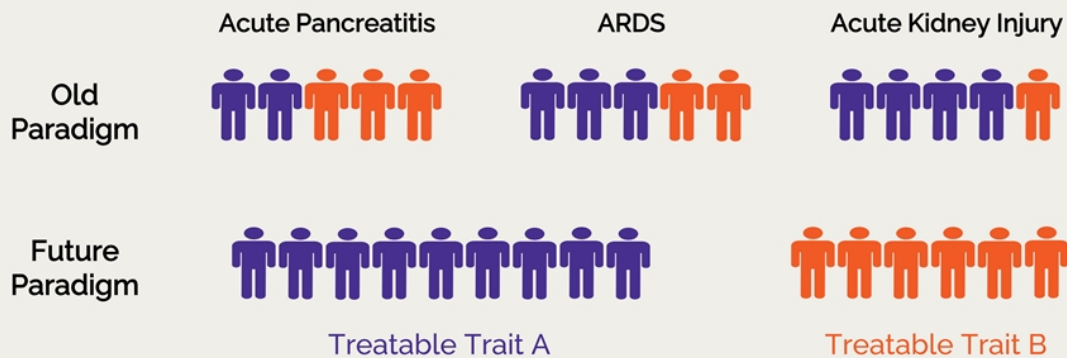


<sup>1</sup> All Auxora programs are IV for rapid onset in the acute care setting. CM6336 is intended for chronic oral dosing.

# Overactivation of Calcium Release-Activated Calcium (CRAC) Channels: Immune System Activation and Tissue Cell Injury



# Acute Inflammation: Underlying Cause Across Many Diseases



Auxora has demonstrated positive clinical results in all 3 of these large, underserved patient populations



## Auxora Has Shown Consistent Reduction and Prevention of Acute Respiratory Failure and Mortality

Trial	Acute Pancreatitis Phase 2a	COVID-19 Pneumonia Phase 2a	CARDEA: COVID-19 Pneumonia Phase 2	CARPO: Acute Pancreatitis Phase 2b	KOURAGE: Acute Kidney Injury Phase 2
Year	2019 →	2020 →	2021 →	2024 →	Expected 2025
Number of Patients	21	30	284	216	150
Hypoxemia at Enrollment	P/F<360	P/F<300	P/F<200	Not required	P/F<300
Expected Mortality	<10%	15-25%	15-25%	<5%	~50%
<b>Auxora Results</b>					
Respiratory Failure	↓ Ventilator use	↓ Ventilator use	↓ 33% Ventilator use	↓ 100%* New onset severe respiratory failure	Primary Endpoint Days ALIVE, not on a VENTILATOR and not on DIALYSIS
Severe Organ Failure	Too few events	Too few events	↓ 40% New onset AKI	↓ ~60%* Severe organ failure (respiratory, renal and cardio)	
Mortality	Too few events	↓ 50%	↓ 56%	Too few events	



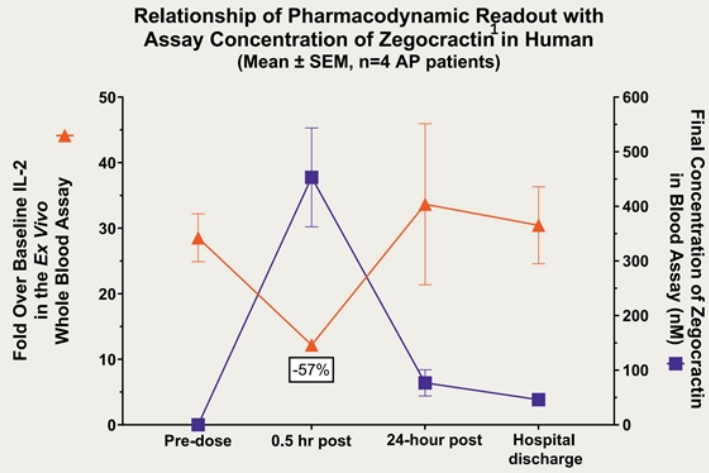
CalciMedica

*Note: For illustrative purposes only. Not a head-to-head comparison. Differences exist between clinical trial design and patient populations, and caution should be excised when comparing data across trials.*

\* The high and medium dose patients showed a reduction in respiratory failure and severe organ failure compared to both the placebo and low dose patients.

# IV Formulation Has the Potential to Provide Ideal Benefits for Acute Inflammation

Rapid onset of immunomodulatory action reaches peak by the end of 4-hour infusion



Recovery within 24-48 hours of dosing may limit the potential for long-term immunosuppression

## Large U.S. Market Opportunity in Acute Inflammatory Diseases

AP with SIRS<sup>1</sup>



- **No approved therapies**
- SOC<sup>2</sup> primarily supportive care
- Disease progression:
  - Severe AP
  - Pancreatic necrosis
  - Mortality

AKI Stages 2 & 3



- **No approved therapies**
- SOC primarily supportive care
- Disease progression:
  - Chronic kidney disease
  - End stage renal disease
  - Mortality

AIPT



- **No approved therapies**
- Ultra-orphan pediatric indication
- Accelerated approval opportunity
- Disease progression:
  - Pancreatic necrosis in 50%

Patient figures represent estimated numbers of annual U.S. cases<sup>3</sup>

# Auxora for Acute Pancreatitis (AP)



## AP Carries a Significant Disease Burden

### Disease Progression in Acute Pancreatitis



US Patients/yr

300K<sup>1</sup>

100K<sup>2</sup>

20-60K<sup>2</sup>

3-6K<sup>1,3</sup>

**Notes**

- Standard of care for AP limited to support therapy

- Characterized by development of SIRS (systemic inflammatory response syndrome)

- Most often respiratory failure
- Can progress to multiple organ failure with sterile or infected necrosis

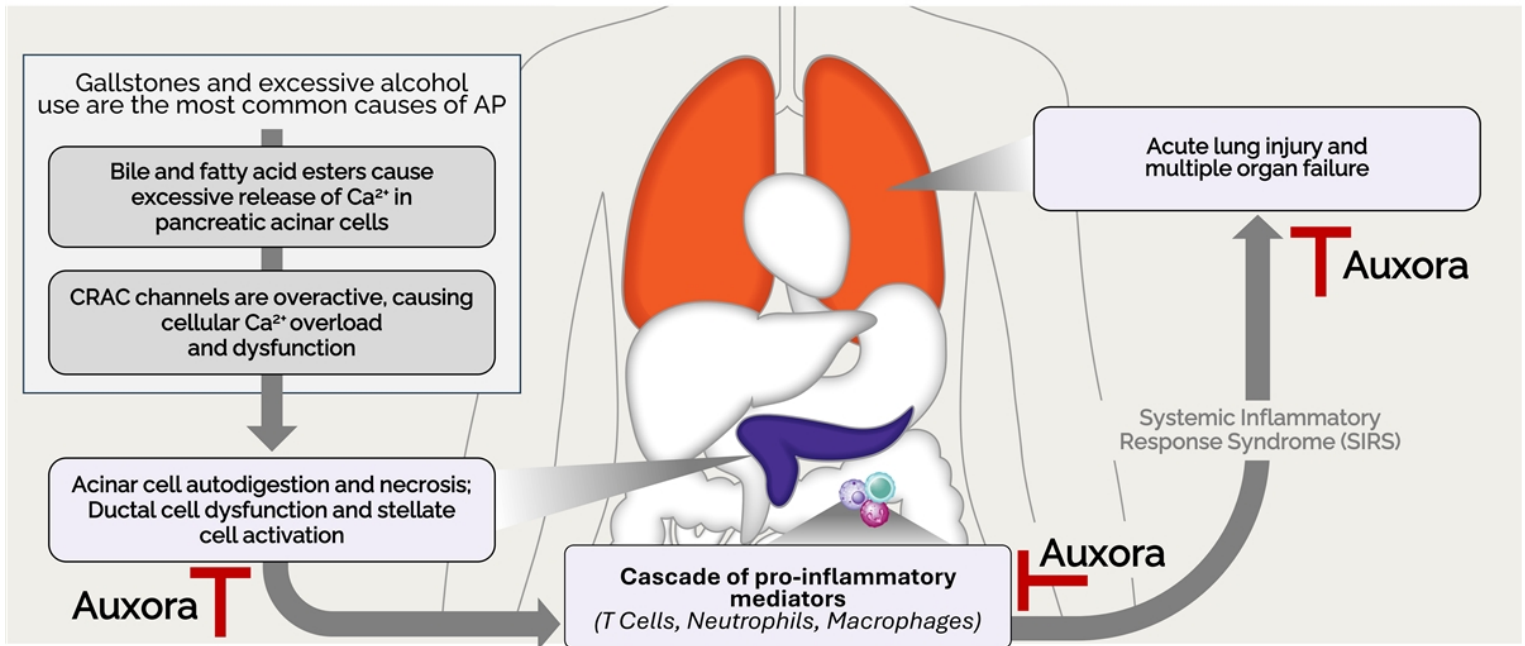
- Even without mortality, some patients spend weeks to months in the hospital or ICU

Additionally, a major economic burden: >1M+ patient days in hospital per year and >\$3B cost per year<sup>1</sup>



Sources: 1) Peery et al. Burden and Cost of Gastrointestinal, Liver, and Pancreatic Diseases in the United States: Update 2021. *Gastroenterology*. 2022 Feb;162(2):621-644. 2) Garg PK, Singh VP. Organ Failure Due to Systemic Injury in Acute Pancreatitis. *Gastroenterology*. 2019 May;156(7):2008-2023. 3) Cheema, Huzaiifa et al. 27: Acute-Pancreatitis Mortality in the United States, 1999-2021: An Observational Analysis. *Critical Care Medicine* 52(1):p S111. Jan 2024

# Overactive Calcium Release-Activated Calcium (CRAC) Channels Contribute to AP; Auxora, a CRAC Channel Inhibitor, Targets Multiple Pathways



## Initial Signs of Efficacy in a Phase 2a Prompted Further Development in a Phase 2b

### Phase 2a Outcomes<sup>1</sup>

An open-label trial in patients with AP plus SIRS and hypoxemia demonstrated Auxora plus standard of care (SOC) compared with SOC alone:

- ✓ Reduced the median hospital stay
- ✓ Reduced disease severity in patients presenting with moderate or severe AP
- ✓ Reduced incidence of persistent SIRS
- ✓ Rapidly restored tolerance of solid food
- ✓ Generally well-tolerated

### Goals for Phase 2b CARPO Trial in AP Patients with SIRS



Demonstrate *dose response* and biological activity across multiple primary and secondary endpoints including the pre-defined hyper-inflammatory patient population (high hematocrit)



Demonstrate *impact on organ failure*, especially in the lung, which is a significant risk for AP patients presenting with SIRS



Demonstrate *reduction in duration of hospital stays* for patients

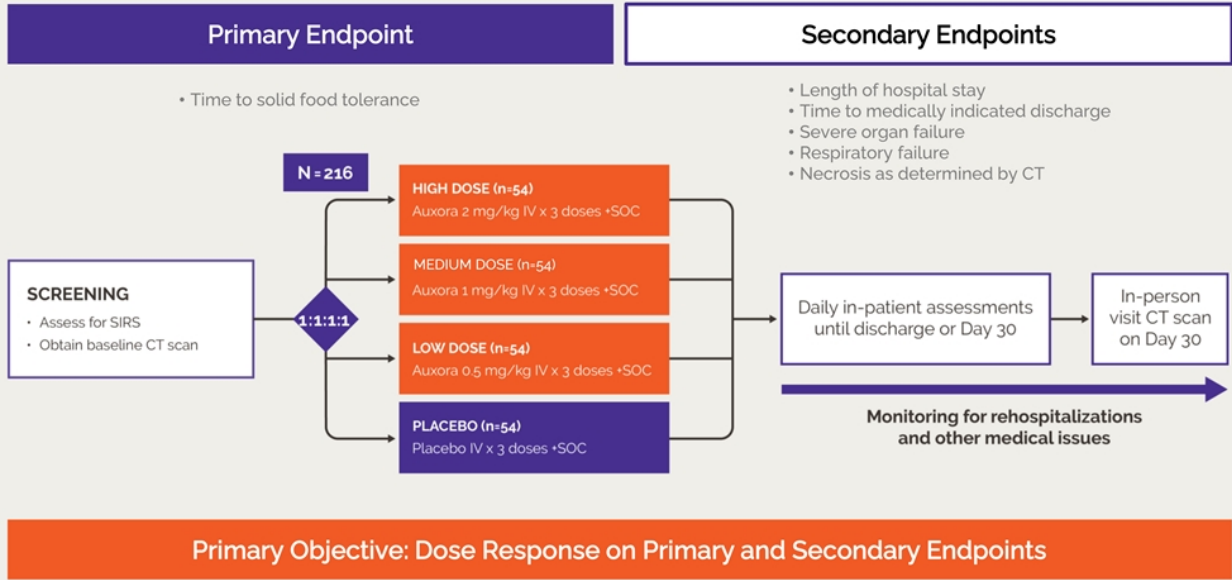


Continued *tolerability* of Auxora



Understand Auxora's potential benefits to patients to *design a Phase 3 trial* for discussion with the FDA

# CARPO Phase 2b Clinical Trial in AP





## Baseline Characteristics were Generally Aligned Across Groups

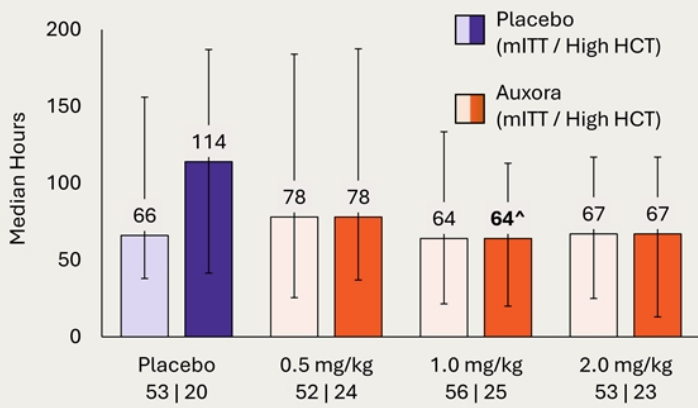
Baseline Demographics mITT Population	Placebo N=53	0.5 mg/kg N=52	1.0 mg/kg N=56	2.0 mg/kg N=53
Median Age (Minimum, Maximum)	42 (20, 78)	48.5 (23, 85)	43.5 (22, 84)	42 (19, 91)
Male (%)	33 (62.3)	32 (61.5)	33 (58.9)	33 (62.3)
Female (%)	20 (37.7)	20 (38.5)	23 (41.1)	20 (37.7)
High Hematocrit (% of N) ( $\geq 44$ males, $\geq 40$ females)	20 (37.7)	24 (46)	25 (44.6)	23 (43.4)
Any Respiratory Failure (%)	6 (11.3)	4 (7.6)	4 (7.1)	3 (5.6)
Readable Necrotizing Pancreatitis (%)	1/53 (1.9)	4/51 (7.8)	3/56 (5.3)	4/49 (8.1)

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

Patients were recruited across 37 sites in both the US and India

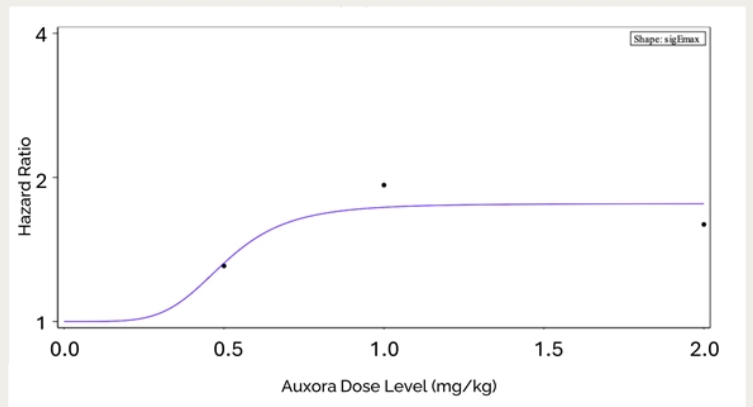
## Dose Response Observed on the Primary Endpoint (Time to Solid Food Tolerance)

Time to Solid Food Tolerance  
mITT Population and Pre-Defined High Hematocrit (HCT) Sub-Group



<sup>^</sup>p < 0.05 | Error bars represent IQR

gMCP-Mod Analysis  
Time to Solid Food Tolerance  
in the High Hematocrit Group



p-value of 0.057 | (The pre-defined  $\alpha$  was 0.15)

## Auxora High and Medium Doses Reduced All Types of Severe Organ Failure

### Severe Organ Failure

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

**Severe Respiratory Failure:** Receiving invasive mechanical ventilation (IMV) OR use of either high flow nasal cannula (HFNC) or non-invasive mechanical ventilation (NIMV) for  $\geq$  48 hours

**Severe Renal Failure:** Initiation of renal replacement therapy

**Severe Cardiovascular Failure:** Use of vasopressor or inotropic support for  $\geq$ 48 hours

## Dose Response was Observed for both New Onset Persistent & Severe Respiratory Failure

### Reduced New Onset Persistent Respiratory Failure

	Placebo	0.5 mg/kg	1.0 mg/kg	2.0 mg/kg
New Onset Persistent Respiratory Failure	8/47 (17.0%)	5/48 (10.4%)	1/52 (1.9%)	4/50 (8%)

	Placebo + 0.5 mg/kg	1.0 mg/kg + 2.0 mg/kg
New Onset Persistent Respiratory Failure	13/95 (13.7%)	5/102 (4.9%)
Difference		-8.8 %
Relative Reduction		64.2%
p-value		0.0476

#### Respiratory failure:

- P/F  $\leq$ 300 by arterial blood gas or imputed from pulse oximetry

#### Persistent respiratory failure was defined as either:

- Severe respiratory failure; OR
- Not Severe: P/F  $\leq$ 300 for 48 hours, but no use of ventilatory support other than low flow oxygen

### Prevented New Onset Severe Respiratory Failure

	Placebo	0.5 mg/kg	1.0 mg/kg	2.0 mg/kg
New Onset Severe Respiratory Failure	4/47 (8.5%)	4/48 (8.3%)	0/52 (0%)	0/50 (0%)

	Placebo + 0.5 mg/kg	1.0 mg/kg + 2.0 mg/kg
New Onset Severe Respiratory Failure	8/95 (8.4%)	0/102 (0%)
Difference		-8.4 %
Relative Reduction		100%
p-value		0.0027

#### Severe Respiratory Failure:

- Receiving invasive mechanical ventilation (IMV); OR
- Use of either high flow nasal cannula (HFNC) or non-invasive mechanical ventilation (NIMV) for  $\geq$  48 hours

## Auxora High-Dose Demonstrated Improvements in Additional Key Secondary Endpoints

### New Onset Necrotizing Pancreatitis (NP)

	NP At Day 30* (%)	Diff^1(%)
Placebo N=53	17/46 (37.0%)	-
0.5 mg/kg N=52	17/44 (38.6%)	1.1%
1.0 mg/kg N=56	20/49 (40.8%)	2.2%
2.0 mg/kg N=53	11/37 (29.7%)	-8.0%

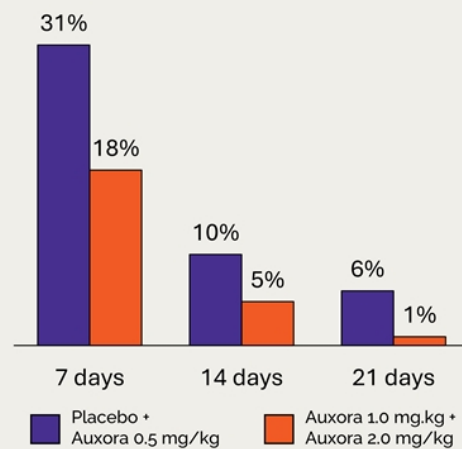
Percentage is based on the number of subjects without Necrotizing Pancreatitis at Screening and non-missing Day 30 Visit or post-treatment unscheduled visit CECT reading results

### Time to Medically Indicated Discharge (TMID)

	TMID Median Hours
Placebo N=53	104.0
0.5 mg/kg N=52	109.5
1.0 mg/kg N=56	104.5
2.0 mg/kg N=53	89.0

TMID defined as: 1) No clinical evidence of infection necessitating continued hospitalization; 2) Solid food tolerance; 3) Abdominal pain has resolved or controlled with medications (non-opiate)

### Proportion of Patients Remaining in the Hospital



## Integration of Key Endpoints into Win Ratio Demonstrates Potential Benefits of Auxora High-Dose Compared to Placebo

Win Ratio	All-cause Mortality	New Onset Severe Respiratory Failure	Necrotizing Pancreatitis	Time to Medically Indicated Discharge	Total Wins
Placebo wins	0	0	374	546	920
Auxora 2.0 mg/kg dose wins	0	208	615	730	1553

**Stratified Win Ratio: 1.640 | p-value: 0.0372 | 95% CI: 1.030 – 2.612**

**The win ratio approach provides a comprehensive evaluation of Auxora for AP**

Reduction in respiratory failure will reduce mortality

Reduction in necrotizing pancreatitis will reduce morbidity

Reduction in hospital stays will reduce economic burden

Overall, Auxora Was Well Tolerated with Few Discontinuations Across all Doses and No Related TESAEs or Deaths for the High Dose Group

Safety Summary: Number of Patients	Placebo N=53	0.5 mg/kg N=52	1.0 mg/kg N=56	2.0 mg/kg N=53
At least one TEAE leading to discontinuation of study drug (%)	3 (5.7)	2 (3.8)	2 (3.6)	2 (3.8)
At least one related TESAE (%)	0	1 (1.9)	0	0
TEAE leading to death (%)	1 (1.9)	0	1 (1.8)	0
At least one TEAE (%)	25 (47.2)	28 (53.8)	36 (64.3)	23 (43.4)
At least one related TEAE (%)	5 (9.4)	9 (17.3)	6 (10.7)	4 (7.5)
At least one TESAE (%)	6 (11.3)	3 (25.0)	12 (21.4)	8 (15.1)

## The Primary Objective of Dose Response was Achieved While Providing Clinically Meaningful Improvements in Key Outcome Measures

### The Phase 2b trial results demonstrate Auxora's potential to reduce mortality and morbidity in AP with SIRs and provide savings to the healthcare system

- ✓ Dose response observed on primary and across multiple secondary endpoints
- ✓ Positive impact on organ failure, particularly new onset severe respiratory failure
- ✓ Reduction of necrotizing pancreatitis
- ✓ Reduction in time to medically indicated discharge and length of hospital stays
- ✓ Generally well-tolerated

Auxora is ready for Phase 3 clinical development pending FDA discussion



# Auxora for Asparaginase-Induced Pancreatic Toxicity (AIPT) in Pediatric Patients



## Potential Clinical Benefits to Children with AIPT



Auxora has potential to rapidly resolve AIPT with improvement in food tolerance and pain while preventing development of further complications such as pancreatic necrosis

## Proof-of-Concept Ongoing in AIPT

### Pediatric Patients Had Rapid Resolution of Pain and Food Intolerance

#### CRSPA Phase 1/2 Trial in Pediatric AIPT

- Investigator-initiated open-label trial being conducted at St. Jude Children's Research Hospital
- Assess the safety in pediatric patients with ALL who have developed AIPT
- Estimate the efficacy of Auxora to prevent pseudocyst or necrotizing pancreatitis in pediatric patients with AIPT

#### Trial Status

- Cohort 1 complete (9 patients)
  - 8 patients received four daily infusions of Auxora and had rapid resolution of pain and food intolerance
  - 1 patient received less than a single infusion of Auxora and developed pancreatic necrosis
  - Blinded matched, historical control comparison for Cohort 1 completed
- Cohort 1 dosing selected as recommended dose for patients
- Expanding to additional sites to complete trial (24 patients) with data expected in 2025

#### Results for First Cohort Compared to Blinded, Matched Historical Controls Presented at ASH 2023

## CRSPA First Cohort Data: Presented at ASH 2023

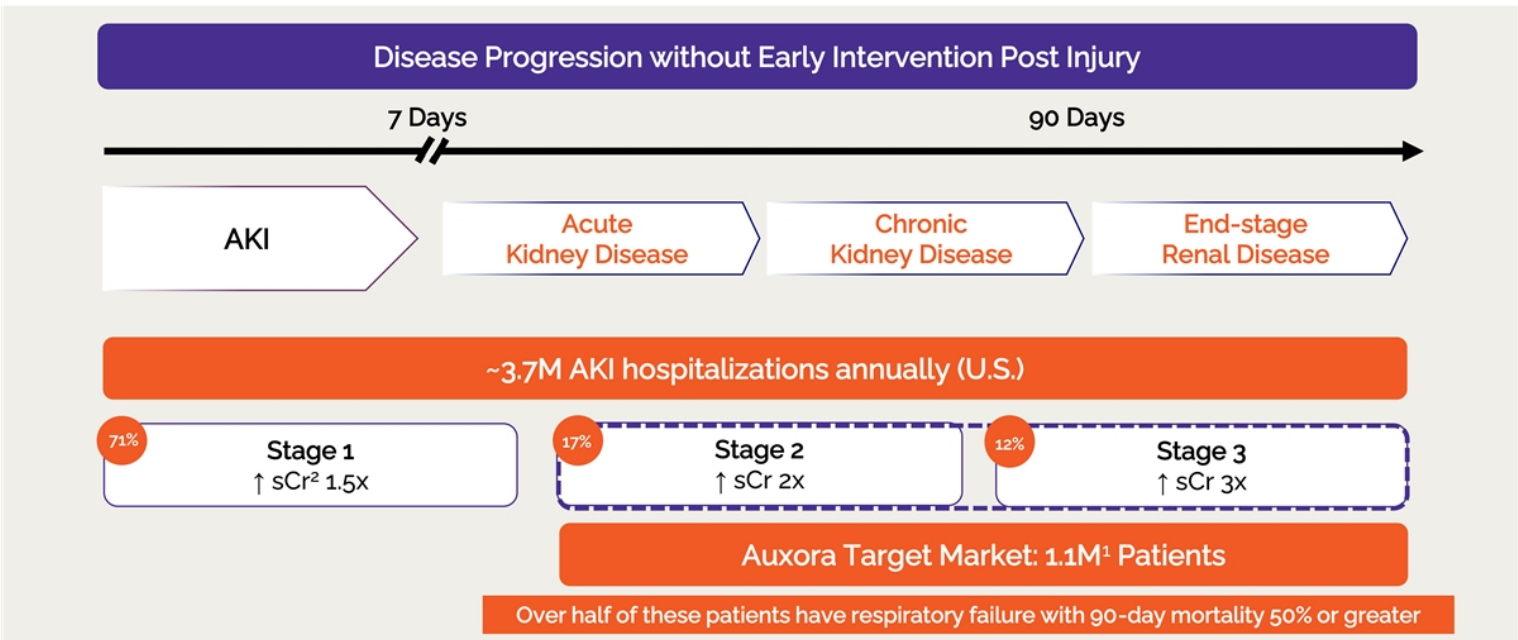
	Total 16 (T16): All AIPT	Matched T16 AIPT cohort	CRSPA evaluable for efficacy
Patients with AIPT	51	16	8
Age: mean (range)	10.3 (2.2-19.4)	9 (2.2-18.4)	8.2 (3.1-17.6)
Female (%)	17 (33.3%)	5 (31.3%)	3 (37.5%)
Low-risk therapy (%)	9 (17.6%)	1 (6.3%)	2 (25%)
Hospital days (range)	12.1 (2-70)	13.4 (2-27)	6.3 (5-8)
ICU needed (%)	11 (21.6%)	3 (18.8%)	1 (12.5%)
ICU days mean (range)	5.1 (1-9)	5 (3-7)	3
TPN needed (%)	27 (52.9%)	11 (68.8%)	0
TPN days mean (range)	37.7 (3-153)	27.2 (4-63)	NA
≥30% pancreatic necrosis (%)	NA	4 (26.7%) *	0
CTSI mean (range)	NA	5.4 (0-10) *	2.4 (0-4)
CTSI ≥ 7 (%)	NA	4 (26.7%) *	0

\*One patient in matched T16 cohort was unable to be evaluated for pancreatic necrosis or a CTSI score  
 CTSI score definitions: 0-3 mild acute pancreatitis, 4-6 moderately severe acute pancreatitis, ≥7 severe acute pancreatitis

# Auxora for Acute Kidney Injury (AKI)



# Patient Journey in AKI



## Potential Clinical Benefits to Patients with AKI

Current standard of care is limited to supportive therapy

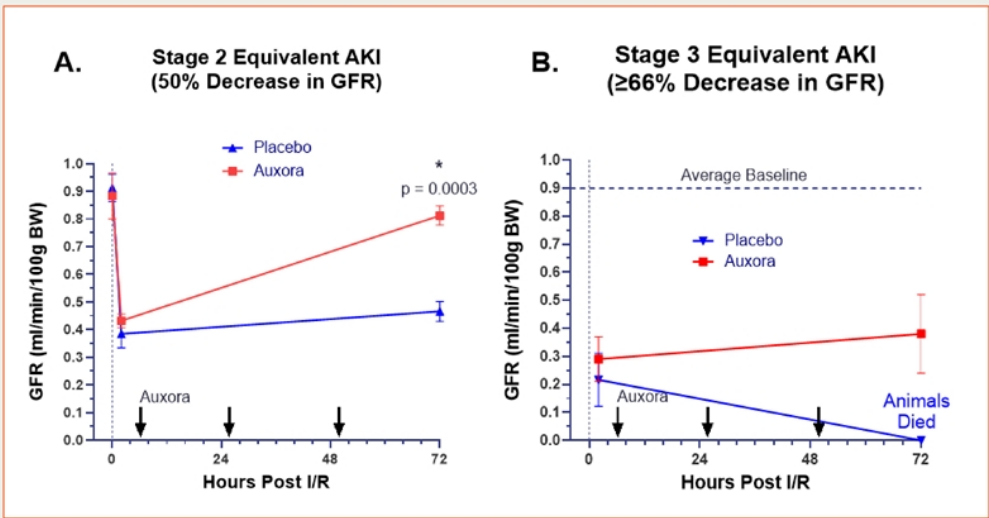
- Fluid resuscitation / Diuretics
- Nutrition
- Correction of underlying cause

Potential Benefits of Auxora

- Reduced need for dialysis
- Reduced risk of respiratory failure
- Reduced risk of mortality
- Greater recovery of renal function

# Auxora Improved Kidney Recovery and Survival in Severe AKI models

Three doses of Auxora or placebo were administered daily starting 6 hours after ischemia/reperfusion injury

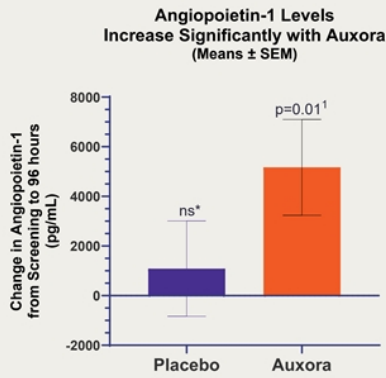


Note: GFR is Glomerular filtration rate and data is courtesy of David Basile, PhD, Indiana University

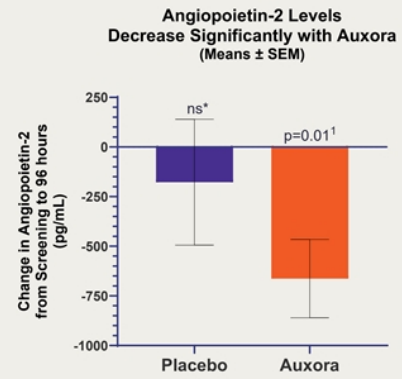


## Evidence of Renal Protection: Phase 2 CARDEA Trial

Ang-1/Tie2 signaling maintains vascular integrity



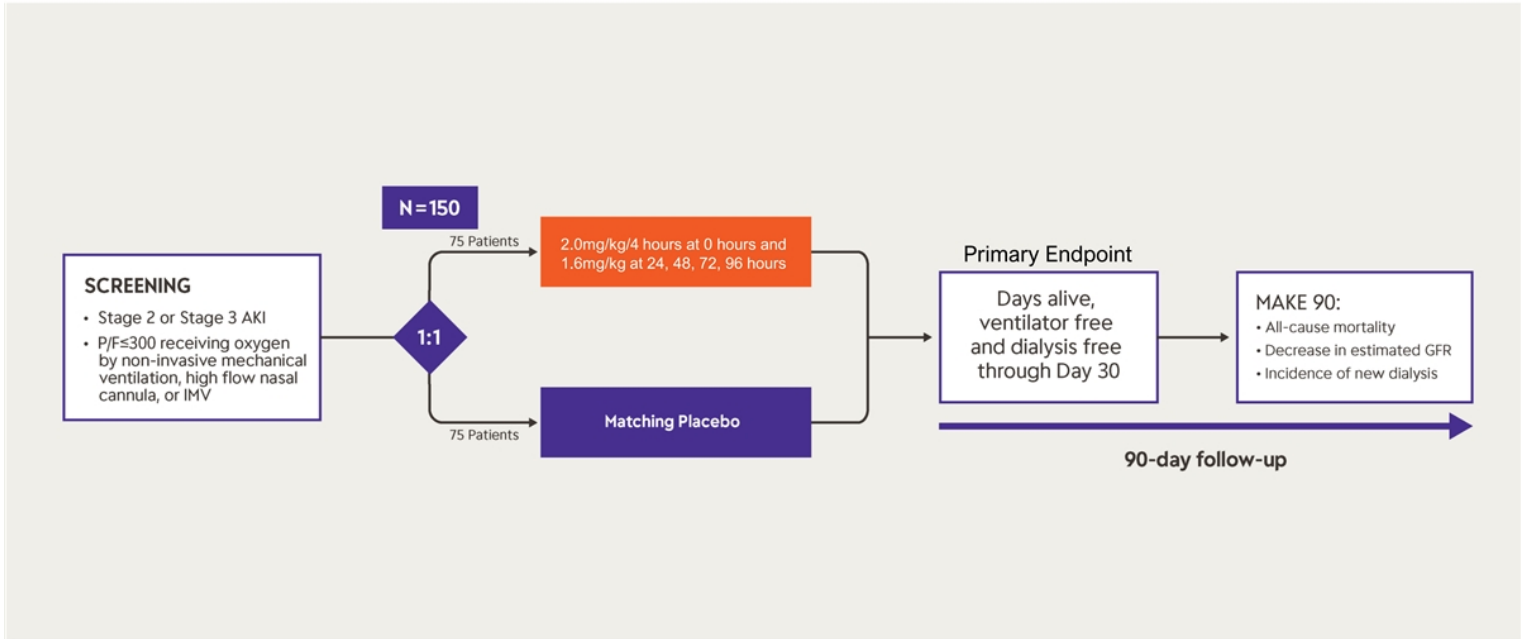
Ang-2/Tie2 results in endothelial inflammation with increased endothelial permeability



### Clinical Observations

- Mortality benefit with Auxora vs Placebo observed in patients with compromised kidney function (low GFR) at time of enrollment
- ~40% reduction in reported AKI with Auxora vs Placebo

# KOURAGE: Acute Kidney Injury with Associated AHRF Phase 2 Trial Design



# Auxora for Acute Respiratory Distress Syndrome (ARDS)



## Promising Phase 2 Data from Trials in COVID-19 Pneumonia and in Ventilated Patients with Respiratory Failure

CARDEA Phase 2  
Severe and Critical COVID-19  
Pneumonia Patients  
N=284

### Trial Complete

- 56% reduction in mortality at Day 30 (p=0.0165)
- 33% reduction ventilation (p=0.18)
- Three-day shorter hospital stay (p=0.09)

Phase 2  
COVID-19 Ventilated  
Patients N=9

### Trial Complete

- Reduction in inflammatory cell-type gene expression by macrophages in lungs
- No reduction in mitochondrial and ribosomal gene expression

# Platform Application for CRAC Channel Inhibition



## Preclinical Results Supporting Other I&I Indications

Indication	Intended Formulation	Preclinical Observations	Next Steps
Chronic Pancreatitis (CP)	Oral	In vivo efficacy in a mouse model of CP using CM5480 (Szabo et al, 2023)	Confirm with lead oral candidate
Acute Ulcerative Colitis	IV	In vivo efficacy of zegocractin in a mouse model of inflammatory bowel disease (Letizia et al., 2022)	Ongoing discussions with investigators about potential clinical trials
Allergic Asthma	IV or Inhaled	In vivo efficacy of zegocractin in a mouse model of allergic asthma (Kahlfuss et al., 2022)	Pursue strategic partnership
Traumatic Brain Injury (TBI)	IV or Oral	In vivo efficacy of CM5480 in a mouse model of TBI (Mizuma et al., 2018)	Confirm results with lead oral compound or Auxora
Rheumatoid Arthritis (RA)	Oral	In vivo efficacy of zegocractin and CM5480 in rat RA models (CalciMedica unpublished data)	Confirm results with lead oral candidate

# Platform Application for CRAC Channel Inhibition

## Anticipated Milestones

AP	CARPO Phase 2b Trial Completed and Positive Data Announced Next Step: End-of-Phase 2 Meeting with FDA
AKI	KOURAGE Trial Underway Data Expected in 2025
AIPT	CRSPA Initial First Cohort Data Released at ASH 2023 Trial Expansion Underway; Data Expected in 2025
Cash Runway	Current Cash Runway into 2H25 Expected to Fund Operations and Completion of KOURAGE Phase 2 Trial