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

February 13, 2024
Date of Report (Date of earliest event reported)

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

Delaware	001-39538	45-2120079
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

505 Coast Boulevard South, Suite 307 La Jolla, California	92037
(Address of principal executive offices)	(Zip Code)

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:

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

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 February 13, 2024, CalciMedica, Inc. (the "Company") posted an updated corporate presentation under the "Investors and Media" section of the Company's website. The Company may use the corporate presentation from time to time in conversations with analysts, investors and others. A copy of the corporate presentation is included as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 7.01, including the attached Exhibit 99.1, 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.

FDA Clearance of IND Application for Phase 2 Trial of Auxora for the Treatment of Severe Acute Kidney Injury

On February 13, 2024, the Company announced the clearance of its Investigational New Drug application ("IND") by the U.S. Food and Drug Administration ("FDA") for the Company's lead product candidate, Auxora, a potent and selective small molecule inhibitor of Orai1-containing calcium release-activated calcium channels, to be evaluated in a Phase 2 trial in acute kidney injury ("AKI") with associated acute hypoxemic respiratory failure ("AHRF"). The Company expects to initiate the trial, named KOURAGE, in the first half of 2024 with data expected in 2025.

AKI is classified as stages 1, 2 and 3 depending on the degree of kidney injury. In the presence of AHRF, stage 2 and stage 3 AKI, both classified as severe, put patients at a 50% or greater risk for death while hospitalized and in the 90 days after discharge. Survivors of severe AKI may develop or progress to chronic kidney disease, leading to an eventual need for dialysis. There are approximately 1.1 million patients in the United States suffering from stage 2 and 3 AKI over half of whom have associated AHRF. There are currently no approved therapies for 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"). Patients will be stratified by classification of stage of AKI as well as the use of IMV. Patients will receive either a four-hour infusion of Auxora or placebo at 1.25 mL/kg as a first dose, after which they will receive Auxora or placebo at 1.0 mL/kg at hours 24, 48, 72 and 96. The primary endpoint of the trial will be evaluation of patients through day 30 to determine days alive, ventilator-free and dialysis-free. Secondary endpoints will include a composite of all-cause mortality, decrease in estimated glomerular filtration rate ("eGFR"), and the incidence of dialysis over a period of 90 days, also known as MAKE-90 (Major Adverse Kidney Events at 90 days).

AKI is a common consequence of severe COVID-19 pneumonia and in the Company's CARDEA trial, which studied Auxora in patients with severe and critical COVID-19 pneumonia, results showed a nearly 40% reduction in reported AKI in Auxora-treated patients as compared to placebo-treated patients. In a post-hoc analysis of CARDEA patients with compromised kidney function (eGFR$\leq$ 60 mL/min/1.73 m^2) at enrollment, the drug was well tolerated and there was a survival benefit for patients treated with Auxora compared to those on placebo. Biomarker analysis from blood samples taken from over 190 CARDEA patients showed that Auxora increased Angiopoietin-1 while decreasing Angiopoietin-2, suggesting stabilization of the endothelium and the potential to treat AKI. Finally, published work from others showed that elevated serum IL-17 levels, a CRAC channel-mediated cytokine, were differentially elevated in critically ill patients with stage 2 and 3 AKI when compared to those without AKI, and the elevation was independently associated with both hospital mortality and long-term adverse outcomes.

The Company's initial pre-clinical studies in an ischemia/reperfusion injury ("IRI") model of AKI were encouraging. A single dose of Auxora after IRI increased GFR by 61% and decreased mononuclear (inflammatory) cell infiltration by 30%. Further details from this study and results from the Company's more recent pre-clinical study of multiple doses of Auxora given over several days and initiated after a greater time interval following IRI were also very strong and will be presented at the 29th International AKI & Continuous Renal Replacement Therapy Conference taking place March 12-15, 2024 in San Diego, CA.

Pipeline and Corporate Updates

On February 13, 2024, the Company provided the following updates to its pipeline for its product candidates:

- data is expected in the first half of 2024 for the Company's Phase 2b CARPO trial of Auxora in acute pancreatitis ("AP") with accompanying systemic inflammatory response syndrome ("SIRS");
- data is expected in the second half of 2024 for the investigator-sponsored Phase 1/2 CRSPA trial of Auxora in pediatric patients with asparaginase-induced pancreatic toxicity ("AIPT") as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase;
- data is expected in the first half of 2024 for the Company's Phase 2 biomarker clinical trial of Auxora in mechanically ventilated COVID-19 pneumonia patients with acute respiratory distress syndrome ("ARDS");
- the Company plans to submit an IND to the FDA in the second half of 2024 for the Company's oral candidate (CM6336) for the treatment of chronic pancreatitis; and
- the Company plans to submit an IND to the FDA in the second half of 2024 for the Company's oral candidate (CM6336) for the treatment of rheumatoid arthritis.

In addition, following the completion of the previously announced private placement transaction, the Company expects to have a cash runway into the second half of 2025.

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 regarding the Company's planned and ongoing clinical trials and the timing, design, expected patient enrollment and timing for the release of data thereof, including its planned Phase 2 clinical trial of Auxora in AKI with associated AHRF, its ongoing Phase 2b CARPO trial of Auxora in AP with accompanying SIRS, its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with AIPT; the potential benefits of Auxora for the treatment of AKI; the estimated patient population in the United States for AKI; plans to present results from the Company's pre-clinical studies in an ischemia/reperfusion injury model of AKI at the 29th International AKI & Continuous Renal Replacement Therapy Conference; the Company's development plans for Auxora; the Company's plans to submit IND applications to the FDA for its oral candidate CM6336 for the treatment of chronic pancreatitis and rheumatoid arthritis and the timing thereof; and the Company's expectations regarding its cash runway. 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 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; 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" and elsewhere in the Company's most recent filings with the SEC, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 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

Exhibit Number	Description
99.1	Corporate Presentation of the Company, dated February 2024.
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.

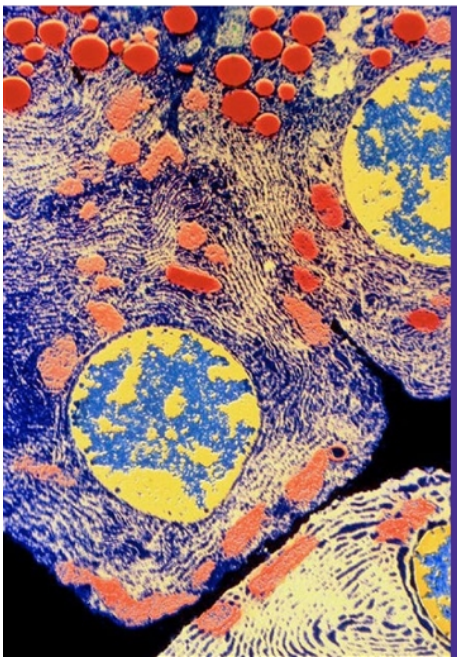
Date: February 13, 2024

CalciMedica, Inc.

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

Exhibit 99.1

CalciMedica



Developing Novel Therapies for Acute Inflammatory and Immunologic Diseases

February 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; the timing for CalciMedica's receipt and announcement of data from its clinical trials; 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; 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 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. These documents can be accessed on CalciMedica's web page at 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

Differentiated Technology	Proprietary technology targeting CRAC channel inhibition to develop novel therapies for life-threatening inflammatory diseases with high unmet need
Compelling Proof-of-Concept Data	Auxora has demonstrated positve, consistent clinical results and was well tolerated in multiple Phase 2 trials: notably, the 284-patient **CARDEA** trial in COVID pneumonia patients showed a **56% reduction in 30-day mortality**
Substantial Market Opportunity	~100K target AP population and ~1 million target AKI population represent $ multi-billion U.S. market opportunities with no approved therapies
Strong IP	Composition of matter (2036), formulation (2038), and methods of use (2036-2041+) worldwide patent protection
Cash to Fund Clinical Programs	Completed private placement in 1Q24 which is expected to fund the ongoing CARPO Phase 2b trial in AP patients with data expected in 1H24 and KOURAGE Phase 2 trial in AKI patients with data expected in 2025

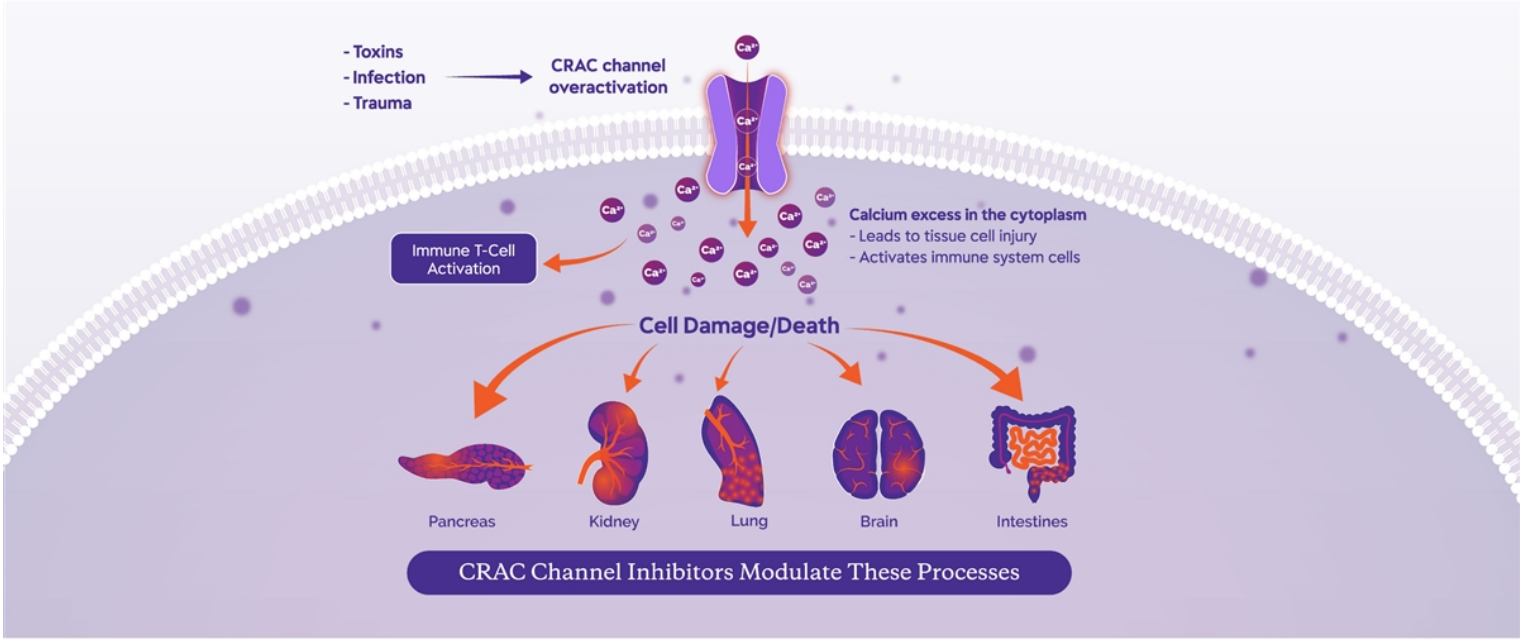
Notes: CRAC: Calcium release-activated calcium; AP: Acute Pancreatitis; AKI: Acute Kidney Injury

Differentiated Pipeline in Acute and Chronic Inflammatory and Immunologic Diseases

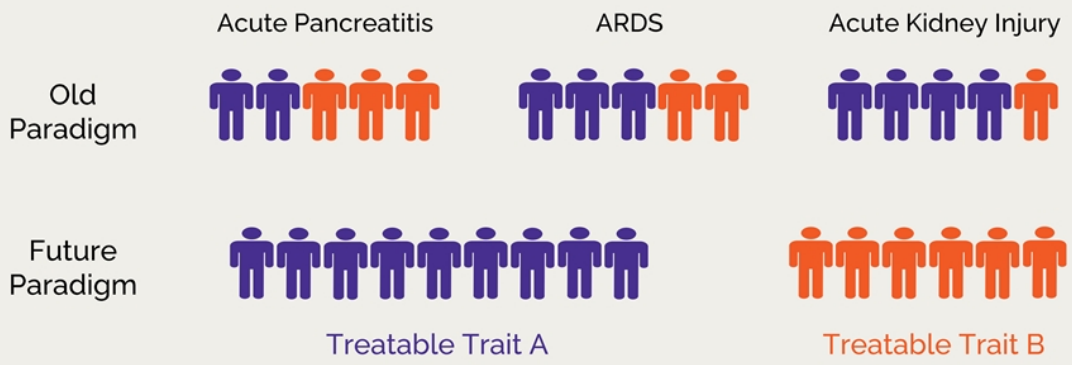
Program[1]	Indication	Phase of Development				Anticipated Milestones
		Preclinical	Phase 1	Phase 2	Phase 3	
Acute Disease (IV)						
Auxora	Acute Pancreatitis					CARPO Phase 2b trial ongoing; Data expected in 1H24
Auxora	Asparaginase-Induced Pancreatic Toxicity in Pediatric Patients					CRSPA Phase 1/2 trial ongoing; Data expected in 2H24
Auxora	Acute Kidney Injury					KOURAGE Phase 2 trial first patient expected 1H24; Data expected in 2025
Auxora	ARDS - Ventilated COVID-19 Patients					Data expected 1H24; Will inform the development plan for ARDS
Chronic Disease (Oral)						
CM6336	Chronic Pancreatitis					Submit IND in 2H24
CM6336	Rheumatoid Arthritis					Submit IND in 2H24

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

Overactivation of CRAC Channels:
Immune System Activation and Tissue Cell Injury



Acute Inflammation: Underlying Cause Across Many Diseases

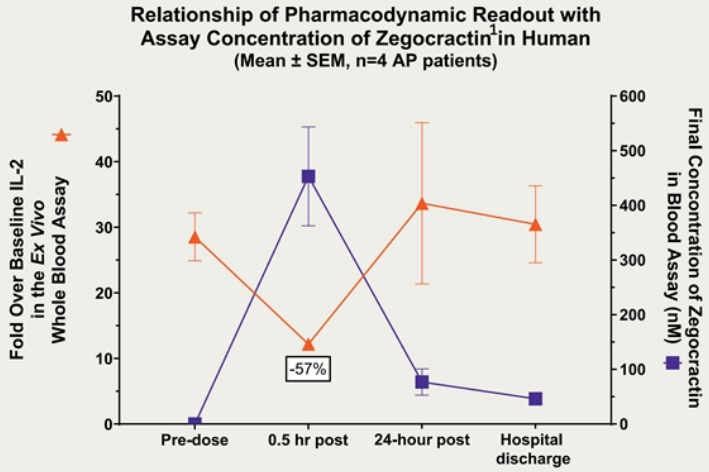


Auxora has demonstrated positive clinical results in all 3 of these large, underserved patient populations

1) Sources: Reddy, Kiran, Carolyn S. Calfee, and Danny F. McAuley. "Acute respiratory distress syndrome subphenotypes beyond the syndrome: a step toward treatable traits?." American Journal of Respiratory and Critical Care Medicine 203.12 (2021): 1449-1451.

IV Formulation Provides 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 limits the potential for long-term immunosuppression

1) Zegocractin is the active pharmaceutical ingredient in Auxora

Demonstrated Biological Activity and was well tolerated in Multiple Phase 2 Trials

Population	Results
Pancreas	
Asparaginase- Inducted Pancreatic Toxicity	• Trial ongoing, preliminary results show rapid resolution of pain and food tolerance
Acute Pancreatitis With SIRS	• Trial ongoing
Acute Pancreatitis[1]	• Target engagement of CRAC channels in peripheral lymphocytes
Acute Pancreatitis[1] Accompanied by SIRS and Hypoxemia	• Rapid increase in patients tolerating solid diet (potential trial pivotal endpoint) • >2-day reduction in hospital stay and 50% reduction SIRS
Lung	
COVID-19 with Respiratory Failure on LFO_2[2] and HFNC[3]	• 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
COVID-19 with Respiratory Failure on IMV[4]	• Open-label trial with varying doses showing pharmacodynamic response

1) Completed Phase 1 trials in healthy volunteers showed no evidence of dose-dependent safety or tolerability findings through 365 days
2) LFO_2: Low Flow Oxygen; 3) HFNC: High-Flow Nasal Cannula; 4) IMV: Invasive Mechanical Ventilation

Large U.S. Market Opportunity in Acute Inflammatory Diseases

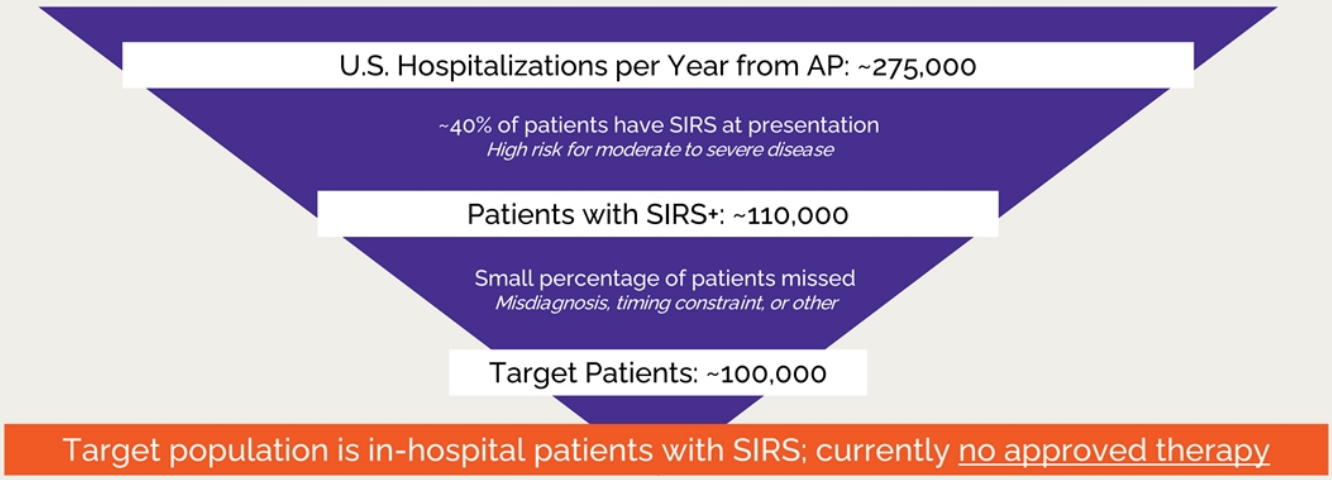
AP with SIRS[1]	AKI Stages 2 & 3	AIPT
		
• No approved therapies • SOC[2] primarily supportive care • Disease progression: ➢ Severe AP ➢ Pancreatic necrosis ➢ Mortality	• No approved therapies • SOC primarily supportive care • Disease progression: ➢ Chronic kidney disease ➢ End stage renal disease ➢ Mortality	• 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[3]

1) SIRS: Systemic Inflammatory Response Syndrome; 2) SOC: Standard of Care; 3) Sources: Primary Market Research, KOLs, Healthcare Cost and Utilization Project, Pancreatitis Foundation, and https://www.hcup-us.ahrq.gov/reports/statbriefs/sb231-Acute-Renal-Failure-Hospitalizations.pdf
Criteria: Based on RIFLE staging criteria for AKI classification; Serum creatinine increase over baseline

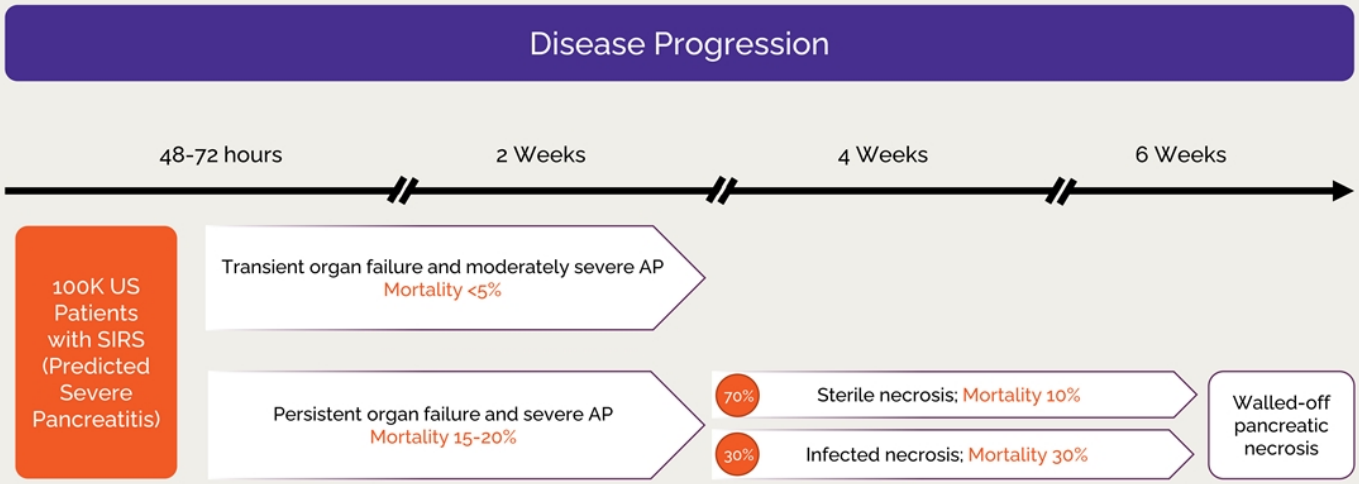
Auxora for Acute Pancreatitis (AP)

AP Population: Significant Unmet Need



1) Source: Fletcher Spaght Market Research Report (2016)

Patient Journey in Severe AP



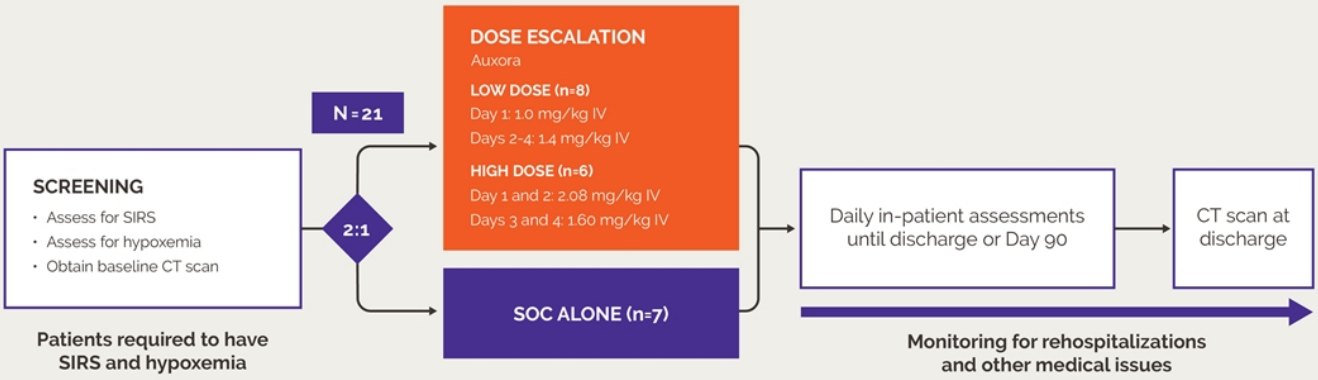
1) Source: Adapted from N Engl J Med 2016;375:1972-81. DOI: 10.1056/NEJMra1505202

Potential Clinical Benefits to Patients with Predicted Severe AP

Current standard of care is limited to supportive therapy	• Fluid resuscitation • Enteral nutrition for food tolerance • Antibiotics for infection • Minimally invasive therapy for local complications
Auxora benefits are expected to drive adoption	• Reduction in organ failure • Reduction in pancreatic necrosis • Earlier food tolerance • Fewer days in hospital or ICU

AP Phase 2a Clinical Trial

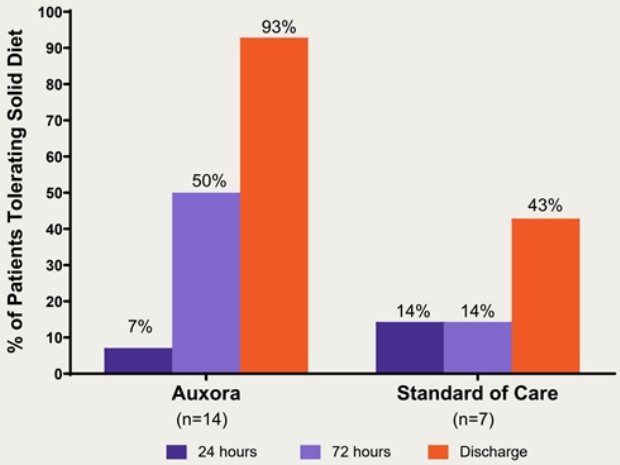
Safety, tolerability, and efficacy trial for various doses of Auxora compared to standard of care



Positive Phase 2a Results on Potential Pivotal Trial Primary Endpoints

Rapid Increase in Patients Tolerating Solid Diet

Potential Pivotal Trial Primary Endpoint



>2 Fewer Days Spent in Hospital

Median Hospital Stay	
SOC patients (n=7)	6.0 days
Auxora-treated patients (n=14)	3.7 days

Only Auxora Patients Improved on CTSI[1] Scores

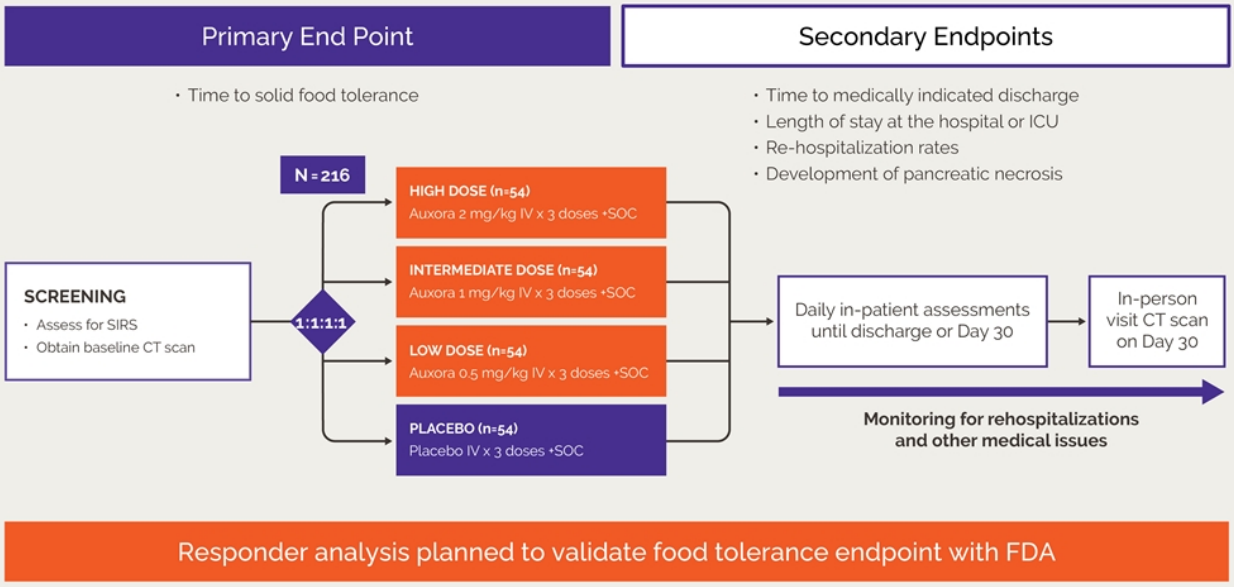
Moderate to Severe CTSI[1] Scores	
SOC patients (n=4)	0/4 (0%)
Auxora-treated patients (n=8)	3/8 (38%)

50% Reduction in Persistent SIRS

Patients with Persistent SIRS	
SOC patients (n=7)	5/7 (71%)
Auxora-treated patients (n=14)	5/14 (36%)

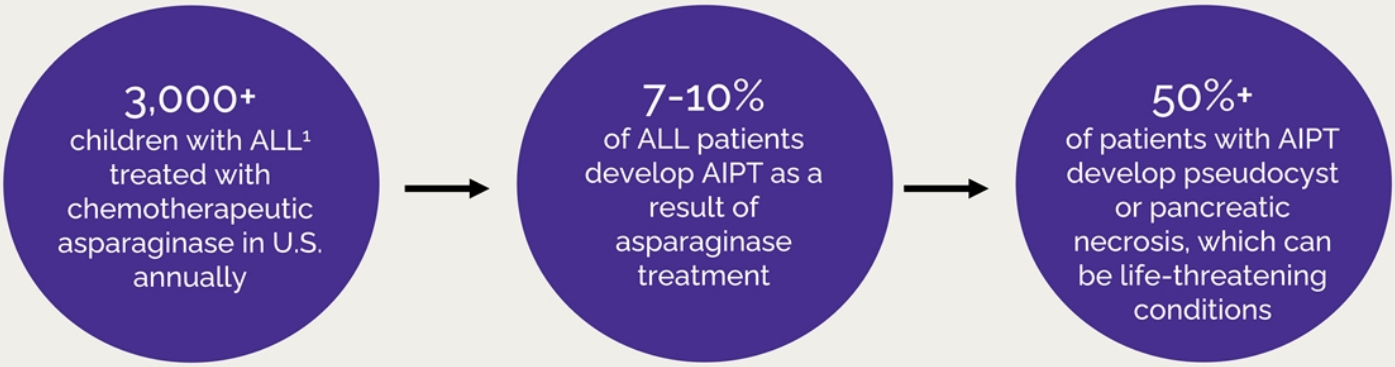
1) CTSI: CT Severity Index

CARPO Phase 2b Clinical Trial in AP
Ongoing with Data Expected 1H 2024



Responder analysis planned to validate food tolerance endpoint with FDA

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

1) ALL: Acute Lymphoblastic Leukemia
2) Sources: Liu C, Yang W, Devidas M, et al. Clinical and Genetic Risk Factors for Acute Pancreatitis in Patients With Acute Lymphoblastic Leukemia. J Clin Oncol. 2016. Abaji R, Gagne V, Xu CJ, et al. Whole-exome sequencing identified genetic risk factors for asparaginase-related complications in childhood ALL patients. Oncotarget. 2017;8: 43752-43767. Rank C, Wolthers B, Grell K, et al. Asparaginase-associated pancreatitis in acute lymphoblastic leukemia: results from the NOPHO ALL 2008 treatment of patients 1-45 years of age. J Clin Oncol. 2019 38:145-154.

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 pancreatis 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 2H24

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

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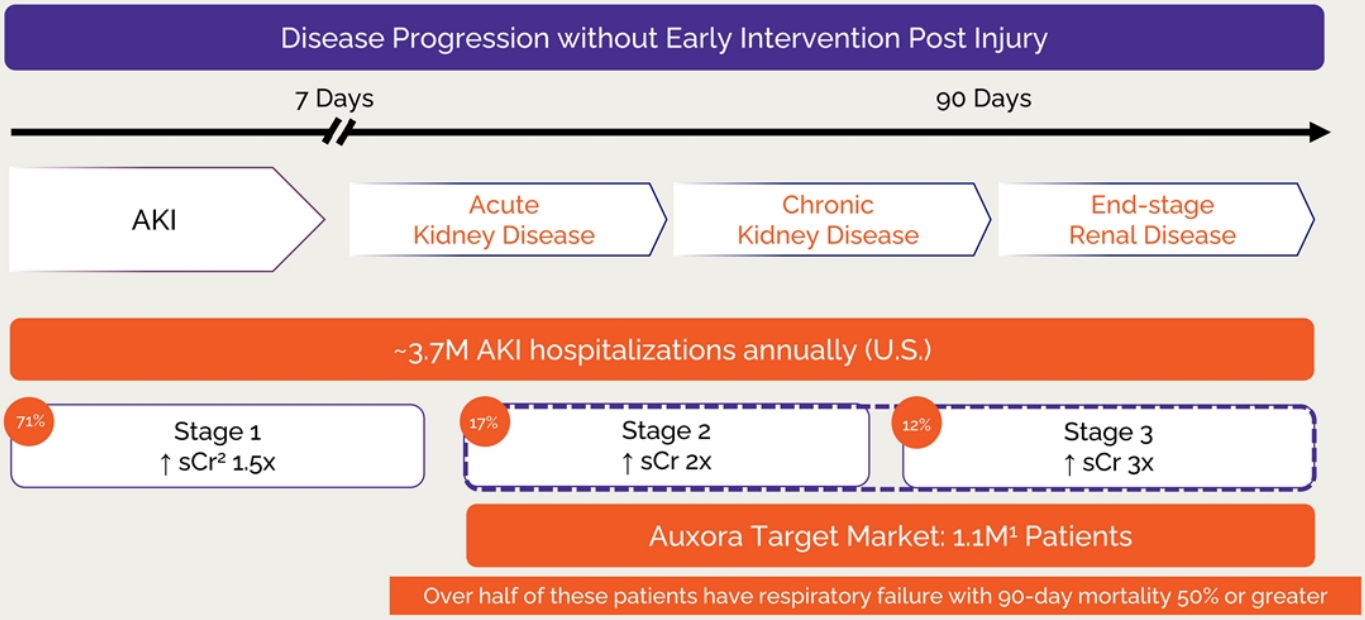
Source: Seth Karol et al., Zegocractin to reduce the severity of asparagine-associated pancreatitis in children with acute lymphoblastic leukemia: results of the Phase 1 portion of the CRSPA study, ASH Poster #2837, December 2023.

Auxora for Acute Kidney Injury (AKI)

Patient Journey in AKI



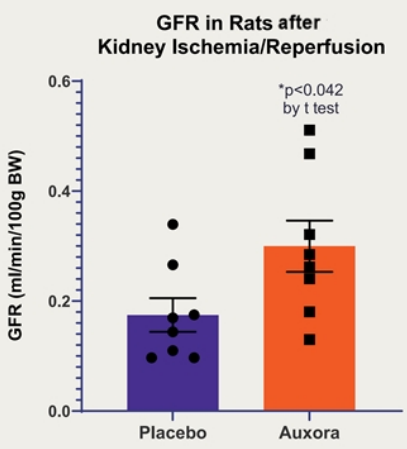
1) Source: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb231-Acute-Renal-Failure-Hospitalizations.pdf
Criteria: Based on RIFLE staging criteria for AKI classification; Serum creatinine increase over baseline
2) sCr: Serum Creatinine

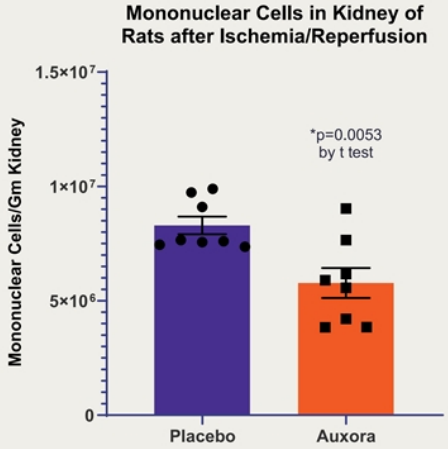
Potential Clinical Benefits to Patients with AKI

Current standard of care is limited to supportive therapy	• Fluid resuscitation / Diuretics • Nutrition • Correction of underlying cause
Auxora benefits are expected to drive adoption	• Reduced need for dialysis • Reduced risk of mortality • Greater recovery of renal function

Improved GFR[1] and Decreased Inflammatory Cell Infiltrates Within 24 Hours in AKI Model

A single dose of Auxora or placebo was administered 30 min after bilateral kidney ischemia/reperfusion



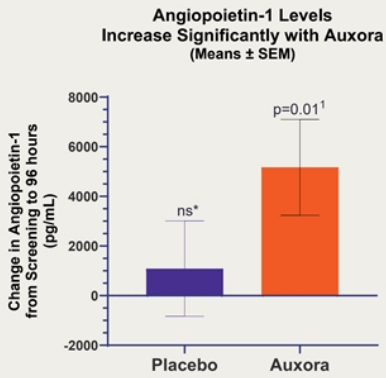


Recent studies with 3-day Auxora or Placebo dosing initiated 6 hours following ischemia/reprofusion will be presented in March 2024 at the 29th International AKI and CRRT Conference

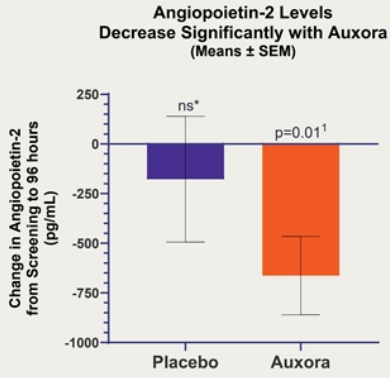
1) GFR: Glomerular filtration rate
2) Data courtesy of David Basile, PhD, Indiana University

Phase 2 CARDEA Trial: Evidence of Renal Protection

Ang-1/Tie2 signaling maintains vascular integrity



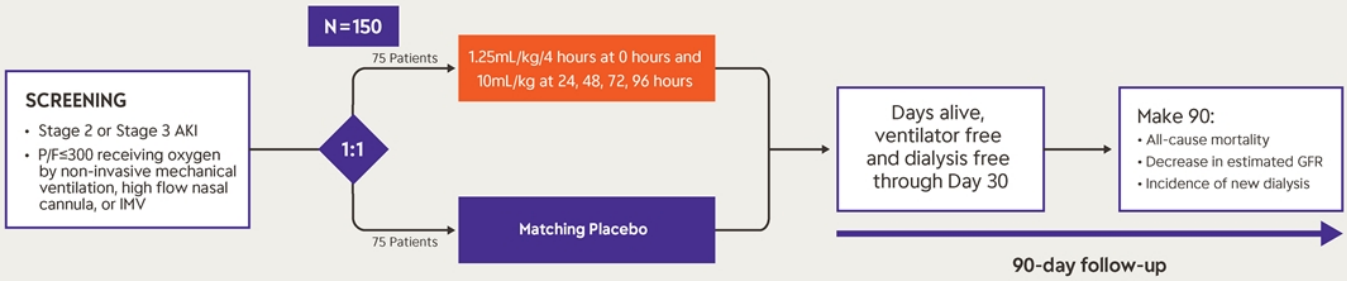
Ang-2/Tie2 results in endothelial inflammation with increased endothelial permeability



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 Ongoing; Data Analysis Underway • Reduction in inflammatory cell-type gene expression by macrophages in lungs • No reduction in mitochondrial and ribosomal gene expression

Data Analysis of Biomarker and Mechanism-of-Action in Ventilated Patients to Inform Development Plan for ARDS expected in 1H24

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

Anticipated Milestones

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AP	CARPO Phase 2b Data Expected in 1H24 Phase 3 Initiation Expected in 2025
AIPT	CRSPA Initial First Cohort Data Released at ASH 2023 Trial Expansion Underway; Completion Expected 2H24
AKI	KOURAGE First Patient Enrolled Expected in 1H24 Data Expected in 2025
ARDS	Phase 2 Data in Ventilated COVID Patients Publication Expected in 1H24 Will Inform the Development Plan for ARDS
Cash Runway	Current Cash Runway into 2H25