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 14, 2023
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 June 14, 2023, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Corporate Presentation of the Company, dated June 2023.
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.

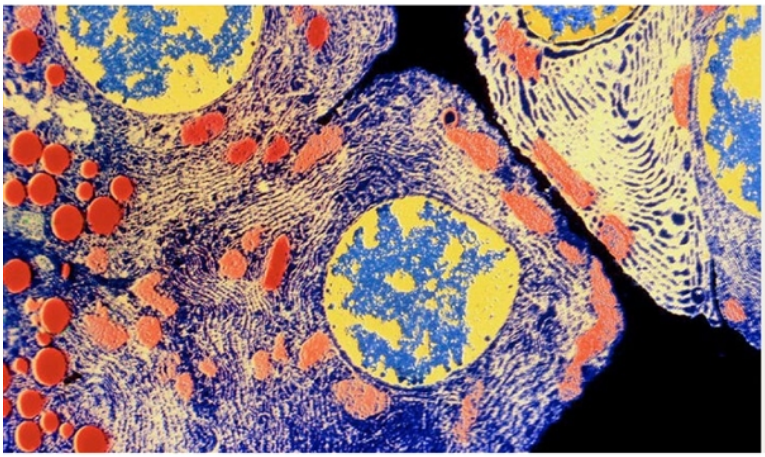
Date: June 15, 2023

CalciMedica, Inc.

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

Exhibit 99.1

CalciMedica



CalciMedica

Developing First-in-Class Therapies for Acute Inflammatory Diseases with High Unmet Need

June 2023

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; and the timing for CalciMedica's receipt and announcement of data from its clinical trials. 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.

CalciMedica is Building a Leading Company Dedicated to Treating Life-threatening

Differentiated Technology	Proprietary technology targeting CRAC channel inhibition to develop first-in-class therapies for life-threatening inflammatory diseases with high unmet need
Compelling Proof-of-Concept Data	Auxora has been studied in **four completed efficacy trials**, demonstrating positive and consistent clinical results and favorable safety profile
Attractive Lead Indication	~100K target patient population in acute pancreatitis represents a potential $1B+ U.S. market opportunity, with no approved therapies
Next Clinical Milestones	**Acute Pancreatitis (AP)** Phase 2b Data **Asparaginase-Induced Pancreatic Toxicity (AIPT)** Phase 1/2 Data **Acute Kidney Injury (AKI)** IND/Phase 2 (Trial pending additional funding)
Strong IP	Composition of matter (2036), formulation (2038), and methods of use (2036-2041+) worldwide patent protection

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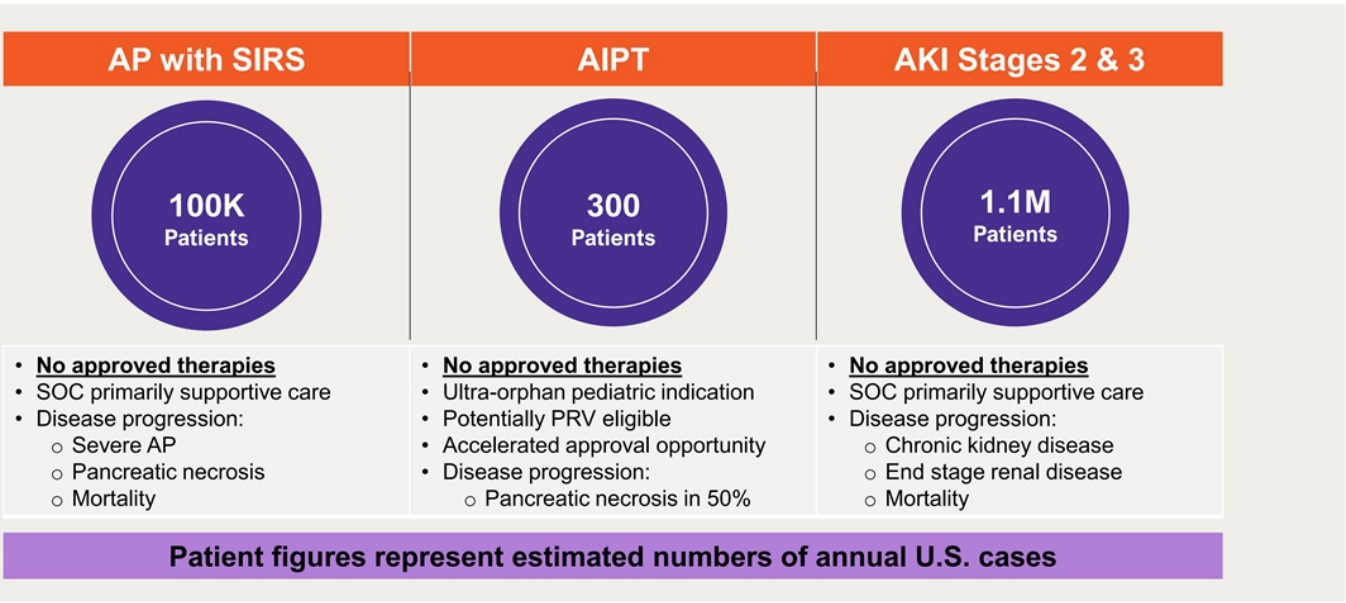
CRAC: Calcium release-activated calcium

Differentiated Pipeline Addressing Significant Unmet Patient Needs

Program[1,2]	Indication	Phase of Development				Anticipated Milestones
		Preclinical	Phase 1	Phase 2	Phase 3	
Pancreas						
Auxora™	Acute Pancreatitis					CARPO Phase 2b Trial Ongoing Data in 1H24
Auxora™	Asparaginase-Induced Pancreatic Toxicity					CRSPA Phase ½ Trial ongoing Trial Expansion Underway
CM6018	Chronic Pancreatitis (Oral)					Submit IND in 2024 (pending funding)
Kidney						
Auxora™	Acute Kidney Injury					Submit IND 2H23 Phase 2 Trial in 1H24 (pending funding)
Lung						
Auxora™	ARDS – Ventilated COVID-19 Patients					Data Publication expected 2H23 Will inform the development plan for ARDS

1 Programs in pancreatitis except chronic pancreatitis are funded through steps indicated. Other studies and programs are subject to further funding.
2. All programs are IV for rapid onset in the acute care setting; CM6018 is intended for chronic oral dosing.

Market Opportunity for Auxora Across Acute Inflammatory Diseases



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AP with SIRS: Acute Pancreatitis with systemic inflammatory response syndrome; **AIPT:** Asparaginase-Induced Pancreatic Toxicity; **PRV**: Priority Review Voucher; **AKI**: Acute Kidney Injury; **SOC**: Standard of Care
Sources: Primary Market Research, KOLs, Healthcare Cost and Utilization Project, Pancreatitis Foundation

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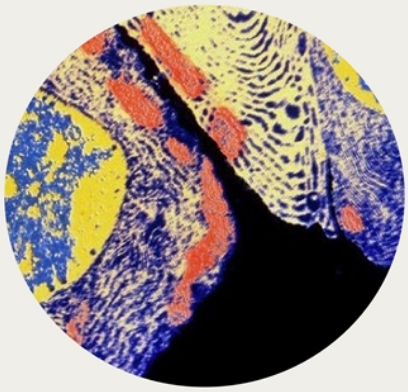
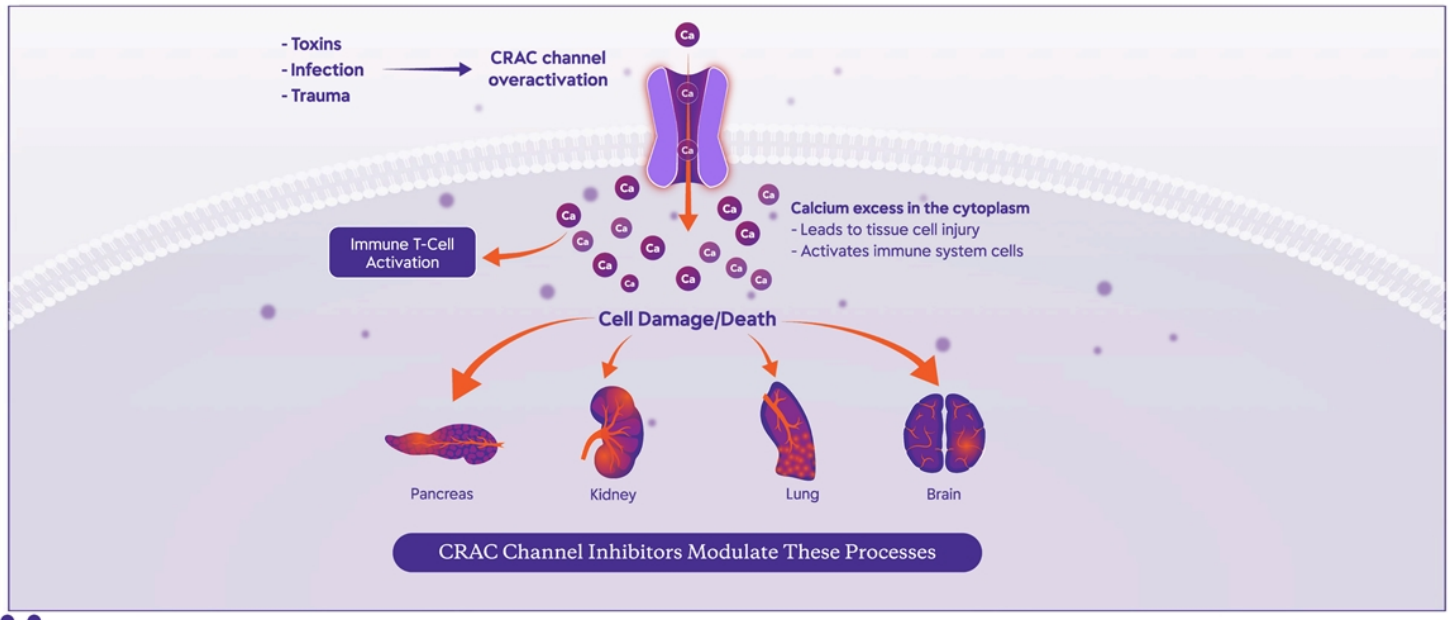
Auxora's MOA Addresses Multiple Acute Inflammatory Diseases



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



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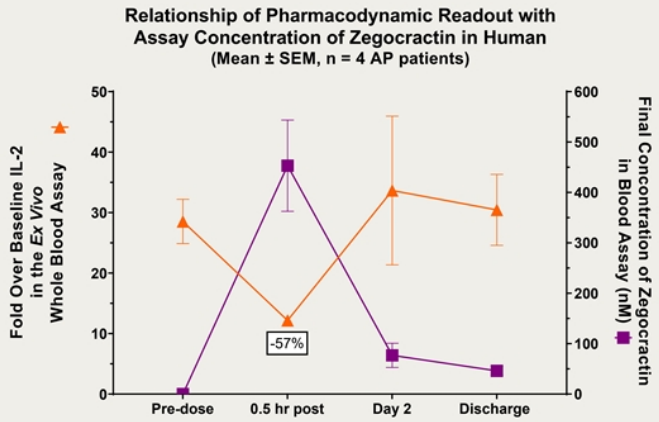
Proprietary IV Formulation Provides Rapid Onset of Action Without Long-Term Risk of Immune-Suppression

Auxora IV Formulation: Ideal Characteristics for Acute Care Setting



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 immunosuppression

Auxora Has Demonstrated Biological Activity and Favorable Safety Profile in Two Ongoing and Four Completed Phase 2 Trials

Population	Trial Size	Results
Pancreas		
Asparaginase-Associated Pancreatitis	N=9	• Trial ongoing, preliminary results show rapid resolution of pain and food tolerance
Acute Pancreatitis	N=216 Planned	• Trial ongoing
Acute Pancreatitis*	N=7	• Target engagement of CRAC channels in peripheral lymphocytes
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
Lung		
COVID-19 with **Respiratory Failure** on LFO_2 and HFNC	N=314	• 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	N=9	• Open-label trial with varying doses showing pharmacodynamic response

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* Completed Phase 1 trials in healthy volunteers showed no evidence of dose-dependent safety or tolerability findings through 365 days

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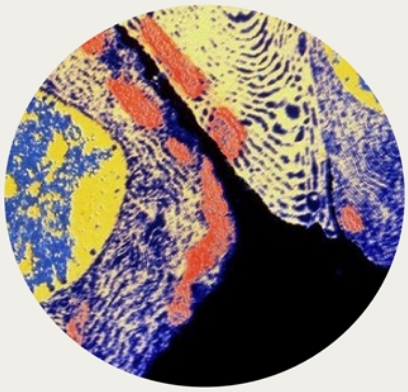
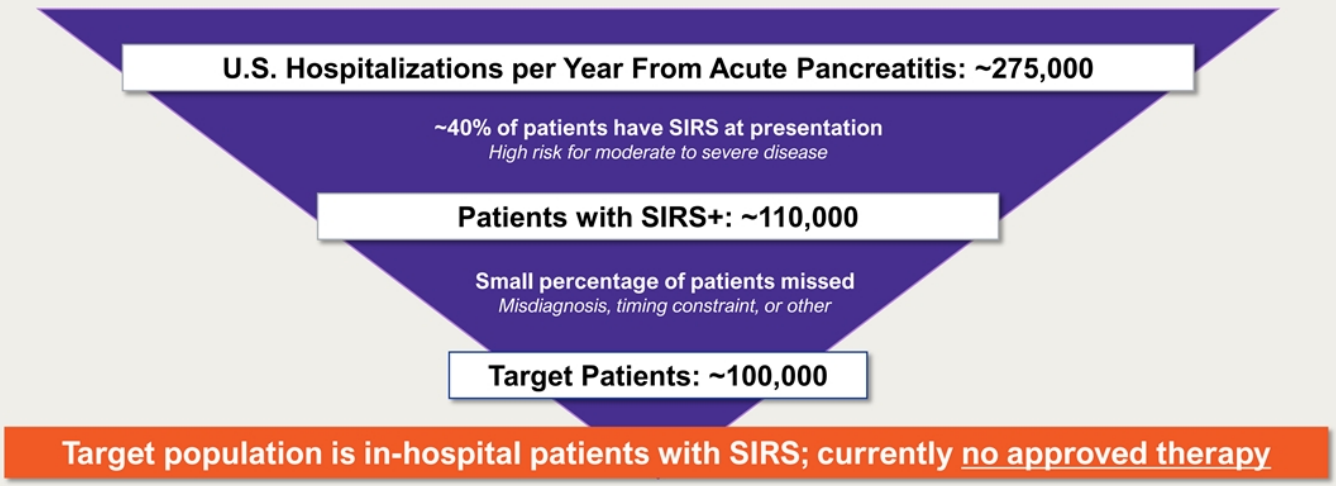
Auxora for Acute Pancreatitis



Significant Unmet Need in Treatment of Acute Pancreatitis



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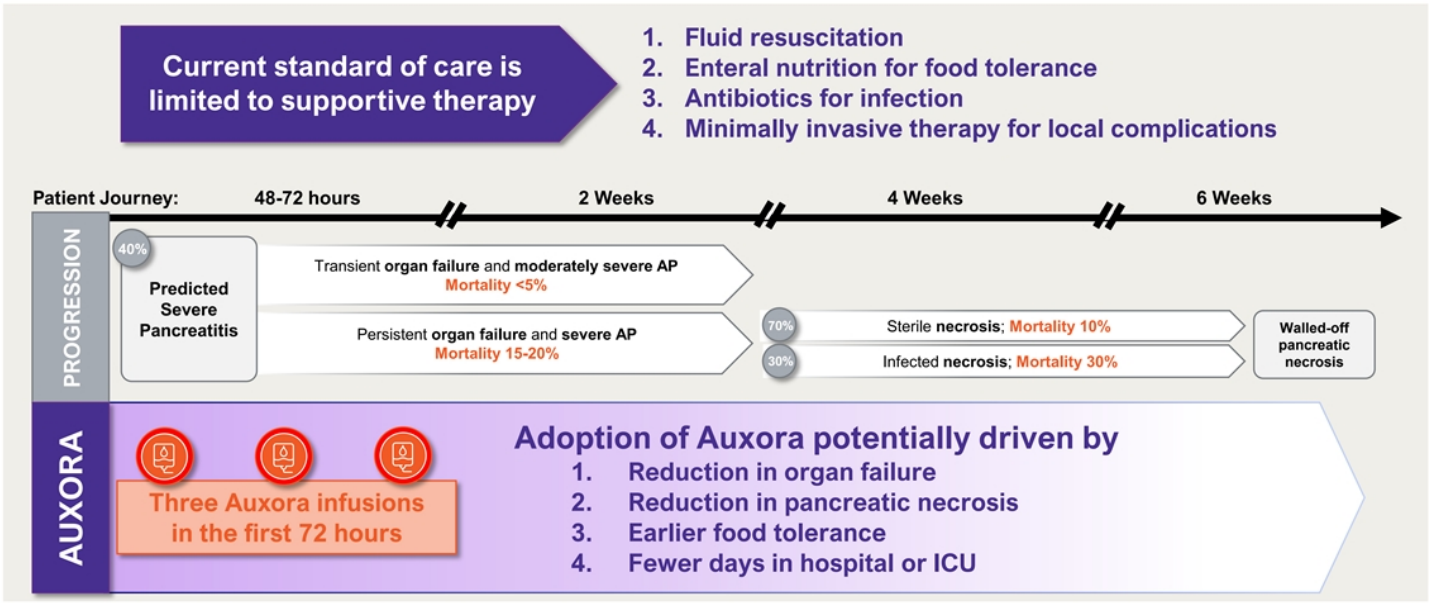
SIRS: Systemic inflammatory response syndrome
Fletcher Spaght Market Research Report (2016)

Potential to Offer Significant Clinical Benefits to Patients with Predicted Severe AP



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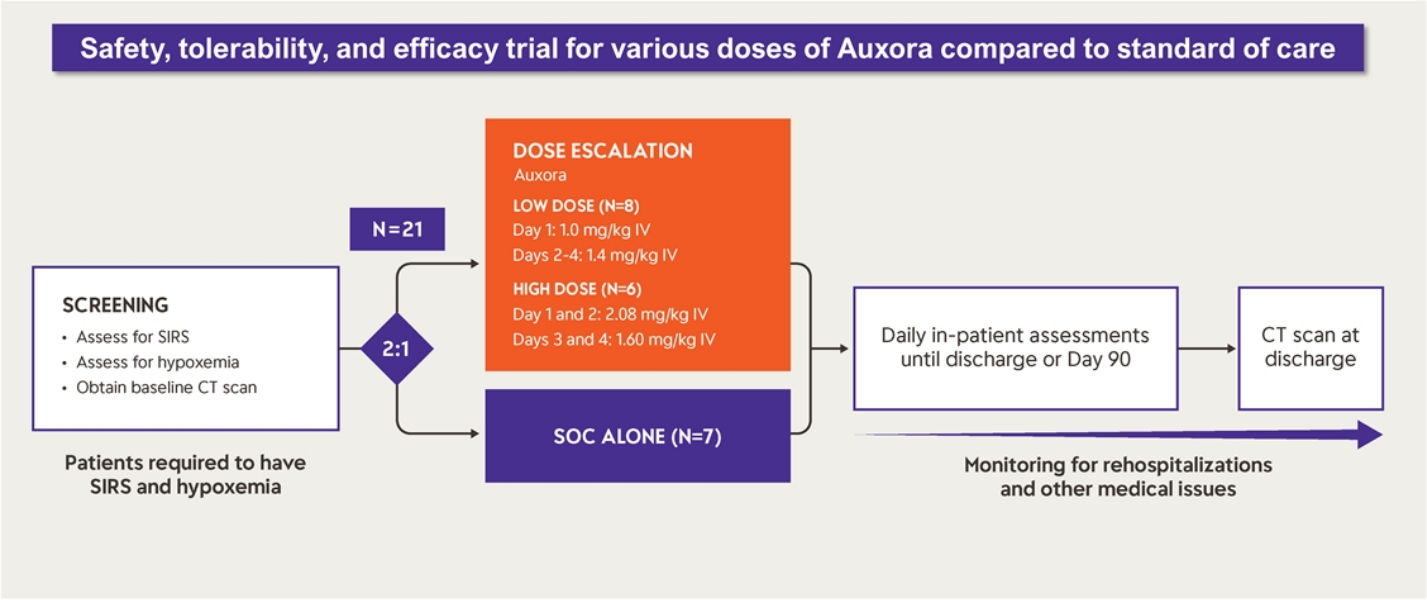
Adapted from N Engl J Med 2016;375:1972-81. DOI: 10.1056/NEJMra1505202

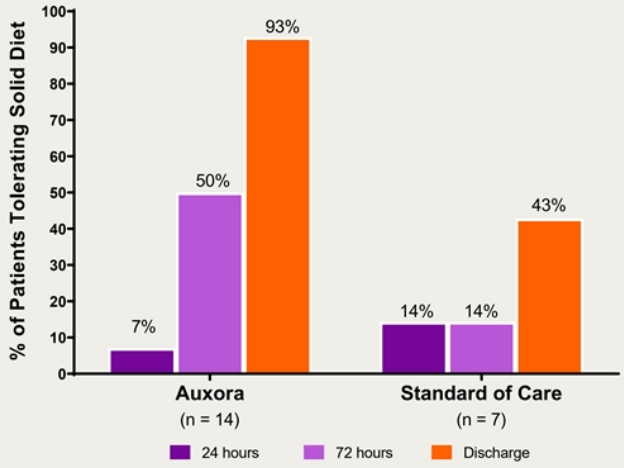
Acute Pancreatitis Phase 2a Clinical Trial



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 Scores

Moderate to Severe CTSI Scores	
SOC patients (n=4)	0/4
Auxora-treated patients (n=8)	**3/8**

50% Reduction in Persistent SIRS

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

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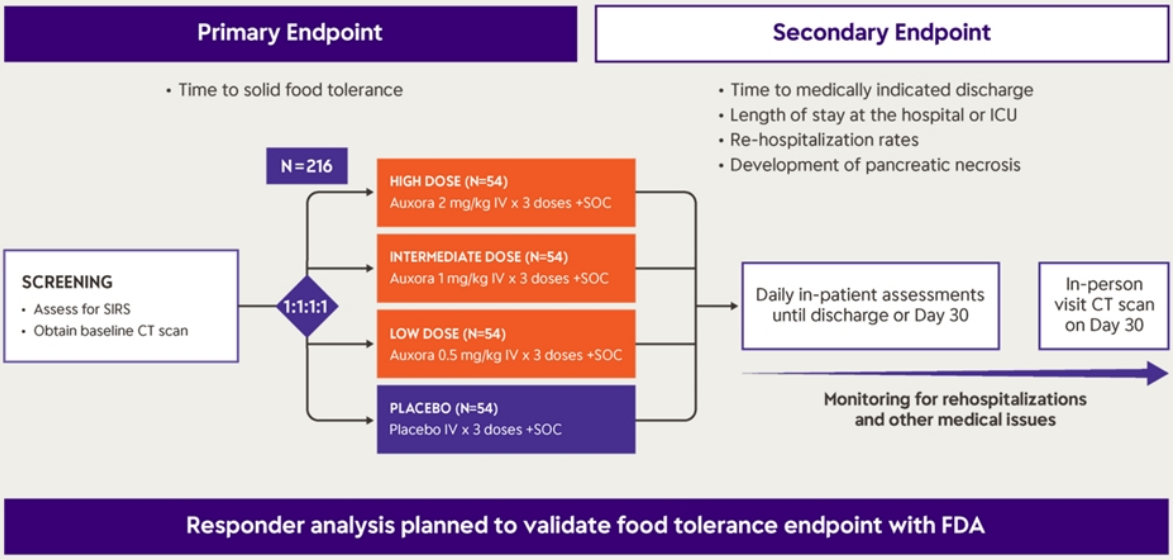
SIRS: systemic inflammatory response syndrome
CTSI: CT Severity Index

CARPO Phase 2b Clinical Trial in Acute Pancreatitis

Ongoing with Data Expected 1H 2024



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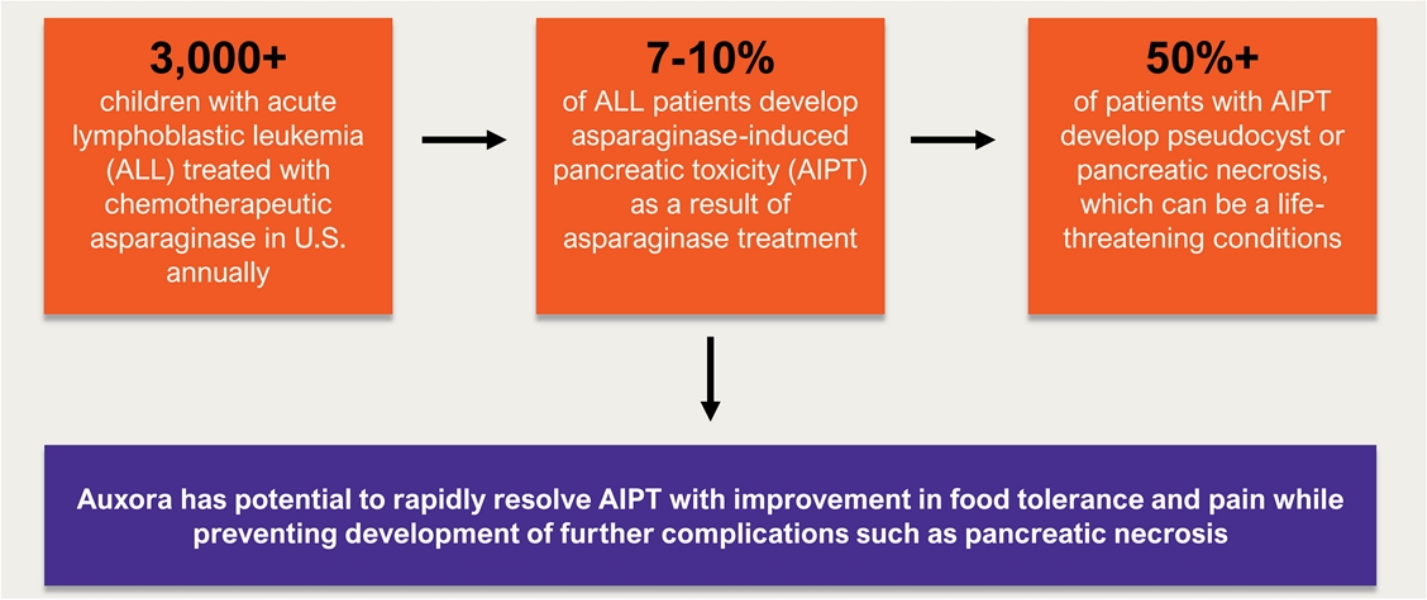
Potential to Offer Significant Clinical Benefits to Children with Asparaginase-Induced Pancreatic Toxicity



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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 ALL2008 treatment of patients 1-45 years of age. J Clin Oncol. 2019 38:145-154.

Proof-of-Concept Ongoing in AIPT

Pediatric Patients Receiving Auxora Had Rapid Resolution of Pain and Food Tolerance

- **CRSPA Phase 1/2 Trial in Pediatric Asparaginase-Induced Pancreatic Toxicity (AIPT)**
  - Investigator-initiated, open-label trial being conducted at St. Jude Children's Research Hospital
- **Trial Status**
  - Assess the safety in pediatric patients with acute lymphoblastic leukemia (ALL) who have developed AIPT
  - Estimate the efficacy of Auxora to prevent pseudocyst or necrotizing pancreatitis in pediatric patients with AIPT
  - Cohort 1 complete; **trial being expanded to additional sites and additional patients being enrolled**
- **Preliminary Results**
  - 8 patients received four daily infusions of Auxora and had rapid resolution of pain and food tolerance
  - 1 patient received less than a single infusion of Auxora and developed pancreatic necrosis

Data release planned for 4Q23

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[1]St. Jude historical database??

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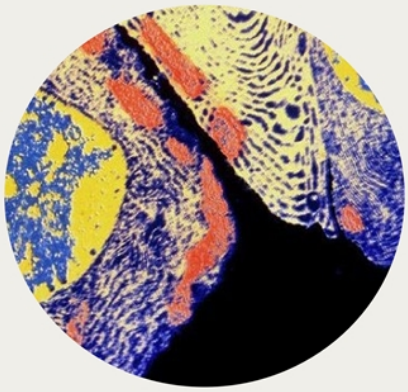
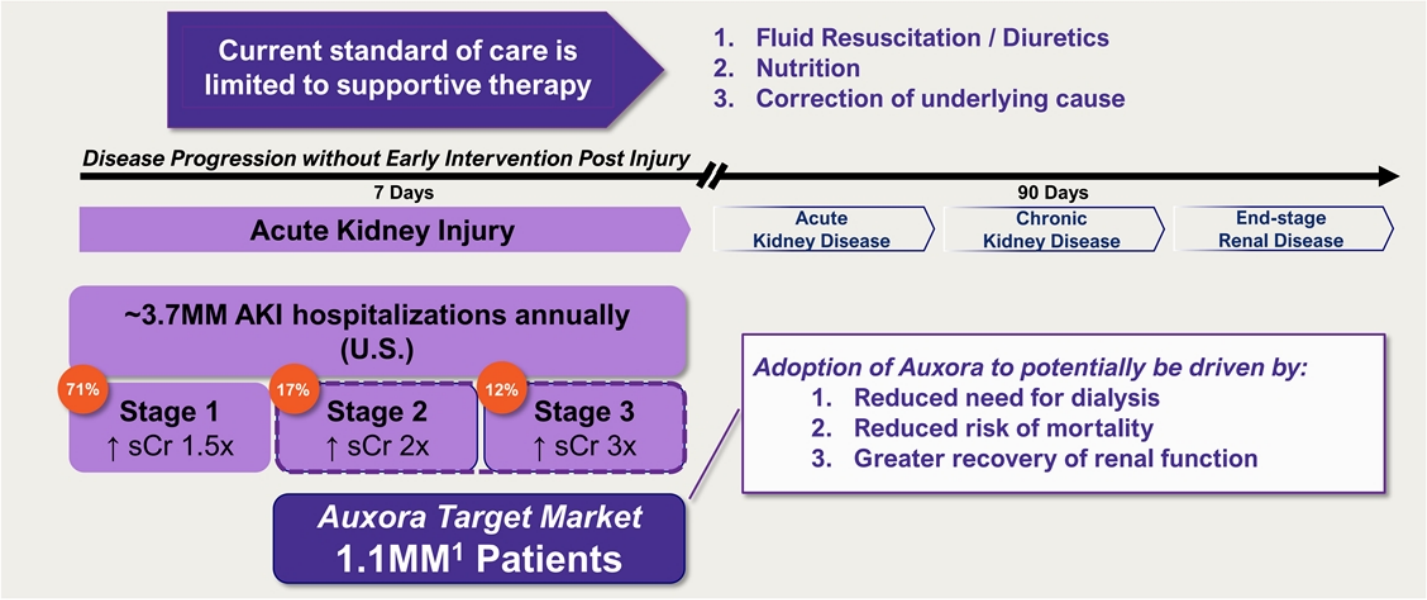
Auxora for Acute Kidney Injury



Early Treatment with Auxora Could Offer Significant Benefits to AKI Patients and Prevent Disease Progression



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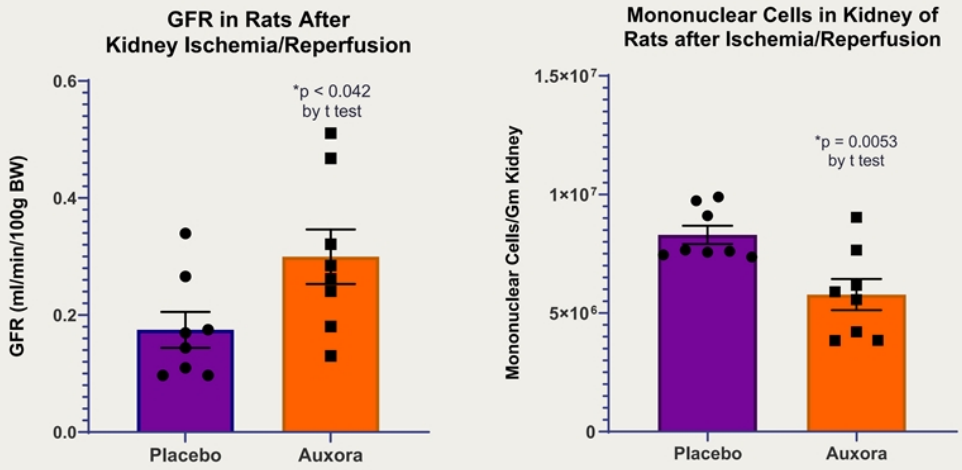
1) Source: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb231-Acute-Renal-Failure-Hospitalizations.pdf
Criteria: Based on RIFLE staging criteria for AKI classification; Serum creatinine increase over baseline
sCr: Serum Creatinine

Improved GFR* 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



Data courtesy of David Basile, PhD, Indiana University

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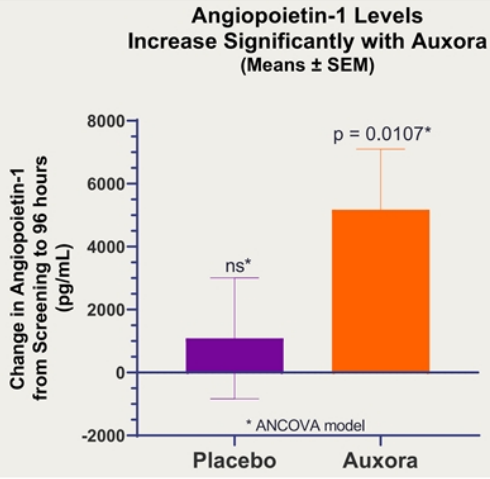
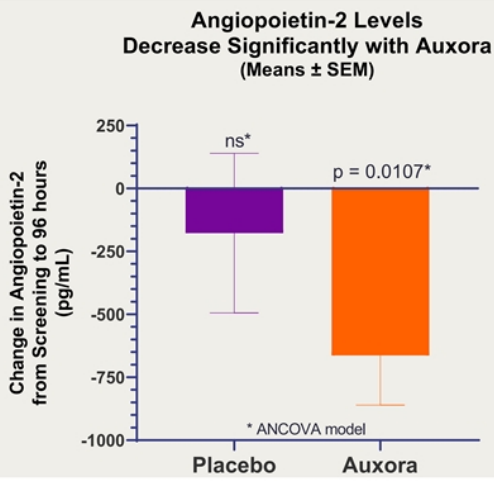
*GFR: Glomerular filtration rate

Phase 2 CARDEA Trial Showed 40% Reduction in Reported Acute Kidney Injury in COVID Pneumonia Patients

Ang-1/Tie2 signaling maintains vascular integrity



Ang-2/Tie2 results in endothelial inflammation with resulting endothelial cell activation and increased endothelial permeability



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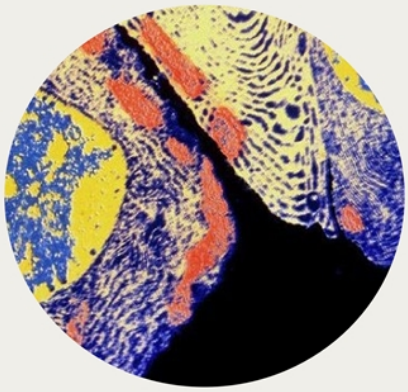
Auxora for Acute Respiratory Distress Syndrome



Clinical Evidence in Phase 2 COVID-19 Pneumonia and Ventilated Patients Demonstrate Promising Data in Respiratory Failure

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

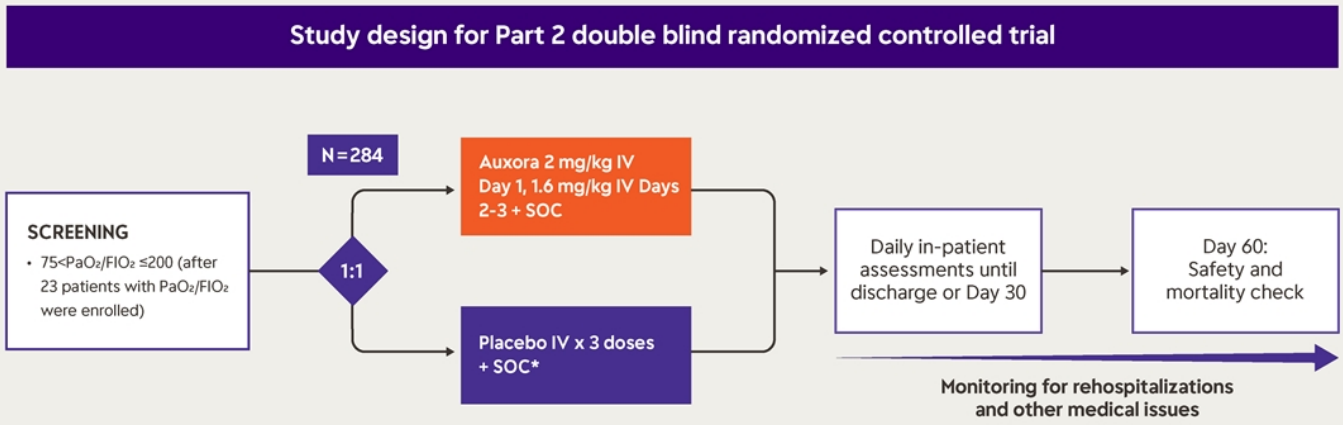
Trial Complete
- 56% reduction in mortality at Day 30 (p=0.023)
- 33% reduction ventilation (p=0.18)
- Three-day shorter hospital stay (p=0.09)

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

CARDEA Phase 2 Trial
Auxora in Severe COVID-19 Pneumonia

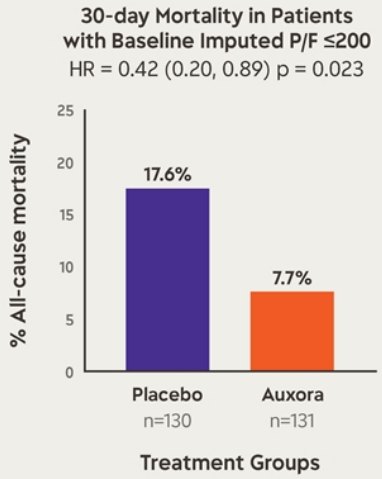


SOC INCLUDED 100% CORTICOSTEROID USE AND 99% ANTICOAGULATION USE

CARDEA Phase 2 Positive Results on Key Endpoints

Reduction in Mortality and Ventilator Use in COVID-19 Pneumonia Patients

56% Relative Risk Reduction in Mortality at Day 30 (p=0.023)



33% Relative Risk Reduction in Ventilator Use at Day 60 (p=0.18)

Ventilated Patients	
Placebo	27.5%
Auxora-treated patients	**18.5%**

>2 Fewer Days Spent in Hospital

Median Hospital Stay	
Placebo	11 days
Auxora-treated patients	**8.5 days**

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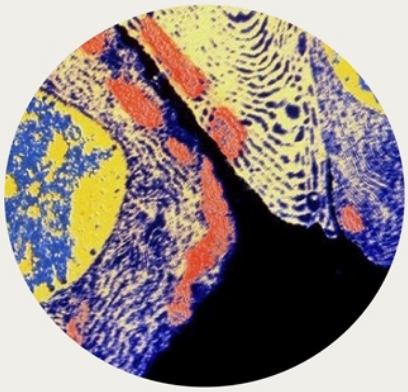
Platform Applications for CRAC Channel Inhibition



Preclinical Results Supporting Other Indications

Indication	Intended Formulation	Preclinical Observations	Next Steps
Chronic Pancreatitis (CP)	Oral	*In vivo* efficacy in a mouse model of CP using CM5480* (Submitted for publication)	Confirm with lead oral candidate
Acute Ulcerative Colitis (AUC)	IV	*In vivo* efficacy of zegocractin in a mouse model of inflammatory bowel disease (Letizia et al., 2022)	Ongoing discussions 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

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*CM5480 is a CalciMedica portfolio compound

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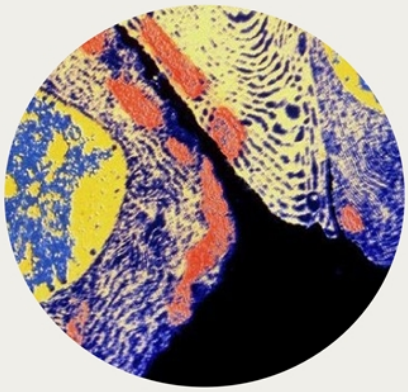
Anticipated Milestones



Existing Cash Provides Runway through 2H24 With Key Clinical Readouts by 1H24

Acute Pancreatitis	Phase 2b Data Expected in 1H24 Phase 3 Initiation Expected in 2024
Asparaginase-Induced Pancreatic Toxicity	Initial First Cohort Data Release Expected in 4Q23 Trial Expansion Underway
Acute Kidney Injury	IND filing Expected in 2H23 Phase 2 Clinical Trial Initiation 1H24 (pending funding)
ARDS	Phase 2 Data in Ventilated COVID Patients Publication Expected in 2H23 Will inform the development plan for ARDS

AIPT: Asparaginase-Induced Pancreatic Toxicity
ARDS: Acute respiratory distress syndrome