

**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**

**Date of Report (Date of earliest event reported): November 21, 2022**

**Graybug Vision, Inc.**  
(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**001-39538**  
(Commission  
File Number)

**45-2120079**  
(I.R.S. Employer  
Identification No.)

**203 Redwood Shores, Suite 620**  
**Redwood City, California**  
(Address of principal executive offices)

**94065**  
(Zip Code)

**Registrant's telephone number, including area code: (650) 487-2800**

**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 obligation 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
<b>Common Stock, \$0.0001 par value per share</b>	<b>GRAY</b>	<b>The Nasdaq Global Market</b>

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 8.01 Other Events.**

### **Investor Presentation and Conference Call Script**

On November 22, 2022, representatives of Graybug Vision, Inc. (“Graybug”) and CalciMedica, Inc. (“CalciMedica”) will hold a conference call to investors, which investor presentation and conference call script are attached hereto as Exhibit 99.1.

The investor presentation and conference call script contain statements intended as “forward-looking statements,” which are subject to the cautionary statements about forward-looking statements set forth therein.

### **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 proposed merger between Graybug and CalciMedica. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Graybug’s and 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 ability of the parties to consummate the merger and the transactions contemplated by the merger agreement in a timely manner or at all; the satisfaction (or waiver) of closing conditions to the consummation of the merger, including but not limited to those with respect to: the approval of Graybug’s stockholders; potential delays in consummating the merger, the ability of the combined company to timely and successfully achieve the anticipated benefits of the merger; and the impact of health epidemics, including the COVID-19 pandemic, or fluctuations in global financial markets on the parties’ respective businesses and the actions the parties may take in response thereto; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; the effect of the announcement or pendency of the merger on Graybug’s or CalciMedica’s business relationships, operating results and business generally; costs related to the merger; the outcome of any legal proceedings that may be instituted against Graybug, CalciMedica or any of their respective directors or officers related to the merger agreement or the transactions contemplated thereby and the ability to obtain and maintain regulatory approval for Auxora. 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 Graybug’s most recent filings with the SEC, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 and any subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from time to time and available at [www.sec.gov](http://www.sec.gov). These documents can be accessed on Graybug’s web page at <https://investors.graybug.vision/> under the SEC Filings” section.

The forward-looking statements included in this communication are made only as of the date hereof. Graybug assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

### **Important Additional Information**

In connection with the merger, Graybug intends to file with the SEC preliminary and definitive proxy statements relating to the proposed merger and any other relevant documents. The definitive proxy statement will be mailed to Graybug’s stockholders determined as of a record date, which is to be established for voting on the proposed merger and any other matters to be voted on at the special meeting. Before making any voting decision, Investors and security holders are urged to read the preliminary and definitive proxy statements, any amendments or supplements thereto, and any other documents to be filed with the SEC in connection with the proposed merger or incorporated by reference in the proxy statements when they become available because they will contain important information about Graybug, CalciMedica and the proposed merger. Investors and security holders may obtain free copies of these documents (when they are available) on the SEC’s web site at [www.sec.gov](http://www.sec.gov), on Graybug’s website at <https://investors.graybug.vision/> or by contacting Graybug’s Investor Relations via email at [IR@graybug.vision](mailto:IR@graybug.vision) or by telephone at (650) 487-2409.

### **Participants in the Solicitation**

Graybug and its directors and certain of its executive officers may be deemed participants in the solicitation of proxies from the stockholders of Graybug in connection with the proposed merger and any other matters to be voted on at the special meeting. Information regarding the names, affiliations and interests of such directors and executive officers will be included in the preliminary and definitive proxy statements (when available). Additional information regarding such directors and executive officers is included in Graybug’s definitive proxy statement on Schedule 14A for the 2022 Annual Meeting of Stockholders, which was filed with the SEC on April 22, 2022.

Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies of Graybug's stockholders in connection with the proposed merger and any other matters to be voted upon at the special meeting will be set forth in the preliminary and definitive proxy statements (when available) for the merger.

These documents are available free of charge as described in the preceding paragraph.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Investor Presentation and Conference Call Script, dated November 22, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURE**

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

**GRAYBUG VISION, INC.**

Date: November 22, 2022

By: /s/ Frederic Guerard

**Frederic Guerard, Pharm.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**



**[OPERATOR]:** Ladies and gentlemen, thank you for standing by and welcome to the Graybug and CalciMedica Merger Announcement call.

I would now like to turn the call over to Fred Guerard, Chief Executive Officer of Graybug.

**[FRED GUERARD]:** Thank you for joining us today. I'm Fred Guerard, Chief Executive Officer of Graybug Vision, and I am joined by Rachel Leheny, Chief Executive Officer of CalciMedica. Yesterday, after market close, we announced the proposed merger between our two companies. Today, we are pleased to discuss our plans with you, share our excitement about this important and transformative business combination, and describe the value proposition for current and future shareholders.

Slide 1





**Merger to create Nasdaq-listed, clinical-stage biopharmaceutical company focused on developing first-in-class therapies for life-threatening inflammatory diseases**

**CalciMedica Opportunity**

Provides Graybug shareholders with opportunity to participate in company with strong clinical-stage pipeline and compelling growth prospects

**Pipeline Targeting High Unmet Need**

Auxora™, a proprietary, intravenous-formulated, small molecule calcium-release activated calcium (CRAC) channel inhibitor, is in development for acute pancreatitis (AP) and asparaginase-associated pancreatitis (AAP), for which there are no currently approved therapies

**Combined Financial Strength**

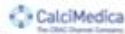
Combined company expected to have ~\$35 million in cash and cash equivalents upon closing, with expected runway into 2H24, funding key value inflection milestones, including Phase 2b AP data and Phase 1/2 AAP data in 2023



**[FRED GUERARD]:** After an extensive review of strategic alternatives, Graybug’s Board of Directors and leadership team believe the proposed merger with CalciMedica represents the best potential value creation opportunity for Graybug shareholders. CalciMedica is a clinical-stage biopharmaceutical company focused on the development of first-in-class therapies for life-threatening inflammatory diseases. The company’s lead product candidate Auxora expects clinical milestones in the next 12 months, including a Phase 2b readout in the second half of next year in its lead indication, acute pancreatitis. There are currently no approved therapies for any of the indications being pursued by CalciMedica.

## Transaction Summary

- |                      |                                                                                                                                                                                                                                                                                                            |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ownership</b>     | <ul style="list-style-type: none"><li>• Combined company expected to trade on Nasdaq Global Market</li><li>• Expected ownership ~71% CalciMedica, ~29% Graybug, subject to adjustment based on Graybug's net cash at closing</li></ul>                                                                     |
| <b>Management</b>    | <ul style="list-style-type: none"><li>• Existing CalciMedica management to lead combined company</li><li>• Board of Directors will be composed of 7 members, 5 selected by CalciMedica and 2 selected by Graybug</li></ul>                                                                                 |
| <b>Balance Sheet</b> | <ul style="list-style-type: none"><li>• Strong financial position with ~\$35M in cash and cash equivalents to provide funding of operations into 2H24<ul style="list-style-type: none"><li>• Projected ~\$25M net cash from Graybug with an additional ~\$10M from a private financing</li></ul></li></ul> |
| <b>Timing</b>        | <ul style="list-style-type: none"><li>• Expected close 1Q23, subject to approval of shareholders</li></ul>                                                                                                                                                                                                 |



**[FRED GUERARD]:** Moving to an overview of the transaction, the ownership split of the combined company at closing will be approximately 71% for CalciMedica's shareholders and 29% for Graybug's shareholders, subject to adjustments based on Graybug's net cash at closing. The combined company anticipates having a net cash balance of approximately \$35M. This cash balance will provide a runway into the second half of 2024, which is expected to be 9 to 12 months beyond the anticipated Phase 2b trial read-out in acute pancreatitis. The combined company will be led by Rachel Leheny as CEO and existing members of CalciMedica's leadership team. The board composition of the combined company will consist of seven board members – five selected by CalciMedica and two selected by Graybug. We expect the closing to happen in the first quarter of 2023, subject to approval from the respective shareholders.



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

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

CalciMedica The CRAC Channel Company CRAC: Calcium release-activated calcium

**[FRED GUERARD]:** CalciMedica’s differentiated platform targets calcium release-activated calcium channel inhibition, or “CRAC” channel inhibition. The lead product candidate, Auxora, is an intravenously administered, small molecule, CRAC channel inhibitor that was discovered and formulated in-house by CalciMedica and has since been studied in four completed efficacy trials in more than 300 patients, demonstrating positive and consistent clinical results and a favorable safety profile. CalciMedica’s IP protection is robust with composition of matter protected to 2036, formulation protected until 2038, and methods of use protected to 2041.

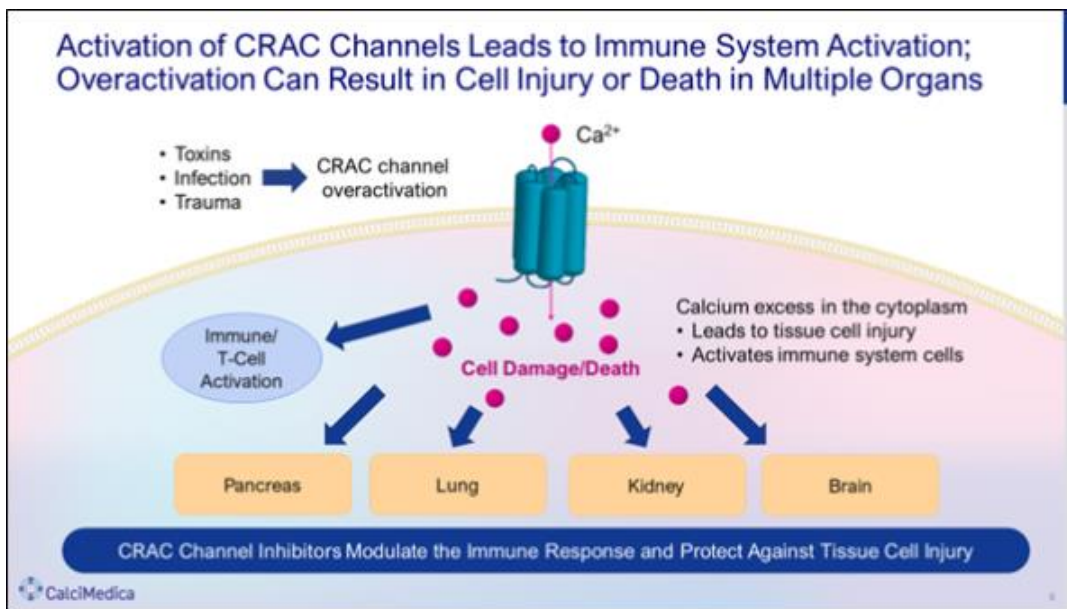
Auxora’s lead indication is Acute Pancreatitis, or AP. The target population for Auxora are patients with predicted severe AP and persistent systemic inflammatory response syndrome, or AP with SIRS, which has the potential to be a billion-dollar market opportunity in the U.S. alone. There are currently no approved therapies for AP.

Auxora is also being developed for asparaginase-associated pancreatitis, or AAP, a pediatric indication that impacts 7 to 10% of all patients being treated for acute lymphoblastic leukemia that develop AAP as a result of asparaginase treatment. There are currently no approved therapies for the approximately 300 children a year with AAP in the U.S., and it is estimated that 50% of these children will develop pancreatic necrosis.

CalciMedica anticipates a Phase 2b readout in the lead acute pancreatitis indication in the second half of 2023, and a Phase 1/2 readout in AAP for the first cohort in the first half of 2023.

These highlights form the basis of our excitement for the proposed merger, and it’s why we believe this combination represents a unique value creating opportunity for our shareholders. The focus to develop CalciMedica’s pipeline to make meaningful improvements in the standard of care for patients with high unmet need also aligns with Graybug’s own values and mission.

With that, I will turn the call over to Rachel.



**[RACHEL LEHENY]:** Thanks, Fred. Again, welcome everyone. I'm Rachel Leheny, CEO of CalciMedica.

I'd like to begin by talking about why we're so excited about CRAC channels as a target for a new class of therapies for immuno-inflammatory diseases of high unmet need.

CRAC channels maintain calcium homeostasis in certain cells. They are found both in the immune system and in a number of organs, like the pancreas, lung, kidney, and brain. They were originally identified in T-cells, where they play a key role in the adaptive immune response.

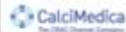
In a disease state where there is an infection, toxin overload, or trauma, CRAC channels in the organ tissue cells become hyperactivated and allow excess calcium to enter the cell causing apoptosis and tissue damage.

Shutting down activated CRAC channels results in a two-pronged benefit by acting on both the immune system and in the organs directly. First, the inhibition reduces the pro inflammatory response of the immune system. And second, it directly protects organ tissues from injury. It's this two-pronged effect that we believe is one of the key drivers of the efficacy data we've seen in the clinic to date.

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

Population	Trial Size	Results
<b>Pancreas</b>		
Asparaginase-Associated Pancreatitis	N=9	• Trial ongoing, preliminary results show rapid resolution of pain and food tolerance
Acute Pancreatitis (CARPO)	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 pivotal trial endpoint) • >2-day reduction in hospital stay and 50% reduction persistent SIRS
<b>Lung</b>		
COVID-19 with Respiratory Failure on LFO <sub>2</sub> and HFNC (CARDEA)	N=314	• 56% decrease in mortality at Day 30 (p=0.023) • 33% reduction in the need for mechanical 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

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



**[RACHEL LEHENY]:** We have already studied Auxora in a number of clinical trials, including four completed Phase 2 trials in acute indications with two of those trials in our lead indication, acute pancreatitis. Across all four trials, we have included over 300 patients, and Auxora has consistently shown clinical activity and a favorable safety profile, which gives us the confidence in the promise of Auxora and our technology.

In addition to our Phase 2a data in acute pancreatitis, we are also encouraged by the preliminary observations of an ongoing Phase 1/2 asparaginase-associated pancreatitis, or AAP, trial, in pediatric leukemia patients.

Our largest Phase 2 trial to date was conducted in respiratory failure where we enrolled over 280 patients with COVID-19 pneumonia. The positive results from this trial not only validate the clinical effect of Auxora in life-threatening inflammatory conditions but also further de-risk our platform.

I will go over the compelling data we've generated to date in a few moments. But first, I'll turn to our pipeline.

## Auxora Pipeline Addressing Significant Unmet Patient Needs Near-Term Readouts for Auxora in Development for Pancreas

Program*	Indication	Phase of Development				Anticipated Milestones
		Preclinical	Phase 1	Phase 2	Phase 3	
<b>Pancreas</b>						
Auxora	Acute Pancreatitis	█	█	█	█	CARPO Phase 2b Trial Ongoing Data in 2H23
Auxora	Asparaginase-Associated Pancreatitis	█	█	█	█	CRSPA Phase 1/2 Trial Ongoing FDA Meeting in 1H23
<b>Kidney</b>						
Auxora	Acute Kidney Injury	█	█	█	█	Submit IND Initiate Phase 2 Trial in 2H23
<b>Lung</b>						
Auxora	ARDS Ventilated COVID Patients	█	█	█	█	Phase 2 Data Publication 1H23

\* All programs are IV (for rapid onset in acute care setting)



**[RACHEL LEHENY]:** As Fred mentioned, Auxora is being evaluated in multiple clinical trials.

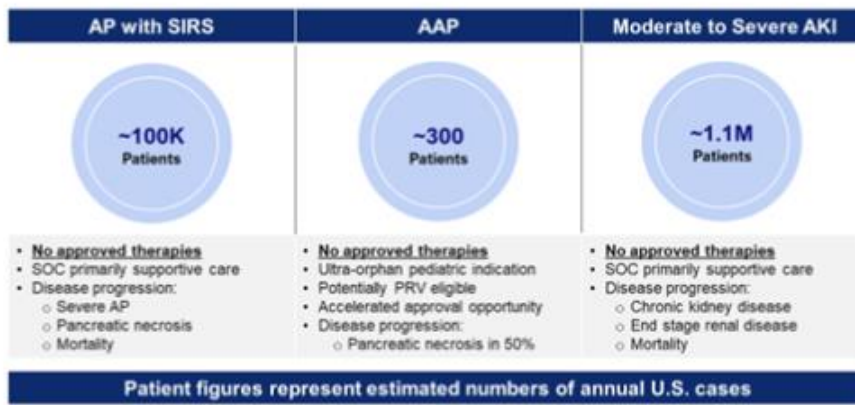
Acute pancreatitis is our lead indication. We have an ongoing Phase 2b study called CARPO. We expect a read-out of the data from our CARPO trial in late 2023.

In addition, we have finished enrolling the first cohort of our Phase 1/2 open-label CRSPA trial in pediatric AAP patients. We expect to report initial results in the first half of next year. We also expect to expand this trial to multiple centers, and to talk to the FDA to determine the path forward for a potential accelerated approval of Auxora in this indication.

We are further exploring other indications for Auxora, including acute kidney injury. We intend to treat patients who already have acute kidney injury, which will be a differentiated approach.

Finally, we are completing a Phase 2 biomarker and mechanism of action trial with Auxora in COVID-19 ventilated patients. This trial is designed to provide evidence of the immunomodulatory and tissue protective effects of Auxora. Data is expected to be published in early 2023.

## Market Opportunity for Auxora Across Acute Inflammatory Diseases with High Unmet Need

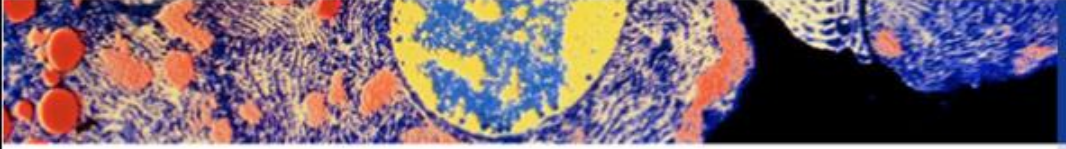


AP with SIRS: Acute Pancreatitis with systemic inflammatory response syndrome; AAP: Asparaginase-Associated Pancreatitis; PRV: Priority Review Voucher; AKI: Acute Kidney Injury; SOC: Standard of Care  
 Sources: Primary Market Research, KOLA, Healthcare Cost and Utilization Project, Pancreatitis Foundation

**[RACHEL LEHENY]:** Auxora has the potential to address high unmet medical needs in large markets with no currently approved therapies. In each case, the current standard of care for patients is supportive or palliative treatment. Disease progression puts stress on hospitals and the medical system with long hospital stays, often weeks and months, long-term complications, and even mortality.

We will discuss the patient journey and target population for each of these indications in more detail in a bit. We are excited about the market opportunity for our pipeline, as Auxora has the potential to become a much-needed therapy for significant patient populations.

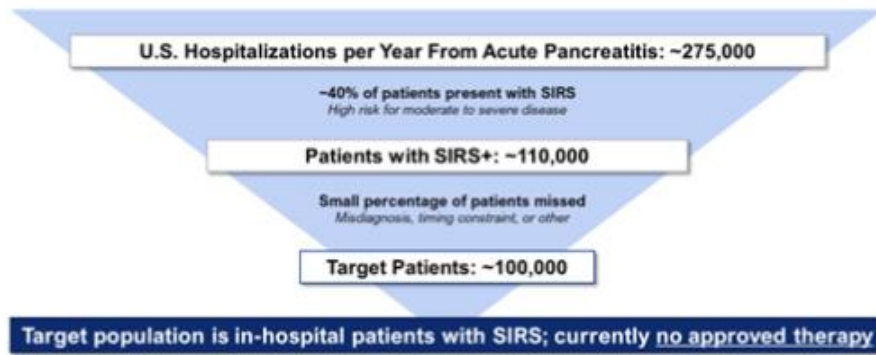
## Auxora for Acute Pancreatitis



**[RACHEL LEHENY]:** Before we discuss our clinical results to-date, we want to tell you a bit more about acute pancreatitis.

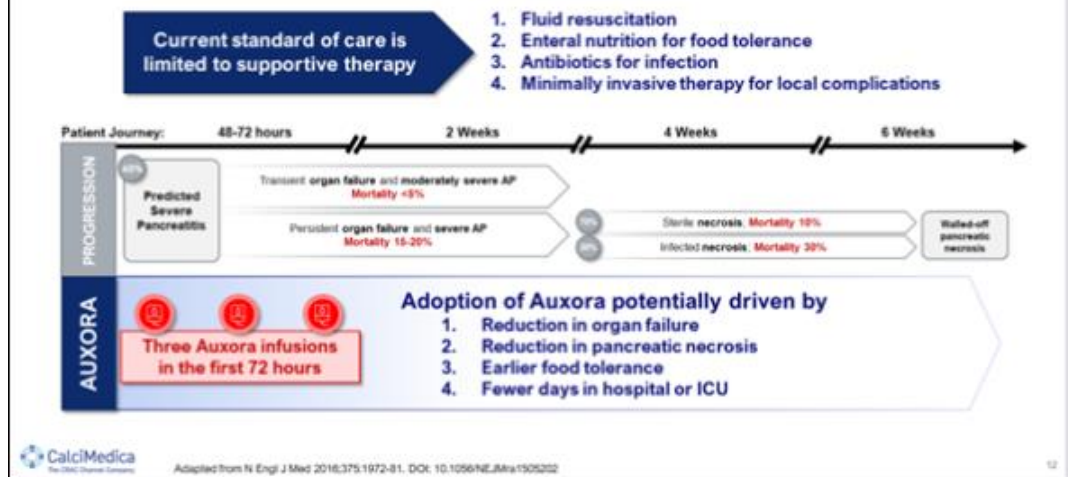
Slide 10

## Significant Unmet Need in Treatment of Acute Pancreatitis



**[RACHEL LEHENY]:** There are roughly 275,000 patients hospitalized for acute pancreatitis each year in the United States alone. Our target market is about 40% of these patients, or roughly 100,000 per year, who are diagnosed with SIRS, or systemic inflammation. These patients are the most likely to progress to severe pancreatitis, which can lead to infection and life-threatening organ failure.

## Auxora has the Potential to Offer Significant Clinical Benefits to Patients with Predicted Severe AP



[RACHEL LEHENY]: On this slide, we show you the journey for a patient with acute pancreatitis.

Patients present to the emergency room with stomach pain so severe that they often cannot stand up straight. They cannot eat without pain or vomiting. Upon hospital admission, patients receive supportive therapy, including fluids, IV or liquid nutrition, and antibiotics to avoid infection. In certain cases, minimally invasive therapy may be needed for local complications.

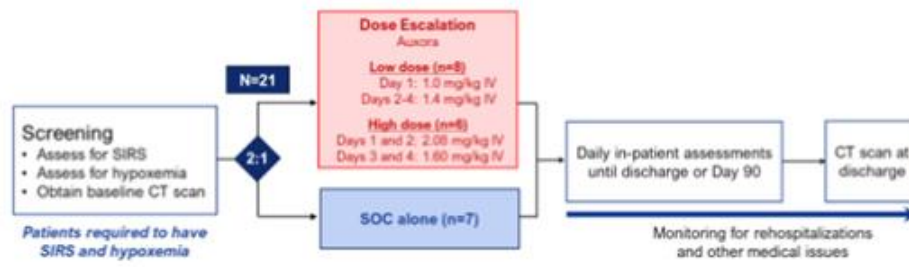
Upon admission, patients are also screened for SIRS, and again, roughly 40% of these patients are likely to suffer from SIRS. As mentioned earlier, these patients are the most likely to develop severe disease, and for some of these patients, the disease may become life-threatening.

Auxora is designed to be used as a once-daily, four-hour infusion in the first three days of hospital admittance and it is being studied to stop the progression to severe pancreatitis.

One key treatment goal is to get patients to tolerate solid food more rapidly. Eating solid food is an indication that the pancreas is functioning and that the patient may be ready for discharge. This translates into fewer days in the hospital or ICU, which provides a strong pharmaco-economic argument for Auxora. Adoption of Auxora may be further driven by reductions in organ failure and reductions in pancreatic necrosis.



## Auxora Phase 2a Trial in Acute Pancreatitis Exploring Safety, Tolerability and Efficacy Compared to Standard of Care



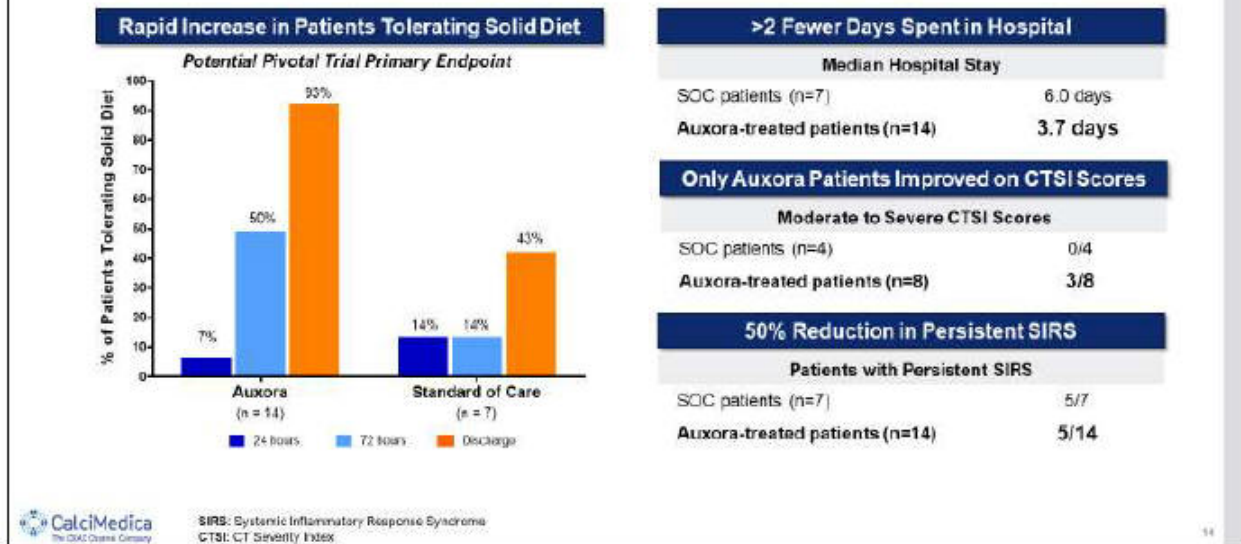
SOC: Standard of Care, SIRS: Systemic Inflammatory Response Syndrome

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**[RACHEL LEHENY]:** This slide illustrates the trial design of our Phase 2a trial for Auxora in acute pancreatitis. In this trial we evaluated 21 patients, of which 14 were treated with Auxora and 7 were treated with standard of care.

We assessed these patients over 90 days. Importantly, we did a CT scan both at entry and when the patients were discharged from the hospital to determine if there was an improvement in the condition of the pancreas over the course of treatment.

## Auxora Positive Phase 2a Results on all Primary Endpoints



**[RACHEL LEHENY]:** In the trial, we saw positive results on all primary endpoints. The most striking observation was that after treatment with Auxora, patients tolerated solid food more rapidly than those on standard of care.

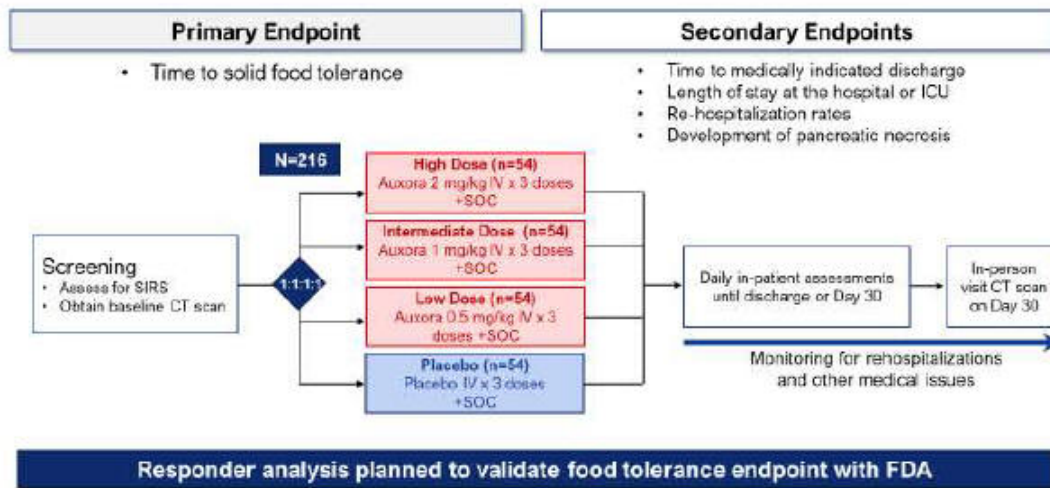
At enrollment, there was only one patient in the treated group and one patient in the standard-of-care group who were eating. Over time, we observed a divergence. At 72 hours, about half the patients in the treated group were eating, compared to only one in the standard of care group. At discharge, nearly all the patients in the treated group were eating, as compared to about half the patients in the standard of care group. Importantly, patients who are not eating at discharge are at particular risk of re-admission, and with the more rapid recovery of food tolerance, we also observed a decrease in hospital stay of over two days for patients treated with Auxora.

As I mentioned, CT scans were performed on all patients to evaluate improvement in the CT Severity Index score, or CTSE. This is a measure of the severity of pancreatic inflammation and necrosis. Over the course of the hospital stay, none of the standard of care patients with elevated CTSE scores improved. However, over only 3 to 5 days, three out of the eight Auxora patients with elevated scores saw improvement.

Finally, we saw a 50% greater reduction in persistent inflammation in Auxora treated patients compared to standard of care.

Seeing such measurable improvements in such a short period of time suggests efficacy of Auxora in acute pancreatitis.

## Auxora Phase 2b Trial (CARPO) in Acute Pancreatitis Ongoing, with Data Expected 2H23



**[RACHEL LEHENY]:** Based on these positive Phase 2a results, we initiated CARPO, our Phase 2b trial that I mentioned earlier. This is a placebo-controlled, randomized trial in acute pancreatitis.

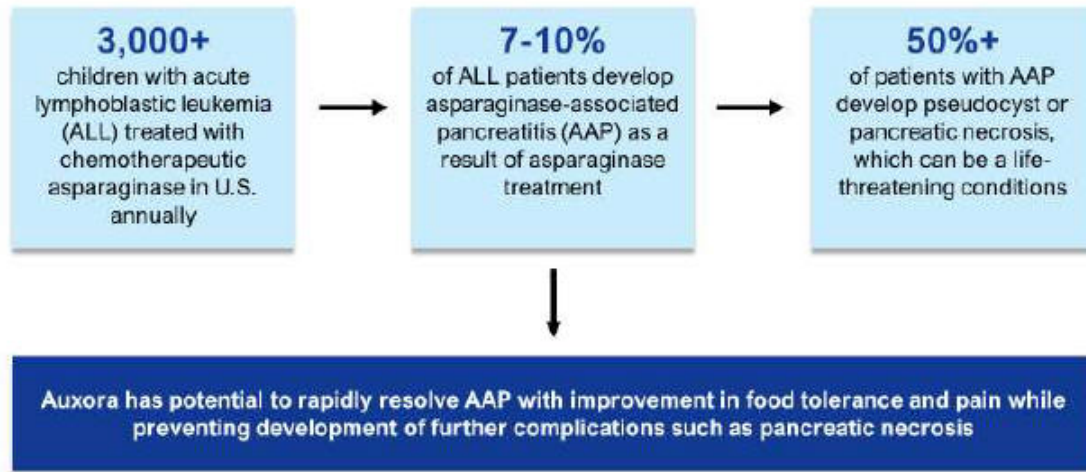
CARPO has four equally weighted arms: three doses of Auxora and a placebo. Baseline CT scans were obtained for each patient at entry and then CT scans were performed at Day 30 to observe the potential long-term benefits of Auxora compared to the standard of care.

The primary endpoint is time to solid food tolerance. Secondary endpoints include time to medically indicated discharge, time in hospital and in the ICU, and re-admission rates.

We will also conduct a responder's analysis to validate the food tolerance endpoint for the FDA. This analysis will correlate food tolerance with patient outcomes such as length of hospital stay.

We are planning to review the results from CARPO with the FDA in the first half of 2024.

## Potential to Offer Significant Clinical Benefits to Children with AAP



Shawar, S.B., Wang, W., Baxendale, R., et al. Clinical and Economic Burden of Acute Pancreatitis in Patients With Acute Lymphoblastic Leukemia. J Clin Oncol 2017; 35:4370-4376. DOI: 10.1200/JCO.2017.35.4370. Risk, C., Pineda, S., Dhill, A., et al. Asparaginase-Associated Pancreatitis in Acute Lymphoblastic Leukemia: Results from the ADAPT-ALL2008 Cohort of Patients 1-45 Years of Age. J Clin Oncol 2013; 31:160-164.

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**[RACHEL LEHENY]:** Moving now to AAP, we believe that Auxora can also provide significant benefits to children with acute lymphoblastic leukemia, or ALL. These patients are being treated with asparaginase as part of their chemotherapeutic regimen. ALL is the most common cancer in children, with an incidence of 3 to 5 per 100,000 children in the United States. While asparaginase is extremely effective and is an important factor in making ALL a curable disease, it is also associated with a number of serious side-effects.

Out of the approximately 3,000 children in the United States treated annually for ALL, about 7 to 10% will develop asparaginase-associated pancreatitis, which is actually a particularly aggressive form of pancreatitis.

Over half of children with AAP are expected to develop a pancreatic pseudocyst or pancreatic necrosis, potentially life-threatening conditions.

If a child gets pancreatic necrosis, that child can no longer be treated with asparaginase for their leukemia, and may have life-long problems, like chronic pancreatitis.

## Proof-of-Concept Ongoing in AAP Pediatric Patients Receiving Auxora Had Rapid Resolution of Food Tolerance and Pain

- **CRSPA Phase 1/2 Trial in pediatric Asparaginase-Associated Pancreatitis (AAP)**
  - Investigator-initiated, open-label trial
- **Trial Status**
  - Assess the safety in pediatric patients with acute lymphoblastic leukemia (ALL) who have developed AAP
  - Estimate the efficacy of Auxora to prevent pseudocyst or necrotizing pancreatitis in pediatric patients with AAP
  - First cohort of nine patients complete
- **Preliminary Observations**
  - All patients who received four daily infusions of Auxora had rapid resolution of food tolerance and pain

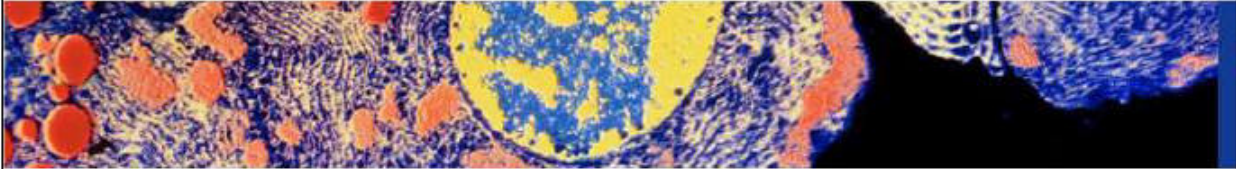
**FDA meeting expected in 1H23 to discuss trial expansion and potential accelerated approval**

**[RACHEL LEHENY]:** We are currently working with academic investigators to run CRSPA, an open-label Phase 1/2 proof-of-concept trial in AAP.

Preliminary observations are encouraging, with all patients who received four daily infusions of Auxora showing rapid resolution of food tolerance and pain.

In the first half of next year, we will announce data from this study. We will also be expanding the study to additional centers and plan to meet with the FDA to discuss path forward for a potential accelerated approval of Auxora in this indication.

## Supporting Data in COVID-19 Pneumonia Patients



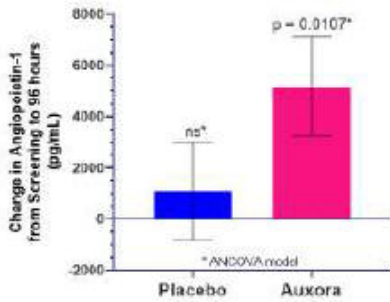
**[RACHEL LEHENY]:** I would also like to share data from our clinical trial CARDEA, which studied over 280 severe COVID-19 pneumonia patients.

Slide 18

## CARDEA Phase 2 Trial Showed 40% Reduction in Reported Acute Kidney Injury in COVID-19 Pneumonia Patients

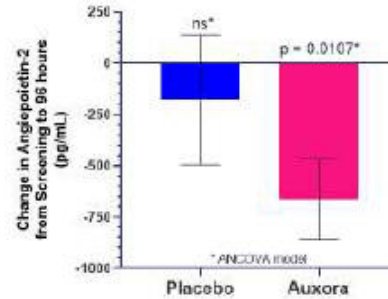
Ang-1/Tie2 signaling maintains vascular integrity

Angiotensin-1 Levels Increase Significantly with Auxora (Means  $\pm$  SEM)



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

Angiotensin-2 Levels Decrease Significantly with Auxora (Means  $\pm$  SEM)

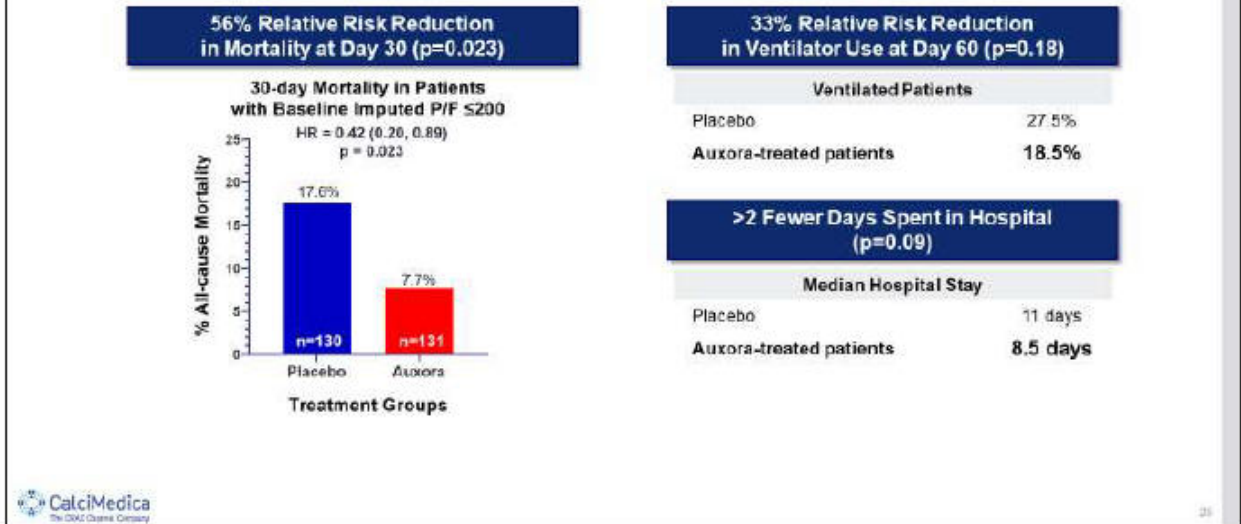


**[RACHEL LEHENY]:** While the purpose of CARDEA was to test Auxora in COVID-19, we also looked at the occurrence of acute kidney injury in this patient population, as AKI is a relatively frequent sequelae of COVID. We observed a 40% reduction in reported AKI in patients treated with Auxora compared with the placebo group patients.

We further measured Angiotensin-1 and Angiotensin-2 levels in these patients, as these are biomarkers for vascular endothelial cell function. Increased Ang-1 is a signal that vascular integrity is being maintained, while increased Ang-2 suggests there is endothelial inflammation and malfunction.

What we observed in CARDEA was that in the treated patients, Ang-1 went up, and Ang-2 went down. This result suggests a potential application for Auxora for acute kidney injury, where endothelial cell function is compromised.

## CARDEA Phase 2 Showed Reduction in Mortality and Ventilator Use in COVID-19 Pneumonia Patients



[RACHEL LEHENY]: Further results from CARDEA are illustrated on this slide.

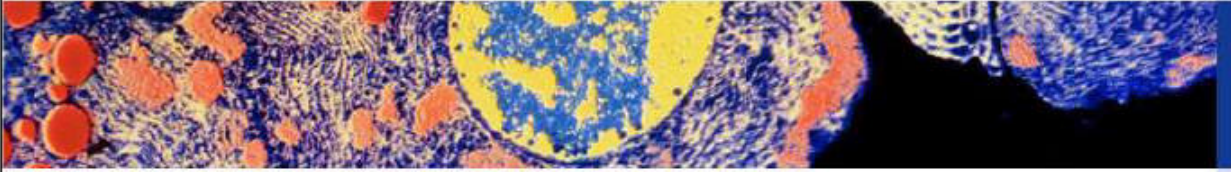
Importantly, compared to placebo, Auxora showed a statistically significant 56% reduction in mortality at Day 30 in these severe COVID-19 pneumonia patients, as well as a 33% relative risk reduction in the need for ventilator use at Day 60, and a more than two day reduction in median hospital stay. We are currently evaluating further opportunities for Auxora in viral pneumonia respiratory failure.

These data from this large placebo-controlled trial give us further confidence that our proprietary technology targeting the inhibition of CRAC channels, designed to modulate the immune response as well as protect against tissue cell injury, has the potential to provide therapeutic benefits in life-threatening inflammatory diseases for which there are currently no approved therapies.

Slide 20



## Anticipated Milestones



## Cash at Close Expected to Provide Runway into 2H24 Funding Key Clinical Milestones



**[RACHEL LEHENY]:** In summary, our lead product candidate, Auxora for Acute Pancreatitis, has the potential to address the high unmet medical needs of patients with both AP and AAP. Our current Phase 2b trial of Auxora, CARPO, is underway in AP, and Cohort 1 of our Phase 1/2 trial in AAP, or CRSPA, has been completed.

Next year, we anticipate the readout from our Phase 2b CARPO AP trial in the second half of 2023. We also expect data from our Phase 1/2 AAP trial, as well as a meeting with the FDA for this program, in the first half of 2023.

As a result of this transaction, we expect to have sufficient runway into the second half of 2024, which funds the company beyond several meaningful clinical milestones that will happen in the next 12 to 18 months.

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



**[RACHEL LEHENY]:** To conclude, I would like to leave you with four key points.

- We at CalciMedica are leading the development of a potential first-in-class therapy for life-threatening acute inflammatory diseases for which there are currently no available therapies. Auxora has demonstrated positive and consistent clinical trial results and a favorable safety profile in four completed efficacy clinical trials.
- Our lead indication in acute pancreatitis is very attractive and represents a potential billion-dollar opportunity in the United States alone.
- We have multiple near-term clinical readouts, which represent key value-inflection points over the next 12 to 18 months.
- As a result of this merger, the combined company will have a strong balance sheet with cash runway into the second half of 2024.

Fred and I appreciate this opportunity to share with you what is a pivotal moment for both of our companies, and a deal that has the potential to be attractive for shareholders, and, most importantly, life changing for many patients suffering from these serious acute illnesses. We look forward to providing you with updates on our progress in the coming months.

Thank you.

**[OPERATOR]:** This concludes today's presentation. You may now disconnect.

## **Forward-Looking Statements**

This presentation contains “forward-looking statements” under the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Graybug’s and CalciMedica’s actual results may differ from their expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue,” “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements contained in this presentation include, but are not limited to, statements about: Graybug’s and CalciMedica’s expectations with respect to future performance and anticipated financial impacts of the proposed transaction, the satisfaction of closing conditions to the proposed transaction and the timing of the completion of the proposed transaction. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside Graybug’s and CalciMedica’s control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the outcome of any legal proceedings that may be instituted against Graybug or CalciMedica following the announcement of the proposed transaction; the inability to complete the proposed transaction, including due to the inability to concurrently close the merger and the private placement of common stock or due to failure to obtain approval of the stockholders of Graybug; delays in obtaining, adverse conditions contained in, or the inability to obtain necessary regulatory approvals or complete regular reviews required to complete the proposed transaction; the ability of Graybug to remain listed on the Nasdaq stock market; the inability to recognize the anticipated benefits of the proposed transaction, which may be affected by, among other things, competition, the ability of the combined company to grow and successfully execute on its business plan; costs related to the proposed transaction; changes in the applicable laws or regulations; the possibility that the combined company may be adversely affected by other economic, business, and/or competitive factors; the impact of the global COVID-19 pandemic; and other risks and uncertainties indicated from time to time described in Graybug’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, the proxy statement, once available, relating to the proposed transaction, including those under “Risk Factors” therein, and in Graybug’s other filings with the U.S. Securities and Exchange Commission (the “SEC”). Graybug and CalciMedica caution that the foregoing list of factors is not exclusive, and not to place undue reliance upon any forward-looking statements, including projections, which speak only as of the date made. Moreover, Graybug and CalciMedica operate in a very competitive and rapidly changing environment. New risks emerge from time to time. Except as required by law, neither Graybug nor CalciMedica undertakes any obligation to update publicly any forward-looking statements for any reason after the date of this presentation, whether to conform these statements to actual results or to changes in their expectations.

## **Important Additional Information**

In connection with the merger, Graybug intends to file with the SEC preliminary and definitive proxy statements relating to the proposed merger and any other relevant documents. The definitive proxy statement will be mailed to Graybug’s stockholders determined as of a record date, which is to be established for voting on the proposed merger and any other matters to be voted on at the special meeting. Before making any voting decision, Investors and security holders are urged to read the preliminary and definitive proxy statements, any amendments or supplements thereto, and any other documents to be filed with the SEC in connection with the proposed merger or incorporated by reference in the proxy statements when they become available because they will contain important information about Graybug, CalciMedica and the proposed merger. Investors and security holders may obtain free copies of these documents (when they are available) on the SEC’s web site at [www.sec.gov](http://www.sec.gov), on Graybug’s website at <https://investors.graybug.vision/> or by contacting Graybug’s Investor Relations via email at [IR@graybug.vision](mailto:IR@graybug.vision) or by telephone at (650) 487-2409.

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**Participants in the Solicitation**

Graybug and its directors and certain of its executive officers may be deemed participants in the solicitation of proxies from the stockholders of Graybug in connection with the proposed merger and any other matters to be voted on at the special meeting. Information regarding the names, affiliations and interests of such directors and executive officers will be included in the preliminary and definitive proxy statements (when available). Additional information regarding such directors and executive officers is included in Graybug's definitive proxy statement on Schedule 14A for the 2022 Annual Meeting of Stockholders, which was filed with the SEC on April 22, 2022.

Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies of Graybug's stockholders in connection with the proposed merger and any other matters to be voted upon at the special meeting will be set forth in the preliminary and definitive proxy statements (when available) for the merger.

These documents are available free of charge as described in the preceding paragraph.