# 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 09, 2023**

# 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**<br>**La Jolla, California**<br>**(Address of Principal Executive Offices)** | **92037**<br>**(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 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 |
|---|---|---|
| Common Stock, par value $0.0001 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 2.02. Results of Operations and Financial Condition.**

On November 9, 2023, CalciMedica, Inc. issued a press release announcing its financial results for the fiscal quarter ended September 30, 2023. A copy of the press release is attached as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 to this report, shall not be deemed to be "filed" for 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 or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

*(d) Exhibits*

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Press release, dated November 9, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CalciMedica, Inc.

Date: November 9, 2023

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

**CalciMedica Reports Third Quarter 2023 Financial Results and Provides Clinical & Corporate Updates**

*Continued expansion of Phase 1/2 CRSPA study of Auxora™ in asparaginase-induced pancreatic toxicity (AIPT); data from initial cohort to be presented at 65th Annual American Society of Hematology (ASH) Meeting & Exposition*

*International expansion of Phase 2b CARPO trial in acute pancreatitis (AP) patients with accompanying systemic inflammatory response syndrome (SIRS) continues; topline data expected in the first half of 2024*

LA JOLLA, Calif., Nov. 9, 2023 – CalciMedica Inc. ("CalciMedica") (Nasdaq: CALC), a clinical-stage biopharmaceutical company focused on developing novel calcium release-activated calcium (CRAC) channel inhibition therapies for acute and chronic inflammatory and immunologic illnesses, today reported financial results for the third quarter ended September 30, 2023.

"As we work towards exciting milestones in the development of Auxora, we have continued to make progress across our pipeline indications throughout the third quarter, which was punctuated by our virtual Acute Pancreatitis Clinical Experts Event with doctors Joseph Miller and Georgios Papachristou," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "We look forward to reporting topline data from our international Phase 2b CARPO study in acute pancreatitis in the first half of 2024. Further, we are greatly encouraged by the promising data from the initial cohort of our Phase 1/2 CRSPA study in AIPT, which will be presented by our collaborators from St. Jude Children's Research Hospital at this year's ASH Meeting and Exposition."

**Clinical and Pre-Clinical Updates and Anticipated Milestones:**

- Collaborators at St. Jude Children's Research Hospital (SJCRH) have continued expansion of the Phase 1/2 CRSPA trial of Auxora™ in pediatric patients with asparaginase-induced pancreatic toxicity (AIPT). Data from the initial cohort of the CRSPA study, including comparisons of data from CRSPA with matched historical control patients at SJCRH, will be presented by SJCRH investigators at the 65th Annual ASH Meeting & Exposition, being held December 9-12, 2023 in San Diego, CA.
- Data from the initial cohort of the CRSPA study compared with matched historical controls indicate that Auxora™ showed a 53% reduction in days in hospital, a 40% reduction in intensive care unit days and eliminated the need for total parenteral nutrition (in contrast to an average 27 days of total parenteral nutrition for the matched historical control group).
- CalciMedica's clinical investigators are continuing to enroll patients in CARPO, CalciMedica's Phase 2b clinical trial of Auxora™ in acute pancreatitis (AP) patients with accompanying systemic inflammatory response syndrome (SIRS), including in India, following the international

expansion of the study there. CalciMedica anticipates that topline data from the CARPO trial will be available in the first half of 2024.

- CalciMedica is preparing to file an IND application for Auxora™ in acute kidney injury (AKI). If allowed, CalciMedica expects it will be in a position to initiate a Phase 2 clinical trial in AKI in the first half of 2024, subject to receipt of additional funding.

**Financial Results for the Three and Nine Months Ended September 30, 2023:**

- As of September 30, 2023, CalciMedica had $14.6 million in cash, cash equivalents and short-term investments, which, based on its current operating plan, CalciMedica expects to be sufficient to fund its operations through the third quarter of 2024.
- Total operating expenses were $4.8 million for the three months ended September 30, 2023. Total operating expenses were $33.8 million for the nine months ended September 30, 2023, which included $16.2 million of one-time charges of which $10.5 million was non-cash, related to accelerated vesting of stock options and severance for employees of Graybug Vision, Inc. at the time of the reverse merger with Graybug. The majority of costs stemming from the reverse merger have been expensed.
- Net loss was $4.6 million, or $0.82 per share (basic and diluted), and $30.2 million, or $7.43 per share (basic and diluted), for the three and nine months ended September 30, 2023, respectively.

**Corporate Updates**

- In September 2023, CalciMedica hosted a virtual Acute Pancreatitis Clinical Experts Event featuring Joseph Miller, M.D., Clinical Associate Professor of Emergency Medicine at Henry Ford Health and Michigan State University and Associate Director of Emergency Care Research at Henry Ford Health, and Georgios Papachristou, M.D., Ph.D., Professor of Medicine, Floyd Beman Endowed Chair in Gastroenterology and division director for Gastroenterology, Hepatology and Nutrition at The Ohio State University College of Medicine. Management and the clinical experts discussed current treatment paradigms for AP and the potential implications of CalciMedica's lead clinical compound, Auxora™.

**About Auxora™**

CalciMedica's lead clinical compound, Auxora™, is a potent and selective small molecule inhibitor of Orai1-containing CRAC channels that is being developed for use in patients with acute inflammatory and immunologic illnesses. CRAC channels are found on many cell types, including pancreatic acinar cells, lung endothelium cells and immune system cells, where aberrant activation of these channels may play a key role in the pathobiology of acute and chronic inflammatory syndromes. Auxora is currently being evaluated in: (i) a Phase 2b trial for AP with accompanying SIRS, called CARPO, (ii) an investigator-sponsored Phase 1/2 trial called CRSPA being conducted in pediatric patients with AIPT as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase, and (iii) a Phase 2 dose-ranging pharmacodynamic study in critical COVID-19 patients. There are currently no approved therapies to treat either AP or AIPT. In previous trials, patients responded well to Auxora regardless of severity or cause of disease. CalciMedica is also exploring the potential of Auxora treatment for other acute indications including acute kidney injury and acute respiratory distress syndrome.

**About CRSPA**
CRSPA is an investigator-sponsored Phase 1/2 trial being conducted in pediatric acute lymphoblastic leukemia (ALL) patients with AIPT, which is acute pancreatitis toxicity caused by the administration of asparaginase (such as Oncaspar and Rylaze) and for which there is no approved therapy. Treatment with asparaginase triggers the development of AIPT in 7-10% of these patients, with approximately half developing pancreatic necrosis and/or pseudocysts. CalciMedica believes that the CRSPA trial has defined an optimal pediatric dose for Auxora in this setting and the trial is currently being expanded to additional sites. Details of the CRSPA trial are available on clinicaltrials.gov (NCT04195347).

**About CARPO**
CARPO is an international, randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish efficacy in AP with accompanying SIRS. It is expected to enroll 216 patients. AP can be a life-threatening condition where the pancreas becomes inflamed, sometimes leading to pancreatic cell death or necrosis, systemic inflammation, organ failure and death. There are an estimated 275,000 hospitalizations for AP annually in the United States, of which approximately 40% present with SIRS, which can compromise the function of other tissues or organs, especially the lungs. Organ failure is responsible for much of the mortality seen in AP. There is currently no approved therapy for AP. Details of the CARPO trial are available on clinicaltrials.gov (NCT04681066).

**About CalciMedica**
CalciMedica is a clinical-stage biopharmaceutical company focused on developing novel CRAC channel inhibition therapies for inflammatory and immunologic diseases. CalciMedica's proprietary technology targets the inhibition of CRAC channels to modulate the immune response and protect against tissue cell injury, with the potential to provide therapeutic benefits in life-threatening inflammatory and immunologic diseases for which there are currently no approved therapies. CalciMedica's lead product candidate Auxora™, a proprietary, intravenous-formulated CRAC channel inhibitor, has demonstrated positive and consistent clinical results in multiple completed efficacy clinical trials. CalciMedica is currently conducting a Phase 2b trial in 216 patients called CARPO for acute pancreatitis (AP) with systemic inflammatory response syndrome (SIRS), with topline data expected in the first half of 2024, as well as continuing the Phase 1/2 CRSPA AIPT study, with data from the first cohort expected to be presented in the fourth quarter of 2023. A Phase 2 study in acute kidney injury (AKI) is planned for the first half 2024, subject to receipt of additional funding. CalciMedica was founded by scientists from Torrey Pines Therapeutics and the Harvard CBR Institute for Biomedical Research, and is headquartered in La Jolla, CA. For more information, please visit www.calcimedica.com.

**Forward-Looking Statements**
This communication contains forward-looking statements which include, but are not limited to, statements regarding CalciMedica's expected cash runway; CalciMedica's business strategy; the design and potential benefits of Auxora; CalciMedica's plans and expected timing for developing its product candidates and potential benefits of its product candidates; CalciMedica's ongoing and planned clinical trials; CalciMedica's plans and expected timing for filing an IND application for Auxora in AKI; the development and outcomes of CARPO and CRSPA trial programs, including the milestones, data announcements, expected enrollment and any other potential results related thereto. 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: CalciMedica's need to obtain substantial additional funding to complete the development and any commercialization of its product candidates; CalciMedica's ability to continue as a going concern; the impact of fluctuations in global financial markets on CalciMedica's business and the actions it may take in response thereto; CalciMedica's ability to execute its plans and strategies; the ability to obtain and maintain regulatory approval for Auxora; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from Auxora; the scope, progress and expansion of developing and commercializing Auxora; the size and growth of the market therefor and the rate and degree of market acceptance thereof; economic, business, competitive, and/or regulatory factors affecting the business of CalciMedica generally; CalciMedica's ability to protect its intellectual property position; and the impact of government laws and regulations. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" in CalciMedica's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 and elsewhere in CalciMedica's 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. These documents can be accessed on CalciMedica's web page at ir.calcimedica.com/financials-filings/sec-filings.

**CalciMedica Contact:**

**Investors and Media**
Argot Partners
Sarah Sutton/Kevin Murphy
calcimedica@argotpartners.com
(212) 600-1902

**Selected Financial Information**
**Condensed Consolidated Balance Sheets**
**(In thousands, except par value and share amounts)**

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| | (unaudited) | (See Note 2) |
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 11,644 | $ 1,327 |
| Restricted cash | — | 149 |
| Short-term investments | 2,947 | — |
| Prepaid expenses and other current assets | 682 | 254 |
| Total current assets | 15,273 | 1,730 |
| Property and equipment, net | 187 | 147 |
| Right-of-use asset, net | — | 48 |
| Other assets | 385 | 1,424 |
| Total assets | $ 15,845 | $ 3,349 |
| **Liabilities and Stockholders' Equity (Deficit)** | | |
| Current liabilities | | |
| Accounts payable | $ 1,417 | $ 2,866 |
| Accrued clinical trial costs | 860 | 1,143 |
| Accrued other | 1,409 | 572 |
| Other current liabilities | — | 199 |
| Total current liabilities | 3,686 | 4,780 |
| Long-term liabilities | | |
| Warrant liability | — | 2,645 |
| Convertible promissory notes | — | 5,157 |
| Total liabilities | 3,686 | 12,582 |
| Commitments and contingencies (Note 8) | | |
| Convertible preferred stock | — | 62,071 |
| Stockholders' equity (deficit) | | |
| Common stock | 1 | 1 |
| Additional paid-in capital | 154,076 | 40,402 |
| Accumulated deficit | (141,918) | (111,707) |
| Total stockholders' equity (deficit) | 12,159 | (71,304) |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) | $ 15,845 | $ 3,349 |

**Selected Financial Information**
**Condensed Statements of Operations and Comprehensive Loss**
**(In thousands, except share and per share amounts)**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses: | | | | |
| Research and development | $ 2,772 | $ 1,244 | $ 13,077 | $ 6,428 |
| General and administrative | 2,061 | 2,044 | 20,679 | 4,660 |
| Total operating expenses | 4,833 | 3,288 | 33,756 | 11,088 |
| Loss from operations | (4,833) | (3,288) | (33,756) | (11,088) |
| Other income (expense) | | | | |
| Other income (expense), net | 214 | (49) | 377 | (78) |
| Change in fair value of financial instruments | — | 756 | 3,168 | 1,925 |
| Total other income (expense), net | 214 | 707 | 3,545 | 1,847 |
| Net loss and comprehensive loss | $ (4,619) | $ (2,581) | $ (30,211) | $ (9,241) |
| Net loss per share—basic and diluted | $ (0.82) | $ (31.04) | $ (7.43) | $ (113.24) |
| Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted | 5,667,343 | 83,154 | 4,068,526 | 81,601 |