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

August 9, 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 2.02 Results of Operations and Financial Condition.

On August 10, 2023, CalciMedica, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 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 5.07 Submission of Matters to a Vote of Security Holders.

On August 9, 2023, the Company held its 2023 Annual Meeting of Stockholders (the "Annual Meeting"). As of June 23, 2023, the record date for the Annual Meeting, 5,661,933 shares of common stock were outstanding and entitled to vote at the Annual Meeting. A summary of the matters voted upon by stockholders at the Annual Meeting is set forth below.

Proposal 1. Election of Class III Directors

The Company's stockholders elected the two persons listed below as Class III directors, each to serve a three-year term through the Company's 2026 annual meeting of stockholders and until a successor has been elected and qualified or until earlier resignation or removal. The final voting results are as follows:

	Votes For	Votes Withheld	Broker Non-Votes
Robert N. Wilson	3,927,499	28,075	256,375
Allan Shaw	3,928,740	26,834	256,375

Proposal 2. Ratification of the Selection of Independent Registered Public Accounting Firm

The Company's stockholders ratified the selection by the Audit Committee of the Company's Board of Directors of Ernst & Young LLP as the Company's principal independent registered public accounting firm for the fiscal year ending December 31, 2023. The final voting results are as follows:

Votes For	Votes Against	Abstentions	Broker Non-Votes
4,208,835	2,269	845	—

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated August 10, 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: August 10, 2023

CalciMedica, Inc.

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

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

International expansion of CARPO, a Phase 2b clinical trial of Auxora in acute pancreatitis (AP) patients with accompanying systemic inflammatory response syndrome (SIRS), in India

Expansion of team with key leadership appointments in regulatory and clinical development

Filing of an investigational new drug (IND) application for Auxora in acute kidney injury (AKI) expected by year-end 2023

LA JOLLA, CA, August 10, 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 second quarter ended June 30, 2023.

"Following the completion of our reverse merger in March 2023, CalciMedica has taken critical steps to accelerate clinical activities with our lead compound, Auxora," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "We undertook the international expansion of our Phase 2b CARPO study in acute pancreatitis with systemic inflammatory response syndrome and enrolled our first patient in India. Also, our collaborators at St. Jude Children's Research Hospital are expanding our Phase 1/2 CRSPA study in asparaginase-induced pancreatic toxicity to additional sites. Further, we expect to file our IND application for Auxora in acute kidney injury by year-end."

Dr. Leheny continued, "On the corporate side, we appointed a new Chief Regulatory Officer, Raven Jaeger, M.S., as well as a Senior Vice President of Clinical Development, Andrew Cunningham, M.D., MRCPI. Raven and Andrew have proved to be wonderful additions to our team and are providing leadership in the execution of our clinical and regulatory plans. Finally, due to the diligent work of our entire team, we were able to relist our common stock on the Nasdaq Capital Market in June, and we are pleased to be trading on that exchange."

Clinical and Pre-Clinical Updates and Anticipated Milestones:

- In April 2023, CalciMedica initiated the international expansion of CARPO, a Phase 2b clinical trial of its lead candidate, Auxora, in AP patients with accompanying SIRS, in India and began enrolling patients there during the third quarter of 2023. CARPO enrollment is expected to be complete by the first quarter of 2024, with topline data available in the first half of 2024.
- In May 2023, the Independent Data Monitoring Committee for CARPO met to review data from the first 90 patients enrolled in the trial and determined that the trial should continue without modifications.
- Collaborators at St. Jude Children's Research Hospital are expanding the Phase 1/2 CRSPA trial of Auxora in pediatric patients with asparaginase-induced pancreatic toxicity (AIPT) which has been a single-center study to date. Patient enrollment from additional sites is expected to begin in the fourth quarter of 2023.

- CalciMedica expects to file an IND application for Auxora in AKI by year-end 2023. If allowed, CalciMedica will then be in a position to initiate clinical trials in this indication in the first half of 2024, pending additional funding.
- In May 2023, preclinical data from studies in animal models of recurrent acute pancreatitis (RAP) and early chronic pancreatitis (CP) conducted at University of Szeged were published in *The Journal of Clinical Investigation Insight*. The data showed that inhibiting Orai1-mediated store-operated Ca2+ entry with a selective CRAC channel inhibitor prevented the progression of RAP and early CP into established CP, thus supporting the initiation of clinical studies assessing Orai1 inhibition in patients with RAP and early CP.

Financial Results for the Three and Six Months Ended June 30, 2023:

- Cash, Cash Equivalents and Marketable Securities: As of June 30, 2023, CalciMedica had $19.1 million in cash and cash equivalents, which the Company expects to be sufficient to fund operations for at least the next twelve months.
- Total Operating Expenses: Total operating expenses were $6.6 million for the three months ended June 30, 2023. Total operating expenses were $28.9 million for the six months ended June 30, 2023, which included $16.2 million of one-time charges related to accelerated vesting 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 including the payment of accrued transaction expenses in the second quarter.
- Net Loss: Net loss was $6.3 million, or $1.11 per share (basic and diluted), and $25.6 million, or $7.86 per share (basic and diluted), for the three and six months ended June 30, 2023, respectively.

Corporate Updates

- In May 2023, CalciMedica announced the appointments of Raven Jaeger, M.S. as Chief Regulatory Officer and Andrew Cunningham, M.D., MRCPI as Senior Vice President of Clinical Development.
- In June 2023, CalciMedica's common stock was relisted on the Nasdaq Capital Market. CalciMedica trades on the Nasdaq Capital Market under the ticker symbol "CALC".

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 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 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 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 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 designed 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. Auxora is in development for AP with SIRS and AIPT. 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; 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: 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 March 31, 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:

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

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 19,084	$ 1,476
Prepaid expenses and other current assets	961	254
Total current assets	20,045	1,730
Property and equipment, net	199	147
Right-of-use asset, net	—	48
Other assets	1	1,424
Total assets	$ 20,245	$ 3,349
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,743	$ 2,866
Accrued clinical trial costs	$ 1,207	$ 1,143
Accrued other	1,074	572
Other current liabilities	—	199
Total current liabilities	4,024	4,780
Long-term liabilities		
Warrant liability	—	2,645
Convertible promissory notes	—	5,157
Total liabilities	4,024	12,582
Commitments and contingencies (Note 8)		
Preferred stock	—	62,071
Stockholders' equity (deficit)		
Common stock	1	3
Additional paid-in capital	153,519	40,400
Accumulated deficit	(137,299)	(111,707)
Total stockholders' equity (deficit)	16,221	(71,304)
Total liabilities and stockholders' equity	$ 20,245	$ 3,349

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 3,814	$ 2,259	$ 10,305	$ 5,184
General and administrative	2,769	1,330	18,618	2,616
Total operating expenses	6,583	3,589	28,923	7,800
Loss from operations	(6,583)	(3,589)	(28,923)	(7,800)
Other income (expense)				
Other income (expense), net	279	(29)	163	(29)
Change in fair value of financial instruments	—	588	3,168	1,169
Total other income (expense), net	279	559	3,331	1,140
Net loss and comprehensive loss	$ (6,304)	$ (3,030)	$ (25,592)	$ (6,660)
Net loss per share—basic and diluted	$ (1.11)	$ (36.55)	$ (7.86)	$ (82.42)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	5,661,933	82,923	3,255,868	80,812