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

May 15, 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 registrant's common stock began trading on the OTCQB on April 26, 2023 under the symbol "CALC."

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 May 15, 2023, CalciMedica, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 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 May 15, 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: May 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 Reports First Quarter 2023 Financial Results and Provides Clinical & Corporate Updates

LA JOLLA, CA, May 15, 2023 – CalciMedica Inc. ("CalciMedica") (OTCQB: CALC), a clinical-stage biopharmaceutical company focused on developing therapies for life-threatening inflammatory diseases with high unmet need, today reported financial results for the first quarter ended March 31, 2023.

"We ended our first quarter as a public company in a strong position, with a cash runway that will last into the second half of 2024," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "We are pleased to have entered the second quarter of 2023 with forward momentum, continuing the work towards our near-term clinical milestones with Auxora in acute pancreatitis and asparaginase-associated pancreatitis for critically ill patient populations whose needs are currently unmet."

Financial Results for the Three Months Ended March 31, 2023:

- Cash, Cash Equivalents and Marketable Securities: As of March 31, 2023, CalciMedica had $34.2 million in cash, cash equivalents and short-term investments.
- Total Operating Expenses: Total operating expenses were $22.3 million, which included $16.2 million of one-time charges related to accelerated vesting and severance for employees of Graybug Vision, Inc. (Graybug) at the time of the merger with Graybug.
- Net Loss: Net loss was $19.3 million, or $23.43 per share (basic and diluted), for the three months ended March 31, 2023.

Clinical Updates and Anticipated Milestones:

- In April, 2023, CalciMedica initiated the ex-US expansion of its Phase 2b clinical trial in acute pancreatitis patients (CARPO) in India with an investigator meeting and expects to begin enrolling patients in India in the second quarter of 2023.
- On May 9, 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.
- CalciMedica anticipates results from the first cohort of the investigator-sponsored Phase 1/2 CRSPA study of lead candidate Auxora in patients with Asparaginase-Associated Pancreatitis (AAP) and trial expansion in the second half of 2023.
- The Company also expects to complete enrollment in the ongoing Phase 2b CARPO clinical trial of Auxora in Acute Pancreatitis (AP) patients with systemic inflammatory response syndrome (SIRS) by year-end 2023, with topline results expected in the first quarter of 2024.
- The Company expects to file an IND for Auxora in acute kidney injury in the second half of 2023 and, if accepted, will then be in a position to initiate clinical trials in this indication pending additional funding.

Corporate Updates

- On March 20, 2023, CalciMedica closed a merger with Graybug. Immediately following the closing of the merger, CalciMedica equityholders owned approximately 72% of the combined company and Graybug equityholders owned approximately 28%.
- On March 30, 2023 Company's common stock was suspended from trading on Nasdaq due to non-compliance with Nasdaq listing requirements. The Company's common stock is currently trading on the OTCQB and the Company is working diligently towards relisting its common stock on Nasdaq.

About Auxora

CalciMedica's lead clinical compound, Auxora, is a potent and selective small molecule inhibitor of Orai1-containing calcium release-activated calcium (CRAC) channels that is being developed for use in patients with inflammatory 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 a Phase 2b trial for acute pancreatitis (AP) with accompanying systemic inflammatory response syndrome (SIRS) called CARPO, an investigator-sponsored Phase 1/2 trial being conducted in pediatric patients with asparaginase-associated pancreatitis (AAP) called CRSPA and a Phase 2 dose escalation study in critical COVID-19 patients. There are currently no approved therapies to treat either AP or AAP. In previous trials patients responded well to Auxora regardless of severity or cause of disease. CalciMedica is also exploring potential Auxora treatment for other acute indications including acute kidney injury, acute respiratory distress syndrome and acute lung injury.

About CARPO

CARPO is a randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish efficacy in acute pancreatitis (AP). 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 AAP, 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 AAP 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 therapies for life-threatening inflammatory diseases with high unmet need. 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 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 four completed efficacy clinical trials. Auxora is in development for acute AP with SIRS and AAP. 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; and CalciMedica's ability to relist on Nasdaq. 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:

Investors and Media

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Selected Financial Information
Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2023 (unaudited)	December 31, 2022 (as restated)
Assets		
Current assets		
Cash and cash equivalents	$ 24,386	$ 1,476
Short-term investments	9,776	—
Prepaid expenses and other current assets	336	254
Total current assets	34,498	1,730
Property and equipment, net	134	147
Right-of-use asset, net	10	48
Other assets	27	1,424
Total assets	$ 34,669	$ 3,349
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 2,055	$ 2,866
Accrued other	10,482	1,715
Other current liabilities	113	199
Total current liabilities	12,650	4,780
Long-term liabilities		
Warrant liability	—	2,645
Convertible promissory notes	—	5,157
Total liabilities	12,650	12,582
Commitments and contingencies (Note 8)		
Preferred stock	—	62,071
Stockholders' equity (deficit)		
Common stock	1	3
Additional paid-in capital	153,013	40,400
Accumulated deficit	(130,995)	(111,707)
Total stockholders' equity (deficit)	22,019	(71,304)
Total liabilities and stockholders' equity	$ 34,669	$ 3,349

Selected Financial Information
Condensed Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 6,491	$ 2,925
General and administrative	15,849	1,286
Total operating expenses	22,340	4,211
Loss from operations	(22,340)	(4,211)
Other income (expense)		
Other income (expense), net	(116)	—
Change in fair value of financial instruments	3,168	581
Total other income (expense), net	3,052	581
Net loss and comprehensive loss	$ (19,288)	$ (3,630)
Net loss per share—basic and diluted	$ (23.43)	$ (46.13)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	823,069	78,678