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

January 28, 2026
Date of Report (Date of earliest event reported)

CalciMedica, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39538**	**45-2120079**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

505 Coast Boulevard South, Suite 307 **La Jolla, California**	**92037**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 952-5500

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001, par value per share	CALC	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On January 28, 2026, CalciMedica, Inc. (the "Company") issued a press release announcing the discontinuation of its Phase 2 KOURAGE clinical trial evaluating Auxora™ in patients with Stage 2 or Stage 3 acute kidney injury ("AKI") with associated acute hypoxemic respiratory failure ("AHRF"). The decision follows a recommendation from the trial's Independent Data Monitoring Committee ("IDMC") (the "Trial Discontinuation"). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of this Current Report on Form 8-K, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 information contained in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any filing we make with the U.S. Securities and Exchange Commission ("SEC"), whether before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On January 28, 2026, the Company announced the Trial Discontinuation. During a prescheduled interim data review, the IDMC identified a safety concern that, in its view, warrants reevaluation of the study design, particularly with respect to patient enrollment criteria. There were no deaths in the trial that were assessed by investigators or the Company as being related to study drug (either Auxora or placebo). In addition, no serious adverse events met the criteria for expedited reporting to the U.S. Food and Drug Administration ("FDA"). Based on the IDMC's recommendation, the Company has discontinued the trial and plans to perform a comprehensive review of the unblinded clinical data. The Company will assess the impact of baseline characteristics, disease severity, concomitant therapies, and other factors on patient outcomes. These analyses are expected to inform how future clinical evaluation of Auxora in AKI may proceed. The Company has notified the FDA about the Trial Discontinuation and will work with investigators to ensure all patients currently enrolled in the trial complete the full 90-day follow-up.

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 related to the Company's planned and ongoing clinical trials and the timing, design, expected patient enrollment thereof and the expected timing for updates; statements regarding the safety and efficacy of its product candidates; statements regarding the planned analysis of the unblinded KOURAGE dataset, including the timing of such analysis and whether such analysis will inform future trial parameters; and the potential of the Company's proprietary technology to provide therapeutic benefits in acute and chronic inflammatory and immunologic diseases such as AKI and AP. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. The Company'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 the Company's business and the actions it may take in response thereto; the Company's ability to execute its plans and strategies; the ability to obtain and maintain regulatory approval for Auxora; results from clinical trials or preclinical studies 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 the Company generally; the Company's ability to protect its intellectual property position; the impact of government laws and regulations; and the Company's financial position and need for additional capital. 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 the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the SEC on November 12, 2025, and elsewhere in the Company's subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from time to time. The forward-looking statements included in this Current Report on Form 8-K are made only as of the date hereof. The Company assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated January 28, 2026.
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.

CalciMedica, Inc.

Date: January 28, 2026

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

Exhibit 99.1

CalciMedica Announces Discontinuation of Phase 2 KOURAGE Trial in AKI Following Independent Data Monitoring Committee Recommendation

Safety concern warrants reevaluation of study design, including enrollment criteria

Potential future trial with Auxora™ in AKI to be evaluated after data analysis

LA JOLLA, Calif., January 28, 2026 – CalciMedica Inc. ("CalciMedica" or the "Company") (Nasdaq: CALC), a clinical-stage biopharmaceutical company developing novel calcium release-activated calcium (CRAC) channel inhibition therapies for acute and chronic inflammatory and immunologic illnesses, today announced the discontinuation of its Phase 2 KOURAGE clinical trial evaluating Auxora™ in patients with Stage 2 or Stage 3 acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF), a population characterized by high mortality and a lack of approved therapies. The decision follows a recommendation from the trial's Independent Data Monitoring Committee (IDMC).

During a prescheduled interim data review, the IDMC identified a safety concern that, in its view, warrants reevaluation of the study design, particularly with respect to patient enrollment criteria. There were no deaths in the trial that were assessed by investigators or CalciMedica as being related to study drug (either Auxora or placebo). In addition, no serious adverse events met the criteria for expedited reporting to the U.S. Food and Drug Administration (FDA). Based on the IDMC's recommendation, the Company has discontinued the trial and plans to perform a comprehensive review of the unblinded clinical data.

The Company will assess the impact of baseline characteristics, disease severity, concomitant therapies, and other factors on patient outcomes. These analyses are expected to inform how future clinical evaluation of Auxora in AKI may proceed.

"Based on the IDMC's feedback, we will review the unblinded KOURAGE data and explore modifications to the trial design, particularly patient enrollment criteria, that may support further clinical testing of Auxora in patients with AKI," said Rachel Leheny, Ph.D., CEO of CalciMedica. "To date, no treatment-related safety concern has been observed across more than 350 critically ill patients treated with Auxora in completed clinical trials, including the Phase 2b CARPO trial in acute pancreatitis (AP) and the Phase 2 CARDEA trial in severe COVID-19 pneumonia. We remain optimistic about Auxora's potential in acute inflammatory illnesses and look forward to finalizing the design of a pivotal trial in AP, pending FDA feedback, in the first half of 2026, while also advancing a second CRAC channel inhibitor, CM5480, as a potential first-in-class, differentiated therapy for pulmonary arterial hypertension."

The Company has notified the FDA about the trial discontinuation and will work with investigators to ensure all patients currently enrolled in the trial complete the full 90-day follow-up.

About CalciMedica

CalciMedica is a clinical-stage biopharmaceutical company developing novel calcium release-activated calcium (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 in serious and life-threatening conditions with high unmet need. CalciMedica's lead product candidate, Auxora™, has demonstrated positive clinical results in multiple completed efficacy clinical trials. The Company has reported data from a Phase 2b trial (CARPO; NCT04681066) evaluating Auxora in patients with acute pancreatitis (AP) and accompanying systemic inflammatory response syndrome (SIRS), as well as from a Phase 2 trial (CARDEA; NCT04345614) in patients with severe COVID-19 pneumonia. In addition, CalciMedica is advancing CM5480 as a potential therapy for pulmonary arterial hypertension (PAH), supported by preclinical data demonstrating effects on pulmonary vascular remodeling and right ventricular function. For more information, please visit www.calcimedica.com.

Forward-Looking Statements

This communication contains forward-looking statements which include, but are not limited to CalciMedica's planned and ongoing clinical trials and the timing, design, expected patient enrollment thereof and the expected timing for updates; statements regarding the safety and efficacy of its product candidates; statements regarding the planned analysis of the unblinded KOURAGE dataset, including the timing of such analysis and whether such analysis will inform future trial parameters; and the potential of CalciMedica's proprietary technology to provide therapeutic benefits in PAH and other acute and chronic inflammatory and immunologic diseases such as AKI and AP. 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 or preclinical studies 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; the impact of government laws and regulations; and CalciMedica's financial position and need for additional capital. 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, 2025, filed with the Securities and Exchange Commission (SEC) on November 12, 2025, 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. The forward-looking statements contained herein are made as of the date hereof, and CalciMedica undertakes no obligation to update them after this date, except as required by law.

Contact Information

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