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

November 2, 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.

Based on current estimates, as of September 30, 2023, CalciMedica, Inc. (the "Company") had cash, cash equivalents and short-term investments of $14.6 million. Based on the Company's current operating plan, the Company believes its existing resources will be sufficient to fund its operations through the third quarter of 2024.

These estimates are preliminary, unaudited and are subject to change upon completion of the Company's financial statement closing procedures. The review of the Company's financial statements for the three and nine months ended September 30, 2023 is ongoing and could result in changes to these amounts.

The Company's independent registered public accounting firm has not audited, reviewed or performed any procedures with respect to these preliminary results and, accordingly, does not express an opinion or any other form of assurance about them.

The Company expects to file its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023 on or about November 9, 2023.

Item 8.01. Other Events.

On November 2, 2023, the Company announced that its collaborator, St. Jude Children's Research Hospital, will present data from the initial cohort of the CRSPA study of Auxora™ (zegocractin) in asparaginase-induced pancreatic toxicity in an oral presentation at the 65th Annual American Society of Hematology Meeting & Exposition being held December 9-12, 2023 in San Diego, California. The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 Company's preliminary financial estimates and cash runway, the expected timing of the Company's Quarterly Report on Form 10-Q, the Company's preliminary analysis, assessment and conclusions of the results of the first cohort of the CRSPA study, the design and potential benefits of Auxora, the Company's plans and expected timing for developing its product candidates and potential benefits of its product candidates, the Company'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. 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 Company's need to obtain substantial additional funding to complete the development and any commercialization of its product candidates; the Company's ability to continue as a going concern; the impact of fluctuations in global financial markets on the Company's business and the actions the Company 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; the results that may be observed in the future in comparison to the results from clinical trials; 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 Company's business generally; the Company'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" and elsewhere in the Company's most recent filings with the SEC, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 and any 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 Number	Description
99.1	Press release, dated November 2, 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: November 2, 2023

CalciMedica, Inc.

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

CalciMedica Announces Presentation of Initial Data from the CRSPA Study of Auxora at the 65th Annual ASH Meeting & Exposition

Auxora™ showed a 53% reduction in days in hospital, a 40% reduction in intensive care unit (ICU) days and eliminated the need for total parenteral nutrition (TPN)

LA JOLLA, CA, Nov. 2, 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 diseases, today announced that there will be a presentation of data from the initial cohort of the CRSPA study of Auxora™ (zegocractin) in asparaginase-induced pancreatic toxicity (AIPT) in a poster presentation at the 65th Annual American Society of Hematology (ASH) Meeting & Exposition being held December 9-12, 2023 in San Diego, CA.

The data to be presented by the study sponsor highlights promising early results of the investigational use of Auxora™ in children with acute lymphoblastic leukemia (ALL) experiencing asparaginase-associated pancreatitis, also known as AIPT and referred to as AAP in the abstract. The presentation includes results from the first cohort consisting of nine patients from the CRSPA study. Eight of nine patients received a full regimen of 4 daily doses of Auxora™ and results from these patients are compared to a historical matched control group of 16 patients with complete imaging out of a total of 51 patients who developed pancreatitis in the Total Therapy XVI study (T16). These children were treated at St. Jude Children's Research Hospital ("SJCRH") and developed pancreatitis within 30 days of receiving asparaginase (e.g. ONCASPAR™ and RYLAYZE™), a nearly identical ALL treatment protocol as used in the CRSPA study.

The results showed that treatment with Auxora™ compared to the historical matched control group reduced the average number of days patients spent in the hospital from 13.4 to 6.3 days. Three control patients (18.8%) needed intensive care unit (ICU) care compared to one treated patient (12.5%), and the average number of days in the ICU was reduced from 5 to 3 days. Additionally, no CRSPA patients required total parenteral nutrition (TPN), compared to 68.8% in the historical matched control group. The matched control patients that required TPN needed 27 days of nutritional support on average. Based on the results from cohort 1 of CRSPA, a dose level 1 (30mg/m^2 on day 1 and 42mg/m^2 on days 2-4) has been established as the recommended dose (RP2D) of Auxora™ for children with ALL experiencing AIPT.

Presentation Title: Zegocractin to Reduce the Severity of Asparaginase Associated Pancreatitis in Children with Acute Lymphoblastic Leukemia: Results of the Phase 1 Portion of the CRSPA Study

Presenter: Seth Karol, M.D., St. Jude Children's Research Hospital

Session Date and Time: Sunday, December 10, 2023, from 6:00 p.m. – 8:00 p.m. PT

Session Title: 612. Acute Lymphoblastic Leukemias: Clinical and Epidemiological: Poster II

Publication #: 2837

About AIPT and CRSPA

AIPT is an ultra-orphan indication affecting 300-400 patients in the US each year. One of the mainstays of therapy in pediatric ALL patients is asparaginase (e.g. ONCASPAR™ and RYLAYZE™), an enzyme that degrades the amino acid asparagine, which is essential for the leukemic cells to survive. However, the administration of asparaginase triggers the development of AAP or AIPT in 7-10% of patients, including the over 4,000 pediatric ALL patients treated per year in the United States, with similar numbers in Europe. The first cohort in the dose-finding part of the CRSPA study consisting of 9 patients has been completed at SJCRH and investigators believe that an optimal pediatric dose for Auxora™ in this setting has been defined. The study has continued to enroll patients beyond the initial 9 patient cohort and is being expanded to additional sites. The full study plans for 24 patients at the optimal dose. Details of the CRSPA study 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 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. Additional data from the Phase 1/2 CRSPA AIPT study is expected by 2H 2024. A Phase 2 study in acute kidney injury (AKI) is planned for early 2024. 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 preliminary analysis, assessment and conclusions of the results of the first cohort of the CRSPA study; 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 June 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.

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