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): January 26, 2023

SANA BIOTECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39941**	**83-1381173**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

188 East Blaine Street, Suite 400
Seattle, Washington 98102
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (206) 701-7914

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, $0.0001 par value per share	SANA	The Nasdaq Global Select 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 8.01 Other Events.

On January 26, 2023, Sana Biotechnology, Inc. (the "Company") announced that the U.S. Food and Drug Administration has cleared the Company's Investigational New Drug (IND) application to initiate a first-in-human study of SC291, a CD19-targeted allogeneic CAR T cell therapy that was developed using the Company's hypoimmune platform, in patients with various B-cell malignancies. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

See the Exhibit Index below, which is incorporated by reference herein.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated January 26, 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 thereunto duly authorized.

Sana Biotechnology, Inc.

Date: January 26, 2023

By: /s/ Bernard J. Cassidy

Bernard J. Cassidy
Executive Vice President and General Counsel

Exhibit 99.1

Sana Biotechnology Announces FDA Clearance of Investigational New Drug Application for SC291, a Hypoimmune-modified, CD19-targeted Allogeneic CAR T Therapy for Patients with B-Cell Malignancies

Goal is to report initial SC291 clinical data this year

Goal is to submit a second IND from the platform this year for SC262, a hypoimmune-modified CD22-targeted allogeneic CAR T therapy

SEATTLE, January 26, 2023 — Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on creating and delivering engineered cells as medicines, today announced the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to initiate a first-in-human study of SC291 in patients with various B-cell malignancies.

SC291 is a CD19-targeted allogeneic CAR T cell therapy developed using Sana's hypoimmune platform. The goal of the hypoimmune platform is to overcome the immunologic rejection of allogeneic cells, which if true for SC291 may result in longer CAR T cell persistence and a higher rate of durable complete responses for patients with B-cell lymphomas or leukemias. The hypoimmune platform includes disruption of major histocompatibility (MHC) class I and MHC class II expression to hide cells from the adaptive immune system, which includes antibody and T cell responses, as well as overexpression of CD47 to inhibit activation of the innate immune cell system, in particular macrophages and natural killer (NK) cells. The company has presented data across multiple preclinical models highlighting the potential of this platform to cloak cells from immune recognition and the potential of SC291 as a therapeutic for patients with B-cell malignancies.

"The clearance of our SC291 IND is an important milestone, putting us closer to our goal of making an important medicine for patients with B-cell lymphomas and leukemias," said Steve Harr, Sana's President and CEO. "We look forward to understanding the safety, potency, and persistence of these cells in patients, and we are optimistic that SC291 can become an important medicine for patients with these difficult cancers. Furthermore, this platform forms the backbone for additional development of CAR T cells targeting CD22, BCMA, and beyond. We expect initial clinical data from the SC291 study later this year and believe insights from this study will better inform our opportunities across the broader platform, both for CAR T cells and for programs outside of cancer such as our pancreatic islet cell therapy for patients with type 1 diabetes."

About Hypoimmune Platform

Sana's hypoimmune platform is designed to create cells ex vivo that can "hide" from the patient's immune system to enable the transplant of allogeneic cells without the need for immunosuppression. We are applying the hypoimmune technology to both donor-derived allogeneic T cells, with the goal of making potent and persistent CAR T cells at scale, and pluripotent stem cells, which can then be differentiated into multiple cell types at scale.

Preclinical data demonstrate across a variety of cell types that these transplanted allogeneic cells are able to evade both the innate and adaptive arms of the immune system while retaining their activity. Our most advanced programs utilizing this platform include an allogeneic CAR T program targeting CD19+ cancers, an allogeneic CAR T program targeting CD22+ cancers, an allogeneic CAR T program targeting BCMA+ cancers, and stem-cell derived beta islet cells for patients with type 1 diabetes.

About Sana Biotechnology

Sana Biotechnology, Inc. is focused on creating and delivering engineered cells as medicines for patients. We share a vision of repairing and controlling genes, replacing missing or damaged cells, and making our therapies broadly available to patients. We are a passionate group of people working together to create an enduring company that changes how the world treats disease. Sana has operations in Seattle, Cambridge, South San Francisco, and Rochester. For more information about Sana Biotechnology, please visit https://sana.com/.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements about Sana Biotechnology, Inc. (the "Company," "we," "us," or "our") within the meaning of the federal securities laws, including those related to the Company's vision, progress, and business plans; expectations for its development programs, product candidates and technology platforms, including its pre-clinical, clinical and regulatory development plans and timing expectations, including with respect to the expected timing of IND filings for the Company's product candidates; the Company's expectations regarding the timing and significance of data from its clinical trials; the ability to use the Company's hypoimmune platform to overcome the immunologic rejection of allogeneic cells and the potential benefits associated therewith; the potential benefits of the SC291 program; and the potential to apply the hypoimmune platform to indications outside of cancer. All statements other than statements of historical facts contained in this press release, including, among others, statements regarding the Company's strategy, expectations, cash runway and future financial condition, future operations, and prospects, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results to vary materially, including, among others, the risks inherent in drug development such as those associated with the initiation, cost, timing, progress and results of the Company's current and future research and development programs, preclinical and clinical trials, as well as the economic, market and social disruptions due to the ongoing COVID-19

public health crisis. For a detailed discussion of the risk factors that could affect the Company's actual results, please refer to the risk factors identified in the Company's SEC reports, including but not limited to its Quarterly Report on Form 10-Q dated November 2, 2022. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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