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): June 23, 2025

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 Stock Market LLC**

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 June 23, 2025, Sana Biotechnology, Inc. (the "Company") announced positive six-month clinical results from an investigator-sponsored, first-in-human study transplanting UP421, an allogeneic primary islet cell therapy engineered with the Company's hypoimmune technology, into a patient with type 1 diabetes without any immunosuppression. 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 June 23, 2025
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 hereunto duly authorized.

Sana Biotechnology, Inc.

Date: June 23, 2025

By: /s/ Bernard J. Cassidy

Bernard J. Cassidy
Executive Vice President and General Counsel

Exhibit 99.1

Sana Biotechnology Announces Positive Six-Month Clinical Results from Type 1 Diabetes Study of Islet Cell Transplantation Without Immunosuppression

Groundbreaking First-in-Human Study Establishes Potential to Treat Type 1 Diabetes by Transplanting Insulin-Secreting Cells Without Immunosuppression

Six-Month Patient Follow-up Results Demonstrate that Sana's Transplanted Pancreatic Islet Cells Modified with its Hypoimmune (HIP) Technology are Safe and Well-tolerated, Survive, Evade Detection by the Immune System, and Continue to Produce Insulin in the Patient

Function and Persistence of Pancreatic Islets Were Detectable by Production of Consistent Levels of Circulating C-Peptide, a Marker of Insulin Production, and Increased C-Peptide Levels with a Mixed Meal Tolerance Test (MMTT)

MRI Show Signals Consistent with Graft Survival Six Months after Transplantation

Study Continues to Evaluate Safety, Survival, and Function of Transplanted Cells

Data Shared at an Invited Presentation at the 85th Annual American Diabetes Association (ADA) Scientific Sessions Today

Sana is Incorporating the Tested Immune Evasion Technology to Develop SC451, a HIP-modified, Stem Cell-Derived Therapy as a One-Time Treatment for Patients with Type 1 Diabetes, with a Goal of Normal Blood Glucose, with No Insulin and No Immunosuppression

SEATTLE, June 23, 2025 — Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced six-month follow-up results from an investigator-sponsored, first-in-human study transplanting UP421, an allogeneic primary islet cell therapy engineered with Sana's hypoimmune (HIP) technology, into a patient with type 1 diabetes without any immunosuppression. The study is being conducted in partnership with Uppsala University Hospital. The results are consistent with and build upon the previously reported four-week and 12-week clinical results. Results of the study at six months after cell transplantation demonstrate the survival and function of pancreatic beta cells as measured by the presence of circulating C-peptide, a biomarker indicating that transplanted beta cells are producing insulin. C-peptide levels also increase with a mixed meal tolerance test (MMTT), consistent with insulin secretion in response to a meal. 12-week PET-MRI scanning also demonstrated islet cells at the transplant site, a forearm muscle. The study identified no safety issues, and the HIP-modified islet cells evaded immune responses.

"As an endocrinologist who has dedicated my career to improving outcomes for patients with type 1 diabetes, I am pleased to share these exciting results. Consistent with the previously reported four-week and 12-week data, we believe today's six-month update continues to suggest that a functional cure for type 1 diabetes without immunosuppression is possible," said Per-Ola Carlsson, MD, Study Principal Investigator, Senior Physician and Professor at the Clinic for Endocrinology and Diabetology at Uppsala University Hospital. "These groundbreaking results build upon the extensive preclinical and translational studies of Dr. Sonja Schrepfer and the team at Sana and provide hope for a cure. We look forward to continued follow-up, with study results submitted for publication in a peer-reviewed journal."

"Durable survival, function, and immune evasion of transplanted allogeneic pancreatic islet cells with no immunosuppressive medicines, particularly in the context of a pre-existing autoimmune response to these cells, represents a transformative and necessary step to making cellular and transplant medicine more accessible," said Steve Harr, MD, Sana's President and CEO. "Type 1 diabetes currently impacts over nine million people globally, and there have been relatively few transformational advances in this disease since the discovery of insulin over 100 years ago. The data presented today bring our vision—treating diabetes with a broadly available therapy leading to normal blood glucose control without either insulin or immunosuppression—closer to reality. We are incorporating the immune evasion learnings and technology from the current UP421 trial to develop SC451, a HIP-modified, stem cell-derived islet cell therapy, for which we intend to file an investigational new drug application (IND) as soon as next year."

Aaron J. Kowalski, Ph.D., CEO of Breakthrough T1D (previously known as JDRF), added “A paradigm shift in the treatment of diabetes is long overdue. For more than a century, exogenous insulin administration has remained the only therapy for this chronic disease. Significant improvements in insulin therapy, like automated insulin delivery systems, have improved outcomes for many living with this disease. Yet, most people with type 1 diabetes are still unable to achieve ideal glucose levels, heightening the risk of many complications, including cardiovascular disease, kidney disease, and more. The prospect of administering insulin-producing cells into people with this disease—enabling stable glycemic control without lifelong injections, drugs that suppress their immune system, or constant daily management—represents a transformative and potentially life-changing breakthrough. We are extremely grateful for the collaborative efforts of the research teams at Sana, Uppsala University Hospital, and all those involved, for their dedication to this work. The entire team at Breakthrough T1D looks forward to working with Sana and others to ensure all members of the T1D community can benefit from these life-changing breakthroughs.”

Primary islet cell transplantation with immunosuppression is an established procedure in type 1 diabetes in which allogeneic pancreatic islet cells are isolated from a deceased donor’s pancreas and transplanted into a patient with a goal of normal blood glucose control and insulin independence. As with whole-organ transplants, suppression of the recipient’s immune system has historically been required to prevent immune rejection of the allogeneic transplanted cells and resurgence of the inciting autoimmune attack. Sana’s HIP technology is designed to overcome immunologic rejection of allogeneic cells, and in type 1 diabetes, to evade the autoimmune rejection of pancreatic beta cells as well. UP421 cells were transplanted with no immunosuppression, and the survival of those islet cells provides evidence that they evade both allogeneic and autoimmune detection.

About the Uppsala University Hospital Investigator-Sponsored Study of UP421 in Type 1 Diabetes
The investigator-sponsored study of UP421 is supported by a grant from The Leona M. and Harry B. Helmsley Charitable Trust. The study evaluates whether HIP-engineered insulin-producing pancreatic cells can be transplanted safely and help to regain insulin production in individuals with type 1 diabetes without need of simultaneous treatment with immunosuppressive medicines. To do this, UP421 is engineered using Sana’s HIP platform at Oslo University Hospital. The study involves intramuscular surgical transplantation of primary, or donor-derived, HIP-engineered islet cells into the forearm of patients with type 1 diabetes. The primary objective of the study is to investigate safety of UP421 transplantation in patients with type 1 diabetes, with secondary endpoints including cell survival, immune evasion, and C-peptide production. Circulating C-peptide is a measure of endogenous insulin production. This first-in-human study examines a low dose of HIP-modified primary islets to initially establish the safety and function of HIP-modified islets without immunosuppression and, as a result, is not intended to show improvement in glycemia and/or reduction in exogenous insulin administration.

Results of the study over six months after islet cell transplantation demonstrate the survival and function of pancreatic beta cells through the latest timepoint at month 6, as measured by the presence of circulating C-peptide, a biomarker indicating that transplanted beta cells are producing insulin. C-peptide levels also increase during an MMTT, consistent with insulin secretion in response to a meal. At baseline, the patient had undetectable C-peptide both fasting and during an MMTT. 12-week PET-MRI scanning also demonstrated islet cells at the transplant site, a forearm muscle. The HIP platform has achieved proof-of-concept in humans, showing evasion of immune recognition with the potential broad application for allogeneic transplantation without immunosuppression.

About the Sana Biotechnology Hypoimmune (HIP) Platform
Sana’s HIP platform is designed to generate cells *ex vivo* that can evade the patient’s immune system to enable the transplantation of allogeneic cells without the need for immunosuppression. We are applying the HIP technology to develop therapeutic candidates at scale, including pluripotent stem cells, which can then be differentiated into multiple cell types, including pancreatic islet cells, and donor-derived allogeneic CAR T cells. We and our collaborators have generated significant foundational intellectual property in the area. Early clinical data from Phase 1 trials and preclinical data published in peer-reviewed journals 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. Sana’s most advanced programs using this platform include a stem cell-derived pancreatic islet cell program for type 1 diabetes, an allogeneic CAR T program for B-cell mediated autoimmune diseases, and an allogeneic CAR T program targeting CD22+ cancers.

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, WA, Cambridge, MA, South San Francisco, CA, and Bothell, WA. 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 preclinical, clinical and regulatory development plans and timing expectations, including with respect to the timing and substance of potential INDs, and the Company's SC451 program, including the potential ability of SC451 to be administered as a broadly available, one-time treatment for patients with type 1 diabetes and to achieve normal blood glucose without insulin injections or immunosuppression; the potential impact and significance of data from the UP421 study of islet cell transplantation without immunosuppression in type 1 diabetes ("Study"), including with respect to the potential to transplant insulin-secreting cells and develop a functional cure for the treatment of type 1 diabetes without immunosuppression and the accessibility of cellular and transplant medicines; expectations regarding the presentation at the 85th Annual American Diabetes Association Scientific Sessions; the ability of the HIP platform to generate cells *ex vivo* that can evade the patient's immune system to enable the transplantation of allogeneic cells without the need for immunosuppression and, in type 1 diabetes, enable transplanted pancreatic beta cells to avoid autoimmune rejection, to have broad application for allogeneic transplantation without immunosuppression, and to be applied to develop therapeutic candidates at scale, including pluripotent stem cells that can be differentiated into multiple cell types and donor-derived allogeneic CAR T cells; expectations with respect to Study follow-up and submission and publication of Study results; the potential safety and survival, function, and evasion of immune detection of HIP-modified primary pancreatic islet cells transplanted intramuscularly with no immunosuppression; the potential impact of administering insulin-producing cells to enable stable glycemic control without lifelong injections, immune-suppressing drugs, or constant daily management, including the potential to benefit members of the type 1 diabetes community; the potential application of the learnings from the Study to the Company's SC451 program; the potential significance of the survival of UP421 cells in the Study; and statements made by Study Principal Investigator, Senior Physician and Professor at the Clinic for Endocrinology and Diabetology at Uppsala University Hospital, statements made by the Company's President and CEO, and statements made by the CEO of Breakthrough T1D (previously known as JDRF). 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 economic, market, and social disruptions. 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 Securities and Exchange Commission (SEC) reports, including but not limited to its Quarterly Report on Form 10-Q dated May 8, 2025. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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