Sana Biotechnology Reports First Quarter 2025 Financial Results and Business Updates

May 8, 2025

Presented positive 4- and 12-week clinical results of ongoing type 1 diabetes study showing that hypoimmune-modified pancreatic islet cells transplanted without immunosuppression overcome immune recognition, while continuing to function and persist with stable C-peptide production post-transplant

Enrolling patients in the GLEAM trial for SC291 in B-cell mediated autoimmune diseases and VIVID trial for SC262 in relapsed/refractory B-cell malignancies; expect to report clinical data from both studies in 2025

Presented preclinical data in non-human primates showing safety and deep B-cell depletion using a surrogate for SG299, an in vivo CAR T with CD8-targeted fusogen delivery of a CD19-directed CAR

Expect to file investigational new drug applications (INDs) for SC451 in type 1 diabetes and for SG299 in B-cell related diseases as early as 2026

Q1 2025 cash position of $104.7 million; expected cash runway into 2026

SEATTLE, May 08, 2025 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on creating and delivering engineered cells as medicines, today reported financial results and business highlights for the first quarter 2025.

“Type 1 diabetes (T1D) remains a large, unmet need, impacting the lives of over 9 million people, and we have made significant progress in 2025 toward a functional cure of this disease,” said Steve Harr, Sana’s President and Chief Executive Officer. “We recently presented 12-week clinical data for UP421, showing that hypoimmune-modified pancreatic islets transplanted without any immunosuppression continue to evade immune detection and function three months after transplant, a result that we expect to continue over time and to be broadly generalizable across the population. Additionally, we have established the foundation for a genomically stable, gene-modified master cell bank, a difficult and essential step that clears the path toward an IND as early as 2026 and makes a scalable solution for people with T1D a realistic possibility.”

Recent Corporate Highlights

Announced positive initial results from an investigator-sponsored, first-in-human study transplanting UP421, an allogeneic primary islet cell therapy engineered with hypoimmune platform (HIP) technology, into a patient with type 1 diabetes without the use of any immunosuppression.

- UP421 is a primary human HIP-modified pancreatic islet cell therapy for patients with type 1 diabetes. The goal of this investigator-sponsored trial (IST) is to understand safety, immune evasion, islet cell survival, and beta cell function, as measured by C-peptide production, of HIP-modified pancreatic islet cells in type 1 diabetics without any immunosuppression. The trial is being conducted under a clinical trial authorization at Uppsala University Hospital with Dr. Per-Ola Carlsson as the principal investigator.
- Results of the study through 12-weeks 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 during testing at these timepoints, consistent with insulin secretion in response to a meal. Magnetic resonance imaging scanning also demonstrates a sustained signal at the site of transplanted cells over time, which is consistent with graft survival. The study identified no safety issues, and the HIP-modified islet cells evaded immune detection.
- Sana presented 12-week data at the New York Stem Cell Foundation (NYSCF) conference and expects to report additional data from this study, including longer-term follow-up, as the year progresses at scientific conferences and/or in a peer-reviewed publication.

Advancing our pipeline across multiple indications and modalities:

- **Type 1 Diabetes** – Sana continues the clinical development of gene-modified primary islet cells (UP421) and the pre-clinical development of SC451, a HIP-modified, stem cell-derived pancreatic islet cell therapy. In addition to the human data for UP421 outlined above, Sana shared data for SC451 showing 15-month durability of glycemic control, with no histologic abnormalities, in a mouse model. Sana expects to share additional data in 2025 and file an IND for SC451 as early as 2026.
    - **Allogeneic CAR T cells** – The **GLEAM** study is a Phase 1 study evaluating SC291, a HIP-modified CD19-directed allogeneic CAR T cell therapy, in patients with B-cell mediated autoimmune diseases, including refractory systemic lupus erythematosus and antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis. The **VIVID** study is a

Phase 1 clinical trial evaluating SC262, a HIP-modified CD22-directed allogeneic CAR T cell therapy, in patients with relapsed and/or refractory B-cell malignancies who have received prior CD19-directed CAR T therapy.

    - Data from the suspended ARDENT trial evaluating SC291 in relapsed or refractory non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL) demonstrated the ability to safely dose SC291 with the desired deep B-cell depletion. The goal in the GLEAM study is to demonstrate similar deep B-cell depletion with subsequent clinical benefit for patients with B-cell mediated autoimmune diseases.

- Sana is enrolling patients in both the GLEAM and VIVID trials and expects to share data in 2025.
- ***in vivo* CAR T cells** – SG299, which uses our fusogen platform, allows for cell-specific, *in vivo* delivery of various payloads. SG299 is a CD8-targeted fusosome that delivers to CD8+ T cells the genetic material to make CD19-directed CAR T cells while avoiding potentially troublesome delivery to tissues such as the liver and gonadal tissue. Sana shared data showing that an SG299 surrogate with another component can lead to deep B-cell depletion in non-human primates without the use of any lymphodepleting chemotherapy. Sana expects to file an IND for SG299 as early as 2026, and we look forward to developing it in a range of B-cell cancers and B-cell mediated autoimmune diseases.

First Quarter 2025 Financial Results

GAAP Results

- **Cash Position**: Cash, cash equivalents, and marketable securities as of March 31, 2025 were $104.7 million compared to $152.5 million as of December 31, 2024. The decrease of $47.8 million was primarily driven by cash used in operations of $48.7 million.
- **Research and Development Expenses**: For the three months ended March 31, 2025, research and development expenses, inclusive of non-cash expenses, were $37.2 million compared to $56.4 million for the same period in 2024.The decrease of $19.3 million was primarily due to lower personnel-related, laboratory, and research costs due to a decrease in headcount and the portfolio prioritization announced in the fourth quarter of 2024, a decrease in clinical development costs primarily related to the suspension of the ARDENT trial in the fourth quarter of 2024 and clinical development milestones recorded in the first quarter of 2024 that did not recur in 2025, and a decrease in facility and other allocated costs primarily due to the portfolio prioritization announced in the fourth quarter of 2024. These decreases were partially offset by increased costs for third-party manufacturing. Research and development expenses include non-cash stock-based compensation of $4.6 million and $5.8 million for the three months ended March 31, 2025 and 2024, respectively.
- **Research and Development Related Success Payments and Contingent Consideration**: For the three months ended March 31, 2025, Sana recognized a non-cash expense of $2.0 million compared to $38.0 million for the same period in 2024, in connection with the change in the estimated fair value of the success payment liabilities and contingent consideration in aggregate. The value of these potential liabilities fluctuates significantly with changes in Sana's market capitalization and stock price.
- **General and Administrative Expenses**: General and administrative expenses for the three months ended March 31, 2025, inclusive of non-cash expenses, were $11.5 million compared to $16.3 million for the same period in 2024. The decrease of $4.8 million was primarily due to lower personnel-related costs, including non-cash stock-based compensation, due to a decrease in headcount, and decreased legal and consulting fees. General and administrative expenses include non-cash stock-based compensation of $2.4 million and $3.2 million for the three months ended March 31, 2025 and 2024, respectively.
- **Net Loss**: Net loss for the three months ended March 31, 2025 was $49.4 million, or $0.21 per share, compared to $107.5 million, or $0.49 per share, for the same period in 2024.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn**: Non-GAAP operating cash burn for the three months ended March 31, 2025 was $46.6 million compared to $58.7 million for the same period in 2024. Non-GAAP operating cash burn is the decrease in cash, cash equivalents, and marketable securities, excluding cash inflows from financing activities, costs related to the portfolio prioritizations in the fourth quarters of 2024 and 2023, and the purchase of property and equipment.
- **Non-GAAP Net Loss**: Non-GAAP net loss for the three months ended March 31, 2025 was $47.4 million, or $0.20 per share, compared to $69.5 million, or $0.32 per share, for the same period in 2024. Non-GAAP net loss excludes non-cash expenses and gains related to the change in the estimated fair value of contingent consideration and success payment liabilities.

A discussion of non-GAAP measures, including a reconciliation of GAAP and non-GAAP measures, is presented below under "Non-GAAP Financial

Measures."

About Sana

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.

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 substance and timing of potential INDs and potential indications for its product candidates; the potential ability of HIP-modified cells to evade immune detection and function over time across the population; expectations with respect to development of a genomically stable, gene-modified cell bank, including the potential impact thereof; expectations regarding the timing, substance, significance, and impact of data from clinical trials of the Company's product candidates and technologies and an IST utilizing HIP-modified primary islet cells in patients with type 1 diabetes across multiple disease settings, including type 1 diabetes, B-cell mediated autoimmune diseases, and oncology, including expectations for reporting of additional data from the IST at scientific conferences and/or in peer-reviewed publications; the potential ability of SC291 to be safely dosed and demonstrate deep B-cell depletion and to translate into clinical benefit for patients with B-cell mediated autoimmune diseases; and expectations regarding the Company's cash runway. 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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Sana Biotechnology, Inc.
Unaudited Selected Consolidated Balance Sheet Data

	March 31, 2025	December 31, 2024
	(in thousands)	
Cash, cash equivalents, and marketable securities	$ 104,701	$ 152,497
Total assets	445,470	501,020
Contingent consideration	110,832	108,968
Success payment liabilities	4,649	4,556
Total liabilities	236,391	250,516
Total stockholders' equity	209,079	250,504

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended March 31,	
	2025	2024
	(in thousands, except per share data)	
Operating expenses:		
Research and development	$ 37,189	$ 56,448
Research and development related success payments and contingent consideration	1,957	38,007
General and administrative	11,484	16,269
Total operating expenses	50,630	110,724
Loss from operations	(50,630)	(110,724)
Interest income, net	992	3,034

Other income, net	249	215
Net loss	$ (49,389)	$ (107,475)
Net loss per common share – basic and diluted	$ (0.21)	$ (0.49)
Weighted-average number of common shares – basic and diluted	237,578	217,290

Sana Biotechnology, Inc.
Changes in the Estimated Fair Value of Success Payments and Contingent Consideration

	Success Payment Liability[1]	Contingent Consideration[2]	Total Success Payment Liability and Contingent Consideration
		(in thousands)	
Liability balance as of December 31, 2024	$ 4,556	$ 108,968	$ 113,524
Changes in fair value – expense	93	1,864	1,957
Liability balance as of March 31, 2025	$ 4,649	$ 110,832	$ 115,481
Total change in fair value for the three months ended March 31, 2025	$ 93	$ 1,864	$ 1,957

(1) Cobalt Biomedicine, Inc. (Cobalt) and the President and Fellows of Harvard College (Harvard) are entitled to success payments pursuant to the terms and conditions of their respective agreements. The success payments are recorded at fair value and remeasured at each reporting period with changes in the estimated fair value recorded in research and development related success payments and contingent consideration on the statement of operations.
(2) Cobalt is entitled to contingent consideration upon the achievement of certain milestones pursuant to the terms and conditions of the agreement. Contingent consideration is recorded at fair value and remeasured at each reporting period with changes in the estimated fair value recorded in research and development related success payments and contingent consideration on the statement of operations.

Non-GAAP Financial Measures

To supplement the financial results presented in accordance with generally accepted accounting principles in the United States (GAAP), Sana uses certain non-GAAP financial measures to evaluate its business. Sana's management believes that these non-GAAP financial measures are helpful in understanding Sana's financial performance and potential future results, as well as providing comparability to peer companies and period over period. In particular, Sana's management utilizes non-GAAP operating cash burn, non-GAAP research and development expense and non-GAAP net loss and net loss per share. Sana believes the presentation of these non-GAAP measures provides management and investors greater visibility into the company's actual ongoing costs to operate its business, including actual research and development costs unaffected by non-cash valuation changes and certain one-time expenses for acquiring technology, as well as facilitating a more meaningful comparison of period-to-period activity. Sana excludes these items because they are highly variable from period to period and, in respect of the non-cash expenses, provides investors with insight into the actual cash investment in the development of its therapeutic programs and platform technologies.

These are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with Sana's financial statements prepared in accordance with GAAP. These non-GAAP measures differ from GAAP measures with the same captions, may be different from non-GAAP financial measures with the same or similar captions that are used by other companies, and do not reflect a comprehensive system of accounting. Sana's management uses these supplemental non-GAAP financial measures internally to understand, manage, and evaluate Sana's business and make operating decisions. In addition, Sana's management believes that the presentation of these non-GAAP financial measures is useful to investors because they enhance the ability of investors to compare Sana's results from period to period and allows for greater transparency with respect to key financial metrics Sana uses in making operating decisions. The following are reconciliations of GAAP to non-GAAP financial measures:

Sana Biotechnology, Inc.
Unaudited Reconciliation of Change in Cash, Cash Equivalents, and Marketable Securities to Non-GAAP Operating Cash Burn

	Three Months Ended March 31,	
	2025	2024
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	$ 152,497	$ 205,195
Ending cash, cash equivalents, and marketable securities	104,701	311,082
Change in cash, cash equivalents, and marketable securities	(47,796)	105,887
Cash paid to purchase property and equipment	136	15,845
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	(47,660)	121,732
Adjustments:		
Net proceeds from issuance of common stock	-	(181,468)
Cash paid for personnel-related costs incurred in connection with portfolio prioritizations	1,062	1,019
Operating cash burn – Non-GAAP	$ (46,598)	$ (58,717)

Sana Biotechnology, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP Net Loss and Net Loss Per Share

	Three Months Ended March 31,	
	2025	2024
	(in thousands, except per share data)	
Net loss – GAAP	$ (49,389)	$ (107,475)
Adjustments:		
Change in the estimated fair value of the success payment liabilities[1]	93	32,623
Change in the estimated fair value of contingent consideration[2]	1,864	5,384
Net loss – Non-GAAP	$ (47,432)	$ (69,468)
Net loss per share – GAAP	$ (0.21)	$ (0.49)
Adjustments:		
Change in the estimated fair value of the success payment liabilities[1]	-	0.15
Change in the estimated fair value of contingent consideration[2]	0.01	0.02
Net loss per share – Non-GAAP	$ (0.20)	$ (0.32)
Weighted-average shares outstanding – basic and diluted	237,578	217,290

(1) For the three months ended March 31, 2025, the expense related to the Cobalt success payment liability was $0.1 million compared to $27.9 million for the same period in 2024. For the three months ended March 31, 2025, the gain related to the Harvard success payment liabilities was immaterial compared to an expense of $4.7 million for the same period in 2024.

(2) The contingent consideration is in connection with the acquisition of Cobalt.