Sana Biotechnology Reports First Quarter 2023 Financial Results and Business Updates

May 8, 2023

IND cleared and enrolling patients in SC291 Phase 1 clinical trial in B-cell malignancies with initial data expected later this year

SC291 granted Fast Track Designation by the FDA for the treatment of relapsed/refractory large B-cell lymphoma and relapsed/refractory chronic lymphocytic leukemia

Expect data later this year from investigator-sponsored trial with hypoimmune-modified primary human islet cells

Goal to submit INDs this year for both SC262 and SG299 in hematologic cancers

Strengthened R&D leadership with addition of Dr. Doug Williams as President of Research and Development and Dr. Gary Meininger as Chief Medical Officer

Publication in Nature Communications demonstrates immune evasion, persistence, and anti-tumor activity of hypoimmune-modified CD19-directed CAR T cells in allogeneic humanized mouse model

Publication in Science Translational Medicine highlights multiple preclinical datasets for hypoimmune-modified islet cells demonstrating potential for allogeneic immune evasion, autoimmune evasion, and control of type 1 diabetes

Publication in Nature Biotechnology shows that hypoimmune-modified allogeneic cells survive and escape immune detection while remaining fully functional across several species, including non-human primates with normal immune systems

Presented multiple abstracts from hypoimmune and fusogen platforms at 2023 AACR meeting

Cash position of $355 million expected to support activities through multiple data readouts and last into 2025

SEATTLE, May 08, 2023 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today reported financial results and business highlights for the first quarter 2023.

“Our initial human studies using Sana’s hypoimmune technology remain on track, as we have begun enrolling patients in our SC291 trial and expect to deliver data from two clinical studies in 2023,” said Steve Harr, Sana’s President and Chief Executive Officer. “We are also making progress in our earlier-stage pipeline and are on pace to file two additional INDs later this year and potentially three more in 2024. The quality of our key hires, publications in high quality peer-reviewed journals, and presentations at important scientific conferences are recent validations of the science behind Sana’s programs. Our capital position and people give us the resources for multiple data read-outs with our current balance sheet, and we continue to be optimistic about our future, with the opportunity to see the potential of these medicines in patients starting this year.”

Recent Corporate Highlights

Opportunity for clinical proof of concept for two different first-in-human studies, each with the potential for initial clinical data this year

- SC291 is an *ex vivo* hypoimmune-modified CD19-directed allogeneic CAR T cell therapy. The goal of the hypoimmune platform is to overcome the immunologic rejection of allogeneic cells, which, if successful with SC291, may result in longer CAR T cell persistence and a higher rate of durable complete responses for patients with B-cell malignancies.
    - Received clearance from the Food and Drug Administration (FDA) to initiate a first-in-human Phase 1 study of SC291 in patients with B-cell malignancies (ARDENT).
    - Began enrollment in the ARDENT Phase 1 study.
    - Granted Fast Track Designation for SC291 by the FDA for the treatment of relapsed/refractory (r/r) large B-cell lymphoma and r/r chronic lymphocytic leukemia.
    - SC291 has the potential to serve as clinical proof-of-platform for other hypoimmune-modified CAR T cell candidates using validated CAR constructs in development at Sana for hematological malignancies, such as SC262 (CD22) and SC255 (BCMA). Sana’s goal is to file INDs for SC262 later this year and SC255 in 2024.
- Sana is developing SC451, a hypoimmune-modified stem-cell derived islet cell therapy for patients with type 1 diabetes. SC451, which is engineered with Sana’s hypoimmune technology, has the potential to replace missing islet cells without immunosuppression in persons with type 1 diabetes by evading allogeneic and autoimmune responses.
    - Expect initial data later this year from an investigator-sponsored trial transplanting hypoimmune-modified primary human islet cells into type 1 diabetes patients. The goal of the study is to show cell survival and immune evasion without the need for any immunosuppression.

- Sana's goal is to file an IND for SC451 in 2024.

Published preclinical data in *Nature Communications* describing immune evasion, persistence, and durable anti-tumor activity of Sana's hypoimmune-modified CD19-directed CAR T cells

- Sana developed hypoimmune-modified CD19 targeted allogeneic CAR T cells and compared them to unmodified CD19-targeted allogeneic CAR T cells in a murine leukemia model with a humanized immune system.
- Although both hypoimmune-modified and unmodified CAR T cells showed robust early tumor killing, cell durability was much greater in humanized mice treated with hypoimmune-modified cells. Hypoimmune-modified allogeneic CAR T cells persisted and removed all evidence of tumor for the duration of the study. Hypoimmune-modified CAR T cells also cleared all evidence of tumor after re-injection with cancer cells 90 days into the study. In contrast and consistent with the experience in patients to date, unmodified allogeneic CAR T cells show greatly reduced persistence and a high rate of tumor recurrence in this model.
- These studies provide additional insight for SC291 and the allogeneic hypoimmune CAR T platform more broadly, including SC262 and SC255.

Published preclinical data in *Science Translational Medicine* demonstrating that Sana's hypoimmune-modified pseudo-islets control type 1 diabetes

- Sana developed hypoimmune-modified human islet cells, which cluster into effective endocrine organoids termed "pseudo islets" (p-islets) and studied these p-islets in multiple preclinical models.
- Preclinical data showed that p-islets survive, persist, escape allogeneic rejection, and normalize blood glucose in diabetic models with humanized immune systems.
- Two different murine models showed that the hypoimmune-modified cells can evade autoimmune rejection and normalize blood glucose. First, these cells were studied in the NOD mouse model, which is the standard model for autoimmunity in diabetes. Second, Sana created a humanized mouse model with immune cells from a diabetic person and transplanted pancreatic islet cells derived from the diabetic person's stem cells. In both cases, unmodified pancreatic islet cells were rapidly cleared by the immune system. In contrast, hypoimmune-modified pancreatic islet cells survived, persisted, and provided sustained blood glucose control in both models.
- These studies provide additional insight for SC451 in persons with type 1 diabetes.

Published preclinical data in *Nature Biotechnology* demonstrating that Sana's hypoimmune-modified cells survive allogeneic transplant across several species, including non-human primates (NHPs) with normal immune systems, and remain fully functional

- Sana developed hypoimmune-modified NHP induced pluripotent stem cells (iPSCs) and transplanted them into immune-competent NHPs. Results were compared to transplantation of unmodified iPSCs into immune-competent NHPs.
- Data showed that hypoimmune-modified iPSCs survived for the duration of the study (16 weeks), while unmodified iPSCs disappeared within two weeks. There was an antibody and T cell response directed toward unmodified cells, but not hypoimmune-modified cells.
- Hypoimmune-modified primary NHP pancreatic islet cells survived 40 weeks (duration of the study) after allogeneic transplantation into an immune-competent NHP versus less than one week for unmodified primary islet cells.
- Hypoimmune-modified iPSCs were differentiated into pancreatic islet cells. Transplantation of hypoimmune-modified iPSC-derived pancreatic cells into allogeneic diabetic mice with a humanized immune system showed immune evasion after transplantation for the duration of the studies (4 weeks) and amelioration of diabetes and normalization of blood glucose levels.

Presented multiple abstracts at the 2023 American Association for Cancer Research (AACR) Annual Meeting highlighting *ex vivo* hypoimmune-modified allogeneic CAR T cells, as well as *in vivo* cell-specific delivery of genetic material using Sana's *in vivo* fusogen platform

- Presented preclinical data demonstrating that hypoimmune-modified CAR T cells provide lasting tumor control in immunocompetent allogeneic humanized mice even with tumor re-challenge.
- Presented preclinical data in a late-breaking poster presentation demonstrating that the increased potency of CD8-targeted fusosomes enhances CAR transgene delivery to resting primary T cells.
- Presented preclinical data demonstrating the effectiveness of Sana's fully human CD19 CAR delivered by CD8-targeted fusosomes in tumor killing assays. These fusosomes led to similar levels of tumor control as *ex vivo* generated CD19 CAR

T cells.

- Presented preclinical data demonstrating increased potency of CD8-targeted fusosomes delivering a CD19 CAR with pre-treatment of resting T cells with IL-7, rapamycin, or both. Pre-treatment with these molecules led to increased anti-tumor efficacy through increased T cell transduction and greater CAR T cell expansion.

Strengthened Research and Development leadership with the appointment of two seasoned drug developers

- Appointed Doug Williams, Ph.D., as President of Research and Development. Dr. Williams has over 30 years of experience leading R&D organizations – including at Biogen, Seattle Genetics (now Seagen), Amgen, and Immunex – and over the course of his career has participated in the development of over a dozen approved drugs including multiple blockbusters.

- Appointed Gary Meininger, M.D., as Chief Medical Officer. Dr. Meininger has approximately 20 years of experience in drug development. Most recently, he was at Vertex as Senior Vice President, Head of Clinical Development for Vertex Cell and Genetic Therapies and previously was at Janssen and Merck. Dr. Meininger is currently the industry representative to the FDA's Endocrine and Metabolic Drug Advisory Committee.

First Quarter 2023 Financial Results

GAAP Results

- **Cash Position**: Cash, cash equivalents, and marketable securities as of March 31, 2023 were $355.1 million compared to $434.0 million as of December 31, 2022. The decrease of $78.9 million was primarily driven by cash used in operations of $79.2 million and cash used for the purchase of property and equipment of $2.2 million. Cash used in operations includes multiple cash payments that will not recur this year. In addition, our cash balance will increase by $6.1 million in July 2023 as the letter of credit related to the Fremont facility reduces from $6.7 million to $0.6 million in July 2023.

- **Research and Development Expenses**: For the three months ended March 31, 2023, research and development expenses, inclusive of non-cash expenses, were $67.2 million compared to $72.7 for the same period in 2022. The decrease of $5.5 million was primarily due to a decline in costs to acquire technology, laboratory supplies, third-party manufacturing costs, and other research costs. These decreases were partially offset by increased clinical development costs, personnel-related costs, operating costs for our manufacturing facility in Bothell, Washington, and other allocated costs. Research and development expenses include non-cash stock-based compensation of $6.0 million and $5.7 million, for the three months ended March 31, 2023 and 2022, respectively.

- **Research and Development Related Success Payments and Contingent Consideration**: For the three months ended March 31, 2023, we recognized an expense of $0.1 million and a gain of $55.4 million for the same period in 2022, 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 may fluctuate 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, 2023, inclusive of non-cash expenses, were $16.8 million compared to $14.4 million for the same period in 2022. The increase of $2.4 million was primarily due to operating costs for the previously planned manufacturing facility, formerly in research and development expense, and increased non-cash stock-based compensation and personnel-related expenses. General and administrative expenses include non-cash stock-based compensation of $2.8 million and $2.0 million, for the three months ended March 31, 2023 and 2022, respectively.

- **Net Loss**: Net loss for the three months ended March 31, 2023 was $82.1 million, or $0.43 per share, compared to $31.4 million, or $0.17 per share, for the same period in 2022.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn**: Non-GAAP operating cash burn for the three months ended March 31, 2023 was $74.8 million compared to $82.0 million for the same period in 2022. Non-GAAP operating cash burn is the decrease in cash, cash equivalents, and marketable securities, excluding cash inflows from financing activities, cash outflows from business development and non-recurring restructuring activities, and the purchase of property and equipment.

- **Non-GAAP Net Loss**: Non-GAAP net loss for the three months ended March 31, 2023 was $82.0 million, or $0.43 per share, compared to $86.9 million, or $0.47 per share, for the same period in 2022. Non-GAAP net loss excludes non-cash expenses 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, Cambridge, South San Francisco, and Rochester.

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 the expected timing of IND filings and clinical trials for the Company’s product candidates and indications for which such INDs will be filed, and expected timing, substance, and impact of data from clinical trials of its product candidates and an investigator-sponsored trial utilizing hypoimmune-modified primary human islet cells in type 1 diabetes patients (the “IST”); expectations regarding the IST, including the ability to initiate the IST and the potential of the IST to show cell survival and immune evasion without immunosuppression; the potential ability of SC291 to serve as clinical proof-of-platform for other hypoimmune-modified CAR T cell candidates; expectations with respect to the potential therapeutic benefits and impact of its development programs and platforms, including the potential ability of the hypoimmune platform to overcome immunologic rejection of allogeneic cells and the impact thereof, the potential for hypoimmune-modified islet cells to demonstrate allogeneic immune evasion, autoimmune evasion, and control of type 1 diabetes, and the potential ability to replace missing islet cells without immunosuppression in patients with type 1 diabetes; the potential ability of preclinical data to provide insight for the Company’s development programs and platforms; expectations regarding the Company’s capital position, resources, and balance sheet and the potential impact thereof on the Company’s development programs, including data readouts from such programs; expectations regarding the impact of a reduction in the amount of the letter of credit for the Company’s Fremont, California facility on the Company’s cash balance; and the potential impact of changes in the Company’s market capitalization and stock price on its potential success payment and contingent consideration liabilities. 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, including due to the 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 Securities and Exchange Commission (SEC) reports, including but not limited to its Quarterly Report on Form 10-Q dated May 8, 2023. 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, 2023	December 31, 2022
	(in thousands)	
Cash, cash equivalents, and marketable securities	$ 355,131	$ 434,014
Total assets	746,928	822,720
Contingent consideration	155,839	150,379
Success payment liabilities	15,667	21,007
Total liabilities	318,666	323,405
Total stockholders' equity	428,262	499,315

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended March 31,	
	2023	2022
	(in thousands, except per share data)	

Operating expenses:		
Research and development	$ 67,166	$ 72,689
Research and development related success payments and contingent consideration	120	(55,438)
General and administrative	16,766	14,434
Total operating expenses	84,052	31,685
Loss from operations	(84,052)	(31,685)
Interest income, net	1,976	339
Other expense, net	(47)	(102)
Net loss	$ (82,123)	$ (31,448)
Net loss per common share - basic and diluted	$ (0.43)	$ (0.17)
Weighted-average number of common shares - basic and diluted	191,228	185,955

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, 2022	$ 21,007	$ 150,379	$ 171,386
Changes in fair value – expense (gain)	(5,340)	5,460	120
Liability balance as of March 31, 2023	15,667	155,836	171,506
Total change in fair value for the three months ended March 31, 2023	$ (5,340)	$ 5,460	$ 120

(1) Cobalt Biomedicine, Inc. (Cobalt) and the Presidents 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,	
	2023	2022
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	$ 434,014	$ 746,877
Ending cash, cash equivalents, and marketable securities	355,131	657,392
Change in cash, cash equivalents, and marketable securities	(78,883)	(89,485)

Cash paid to purchase property and equipment	2,176	7,533
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	(76,707)	(81,952)
Adjustments:		
Cash paid for restructuring[1]	1,881	-
Operating cash burn - Non-GAAP	$ (74,826)	$ (81,952)

(1) The non-GAAP adjustment of $1.9 million for the three months ended March 31, 2023 consisted of cash payments related to the portfolio prioritization and corporate restructuring in the fourth quarter of 2022.

Sana Biotechnology, Inc.

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

	Three Months Ended March 31,	
	2023	**2022**
	(in thousands, except per share data)	
Net loss - GAAP	$ (82,123)	$ (31,448)
Adjustments:		
Change in the estimated fair value of the success payment liabilities[1]	(5,340)	(54,910)
Change in the estimated fair value of contingent consideration[2]	5,460	(528)
Net loss - Non-GAAP	$ (82,003)	$ (86,886)
Net loss per share - GAAP	$ (0.43)	$ (0.17)
Adjustments:		
Change in the estimated fair value of the success payment liabilities[1]	(0.03)	(0.30)
Change in the estimated fair value of contingent consideration[2]	0.03	-
Net loss per share - Non-GAAP	$ (0.43)	$ (0.47)
Weighted-average shares outstanding - basic and diluted	191,228	185,955

(1) For the three months ended March 31, 2023, the gains related to the Cobalt and Harvard success payment liabilities were $4.8 million and $0.6 million, respectively, compared to gains of $46.8 million and 8.1 million, respectively, for the same periods in 2022.
(2) The contingent consideration is in connection with the acquisition of Cobalt.