Sana Biotechnology Reports Second Quarter 2024 Financial Results and Business Updates

August 8, 2024

Continue to advance hypoimmune technology in four trials across seven indications in oncology, B-cell mediated autoimmune diseases, and type 1 diabetes

Enrolling patients in the GLEAM trial for SC291 in B-cell mediated autoimmune diseases; expect to report initial clinical data in 2024

Enrolling patients in two oncology trials – ARDENT for SC291 in B-cell malignancies and VIVID for SC262 in relapsed/refractory B-cell malignancies; expect to report additional clinical data in 2024

Enrolling patients in the investigator-sponsored trial with hypoimmune-modified primary islet cells; expect to report initial clinical data in 2024

Publication in Nature Biotechnology shows that healthy transplanted human glial cells replaced diseased glial cell population in a preclinical model

Cash position of $251.6 million and expected 2024 operating cash burn below $200 million

SEATTLE, Aug. 08, 2024 (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 second quarter 2024.

“The hypoimmune platform addresses one of the fundamental challenges with allogeneic cell transplantation and has the opportunity to impact a broad range of diseases,” said Steve Harr, Sana’s President and Chief Executive Officer. “We have four ongoing trials and are pleased with the progress and encouraged by our learnings in the clinic to-date. We are accelerating investments to build our pivotal-ready supply chain, decrease our reliance on external manufacturing given ongoing geopolitical uncertainty, and increase our clinical trial site footprint globally. We continue the dose escalation phases of our studies, which makes predicting the numbers of patients and release date for data an inexact science, but we look forward to reporting clinical data in each therapeutic area later this year with the goal of an initial understanding of the safety and efficacy profiles.”

Recent Corporate Highlights

Advancing four clinical programs across seven indications, including an allogeneic CAR T program targeting CD19+ cancers, an allogeneic CAR T program for B-cell mediated autoimmune diseases, an allogeneic CAR T program for cancer patients that have failed a CD19-targeted therapy, and a gene-modified primary islet cell therapy in type 1 diabetes:

- **Oncology** – The ARDENT trial evaluates SC291, a hypoimmune (HIP)-modified CD19-directed allogeneic CAR T therapy, in patients with B-cell malignancies. Early SC291 data from the ongoing ARDENT trial suggest the ability to dose safely, the desired immune evasion profile, and early clinical efficacy. The VIVID trial evaluates SC262, a HIP-modified CD22-directed allogeneic CAR T therapy, in patients with relapsed or refractory B-cell malignancies who have received prior CD19-directed CAR T therapy. Sana is enrolling patients in both studies and expects to share data in 2024.
- **B-cell Mediated Autoimmune Diseases** – The GLEAM trial evaluates SC291 in patients with B-cell mediated autoimmune diseases including lupus nephritis, extrarenal lupus, and antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis. Sana is enrolling patients in this study and expects to share initial data in 2024.
- **Type 1 Diabetes** – 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 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. Initial screening took longer than anticipated, and after a protocol amendment to expand the eligible patient pool, multiple patients are now enrolled and awaiting donor availability. Sana awaits initial patient dosing at Uppsala University Hospital and expects to share initial data in 2024.

Published preclinical data in *Nature Biotechnology* showing that healthy transplanted human glial progenitor cells replaced diseased glial cell population in a preclinical model:

- In the study, human glial chimeric mice were used to model the impact of competition between healthy and diseased human glia *in vivo*. When wild-type (WT) healthy human glial progenitor cells (hGPCs) were transplanted into adult mice that had been neonatally chimerized with mutant Huntingtin (mHTT)-expressing hGPCs, the healthy cells outcompeted and ultimately eliminated diseased glia, repopulating the brain with the healthy cells.
- These data establish additional proof-of-concept for the development of SC379, Sana’s pluripotent stem cell (PSC)-derived glial progenitor cell (GPC) product candidate, as a potential therapy to deliver healthy allogeneic GPCs to patients with certain central nervous system disorders.

Second Quarter 2024 Financial Results

GAAP Results

- **Cash Position**: Cash, cash equivalents, and marketable securities as of June 30, 2024 were $251.6 million compared to $205.2 million as of December 31, 2023. The increase of $46.4 million was primarily driven by net proceeds from equity financings of $181.0 million, proceeds from stock option exercises and the employee stock purchase plan of $8.4 million, and proceeds of $7.6 million from a loan to fund tenant improvements for our manufacturing facility in Bothell, Washington during the six months ended June 30, 2024, partially offset by cash used in operations of $124.2 million and cash used for the purchase of property and equipment of $28.9 million.

- **Research and Development Expenses**: For the three and six months ended June 30, 2024, research and development expenses, inclusive of non-cash expenses, were $60.9 million and $117.3 million, respectively, compared to $73.0 million and $140.2 million for the same periods in 2023. The decreases of $12.1 million and $22.9 million for the three and six months ended June 30, 2024, respectively, compared to the same periods in 2023 were primarily due to lower personnel-related and laboratory costs due to a decrease in headcount and decreased research costs related to the strategic repositioning in the fourth quarter of 2023, lower costs for third-party manufacturing at contract development and manufacturing organizations, and a decline in facility and other allocated costs. These decreases were partially offset by increased clinical development costs and an increase in costs for the acceleration of internal manufacturing capabilities, further de-risking of the supply chain. Research and development expenses include non-cash stock-based compensation of $7.1 million and $13.0 million, respectively, for the three and six months ended June 30, 2024 and $6.7 million and $12.7 million, for the same periods in 2023.

- **Research and Development Related Success Payments and Contingent Consideration**: For the three and six months ended June 30, 2024, Sana recognized a non-cash gain of $27.9 million and a non-cash expense of $10.1 million, respectively, in connection with the change in the estimated fair value of the success payment liabilities and contingent consideration in aggregate, compared to non-cash expenses of $26.7 million and $26.8 million for the same periods in 2023. The value of these potential liabilities fluctuate significantly with changes in Sana's market capitalization and stock price.

- **General and Administrative Expenses**: General and administrative expenses for the three and six months ended June 30, 2024, inclusive of non-cash expenses, were $16.4 million and $32.7 million, respectively, compared to $16.6 million and $33.3 million for the same periods in 2023. The decrease of $0.2 million for the three months ended June 30, 2024 compared to the same period in 2023 was primarily due to a decrease in costs related to Sana's previously planned manufacturing facility in Fremont, California, lower personnel-related costs due to a decrease in headcount related to the strategic repositioning in the fourth quarter of 2023, and a decrease in legal fees. These decreases were partially offset by an increase in non-cash stock-based compensation and consulting fees. The decrease of $0.6 million for the six months ended June 30, 2024 compared to the same period in 2023 was primarily due to a decrease in costs related to Sana's previously planned manufacturing facility in Fremont, California and lower personnel-related costs due to a decrease in headcount related to the strategic repositioning in the fourth quarter of 2023. These decreases were partially offset by an increase in non-cash stock-based compensation, legal fees, and consulting costs.

- **Net Loss**: Net loss for the three and six months ended June 30, 2024 was $50.3 million, or $0.21 per share, and $157.8 million, or $0.70 per share, respectively, compared to $114.0 million, or $0.59 per share, and $196.1 million, or $1.02 per share for the same periods in 2023.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn**: Non-GAAP operating cash burn for the six months ended June 30, 2024 was $104.6 million compared to $136.5 million for the same period in 2023. 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, non-recurring items, and the purchase of property and equipment.

- **Non-GAAP Net Loss**: Non-GAAP net loss for the three and six months ended June 30, 2024 was $74.2 million, or $0.32 per share, and $143.6 million or $0.64 per share, respectively, compared to $87.3 million, or $0.45 per share, and $169.3 million, or $0.88 per share for the same periods in 2023. 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, and the impairment of an other asset.

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; expectations regarding the timing, substance, significance, and impact of data from clinical trials of the Company's product candidates and an IST utilizing HIP-modified primary islet cells in patients with type 1 diabetes; the potential impact of accelerating our investments on our ability to decrease our reliance on external manufacturing, build out our pivotal-ready supply chain, and increase our clinical site footprint globally for our trials; expectations regarding the Company's 2024 operating cash burn; the potential ability to dose safely, achieve the desired immune evasion profile, and achieve clinical efficacy with SC291 in patients with B-cell malignancies; and the potential of SC379 as a potential therapy to deliver healthy allogeneic GPCs to patients with certain central nervous system disorders. 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 August 8, 2024. 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

	June 30, 2024	December 31, 2023
	(in thousands)	
Cash, cash equivalents, and marketable securities	$ 251,643	$ 205,195
Total assets	618,667	565,299
Contingent consideration	111,621	109,606
Success payment liabilities	20,847	12,799
Total liabilities	279,018	277,793
Total stockholders' equity	339,649	287,506

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 60,874	$ 73,044	$ 117,322	$ 140,210
Research and development related success payments and contingent consideration	(27,944)	26,679	10,063	26,799
General and administrative	16,442	16,566	32,711	33,332
Total operating expenses	49,372	116,289	160,096	200,341
Loss from operations	(49,372)	(116,289)	(160,096)	(200,341)
Interest income, net	3,202	2,374	6,236	4,350
Other expense, net	(4,121)	(84)	(3,906)	(131)
Net loss	$ (50,291)	$ (113,999)	$ (157,766)	$ (196,122)

Net loss per common share – basic and diluted	$ (0.21)	$ (0.59)	$ (0.70)	$ (1.02)
Weighted-average number of common shares – basic and diluted	234,440	192,540	225,872	191,888

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, 2023	$ 12,799	$ 109,606	$ 122,405
Changes in fair value – expense	32,623	5,384	38,007
Liability balance as of March 31, 2024	45,422	114,990	160,412
Changes in fair value – gain	(24,575)	(3,369)	(27,944)
Liability balance as of June 30, 2024	$ 20,847	$ 111,621	$ 132,468
Total change in fair value for the six months ended June 30, 2024	$ 8,048	$ 2,015	$ 10,063

(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

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	$ 205,195	$ 434,014
Ending cash, cash equivalents, and marketable securities	251,643	325,915
Change in cash, cash equivalents, and marketable securities	46,448	(108,099)
Cash paid to purchase property and equipment	28,901	3,753
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	75,349	(104,346)
Adjustments:		
Net proceeds from issuance of common stock	(181,029)	(27,014)

Cash paid for personnel-related costs related to portfolio prioritizations	1,110	1,881
Cash received in connection with the Coronavirus Aid, Relief, and Economic Security Act	-	(7,063)
Operating cash burn – Non-GAAP	$ (104,570)	$ (136,542)

Sana Biotechnology, Inc.
Unaudited Reconciliation of GAAP to Non-GAAP Net Loss and Net Loss Per Share

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Net loss – GAAP	$ (50,291)	$ (113,999)	$ (157,766)	$ (196,122)
Adjustments:				
Change in the estimated fair value of the success payment liabilities[1]	(24,575)	20,784	8,048	15,444
Change in the estimated fair value of contingent consideration[2]	(3,369)	5,895	2,015	11,355
Impairment of other asset	4,069	-	4,069	-
Net loss – Non-GAAP	$ (74,166)	$ (87,320)	$ (143,634)	$ (169,323)
Net loss per share – GAAP	$ (0.21)	$ (0.59)	$ (0.70)	$ (1.02)
Adjustments:				
Change in the estimated fair value of the success payment liabilities[1]	(0.11)	0.11	0.03	0.08
Change in the estimated fair value of contingent consideration[2]	(0.02)	0.03	0.01	0.06
Impairment of other asset	0.02	-	0.02	-
Net loss per share – Non-GAAP	$ (0.32)	$ (0.45)	$ (0.64)	$ (0.88)
Weighted-average shares outstanding – basic and diluted	234,440	192,540	225,872	191,888

(1) For the three months ended June 30, 2024, the gain related to the Cobalt success payment liability was $20.7 million compared to an expense of $18.5 million for the same period in 2023. For the six months ended June 30, 2024, the expense related to the Cobalt success payment liability was $7.2 million compared to an expense of $13.7 million for the same period in 2023. For the three months ended June 30, 2024, the gain related to the Harvard success payment liabilities was $3.9 million compared to an expense of $2.3 million for the same period in 2023. For the six months ended June 30, 2024, the expense related to the Harvard success payment liabilities was $0.8 million compared to an expense of $1.7 million for the same period in 2023.
(2) The contingent consideration is in connection with the acquisition of Cobalt.