Sana Biotechnology Reports Third Quarter 2024 Financial Results and Business Updates

November 8, 2024

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

Enrolling patients in the investigator-sponsored trial with hypoimmune-modified primary islet cells, GLEAM trial for SC291 in B-cell mediated autoimmune diseases, and VIVID trial for SC262 in relapsed/refractory B-cell malignancies; expect data from these studies in 2024 and/or 2025

Announced increased focus on type 1 diabetes and B-cell mediated autoimmune diseases

Cash position of $199.0 million with expected cash runway into 2026

SEATTLE, Nov. 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 third quarter 2024.

“Early clinical data with our hypoimmune technology suggest HIP-modified cells evade immune detection, and we look forward to sharing data in 2024 and 2025 across multiple clinical settings, including type 1 diabetes, B-cell mediated autoimmune diseases, and oncology,” said Steve Harr, Sana’s President and Chief Executive Officer. “This past quarter was an important one for the company, as we enhanced our leadership team with the addition of Dhaval Patel as our new Chief Scientific Officer, made progress with our clinical programs, and focused our pipeline. We are optimistic that our recent strategic repositioning to increase focus on immunologic diseases, particularly type 1 diabetes and B-cell mediated autoimmune diseases, will help accelerate development and prolong the capital runway for the company. We look forward to multiple clinical data readouts with our current balance sheet with our cash runway into 2026.”

Payments related to ongoing activities combined with the strategic repositioning may increase the 2024 operating cash burn above prior guidance of less than $200 million.

Recent Corporate Highlights

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

- **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. Sana expects to share initial data in 2024 and/or 2025. Sana is also making progress with the pre-clinical development of SC451, a HIP-modified, stem cell-derived pancreatic islet cell program.
- **B-cell Mediated Autoimmune Diseases** – The GLEAM trial evaluates SC291, a HIP-modified CD19-directed allogeneic CAR T therapy, 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 and/or 2025.
- **Oncology** – 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 and expects to share data in 2025.

Strengthened Research and Development leadership with the appointment of new Chief Scientific Officer

- Appointed Dhaval Patel, M.D., Ph.D., as Executive Vice President and Chief Scientific Officer. Dr. Patel has decades of experience in research, drug discovery, drug development, and clinical care – including roles at UCB, Novartis, University of North Carolina, and the Duke University School of Medicine – and over the course of his career has participated in the development of 10 approved drugs in multiple indications.

Third Quarter 2024 Financial Results

GAAP Results

- **Cash Position**: Cash, cash equivalents, and marketable securities as of September 30, 2024 were $199.0 million compared to $205.2 million as of December 31, 2023. The decrease of $6.2 million was primarily driven by cash used in operations of $176.0 million and cash used for the purchase of property and equipment of $33.0 million, partially offset by net proceeds from equity financings of $181.0 million, proceeds from stock option exercises and the employee stock

purchase plan of $10.3 million, and net proceeds of $7.8 million from a loan to fund tenant improvements for our manufacturing facility in Bothell, Washington during the nine months ended September 30, 2024.

- **Research and Development Expenses**: For the three and nine months ended September 30, 2024, research and development expenses, inclusive of non-cash expenses, were $53.2 million and $170.5 million, respectively, compared to $65.6 million and $205.8 million for the same periods in 2023. The decreases of $12.4 million and $35.3 million for the three and nine months ended September 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. Research and development expenses include non-cash stock-based compensation of $6.5 million and $19.5 million, respectively, for the three and nine months ended September 30, 2024 and $5.7 million and $18.4 million, for the same periods in 2023.
- **Research and Development Related Success Payments and Contingent Consideration**: For the three and nine months ended September 30, 2024, Sana recognized a non-cash gain of $5.5 million and a non-cash expense of $4.6 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 gains of $82.6 million and $55.8 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 nine months ended September 30, 2024, inclusive of non-cash expenses, were $14.1 million and $46.8 million, respectively, compared to $19.2 million and $52.5 million for the same periods in 2023. The decreases of $5.1 million and $5.8 million for the three and nine months ended September 30, 2024, respectively, compared to the same periods in 2023 were primarily due to a decrease in costs related to Sana's previously planned manufacturing facility in Fremont, California, a decrease in legal and consulting fees, and lower personnel-related costs due to a decrease in headcount. These decreases were partially offset by an increase in non-cash stock-based compensation.
- **Net Loss**: Net loss for the three and nine months ended September 30, 2024 was $59.9 million, or $0.25 per share, and $217.7 million, or $0.95 per share, respectively. Net income for the three months ended September 30, 2023 was $1.0 million, or $0.00 per share, and net loss for the nine months ended September 30, 2023 was $195.1 million, or $1.01 per share.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn**: Non-GAAP operating cash burn for the nine months ended September 30, 2024 was $153.1 million compared to $187.2 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 General and Administrative Expenses**: Non-GAAP general and administrative expenses for the three and nine months ended September 30, 2024 were $14.1 million and $46.8 million, respectively, compared to $16.5 million and $49.8 million for the same periods in 2023. Non-GAAP general and administrative expenses for the three and nine months ended September 30, 2023 excludes the loss on termination of the Fremont lease.
- **Non-GAAP Net Loss**: Non-GAAP net loss for the three and nine months ended September 30, 2024 was $64.7 million, or $0.27 per share, and $208.3 million, or $0.91 per share, respectively, compared to $79.0 million, or $0.41 per share, and $248.3 million, or $1.28 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, the impairment of other assets, and, for the three and nine months ended September 30, 2023, the loss on termination of the Fremont lease.

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; the potential ability of HIP-modified cells to evade immune detection; 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 across multiple disease

settings, including type 1 diabetes, B-cell mediated autoimmune diseases, and oncology; the potential of the strategic repositioning to help accelerate development and prolong the Company's capital runway; expectations regarding the Company's cash runway; and expectations regarding the Company's 2024 operating cash burn, including as a result of the strategic repositioning. 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 November 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

	September 30, 2024	December 31, 2023
	(in thousands)	
Cash, cash equivalents, and marketable securities	$ 199,007	$ 205,195
Total assets	559,392	565,299
Contingent consideration	111,856	109,606
Success payment liabilities	15,115	12,799
Total liabilities	266,914	277,793
Total stockholders' equity	292,478	287,506

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 53,206	$ 65,613	$ 170,528	$ 205,823
Research and development related success payments and contingent consideration	(5,497)	(82,615)	4,566	(55,816)
General and administrative	14,052	19,183	46,763	52,515
Total operating expenses	61,761	2,181	221,857	202,522
Loss from operations	(61,761)	(2,181)	(221,857)	(202,522)
Interest income, net	2,579	2,862	8,815	7,212
Other income (expense), net	(742)	303	(4,648)	172
Net income (loss)	$ (59,924)	$ 984	$ (217,690)	$ (195,138)
Net income (loss) per common share – basic	$ (0.25)	$ 0.00	$ (0.95)	$ (1.01)
Weighted-average number of common shares – basic	235,412	196,978	229,076	193,605
Net income (loss) per share – diluted	$ (0.25)	$ 0.00	$ (0.95)	$ (1.01)
Weighted-average shares outstanding – diluted	235,412	200,473	229,076	193,605

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
Changes in fair value – expense (gain)	(5,732)	235	(5,497)
Liability balance as of September 30, 2024	$ 15,115	$ 111,856	$ 126,971
Total change in fair value for the nine months ended September 30, 2024	$ 2,316	$ 2,250	$ 4,566

(1) Cobalt Biomedicine, Inc. (Cobalt) and the Presidents 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

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	$ 205,195	$ 434,014
Ending cash, cash equivalents, and marketable securities	199,007	268,570
Change in cash, cash equivalents, and marketable securities	(6,188)	(165,444)
Cash paid to purchase property and equipment	32,994	5,986
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	26,806	(159,458)
Adjustments:		
Net proceeds from issuance of common stock	(181,000)	(27,009)
Cash paid for personnel-related costs related to portfolio prioritizations	1,110	1,881
Cash paid in connection with the termination of the Fremont lease	-	4,423
Cash received in connection with the Coronavirus Aid, Relief, and Economic Security Act	-	(7,063)
Operating cash burn – Non-GAAP	$ (153,084)	$ (187,226)

Sana Biotechnology, Inc.
Unaudited Reconciliation of GAAP to Non-GAAP General and Administrative Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)			
General and administrative – GAAP	$ 14,052	$ 19,183	$ 46,763	$ 52,515
Adjustments:				
Loss on termination of Fremont lease[1]	-	(2,668)	-	(2,668)
General and administrative – Non-GAAP	$ 14,052	$ 16,515	$ 46,763	$ 49,847

(1) For the three and nine months ended September 30, 2023, the loss of $2.7 million included $4.4 million in fees incurred, offset by a gain of $1.7 million recorded in connection with the derecognition of the right-of use asset and lease liability associated with the Fremont Facility.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Net income (loss) – GAAP	$ (59,924)	$ 984	$ (217,690)	$ (195,138)
Adjustments:				
Change in the estimated fair value of the success payment liabilities[1]	(5,732)	(24,037)	2,316	(8,593)
Change in the estimated fair value of contingent consideration[2]	235	(58,578)	2,250	(47,223)
Loss on termination of Fremont lease[3]	-	2,668	-	2,668
Impairment of other assets	763	-	4,832	-
Net loss – Non-GAAP	$ (64,658)	$ (78,963)	$ (208,292)	$ (248,286)
Net income (loss) per share – GAAP	$ (0.25)	$ -	$ (0.95)	$ (1.01)
Adjustments:				
Change in the estimated fair value of the success payment liabilities[1]	(0.02)	(0.12)	0.01	(0.04)
Change in the estimated fair value of contingent consideration[2]	-	(0.30)	0.01	(0.24)
Loss on termination of Fremont lease[3]	-	0.01	-	0.01
Impairment of other assets	-	-	0.02	-
Net loss per share – Non-GAAP	$ (0.27)	$ (0.41)	$ (0.91)	$ (1.28)
Weighted-average shares outstanding – basic	235,412	196,978	229,076	193,605

(1) For the three months ended September 30, 2024, the gain related to the Cobalt success payment liability was $4.9 million compared to $22.0 million for the same period in 2023. For the nine months ended September 30, 2024, the expense related to the Cobalt success payment liability was $2.3 million compared to a gain of $8.3 million for the same period in 2023. For the three months ended September 30, 2024, the gain related to the Harvard success payment liabilities was $0.8 million compared to $2.0 million for the same period in 2023. For the nine months ended September 30, 2024, the gain related to the Harvard success payment liabilities was immaterial compared to a gain of $0.3 million for the same period in 2023.

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

(3) For the three and nine months ended September 30, 2023, the loss of $2.7 million included $4.4 million in fees incurred, offset by a gain of $1.7 million recorded in connection with the derecognition of the right-of use asset and lease liability associated with the Fremont Facility.