Sana Biotechnology Reports Third Quarter 2023 Financial Results and Business Updates

November 8, 2023

Enrolling Phase 1 ARDENT trial investigating SC291 in patients with refractory B-cell malignancies with initial data expected in 2023 and more robust data in 2024

CTA submitted for investigator-sponsored trial (IST) evaluating hypoimmune (HIP)-modified primary islet cells in patients with type 1 diabetes with data expected in 2023 and 2024

IND submitted to investigate SC291 in multiple B-cell-mediated autoimmune diseases; initial proof of concept data expected in 2024

IND submission on track for this year for SC262 in patients with B-cell malignancies who have failed a CD19 therapy with initial proof of concept data expected in 2024

Presenting multiple abstracts from hypoimmune and fusogen platforms at the 2023 American Society of Hematology Annual Meeting (ASH)

Cash position of $268.6 million expected to last into 2025; supporting activities through multiple data readouts

SEATTLE, Nov. 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 third quarter 2023.

“We continue to execute on our plans to develop our hypoimmune technology, with the potential to deliver data from four different clinical settings in 2023 and 2024,” said Steve Harr, Sana’s President and Chief Executive Officer. “We have increased confidence that this platform can prevent immune recognition of allogeneic cells, unlocking the potential for important medicines in blood cancers, B-cell-mediated autoimmune diseases, and type 1 diabetes, and we look forward to sharing data later this year and next. With our recent strategic repositioning, we expect 2024 operating cash burn to be below $200 million, enabling multiple clinical data readouts with our current balance sheet and a cash runway into 2025.”

Recent Corporate Highlights

Human proof of concept data in multiple clinical settings – including oncology, autoimmune diseases, and type 1 diabetes – expected in 2023 and 2024

- The ARDENT trial evaluates SC291, an *ex vivo* HIP-modified CD19-directed allogeneic CAR T cell therapy, in patients with B-cell malignancies. 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 these patients.
    - Enrollment in the ARDENT Phase 1 study continues, and initial clinical data are expected in 2023 and more robust data expected in 2024.
- The CTA was submitted for an IST evaluating an *ex vivo* HIP-modified primary human pancreatic islet cell therapy in patients with type 1 diabetes patients. The goal of the study is to show that transplantation of HIP-modified pancreatic islets is safe, evades immune recognition, survives, and functions without immunosuppression.
    - Initial HIP proof of concept data are expected in 2023 and 2024.
    - Sana is developing SC451, a hypoimmune-modified stem-cell derived pancreatic islet cell therapy for patients with type 1 diabetes. Sana expects insights from the IST to inform the development of SC451.
- The IND has been submitted for SC291 for the treatment of multiple B-cell-mediated autoimmune diseases, and preliminary clinical data are expected in 2024.
- The IND is on track for submission in 4Q 2023 for SC262, an *ex vivo* HIP-modified CD22-directed allogeneic CAR T cell therapy, for the treatment of B-cell lymphomas and leukemias in patients who have failed CD19-directed CAR T therapies. Preliminary clinical data are expected in 2024.
- Preclinical data are scheduled for presentation at ASH in December regarding HIP-modified CD22-directed and GPRC5D-directed allogeneic CAR T cells and topics related to fusogen specificity, extracorporeal delivery, and applications in targeting hematopoietic stem cells.

Third Quarter 2023 Financial Results

GAAP Results

- **Cash Position**: Cash, cash equivalents, and marketable securities as of September 30, 2023 were $268.6 million compared to $434.0 million as of December 31, 2022. The decrease of $165.4 million was primarily driven by cash used in operations of $201.6 million and cash used for the purchase of property and equipment of $6.0 million. The decrease in cash was offset by net proceeds of $27.0 million from at the market equity offerings during the nine months ended September 30, 2023. The lease for our previously planned manufacturing facility in Fremont, California (the Fremont facility) was terminated during the third quarter of 2023, and the letter of credit of $6.7 million associated with this lease was returned to Sana and is included in cash and cash equivalents as of September 30, 2023.

- **Research and Development Expenses**: For the three and nine months ended September 30, 2023, research and development expenses, inclusive of non-cash expenses, were $65.6 million and $205.8 million, respectively, compared to $76.7 million and $222.0 million for the same periods in 2022. The decrease of $11.1 million for the three months ended September 30, 2023 compared to the same period in 2022 was primarily due to decreased laboratory and research costs associated with lower research and development headcount, personnel-related costs, and third-party manufacturing costs at contract development and manufacturing organizations (CDMOs). The decrease of $16.2 million for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to decreased laboratory and research costs, personnel-related costs, including non-cash stock-based compensation expense, third-party manufacturing costs at CDMOs, costs to acquire technology, and costs related to the Fremont facility that are now included in general and administrative expense. These decreases were partially offset by increased clinical development costs, non-cash lease costs for Sana's planned manufacturing facility in Bothell, Washington (the Bothell facility), and depreciation. Research and development expenses include non-cash stock-based compensation of $5.7 million and $18.4 million, respectively, for the three and nine months ended September 30, 2023, and $7.4 million and $20.6 million, for the same periods in 2022.

- **Research and Development Related Success Payments and Contingent Consideration**: For the three and nine months ended September 30, 2023, Sana recognized gains of $82.6 million and $55.8 million, respectively, in connection with the change in the estimated fair value of the success payment liabilities and contingent consideration in aggregate, compared to gains of $6.1 million and $79.4 million for the same periods in 2022. 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 and nine months ended September 30, 2023, inclusive of non-cash expenses, were $19.2 million and $52.5 million, respectively, compared to $15.5 million and $48.2 million for the same periods in 2022. The increase of $3.7 million for the three months ended September 30, 2023 compared to the same period in 2022 was primarily due to a loss on termination of lease associated with the Fremont facility (Fremont lease) and an increase in patent and other legal fees. These increases were partially offset by a decrease in insurance costs. The increase of $4.3 million for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to an increase in patent and other legal fees, a loss on termination of the Fremont lease, non-cash stock-based compensation, costs related to the Fremont facility, which were formerly in research and development expense, and consulting fees. These increases were partially offset by the write-off of construction in progress costs in 2022 for the Fremont facility, and a decrease in insurance costs.

- **Net Loss**: 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. Net loss for the three and nine months ended September 30, 2022 were $85.1 million, or $0.45 per share, and $189.0, or $1.01 per share, respectively.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn**: Non-GAAP operating cash burn for the nine months ended September 30, 2023 was $187.2 million compared to $219.8 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, costs related to the early termination of the Fremont lease, 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, 2023 was $16.5 million and $49.8 million, respectively, compared to $15.5 million and $43.8 million for the same periods in 2022. Non-GAAP general and administrative expense excludes the loss on termination of the Fremont lease and the write-off of construction in progress costs incurred in connection with the Fremont facility in 2022.

- **Non-GAAP Net Loss**: Non-GAAP net loss for the three and nine months ended September 30, 2023 was $79.0 million, or $0.41 per share, and $248.3 million, or $1.28 per share, respectively, compared to $91.2 million, or $0.48 per share, and $264.0 million, or $1.42 per share for the same periods in 2022. 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 loss on termination of the Fremont lease, and the write-off of construction in progress costs incurred in connection with the

Fremont facility in 2022.

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; 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 patients; expectations regarding the Company’s participation at ASH; expectations regarding the Company’s 2024 operating cash burn and cash runway, including the impact of the Company’s cash position on its ability to obtain data readouts from the Company’s clinical trials; potential indications for the Company’s product candidates; the potential of the IST to serve as clinical proof-of-platform for the Company’s 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, and the potential ability to replace missing islet cells without immunosuppression by evading allogeneic and autoimmune responses; and the impact of data from the IST on the development of SC451. 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, 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

	September 30, 2023	December 31, 2022
	(in thousands)	
Cash, cash equivalents, and marketable securities	$ 268,570	$ 434,014
Total assets	631,440	822,720
Contingent consideration	103,156	150,379
Success payment liabilities	12,414	21,007
Total liabilities	265,588	323,405
Total stockholders' equity	365,852	499,315

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 65,613	$ 76,735	$ 205,823	$ 221,964
Research and development related success payments and contingent consideration	(82,615)	(6,062)	(55,816)	(79,428)
General and administrative	19,183	15,514	52,515	48,240

Total operating expenses	2,181	86,187	202,522	190,776
Loss from operations	(2,181)	(86,187)	(202,522)	(190,776)
Interest income, net	2,862	1,173	7,212	2,149
Other income (expense), net	303	(106)	172	(406)
Net income (loss)	$ 984	$ (85,120)	$ (195,138)	$ (189,033)
Net income (loss) per common share – basic	$ 0.00	$ (0.45)	$ (1.01)	$ (1.01)
Weighted-average number of common shares – basic	196,978	189,303	193,605	187,645
Net income (loss) per share – diluted	$ 0.00	$ (0.45)	$ (1.01)	$ (1.01)
Weighted-average shares outstanding – diluted	200,473	189,303	193,605	187,645

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	155,839	171,506
Changes in fair value – expense	20,784	5,895	26,679
Liability balance as of June 30, 2023	36,451	161,734	198,185
Changes in fair value – gain	(24,037)	(58,578)	(82,615)
Liability balance as of September 30, 2023	$ 12,414	$ 103,156	$ 115,570
Total change in fair value for the nine months ended September 30, 2023	$ (8,593)	$ (47,223)	$ (55,816)

(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

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	$ 434,014	$ 746,877
Ending cash, cash equivalents, and marketable securities	268,570	511,573
Change in cash, cash equivalents, and marketable securities	(165,444)	(235,304)

Cash paid to purchase property and equipment	5,986	16,274
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	(159,458)	(219,030)
Adjustments:		
Net proceeds from issuance of common stock[1]	(27,009)	(724)
Cash paid for restructuring[2]	1,881	-
Cash received in connection with the Coronavirus Aid, Relief, and Economic Security Act	(7,063)	-
Cash paid in connection with the early termination of the Fremont lease	4,423	-
Operating cash burn - Non-GAAP	$ (187,226)	$ (219,754)

(1) Net proceeds of $27.0 million were received in connection with at market equity offerings in the nine months ended September 30, 2023.
(2) The non-GAAP adjustment of $1.9 million for the nine months ended September 30, 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 General and Administrative Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)			
General and administrative – GAAP	$ 19,183	$ 15,514	$ 52,515	$ 48,240
Adjustments:				
Loss on termination of lease associated with the Fremont facility[1]	(2,668)	-	(2,668)	-
Write-off of construction in progress costs incurred in connection with the Fremont facility	-	-	-	(4,474)
General and administrative - Non-GAAP	$ 16,515	$ 15,514	$ 49,847	$ 43,766

(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.

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,	
	2023	2022	2023	2022
	(in thousands, except per share data)			
Net income (loss) – GAAP	$ 984	$ (85,120)	$ (195,138)	$ (189,033)
Adjustments:				
Change in the estimated fair value of the success payment liabilities[1]	(24,037)	2,193	(8,593)	(66,815)
Change in the estimated fair value of contingent consideration[2]	(58,578)	(8,255)	(47,223)	(12,613)
Loss on termination of lease associated with the Fremont facility[3]	2,668	-	2,668	-
Write-off of construction in progress costs incurred in connection with the Fremont facility	-	-	-	4,474
Net loss – Non-GAAP	$ (78,963)	$ (91,182)	$ (248,286)	$ (263,987)
Net income (loss) per share – GAAP	$ -	$ (0.45)	$ (1.01)	$ (1.01)
Adjustments:				
Change in the estimated fair value of the success payment liabilities[1]	(0.12)	0.01	(0.04)	(0.36)
Change in the estimated fair value of contingent consideration[2]	(0.30)	(0.04)	(0.24)	(0.07)
Loss on termination of lease associated with the Fremont facility[3]	0.01	-	0.01	-
Write-off of construction in progress costs incurred in connection with the Fremont facility	-	-	-	0.02
Net loss per share – Non-GAAP	$ (0.41)	$ (0.48)	$ (1.28)	$ (1.42)
Weighted-average shares outstanding – basic	196,978	189,303	193,605	187,645

(1) For the three and nine months ended September 30, 2023, the gains related to the Cobalt success payment liability were $22.0 million and $8.3 million, respectively, compared to an expense of $2.4 million and a gain of $56.5 million, respectively, for the same periods in 2022. For the three and nine months ended September 30, 2023, the gains related to the Harvard success payment liability were $2.0 million and $0.3 million, respectively,

compared to gains of $0.2 million and 10.3 million, respectively, for the same periods in 2022.
(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.