

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): May 10, 2022

SANA BIOTECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39941
(Commission
File Number)

83-1381173
(IRS Employer
Identification Number)

188 East Blaine Street, Suite 400
Seattle, Washington 98102
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (206) 701-7914

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	SANA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2022, Sana Biotechnology, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended March 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Sana Biotechnology, Inc. dated May 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SANA BIOTECHNOLOGY, INC.

Date: May 10, 2022

By: /s/ Nathan Hardy

Nathan Hardy

Executive Vice President and Chief Financial Officer

Sana Biotechnology Reports First Quarter 2022 Financial Results and Business Updates

Plans to present data at multiple scientific conferences in 2022, starting with AACR and ASGCT

Q1 2022 cash position of \$657.4 million

Expect to file INDs this year for *ex vivo* hypoimmune allogeneic CAR T and *in vivo* fusogen CAR T

SEATTLE — May 10, 2022 — Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on creating and delivering engineered cells as medicines, today reported financial results and business highlights for the first quarter 2022.

“In the first quarter, we made significant progress in moving toward clinical trials for programs across our multiple platforms including the *ex vivo* hypoimmune allogeneic CAR T (SC291) and *in vivo* fusogen CAR T (SG295) programs, and we remain on track to file INDs for both of these programs this year,” said Steve Harr, Sana’s President and Chief Executive Officer. “In addition to advancing these programs, we continue to make progress across our earlier pipeline, including SC451, our hypoimmune stem-cell derived pancreatic islet cell therapy for patients with type 1 diabetes, and multiple product candidates in our CAR T portfolio. Our people, broad set of technologies, and strong balance sheet enable us to pursue this ambitious pipeline.”

Continued progress in building Sana’s hypoimmune *ex vivo* platform and *in vivo* fusogen platform with presentations at multiple conferences

- Hypoimmune *ex vivo* platform: Presented preclinical data demonstrating that hypoimmune CAR T cells were able to evade both the innate and adaptive arms of the immune system in animal models while retaining their antitumor activity at the 2022 American Association for Cancer Research Annual Meeting.
- *In vivo* fusogen platform: Scheduled to present preclinical data regarding hypoimmune pancreatic islet cells, generation of hypoimmune allogeneic regulatory T cells, retargeted fusosomes for *in vivo* delivery to T cells, fusosome-targeted gene transfer to human hepatocytes, and a novel vector copy number assay at the 2022 American Society of Gene & Cell Therapy meeting later in May.

Expanded Sana’s CAR T capability to potentially develop best-in-class, broadly accessible CAR T cell therapies

- Entered into an exclusive agreement with the National Institutes of Health (NIH) for worldwide commercial rights to the NIH’s CD22 chimeric antigen receptor with a fully-human binder. This CAR construct has shown efficacy in several clinical studies, including in CD19 CAR T cell therapy failures. Targeting both CD19 and CD22 with an “off-the-shelf” product, whether in combination with Sana’s hypoimmune platform or fusogen platform, offers the potential of higher and more durable complete response rates in earlier-stage patients as well as in patients that have previously failed an autologous CD19 CAR T cell therapy.
- Entered into a non-exclusive agreement with IASO Biotherapeutics and Innovent Biologics for commercial rights to a clinically validated fully-human B cell maturation antigen (BCMA) CAR construct, which Sana intends to incorporate into both the company’s *ex vivo* hypoimmune allogeneic and *in vivo* fusogen platforms for the treatment of multiple myeloma.

First Quarter 2022 Financial Results

GAAP Results

- **Cash Position:** Cash, cash equivalents, and marketable securities as of March 31, 2022 were \$657.4 million compared to \$746.9 million as of December 31, 2021. The decrease of \$89.5 million was primarily driven by cash used in operations of \$77.7 million and cash used for the purchase of property and equipment of \$7.5 million. Cash used in operations includes \$6.2 million of upfront license payments related to licensing CD22 and BCMA as well as multiple cash payments that will not recur this year.
 - **Research and Development Expenses:** For the three months ended March 31, 2022, research and development expenses, inclusive of non-cash expenses, was \$72.7 million compared to \$41.9 million for the same period in 2021. The increase of \$30.8 million was due to an increase in personnel expenses related to increased headcount to expand Sana’s research and development capabilities, increased costs for third-party manufacturing, laboratory supplies, facility and other allocated costs, and costs to acquire technology complementary to our own. Research and development expenses include non-cash stock-based compensation of \$5.7 million and \$2.7 million for the three months ended March 31, 2022 and 2021, respectively.
 - **Research and Development Related Success Payments and Contingent Consideration:** For the three months ended March 31, 2022, we recognized a non-cash gain of \$55.4 million in connection with the change in the estimated fair value of the success payment liabilities and contingent consideration in aggregate, compared to expenses of \$127.1 million for the
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same period in 2021. The value of these potential liabilities can fluctuate significantly with changes in our market capitalization and stock price.

- **General and Administrative Expenses:** General and administrative expenses for the three months ended March 31, 2022, inclusive of non-cash expenses, were \$14.4 million compared to \$11.8 million for the same period in 2021. The increase of \$2.6 million was primarily due to increased personnel-related expenses attributable to an increase in headcount to support our continued research and development activities. General and administrative expenses include stock-based compensation of \$2.0 million and \$1.5 million for the three months ended March 31, 2022 and 2021, respectively.
- **Net Loss:** Net loss for the three months ended March 31, 2022 was \$31.4 million, or \$0.17 per share, compared to \$180.6 million, or \$1.52 per share, for the same period in 2021.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn:** Non-GAAP operating cash burn for the three months ended March 31, 2022 was \$82.0 million compared to \$48.9 million for the same period in 2021. 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 activities, and the purchase of property and equipment.
- **Non-GAAP Net Loss:** Non-GAAP net loss for the three months ended March 31, 2022 was \$86.9 million, or \$0.47 per share, compared to \$53.6 million, or \$0.45 per share, for the same period in 2021. Non-GAAP net loss excludes certain one-time costs to acquire technology and 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 pre-clinical, clinical and regulatory development plans and timing expectations; the potential ability to make hypimmune CAR T cells that evade the immune system while retaining their antitumor activity; the Company’s participation in the 2022 American Society of Gene & Cell Therapy meeting and the subject matter of the Company’s presentation at that meeting; the potential use and utility of licensed technologies for Sana’s programs; the potential efficacy of the NIH’s CAR construct; and the potential benefits of targeting both CD19 and CD22 with an “off-the-shelf” product, including in combination with Sana’s hypimmune or fusogen platform. 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 the economic, market and social disruptions due to the ongoing 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 SEC reports, including but not limited to its Quarterly Report on Form 10-Q dated May 10, 2022. 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

	<u>March 31, 2022</u>		<u>December 31, 2021</u>
	(in thousands)		
Cash, cash equivalents, and marketable securities	\$ 657,392	\$	746,877
Total assets	1,047,613		1,129,407
Contingent consideration	153,215		153,743
Success payment liabilities	47,615		102,525
Total liabilities	345,958		400,905
Total stockholders' equity	701,655		728,502

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended March 31,	
	2022	2021
	(in thousands, except per share data)	
Operating expenses:		
Research and development	\$ 72,689	\$ 41,880
Research and development related success payments and contingent consideration	(55,438)	127,050
General and administrative	14,434	11,821
Total operating expenses	<u>31,685</u>	<u>180,751</u>
Loss from operations	(31,685)	(180,751)
Interest income, net	339	121
Other income (expense), net	(102)	13
Net loss	<u>\$ (31,448)</u>	<u>\$ (180,617)</u>
Net loss per common share - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (1.52)</u>
Weighted-average number of common shares - basic and diluted	<u>185,955</u>	<u>119,131</u>

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, 2021	\$ 102,525	\$ 153,743	\$ 256,268
Changes in fair value - expense (gain)	(54,910)	(528)	(55,438)
Liability balance as of March 31, 2022	47,615	153,215	200,830
Total change in fair value for the three months ended March 31, 2022	\$ (54,910)	\$ (528)	\$ (55,438)

- (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 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 ongoing actual 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,	
	2022	2021
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	\$ 746,877	\$ 411,995
Ending cash, cash equivalents, and marketable securities	657,392	981,864
Change in cash, cash equivalents, and marketable securities	(89,485)	569,869
Cash paid to purchase property and equipment	7,533	6,440
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	(81,952)	576,309
Adjustments:		
Cash paid to acquire technology(1)	-	1,246
Net proceeds received from the initial public offering of common stock	-	(626,405)
Operating cash burn - Non-GAAP	<u>\$ (81,952)</u>	<u>\$ (48,850)</u>

(1) The non-GAAP adjustment of \$1.2 million for the three months ended March 31, 2021 was the holdback payment related to the acquisition of Cytocardia, Inc. in 2019.

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

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
	<u>(in thousands, except per share data)</u>	
Net loss - GAAP	\$ (31,448)	\$ (180,617)
Adjustments:		
Change in the estimated fair value of the success payment liabilities(1)	(54,910)	115,657
Change in the estimated fair value of contingent consideration(2)	(528)	11,393
Net loss - Non-GAAP	<u>\$ (86,886)</u>	<u>\$ (53,567)</u>
Net loss per share - GAAP	\$ (0.17)	\$ (1.52)
Adjustments:		
Change in the estimated fair value of the success payment liabilities(1)	(0.30)	0.97
Change in the estimated fair value of contingent consideration(2)	-	0.10
Net loss per share - Non-GAAP	<u>\$ (0.47)</u>	<u>\$ (0.45)</u>
Weighted-average shares outstanding - basic	<u>185,955</u>	<u>119,131</u>

- (1) For the three months ended March 31, 2022, the gain related to the Cobalt and Harvard success payment liabilities was \$46.8 million and \$8.1 million, respectively, compared to expense of \$91.8 million and \$23.9 million, respectively, for the same period in 2021.
- (2) The contingent consideration was recorded in connection with the acquisition of Cobalt.