

**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): August 4, 2021

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 August 4, 2021, Sana Biotechnology, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2021. 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**

Exhibit No.	Description
99.1	Press release of Sana Biotechnology, Inc. dated August 4, 2021.
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: August 4, 2021

By: /s/ Nathan Hardy

Nathan Hardy

Executive Vice President and Chief Financial Officer

Sana Biotechnology Reports Second Quarter 2021 Financial Results and Business Updates

Presented data showing immune evasion and survival after transplantation of allogeneic cells into primates without immune suppression at ISSCR 2021

Entered long-term lease to establish manufacturing facility in San Francisco Bay Area

Q2 2021 cash position of \$930.8 million

SEATTLE — August 4, 2021 — 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 of 2021.

“We continue to be pleased with the progress across our *in vivo* and *ex vivo* technology platforms and programs as well as our progress in recruiting great people and building the infrastructure necessary to achieve our long-term vision of using engineered cells as medicines,” said Steve Harr, Sana’s President and Chief Executive Officer. “In the second quarter, we presented data demonstrating the survival and immune evasion for transplanted hypimmune cells into non-human primates without immunosuppression, an important step in enabling the use of engineered cells as medicines more broadly across multiple diseases. We also signed a long-term lease to enable the build out of a clinical trial and commercial manufacturing facility capable of supporting our broad pipeline. I would particularly like to thank the Sana team, who despite the ongoing complex operating environment of COVID continues to make progress in moving our product candidates forward, with a goal of beginning human studies for multiple medicines per year beginning as early as next year.”

Recent Corporate Highlights

- Presented data showing survival of transplanted stem cells in non-human primates without immunosuppression at a plenary session at the International Society for Stem Cell Research 2021 Virtual Annual Meeting. The transplanted cells incorporated Sana’s hypimmune gene modifications that enable immune evasion, demonstrating a key step toward widespread treatment of disease using engineered cells.
- Announced a lease agreement to develop a 163,000 square foot manufacturing facility in Fremont, California to support the manufacture of late-stage clinical development and early commercial product candidates across our technology platforms.

Second Quarter 2021 Financial Results

GAAP Results

- **Cash Position:** Cash, cash equivalents, and marketable securities as of June 30, 2021 were \$930.8 million compared to \$412.0 million as of December 31, 2020, an increase of \$518.8 million. Sana successfully completed its initial public offering in February 2021 and issued 27.0 million shares of common stock, including 3.5 million shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a price of \$25.00 per share, for net proceeds of \$626.4 million.
 - **Research and Development Expenses:** For the three and six months ended June 30, 2021, research and development expense, inclusive of non-cash expenses, was \$45.0 million and \$86.9 million, respectively, compared to \$30.0 million and \$56.4 million for the same periods in 2020. The increases of \$15.0 million and \$30.5 million for the three and six months ended June 30, 2021, respectively, were due to an increase in personnel expenses related to increased headcount to expand Sana’s research and development capabilities, costs for preclinical studies, costs for laboratory supplies, and facility costs. Research and development expenses include non-cash stock-based compensation of \$3.1 million and \$5.8 million for the three and six months ended June 30, 2021, respectively, and \$0.9 million and \$1.6 million for the same periods in 2020.
 - **Research and Development Related Success Payments and Contingent Consideration:** For the three and six months ended June 30, 2021, we recognized a gain of \$76.0 million and an expense of \$51.0 million, respectively, in connection with the change in the estimated fair value of the success payment liabilities and contingent consideration, compared to \$51.9 million and \$52.8 million for the same periods in 2020. For the three and six months ended June 30, 2021, we recognized a gain of \$83.2 million and an expense of \$32.4 million, respectively, in connection with the change in the estimated fair value of the success payment liabilities, compared to expenses of \$37.9 million and \$38.5 million for the same periods in 2020. The decreases of \$121.1 million and \$6.1 million during the three and six months ended June 30, 2021, respectively, were due to changes in our market capitalization and stock price during the relative periods. For the three and six months ended June 30, 2021, we recognized expenses of \$7.2 million and \$18.6 million, respectively, in connection with the change in the estimated fair value of contingent consideration and \$14.0 million and \$14.3 million, respectively, for the same periods in 2020. The decrease of \$6.8 million during the three months ended June 30, 2021 and the increase of \$4.3 million during the six months ended June 30, 2021 were due to changes in the discount rate and scientific progress made toward the achievement of milestones during the relative periods.
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- **General and Administrative Expenses:** General and administrative expenses for the three and six months ended June 30, 2021, inclusive of non-cash expenses, were \$12.5 million and \$24.3 million, respectively, compared to \$6.0 million and \$12.0 million for the same periods in 2020. The increases of \$6.5 million and \$12.3 million in the three and six months ended June 30, 2021, respectively, were primarily due to increased personnel-related expenses attributable to an increase in headcount to build our infrastructure, legal fees to support our patent portfolio and license arrangements, insurance associated with being a public company, consulting fees, and facility costs. General and administrative expenses include stock-based compensation of \$1.8 million and \$3.3 million for the three and six months ended June 30, 2021, respectively, and \$0.2 million and \$0.3 million for the same periods in 2020.
- **Net Income (Loss):** Net income for the three months ended June 30, 2021 was \$18.7 million, or \$0.10 per share, and net loss for the six months ended June 30, 2021 was \$161.9 million, or \$1.08 per share, compared to net losses of \$87.8 million, or \$7.18 per share, and \$120.7 million, or \$10.47 per share, for the same periods in 2020.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn:** Non-GAAP operating cash burn for the six months ended June 30, 2021 was \$89.8 million compared to \$56.9 million for the six months June 30, 2020. 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 Research and Development Expenses:** Non-GAAP research and development expenses for the three and six months ended June 30, 2021 were \$45.0 million and \$86.9 million, respectively, compared to \$28.9 million and \$55.0 million for the same periods in 2020. Non-GAAP research and development expenses excludes one-time costs to acquire technology.
- **Non-GAAP Net Loss:** Non-GAAP net loss for the three and six months ended June 30, 2021 was \$57.3 million, or \$0.32 per share, and \$110.9 million, or \$0.74 per share, compared to \$34.8 million, or \$2.85 per share, and \$66.4 million, or \$5.76 per share, for the same periods in 2020. Non-GAAP net loss excludes 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 more than 320 people working together to create an enduring company that changes how the world treats disease. Sana has operations in Seattle, Cambridge, and South San Francisco.

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 ability to make hypimmune-modified induced pluripotent stem cells that survive and evade the immune system without immunosuppression; the ability to treat diseases using the Company’s hypimmune platform technology; its manufacturing plans and strategy; and expectations with respect to the manufacturing capabilities of the facility. 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 Annual Report on Form 10-K dated March 24, 2021 and Quarterly Report on Form 10-Q dated August 5, 2021. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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Investor Relations:

Nicole Keith

investor.relations@sana.com

Media:

Morgan Warners, Finsbury Glover Hering

media@sana.com

Sana Biotechnology, Inc.
Unaudited Selected Consolidated Balance Sheet Data

	<u>June 30, 2021</u>		<u>December 31, 2020</u>
	(in thousands)		
Cash, cash equivalents, and marketable securities	\$ 930,770	\$	411,995
Total assets	1,259,837		730,296
Contingent consideration	140,457		121,901
Success payment liabilities	108,963		76,494
Total liabilities	353,940		298,583
Convertible preferred stock	-		852,897
Total stockholders' equity (deficit)	905,897		(421,184)

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands, except per share data)			
Operating expenses (gains):				
Research and development	\$ 44,996	\$ 29,991	\$ 86,876	\$ 56,397
Research and development related success payments and contingent consideration	(76,025)	51,906	51,025	52,820
General and administrative	12,477	6,009	24,298	11,964
Total operating expenses (gains)	<u>(18,552)</u>	<u>87,906</u>	<u>162,199</u>	<u>121,181</u>
Gain (loss) from operations	18,552	(87,906)	(162,199)	(121,181)
Interest income, net	130	79	251	474
Other income, net	1	19	14	24
Net income (loss)	<u>\$ 18,683</u>	<u>\$ (87,808)</u>	<u>\$ (161,934)</u>	<u>\$ (120,683)</u>
Net income (loss) per share - basic	\$ 0.10	\$ (7.18)	\$ (1.08)	\$ (10.47)
Weighted-average shares outstanding - basic	179,899	12,232	149,683	11,526
Net income (loss) per share - diluted	\$ 0.09	\$ (7.18)	\$ (1.08)	\$ (10.47)
Weighted-average shares outstanding - diluted	190,508	12,232	149,683	11,526

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, 2020	\$ 76,494	\$ 121,901	\$ 198,395
Changes in fair value - expense (gain)	115,657	11,393	127,050
Liability balance as of March 31, 2021	192,151	133,294	325,445
Changes in fair value - expense (gain)	(83,188)	7,163	(76,025)
Liability balance as of June 30, 2021	\$ 108,963	\$ 140,457	\$ 249,420
Total change in fair value for the six months ended June 30, 2021	\$ 32,469	\$ 18,556	\$ 51,025

- (1) Cobalt Biomedicine, Inc. (Cobalt) and the Presidents of Harvard College (Harvard) are entitled to success payments pursuant to the terms 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 changes 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 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 changes 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 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,	
	2021	2020
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	\$ 411,995	\$ 138,982
Ending cash, cash equivalents, and marketable securities	930,770	503,375
Change in cash, cash equivalents, and marketable securities	518,775	364,393
Cash paid to purchase property and equipment	16,596	8,290
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	535,371	372,683
Adjustments:		
Cash paid to acquire technology(1)	1,246	-
Cash paid to satisfy contingent liability(2)	-	6,000
Net proceeds received from the initial public offering of common stock	(626,405)	-
Net cash received from the sale of convertible preferred stock	-	(435,543)
Operating cash burn - Non-GAAP	\$ (89,788)	\$ (56,860)

- (1) The non-GAAP adjustment of \$1.2 million for the six months ended June 30, 2021 was the payment of the holdback amount related to the acquisition of Cytocardia, Inc. in November 2019.
- (2) The non-GAAP adjustment of \$6.0 million for the six months ended June 30, 2020 was the payment of a contingent liability due to Harvard in connection with the closing of the Series B convertible preferred stock financing.

Sana Biotechnology, Inc.
Unaudited Reconciliation of GAAP to Non-GAAP Research and Development Expense

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands)			
Research and development expense - GAAP	\$ 44,996	\$ 29,991	\$ 86,876	\$ 56,397
Adjustments:				
Change in the estimated fair value of contingent liability(1)	-	(1,070)	-	(1,443)
Research and development expense - Non-GAAP	\$ 44,996	\$ 28,921	\$ 86,876	\$ 54,954

(1) The contingent liability was recorded in connection with the Harvard license agreement and paid in June 2020.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2021	2020	2021	2020
	(in thousands, except per share data)			
Net income (loss) - GAAP	\$ 18,683	\$ (87,808)	\$ (161,934)	\$ (120,683)
Adjustments:				
Change in the estimated fair value of the success payment liabilities(1)	(83,188)	37,929	32,469	38,481
Change in the estimated fair value of contingent consideration(2)	7,163	13,977	18,556	14,339
Change in the estimated fair value of contingent liability(3)	-	1,070	-	1,443
Net loss - Non-GAAP	<u>\$ (57,342)</u>	<u>\$ (34,832)</u>	<u>\$ (110,909)</u>	<u>\$ (66,420)</u>
Net income (loss) per share - GAAP(4)	<u>\$ 0.10</u>	<u>\$ (7.18)</u>	<u>\$ (1.08)</u>	<u>\$ (10.47)</u>
Adjustments:				
Change in the estimated fair value of the success payment liabilities(1)	(0.46)	3.10	0.22	3.34
Change in the estimated fair value of contingent consideration(2)	0.04	1.14	0.12	1.24
Change in the estimated fair value of contingent liability(3)	-	0.09	-	0.13
Net loss per share - Non-GAAP	<u>\$ (0.32)</u>	<u>\$ (2.85)</u>	<u>\$ (0.74)</u>	<u>\$ (5.76)</u>
Weighted-average shares outstanding - basic	<u>179,899</u>	<u>12,232</u>	<u>149,683</u>	<u>11,526</u>

- (1) For the three and six months ended June 30, 2021, the gain related to the Cobalt success payment liability was \$66.6 million and the expense was \$25.1 million, respectively, and for the three and six months ended June 30, 2020 the expenses were \$33.5 million and \$33.9 million, respectively. For the three and six months ended June 30, 2021 the gain related to the Harvard success payment liability was \$16.6 million and the expense was \$7.3 million, respectively, and for the three and six months ended June 30, 2020 the expenses were \$4.4 million and \$4.6, respectively.
- (2) The contingent consideration was recorded in connection with the acquisition of Cobalt.
- (3) The contingent liability was recorded in connection with the Harvard license agreement and paid in June 2020.
- (4) Diluted net income per share for the three months ended June 30, 2021 was \$0.09.