

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, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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, 2022, Sana Biotechnology, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended June 30, 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 August 4, 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: August 4, 2022

By: /s/ Nathan Hardy

Nathan Hardy

Executive Vice President and Chief Financial Officer

Sana Biotechnology Reports Second Quarter 2022 Financial Results and Business Updates

Expect cash runway into 2025, enabling multiple data readouts across platforms for lead programs, driven by significant cash savings from manufacturing facility move to Bothell, Washington as well as research prioritization

Expect to file INDs this year for SC291 and SG295

Presented preclinical data showing survival of transplanted hypoinnate allogeneic pancreatic islet cells, cardiomyocytes, and retinal pigment epithelium cells without immunosuppression in non-human primates

Q2 2022 cash position of \$579.6 million

SEATTLE — August 4, 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 second quarter 2022.

“We are pleased with the continued progress this quarter both across our platforms and with our product candidates. We made executive hires in critical operational roles, executed on key pre-IND activities for both SC291 and SG295, made business decisions that extend our cash runway to allow more potential clinical data readouts across multiple drug candidates with our current balance sheet, and presented important preclinical data across multiple platforms at various scientific conferences,” said Steve Harr, Sana’s President and Chief Executive Officer. “We are well-positioned with our current resources to file INDs across several platforms with multiple drug products in both 2022 and 2023, and our team is enthusiastic to understand the potential of these medicines to improve outcomes for patients.”

Continued progress in building Sana’s hypoinnate *ex vivo* platform and *in vivo* fusogen platform with presentations at AACR, ASGCT, ADA, and ISSCR

- *Ex vivo* hypoinnate platform (HIP): Sana’s HIP platform makes multiple genomic modifications to cells with the goal of preventing allogeneic transplant rejection, and importantly includes modifications to prevent both adaptive and innate immune recognition and rejection. Presented data showed survival of transplanted allogeneic HIP cells of several different types – including pancreatic islet cells, cardiomyocytes, and retinal pigment epithelial (RPE) cells – in a variety of locations in non-human primates. Sana also presented data showing that HIP allogeneic regulatory T cells function and are able to evade immune detection in preclinical models. These cells have the potential to treat a variety of autoimmune disorders. Finally, Sana scientists presented *in vitro* and *in vivo* data showing that exposure to an anti-CD47 antibody leads to elimination of HIP induced pluripotent stem cells (iPSCs) as well as HIP pancreatic islet cells. These data provide a path for a potential safety strategy as well as validation of the mechanism of immune protection. Sana’s current pipeline includes HIP-modified cells to replace damaged or missing cells in the body in a number of different diseases, including, among others, cancer, type 1 diabetes, cardiac disease, and various neurologic conditions.
- HIP pancreatic islet cells: Type 1 diabetes is a disease where a person’s immune system destroys one’s own pancreatic beta cells, which are a key component in pancreatic islets. Presented data showed that transplanted HIP pancreatic islet cells evade allogeneic immune response *and* autoimmune response in a type 1 diabetes mouse model. These data build upon previous *in vitro* data showing that HIP pancreatic islet cells are not recognized by serum from type 1 diabetic patients, including no T cell or antibody recognition. HIP technology is incorporated in SC451, Sana’s islet cell product candidate, which has a goal of filing an IND in 2023 for the treatment of type 1 diabetes.
- *In vivo* fusogen platform: Presented additional preclinical data utilizing retargeted fusosomes for *in vivo* delivery of genetic payloads to various cells, including CD8⁺ T cells, CD4⁺ T cells, and human hepatocytes. This technology is the backbone of Sana’s *in vivo* delivery platform and is incorporated into various product candidates, including SG295.

Announced expected cash runway into 2025 to enable multiple data readouts across the platforms; largest part of cash savings from plans to relocate manufacturing facility to Bothell, Washington

- Expect cash runway into 2025 enabling multiple data readouts across the platforms based on current timelines for lead programs. The extension includes a slowed pace of investment for multiple programs with INDs expected in 2024 and beyond.
 - Announced decision to move Sana’s manufacturing plant from Fremont, CA to Bothell, WA, resulting in approximately \$100 million in expected cost savings over the next three years. As part of this decision, Sana signed a lease agreement to develop an approximately 80,000 square foot manufacturing facility in Bothell, WA. The facility will be designed to support the late-stage clinical and early commercial manufacturing of multiple product candidates across the portfolio.
-

Announced key executive hires and appointments, building on the company's scientific excellence and operational capabilities

- Strengthened the leadership team with the appointments of Snehal Patel to lead internal and external manufacturing and Julie Lepin to lead regulatory affairs.

Second Quarter 2022 Financial Results

GAAP Results

- **Cash Position:** Cash, cash equivalents, and marketable securities as of June 30, 2022 were \$579.6 million compared to \$746.9 million as of December 31, 2021. The decrease of \$167.3 million was primarily driven by cash used in operations of \$149.2 million and cash used for the purchase of property and equipment of \$11.9 million. Cash used in operations includes \$6.2 million of upfront payments related to licensing technology for our CD22 and BCMA programs, \$3.2 million of costs incurred related to the previously planned manufacturing facility in Fremont, CA (the Fremont facility) which will be replaced by the Bothell, WA site (the Bothell facility), as well as multiple cash payments that will not recur this year.
- **Research and Development Expenses:** For the three and six months ended June 30, 2022, research and development expenses, inclusive of non-cash expenses, were \$72.5 million and \$145.2 million, respectively, compared to \$45.0 million and \$86.9 million for the same periods in 2021. The increases of \$27.5 million and \$58.3 million were due to increases in personnel expenses related to increased headcount to expand Sana's research and development capabilities, increased third-party manufacturing costs for contract development and manufacturing organizations including pass-through costs for materials, facility and other allocated costs, research and laboratory costs, and costs to acquire technology complementary to our own. Research and development expenses for the three and six months ended June 30, 2022 include non-cash stock-based compensation of \$7.4 million and \$13.1 million, respectively, and \$3.1 million and \$5.8 million for the same periods in 2021.
- **Research and Development Related Success Payments and Contingent Consideration:** For the three and six months ended June 30, 2022, we recognized non-cash gains of \$17.9 million and \$73.4 million, respectively, in connection with the change in the estimated fair value of the success payment liabilities and contingent consideration in aggregate, compared to a gain of \$76.0 million and an expense of \$51.0 million for the same periods 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 and six months ended June 30, 2022, inclusive of non-cash expenses, were \$18.3 million and \$32.7 million, respectively, compared to \$12.5 million and \$24.3 million for the same periods in 2021. The increases of \$5.8 million and \$8.4 million, respectively, were primarily due to the write-off of construction in progress costs incurred in connection with the previously planned Fremont facility which will be replaced by the Bothell facility. The increases were also due to personnel-related expenses attributable to an increase in headcount to support our continued research and development activities, increased facility and information technology costs, including rent. These increases were partially offset by a decrease in legal fees. General and administrative expenses for the three and six months ended June 30, 2022 include stock-based compensation of \$2.5 million and \$4.5 million, respectively, and \$1.8 million and \$3.3 million for the same periods in 2021.
- **Net Loss:** Net loss for the three and six months ended June 30, 2022 was \$72.5 million, or \$0.39 per share, and \$103.9 million, or \$0.56 per share, respectively, compared to net income of \$18.7 million, or \$0.10 per share, and net loss of \$161.9 million, or \$1.08 per share for the same periods in 2021.

Non-GAAP Measures

- **Non-GAAP Operating Cash Burn:** Non-GAAP operating cash burn for the six months ended June 30, 2022 was \$155.4 million compared to \$89.8 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 General and Administrative Expense:** Non-GAAP general and administrative expense for the three and six months ended June 30, 2022 was \$13.8 million and \$28.3 million, respectively, compared to \$12.5 million and \$24.3 million for the same periods in 2021. Non-GAAP general and administrative expense excludes the write-off of construction in progress costs incurred in connection with the previously planned Fremont facility, which will be replaced by the Bothell facility.
 - **Non-GAAP Net Loss:** Non-GAAP net loss for the three and six months ended June 30, 2022 was \$85.9 million, or \$0.47 per share, and \$172.8 million, or \$0.93 per share, respectively, compared to \$57.3 million, or \$0.32 per share, and \$110.9 million, or \$0.74 per share for the same periods in 2021. Non-GAAP net loss excludes certain one-time costs to acquire technology, non-cash expenses related to the change in the estimated fair value of contingent consideration and success
-

payment liabilities, and the write-off of construction in progress costs incurred in connection with the previously planned Fremont facility, which will be replaced by the Bothell facility.

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, including with respect to the expected timing of IND filings for the Company’s product candidates; the Company’s expected cash runway and the impact of the increase in the cash runway on the Company’s business, including with respect to the expected timing of IND filings for its product candidates; the potential ability of Sana’s HIP platform to make genomic modifications to cells that prevent allogeneic transplant rejection and prevent both adaptive and innate immune recognition and rejection; the potential of HIP allogeneic regulatory T cells to treat a variety of autoimmune disorders; the impact of the *in vitro* and *in vivo* data regarding exposure of an anti-CD47 antibody on iPSCs and HIP pancreatic islet cells on a potential safety strategy and validation of the mechanism of immune protection with respect to the HIP platform; the potential cost savings associated with moving the Company’s manufacturing plant from Fremont, CA to Bothell, WA; and the Company’s expectations with respect to the Bothell 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 Quarterly Report on Form 10-Q dated August 4, 2022. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

###

Investor Relations & Media:
Nicole Keith
investor.relations@sana.com
media@sana.com

Sana Biotechnology, Inc.
Unaudited Selected Consolidated Balance Sheet Data

	<u>June 30, 2022</u>		<u>December 31, 2021</u>
	(in thousands)		
Cash, cash equivalents, and marketable securities	\$ 579,566	\$	746,877
Total assets	971,089		1,129,407
Contingent consideration	149,385		153,743
Success payment liabilities	33,517		102,525
Total liabilities	331,584		400,905
Total stockholders' equity	639,505		728,502

Sana Biotechnology, Inc.
Unaudited Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands, except per share data)			
Operating expenses (gains):				
Research and development	\$ 72,540	\$ 44,996	\$ 145,229	\$ 86,876
Research and development related success payments and contingent consideration	(17,928)	(76,025)	(73,366)	51,025
General and administrative	18,292	12,477	32,726	24,298
Total operating expenses (gains)	<u>72,904</u>	<u>(18,552)</u>	<u>104,589</u>	<u>162,199</u>
Gain (loss) from operations	(72,904)	18,552	(104,589)	(162,199)
Interest income, net	637	130	976	251
Other income (expense), net	(198)	1	(300)	14
Net income (loss)	<u>\$ (72,465)</u>	<u>\$ 18,683</u>	<u>\$ (103,913)</u>	<u>\$ (161,934)</u>
Net income (loss) per common share - basic	<u>\$ (0.39)</u>	<u>\$ 0.10</u>	<u>\$ (0.56)</u>	<u>\$ (1.08)</u>
Weighted-average number of common shares - basic	<u>187,626</u>	<u>179,899</u>	<u>186,801</u>	<u>149,683</u>
Net income (loss) per share - diluted	<u>\$ (0.39)</u>	<u>\$ 0.09</u>	<u>\$ (0.56)</u>	<u>\$ (1.08)</u>
Weighted-average shares outstanding - diluted	<u>187,626</u>	<u>190,508</u>	<u>186,801</u>	<u>149,683</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 - gain	(54,910)	(528)	(55,438)
Liability balance as of March 31, 2022	47,615	153,215	200,830
Changes in fair value - gain	(14,098)	(3,830)	(17,928)
Liability balance as of June 30, 2022	\$ 33,517	\$ 149,385	\$ 182,902
Total change in fair value for the six months ended June 30, 2022	\$ (69,008)	\$ (4,358)	\$ (73,366)

- (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

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Beginning cash, cash equivalents, and marketable securities	\$ 746,877	\$ 411,995
Ending cash, cash equivalents, and marketable securities	579,566	930,770
Change in cash, cash equivalents, and marketable securities	(167,311)	518,775
Cash paid to purchase property and equipment	11,924	16,596
Change in cash, cash equivalents, and marketable securities, excluding capital expenditures	(155,387)	535,371
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>\$ (155,387)</u>	<u>\$ (89,788)</u>

(1) The non-GAAP adjustment of \$1.2 million for the six months ended June 30, 2021 was the holdback payment related to the acquisition of Cytocardia, Inc. in 2019.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
General and administrative - GAAP	\$ 18,292	\$ 12,477	\$ 32,726	\$ 24,298
Adjustments:				
Write-off of construction in progress costs incurred in connection with the previously planned Fremont facility ⁽¹⁾	(4,474)	-	(4,474)	-
General and administrative - Non-GAAP	\$ 13,818	\$ 12,477	\$ 28,252	\$ 24,298

(1) The Fremont facility will be replaced with the Bothell facility.

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>	
	2022	2021	2022	2021
	(in thousands, except per share data)			
Net loss - GAAP	\$ (72,465)	\$ 18,683	\$ (103,913)	\$ (161,934)
Adjustments:				
Change in the estimated fair value of the success payment liabilities ⁽¹⁾	(14,098)	(83,188)	(69,008)	32,469
Change in the estimated fair value of contingent consideration ⁽²⁾	(3,830)	7,163	(4,358)	18,556
Write-off of construction in progress costs incurred in connection with the previously planned Fremont facility ⁽³⁾	4,474	-	4,474	-
Net loss - Non-GAAP	<u>\$ (85,919)</u>	<u>\$ (57,342)</u>	<u>\$ (172,805)</u>	<u>\$ (110,909)</u>
Net loss per share - GAAP	\$ (0.39)	\$ 0.10	\$ (0.56)	\$ (1.08)
Adjustments:				
Change in the estimated fair value of the success payment liabilities ⁽¹⁾	(0.08)	(0.46)	(0.37)	0.22
Change in the estimated fair value of contingent consideration ⁽²⁾	(0.02)	0.04	(0.02)	0.12
Write-off of construction in progress costs incurred in connection with the previously planned Fremont facility ⁽³⁾	0.02	-	0.02	-
Net loss per share - Non-GAAP	<u>\$ (0.47)</u>	<u>\$ (0.32)</u>	<u>\$ (0.93)</u>	<u>\$ (0.74)</u>
Weighted-average shares outstanding - basic	<u>187,626</u>	<u>179,899</u>	<u>186,801</u>	<u>149,683</u>

- (1) For the three months and six ended June 30, 2022, the gains related to the Cobalt success payment liability were \$12.1 million and \$58.9 million, respectively, compared to a gain of \$66.6 million and an expense of \$21.5 million for the same periods in 2021. For the three months and six ended June 30, 2022, the gains related to the Harvard success payment liability were \$2.0 million and \$10.1 million, respectively, compared to a gain of \$16.6 million and an expense of \$7.3 million for the same periods in 2021.
- (2) The contingent consideration was recorded in connection with the acquisition of Cobalt.
- (3) The Fremont facility will be replaced with the Bothell facility.