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): January 7, 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. \Box

Item 1.01 Entry into a Material Definitive Agreement.

On January 7, 2022 (the "Effective Date"), Sana Biotechnology, Inc. (the "<u>Company</u>") entered into a Patent License Agreement (the "<u>Agreement</u>") with the U.S. Department of Health and Human Services, as represented by The National Cancer Institute, an institute of the National Institutes of Health (the "<u>NIH</u>"), pursuant to which the NIH granted to the Company an exclusive, worldwide, commercial license under certain patent rights related to certain fully-human anti-CD22 binders and CD22 CAR constructs comprising such binders (the "<u>Licensed Patent Rights</u>") for use in certain *in vivo* gene therapy and *ex vivo* allogeneic CAR T cell applications for B cell malignancies. The license grant is subject to customary statutory requirements and reserved rights as required under federal law and NIH requirements. The Company has the right to grant sublicenses under the Licensed Patent Rights with the NIH's prior consent.

Pursuant to the Agreement, the Company agreed to pay to the NIH an upfront payment of \$1.0 million. Additionally, the Company will be obligated to pay to the NIH (i) up to an aggregate of \$9.6 million in specified regulatory, developmental and commercial milestone payments with respect to each product developed through exploitation of the Licensed Patent Rights (each, a "Licensed Product") and (ii) a payment of \$1,000,000 upon the assignment of the Agreement to an affiliate upon a change of control of the Company. In addition, the Company is obligated to pay to the NIH (i) a royalty on net sales of Licensed Products in the low-single digits, subject to reduction in certain circumstances, and subject to certain annual minimum royalty payments, and (ii) a percentage, ranging from the mid-single digits to mid-teens, of revenues from sublicensing arrangements. Additionally, if the Company is granted a priority review voucher by the U.S. Food and Drug Administration with respect to a Licensed Product, the Company will be obligated to pay to the NIH the greater of (i) \$5,000,000 or (ii) a percentage in the mid-single digits of any consideration received for the sale, transfer or lease of such priority review voucher. The Company is also obligated to pay to the NIH a percentage in the low-single digits of the consideration received by the Company for any assignment of the Agreement to a non-affiliate.

The Company is obligated to use commercially reasonable efforts to exploit, and make publicly available, inventions developed by the exploitation of the Licensed Patent Rights, including Licensed Products.

Unless earlier terminated by either party, the Agreement will terminate upon expiration of the last-to-expire valid claim in the Licensed Patent Rights. The NIH may terminate the Agreement with written notice for the Company's material breach if the Company fails to timely cure such breach or upon certain insolvency events involving the Company. In addition, the NIH may terminate or modify the Agreement, at its option, if the NIH determines that such termination or modification is necessary to meet the requirements for public use specified by federal regulations issued after the effective date of the Agreement, and these requirements are not reasonably and timely satisfied by the Company. The Company may terminate the Agreement or any licenses in any country or territory upon 60 days' prior written notice.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which the Company plans to file as an exhibit to its Annual Report on Form 10-K for its fiscal year ended December 31, 2021.

Item 7.01 Regulation FD Disclosure.

The Company intends to present an updated corporate presentation (the "<u>Corporate Presentation</u>") at the 40th Annual J.P. Morgan Healthcare Conference on January 11, 2022. A copy of the Corporate Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "<u>Current Report</u>") and is incorporated by reference herein.

By furnishing the information in this Item 7.01 of this Current Report, including Exhibit 99.1, the Company makes no admission as to the materiality of such information. The information contained herein is intended to be considered in the context of the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in the Corporate Presentation, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

In accordance with General Instruction B.2 of Form 8-K, the information furnished under Item 7.01 of this Current Report and Exhibit 99.1 to this Current Report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("<u>Exchange Act</u>"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.



On January 11, 2022, the Company issued a press release announcing the Agreement, described above under Item 1.01 of this Current Report. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

See the Exhibit Index below, which is incorporated by reference herein.

EXHIBIT INDEX		
Exhibit Number	Description	
99.1	Corporate Presentation, dated January 11, 2022	
99.2	Press Release, dated January 11, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Sana Biotechnology, Inc.

Date: January 11, 2022

Ву:

/s/ James J. MacDonald

James J. MacDonald Executive Vice President and General Counsel

Corporate Presentation January 2022



Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements about Sana Biotechnology, Inc. (the "Company," "we," "us," or "our") within the meaning of the federal securities laws. All statements other than statements of historical facts contained in this presentation, 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, 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.

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 Quarterly Report on Form 10-Q dated November 8, 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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Sana Biotechnology Engineered Cells as Medicines

Ability to modify the genome and use engineered cells as medicines has the potential to be one of the most important advances in healthcare over the next several decades:

- Nearly every disease is caused by damage to or dysfunction of a cell
- · Sana's ambition is to repair or replace any cell in the body

Platform progress, broad capabilities, and strong balance sheet enable us to execute on a broad vision:

- Goal: allo T and in vivo CAR T INDs this year with 2-3 INDs per year going forward
- Building expertise in key areas: delivery of genetic material, gene modification, immunology, biology, and manufacturing
- \$866M as of the end of the third quarter 2021

Sana

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Sana goal: Repair cells in the body when possible or replace them when needed

in vivo Cell Engineering

Repair and control the genes of any cell in the body

Deliver any payload... (DNA, RNA, protein, organelle, integrating vs non-integrating)

To any cell... (unlimited volume of distribution)

In a specific... (e.g., just T cell)

And repeatable way (limit immunogenicity)



ex vivo Cell Engineering

Replace any cell in the body

Manufacture any cell at scale...

That engrafts... (the right cell in the right environment)

Functions... (understand exact phenotype desired)

And persists (overcome immune rejection and cellular signaling, such as apoptotic signaling)

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Sana's platforms, technology, and programs

	-	PROGRAMS		PRE-CLINICAL	POTENTIAL
PLATFORM	TECHNOLOGY	(CELL TYPES)	THERAPEUTIC AREA	PRODUCT CANDIDATE	INDICATIONS
<i>in viv</i> o cell engineering	Fusogen			SG295 (CD8/CD19)	NHL/ALL/CLL
			Oncology	SG239 (CD8/BCMA)	Multiple myeloma
		T cells		SG242 (CD4/CD19)	NHL/ALL/CLL
				SG221 (CD4/BCMA)	Multiple myeloma
				SG2XX (CD8/CD4/CD22)	NHL/ALL/CLL
		Hepatocytes	Liver-related genetic disorders	SG328	OTC1
		Hematopoietic	Hemoglobinopathies	80.449	Sickle cell disease
		stem cells	Hemoglobinopathes	36418	Beta-thalassemia
ex vivo cell engineering Std (to hy	Hypoimmune donor-derived	T cells	Oncology	SC291 (CD19)	NHL/ALL/CLL
				SC2XX (CD19/CD22)	NHL/ALL/CLL
				SC255 (BCMA)	Multiple myeloma
	Hypoimmune stem cell-derived	Beta cells	Diabetes	SC451	Type 1 diabetes
	Stem cell-derived (to migrate to hypoimmune)		Central nervous system		Huntington's disease
		Glial progenitor		SC379	Pelizaeus-Merzbacher disease
		cells	(CNS)		Secondary progressive multiple sclerosis
		Cardiomyocytes	Cardiovascular	SC187	Heart failure



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• HYPOIMMUNE-

Hypoimmune technology: Protecting cells from immune rejection

Sana approach: Leverage insights from nature to create hypoimmune cells (HIP)



Hypoimmune cells evade rejection from the adaptive **and** innate immune system in mice





Sana

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Hypoimmune cells evade rejection from the adaptive **and** innate immune system in NHPs





Sana is pursuing a broad ex vivo cell engineering strategy

Transforming ex vivo cell engineering through development of hypoimmune cell platform



High unmet need remains for blood cancers

- Significant unmet need in B cell malignancies and multiple myeloma in the US and EU alone:
 - ~250,000 new cases annually¹
 - Est. 100,000 deaths annually¹
- <10,000 patients have been treated with CAR T therapy to date²
- Of those treated, many do not respond and many relapse
- Manufacturing and access challenges remain for many patients







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Sana's hypoimmune allo T is potentially best-in-class

Immune Challenges	Current Allo T	Sana Hypo Allo T
GvHD		
HvGD: Adaptive immune system	?	
HvGD: Innate immune system	\mathbf{x}	

GvHD, graft versus host disease; HvGD, host versus graft disease.



1 Donor or iPSC T cells
2 Cell engineering
3 CD19 targeted HIP allogeneic T cell

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CD19 HIP CAR T cells clear tumor in vivo





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Clinical study shows CD22 CAR T efficacy in treating relapsed lymphoma after prior CD19 CAR T therapy

	Patient 1						
Prior lines of therapy	5	121	Pre	Minimal IC	ANG / CDS		
Prior CAR T therapy	Yes	200	The second se	observed	across dose	levels	
Product previously received	Yescarta		028	Deservator	DLBCL	DLBCL	Total
Antigen targeted	CD19		PR	Parameter	DL1 (N=15)	DL2 (N=9)	(N=24)
Ri		- ± -	and the second second	Cytokine release syndrome*, n (%)			
Brood 2021 Apr 29;137(17):2321-2325. doi: 10.1182/biood.2020009432.			M3	None	1 (7%)	0 (0%)	1 (4%)
				Grade 1	6 (40%)	1 (11%)	7 (29%)
		33	M6	Grade 2	8 (53%)	7 (78%)	13 (54%)
		pre sea	CR	Grade 3	0 (0%)	1 (11%)	1 (4%)
LBCL		То	tal (N=24)	Neurologic eve	ents / ICANS*, n (%)	
Median follow up, months [range]	8.6	6 [1.6-21.3]	Grade 1	1 (7%)	1 (11%)	2 (8%)
Overall Response Rate*, n (%)			19 (79%)	Grade 2	1 (7%)	1 (11%)	2 (8%)
CR Rate			14 (58%)			M	liklos et al, ASH 2021
		Total is a co	Miklos et al, ASH 2021 mbination of DL1 and DL2				

Sana

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• HYPOIMMUNE ALLO T

Best-in-class, broadly accessible allogeneic CAR T cells

- · Expect to file our first allo T IND targeting CD19 as early as this year
- · CD19/CD22 dual targeting offers potential of higher and more durable complete response rates
- Fully-human, clinically validated CD22 CAR with potential to address CD19 CAR T failures
- · Fully-human, clinically validated BCMA CAR to potentially treat multiple myeloma
- Targets beyond CD19, CD22, and BCMA



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Type 1 diabetes represents a large unmet need with a loss of ~15 years of life¹

Large unmet need remains

- Disease where destruction of insulin-producing beta cells in the pancreas results in inability to control blood glucose
- 1.6M patients with type 1 diabetes in the US and 2.4M in Europe²; 51k new patients/year combined³
- Long-term complications: end-organ damage, including heart attack, stroke, retinopathy, and nephropathy

Our goal is to produce hypoimmune beta cells that evade the immune system and normalize glucose

¹Rawshani et al, Lancet 2018 ²Centers for Disease Control and Prevention, Diabetes Report, 2017-2018 ³National Institutes of Health, Health Promot Perspect 2020





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Progress toward turning beta cells into medicines

- 1.Make functional beta cells from iPSCs cells ✓
- **2. Hide** beta cells from allogeneic rejection \checkmark
- **3. Hide** beta cells from autoimmune reaction \checkmark
- 4. Create GMP supply chain





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Stem cell-derived pancreatic islet cells lead to robust function

Superior insulin secretion and faster kinetics in vitro Robust rescue of type 1 diabetes mouse model STZ Nephrectomy (graft removal) Fransplant subrenal graft as Diabetic (>55 mg/dl Not diabetic Not diabetic Diabetic Insulin Secretion (µIU/µg DNA) 300 High Glucose Fasting blood glucose (mg dl⁻¹) 600-----Human islets -O- Untreated control WashU (Sana) Tech - STZ, no transplant 200 Pagliuca Tech 400 Transplant: STZ, suspension STZ, planar STZ, human islets 100 200 0. 0 ό 10 20 30 40 50 ò 2 4 6 8 10 12 30 36 -2 Time (min) Week after transplant Sana 18 © 2020-2022 Sana Biotechnology. All rights reserved.

BETA CELL EX VIVO Hypoimmune pancreatic islet cells evade immune detection and regulate glucose levels



BETA CELL EX VIVO-

Hypoimmune pancreatic islet cells evade autoimmune killing in testing of blood from type 1 diabetic patients



Robust GMP supply chain required to use iPSC-based therapies as medicines

1	GMP genomically stable cells lines	FCDI licenses and bespoke lines
2	GMP gene editing reagents	Beam license enables editing requirements for current programs
3	GMP gene-edited master cell bank	Creating internal master cell banks for GMP HIP-edited iPSCs
Sana		© 2020-2022 Sana Biotechnology. All rights reserved.

Fusosome technology: Development of cell-specific in vivo delivery platform

Sana approach: Leverage insights from nature to deliver various payloads to specific cells





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In vivo cell engineering: Creating targeted medicines across a diverse set of cell types

in vivo cell engineering strategy focused on developing therapies with transformative **fusogen platform delivery based on cell specificity and payload diversity**



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High unmet need remains for blood cancers



T cell fusosome carrying CAR construct infused into patient



IV administration of CD19 CAR delivered by fusosome can clear B cell tumors in humanized mice comparably to *ex vivo* CD19 CAR T



Sana aspiration: Engineered cells as medicines





Sana Biotechnology www.sana.com



Sana Biotechnology Obtains Exclusive License from National Institutes of Health for CD22 CAR Construct

License will enable Sana's in vivo and ex vivo engineered T cell programs for B cell malignancies

Technology expected to help address key relapse challenges for CD19-directed CAR T cell therapies

SEATTLE — January 11, 2022 — Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on creating and delivering engineered cells as medicines, today announced that the company entered into an agreement with the National Cancer Institution (NCI), an institute of the National Institutes of Health (NIH), for worldwide exclusive commercial rights to the NIH's CD22 chimeric antigen receptor (CAR) with a fully-human binder for use in certain *in vivo* gene therapy and *ex vivo* allogeneic CAR T applications for B cell malignancies.

Engineered CAR T cell therapies for B cell malignancies use binders to target proteins expressed on the surface of B cells. One such protein, CD19, has been the target of all approved autologous CAR T therapies for B cell lymphoma and B cell acute lymphoblastic leukemia to date. Unfortunately, incomplete responses or relapses occur in over 50% of CD19 CAR T-treated patients, often due to CD19 antigen loss. CD22, which is also a B cell surface protein, has emerged as an alternative to address failure to achieve durable complete responses with CD19-directed CAR T therapy. Multiple academic clinical trials using this CD22 CAR have shown complete responses in a substantial number of patients in the relapse setting after treatment with a CD19-directed CAR T therapy for patients with B malignancies.

"We are thrilled to enter an agreement with the NIH for an exclusive license to this fully-human CD22 CAR, particularly given the clinical data with this specific construct to date. One of Sana's primary goals has been to meaningfully expand the number of patients that benefit from CAR T therapies, with an initial focus on B cell malignancies, including leukemia and lymphoma," said Terry Fry, M.D., Sana's Head of T Cell Therapeutics. "Combining this CD22 CAR with Sana's platforms gives us the potential to improve the overall rate of durable complete responses for patients with B cell malignancies – including non-Hodgkin lymphoma, chronic lymphocytic leukemia, and acute lymphoblastic leukemia – and expand the number of patients who can receive these therapies."

Under the terms of the agreement, Sana agreed to pay the NIH an upfront amount, certain milestone payments, and royalties on net sales of royaltybearing products.

About Sana Biotechnology

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 350 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. For more information about Sana Biotechnology, please visit <u>https://sana.com/</u>.

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; expectations with respect to the use and benefits of the technology; the potential of CD22 as an alternative target for B cell malignancies; the potential efficacy of CD22 in vivo gene therapy and ex vivo allogeneic CAR T applications; the potential benefits of combining the technology with the Company's platforms; and the Company's potential milestone and royalty obligations. 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 November 8, 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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