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): March 16, 2022

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-12584**	**13-3808303**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
(Address of principal executive offices and zip code)

(301) 417-4364
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

☐ 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, par value $0.001 per share	SYN	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by checkmark 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 March 16, 2022, Synthetic Biologics, Inc., a Nevada corporation (the "Registrant") issued a press release that included financial information for its year ended December 31, 2021. A copy of the press release is attached as Exhibit 99.1 to this Report on Form 8-K. The information contained in the press release is being furnished to the Securities and Exchange Commission (the "Commission") and shall not be deemed incorporated by reference into any of the Registrant's registration statements or other filings with the Commission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press Release issued by Synthetic Biologics, Inc., dated March 16, 2022
104	Cover Page Interactive Data File (embedded within the 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 hereunto duly authorized.

Dated: March 16, 2022

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Executive Officer
and Chief Financial Officer

Exhibit 99.1

Synthetic Biologics Reports 2021 Year End Operational Highlights and Financial Results

-Completed acquisition of VCN Biosciences, expanding pipeline into oncology-

-VCN-01 received Orphan Drug Designation for retinoblastoma from the U.S. FDA-

-As of December 31, 2021, Synthetic Biologics reports $67.3 million in cash, which is expected to provide runway through the end of 2023-

-Conference call and webcast to be held today at 4:30 p.m. ET-

Rockville, MD, March 16, 2022 – Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company developing therapeutics designed to treat diseases in areas of high unmet need, today reported financial results for the year ended December 31, 2021, and provided a corporate update.

Recent Developments:

- *VCN acquisition:* Synthetic Biologics completed the acquisition of privately held VCN Biosciences, developer of a novel oncolytic adenovirus (OV) platform designed for intravenous (IV), intravitreal (IVit) and intratumoral delivery to trigger tumor cell death, improve access of co-administered cancer therapies to the tumor, and promote a robust and sustained anti-tumor response by the patient's immune system.
- *Pipeline updates:* The acquisition of VCN Biosciences transformed Synthetic Biologics' pipeline with the addition of VCN's lead clinical-stage drug candidate, VCN-01, as well as preclinical stage VCN-11, which incorporates a proprietary albumin binding domain in the virus shell with the potential to extend the effectiveness of the therapy.
    - In February of 2022, VCN-01 received Orphan Drug Designation (ODD) from the U.S. FDA for the treatment of retinoblastoma; VCN-01 has previously been granted ODD by the EMA for the treatment of pancreatic cancer.
    - Regulatory agency recognition builds upon the encouraging clinical data generated to date; VCN-01 has been evaluated in 72 patients across four Phase 1 clinical trials, including patients with pancreatic cancer, head and neck squamous cell carcinoma, colorectal cancer, and retinoblastoma.
    - Enrollment progressed in the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease; and topline data for this cohort are expected in H1 2022.
    - Completed dosing and follow-up in a Phase 1, placebo-controlled, multiple ascending dose study of SYN-020 in healthy volunteers; SYN-020 was very well tolerated at all doses and patient samples are undergoing pharmacokinetic and pharmacodynamic analyses.

Anticipated Milestones:

VCN-01

- Initiation of VCN-01 dosing in an investigator sponsored study of brain tumors at the University of Leeds (H1 2022).
- Initiation of VCN-01 dosing in combination with mesothelin-directed CAR-T cells for pancreatic and ovarian cancer in an investigator sponsored study at the University of Pennsylvania (H1 2022).
- Initiation of a Phase 2 study of VCN-01 in combination with standard-of-care chemotherapy (gemcitabine/nab-paclitaxel) as a first line therapy in newly diagnosed metastatic PDAC patients (H2 2022).

- Initiation of a Phase 2/3 pivotal trial of VCN-01 as either an adjunct to chemotherapy or a potential rescue therapy in pediatric patients with advanced retinoblastoma (early 2023).

VCN-11

- Evaluating CMOs for GMP manufacture of VCN-11.
- Preclinical studies characterizing VCN-11 are on-going.

SYN-004

- Data read out from the first cohort of the SYN-004 study in allo-HCT patients (H1 2022).

SYN-020

- Top-line data from the multiple ascending dose study of SYN-020 in healthy volunteers (H1 2022).
- Planning for the initiation of a Phase 2a study of SYN-020 (H2 2022).

"2021 was a monumental year for the Company, setting the stage for continued progress and a number of important upcoming milestones in 2022," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "The recent acquisition of VCN Biosciences positions us at the forefront of oncolytic virus development. VCN's systemically administered, selectively replicating adenoviruses are designed to break down the tumor stroma, which hides the tumor from the patient's immune system. In turn, this improves the anti-tumor effect of the oncolytic virus, as well as chemotherapies and immuno-oncology products."

Mr. Shallcross continued, “We are poised for another exciting year ahead as we anticipate the initiation of multiple international studies, including a Phase 2 clinical trial of intravenous VCN-01 in combination with standard-of-care chemotherapy as a first line therapy in newly-diagnosed metastatic PDAC patients, as well as a Phase 2/3 pivotal trial of intravitreal VCN-01 as either an adjunct to chemotherapy or a potential rescue therapy in pediatric patients with advanced retinoblastoma. We do not plan any clinical activities in Eastern Europe; however, we recognize that the war in the Ukraine may have follow-on effects globally that could adversely impact the cost and conduct of our international clinical trials. We will seek to mitigate this impact where possible. In parallel with our development of VCN-01, we continue to advance the clinical development of both SYN-004 and SYN-020 and look forward to providing further updates on key upcoming milestones. We remain well-capitalized through the end of 2023 and highly encouraged by the potential for each of our clinical programs.”

Year Ended December 31, 2021 Financial Results

General and administrative expenses increased to $6.5 million for the year ended December 31, 2021, from $5.0 million for the year ended December 31, 2020. This increase of 28.7% is primarily composed of increased consulting and legal costs related to the VCN acquisition, higher insurance costs, audit fees, and public relations expenses. The charge relating to stock-based compensation expense was $0.3 million for the year ended December 31, 2021, compared to $0.3 million for the year ended December 31, 2020.

Research and development expenses increased to $7.8 million for the year ended December 31, 2021, from $5.1 million for the year ended December 31, 2020. This increase of 53% is primarily the result of increased clinical trial expenses as we continued dosing patients in the Phase 1b/2a clinical trial of SYN-004, the dosing of healthy volunteers in the SAD and MAD Phase 1 clinical trials for SYN-020, and by higher indirect program costs for the year ended December 31, 2021, including an increase in manufacturing costs for SYN-020. We anticipate research and development expense to increase as our ongoing clinical trials continue to enroll patients and new patients are enrolled in the VCN-01 clinical trials. Research and development expenses also included a charge relating to non-cash stock-based compensation expense of $76,000 for the year ended December 31, 2021, compared to $66,000 for the year ended December 31, 2020.

Other income was $6,000 for the year ended December 31, 2021, compared to other income of $44,000 for the year ended December 31, 2020. Other income for the year ended December 31, 2021 and 2020 is primarily composed of interest income from investments.

Cash and cash equivalents totaled $67.3 million as of December 31, 2021, an increase of $61.1 million from December 31, 2020.

For further details on Synthetic Biologics’ financial results refer to the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission.

Conference Call

Synthetic Biologics will host a conference call at 4:30 p.m. ET today to review year end 2021 operational highlights and financial results. Individuals may participate in the live call via telephone by dialing (877) 451-6152 (domestic) or (201) 389-0879 (international) and using the conference ID: 13727535. Participants are asked to dial in 15 minutes before the start of the call to register. Investors and the public can access the live and archived webcast of this call via the “News & Media” section of the company’s website, https://www.syntheticbiologics.com, under “Events” or by clicking here, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a diversified clinical-stage company developing therapeutics designed to treat diseases in areas of high unmet need. The Company recently consummated the acquisition of VCN Biosciences, S.L. (VCN), which is developing a new oncolytic adenovirus (OV) platform designed for intravenous (IV), intravitreal and antitumoral delivery to trigger tumor cell death, improve access of co-administered cancer therapies to the tumor, and promote a robust and sustained anti-tumor response by the patient’s immune system. In addition, the Company's lead candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used IV beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent (a) microbiome damage, (b) Clostridioides difficile infection (CDI), (c) overgrowth of pathogenic organisms, (d) the emergence of antimicrobial resistance (AMR), and (e) acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions, and include statements regarding initiation of VCN-01 dosing in an investigator sponsored study at the University of Leeds (H1 2022); initiation of VCN-01 dosing in combination with mesothelin-directed CAR-T cells in an investigator sponsored study at the University of Pennsylvania (H1 2022); initiation of a Phase 2 study of VCN-01 in combination with standard-of-care chemotherapy (gemcitabine/nab-paclitaxel) as a first line therapy in newly diagnosed metastatic PDAC patients (H2 2022); initiation of a Phase 2/3 pivotal trial of VCN-01 as either an adjunct to chemotherapy or a potential rescue therapy in pediatric patients with advanced retinoblastoma (early 2023); data read out from the first cohort of the SYN-004 study in allo-HCT patients (H1 2022); top-line data from the multiple ascending dose study of SYN-020 in healthy volunteers (H1 2022); initiation of a Phase 2a study of SYN-020 (H2 2022), and providing further updates on key upcoming milestones, remaining well-capitalized through the end of 2023 and the potential for each of our clinical programs. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, whether the combined business of Synthetic Biologics and VCN will be successful; Synthetic Biologics' and VCN's product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results; the ability to initiate clinical trials (including initiation of VCN-01 dosing in an investigator sponsored study at the University of Leeds (H1 2022), initiation of VCN-01 dosing in combination with mesothelin-directed CAR-T cells in an investigator sponsored study at the University of Pennsylvania (H1 2022), the planned Phase 2 trial of VCN-01 in combination with standard-of-care gemcitabine/nab-paclitaxel as a first line therapy in newly diagnosed metastatic PDAC patients (H2 2022), and a Phase 2/3 pivotal trial as either an adjunct to chemotherapy or a potential rescue therapy in in pediatric patients with advanced retinoblastoma (early 2023)); the data read out from the first cohort of the SYN-004 study (H1 2022); the ability to complete clinical trials on time and achieve the desired results and benefits; continuing clinical trial enrollment as expected; the ability to obtain regulatory approval for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Synthetic Biologics' and VCN's ability to promote or commercialize their product candidates for the specific indications; acceptance of product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' and VCN's products; developments by competitors that render such products obsolete or non-competitive; Synthetic Biologics' and VCN's ability to maintain license agreements;, the continued maintenance and growth of Synthetic Biologics' and VCN's patent estate; the ability to continue to remain well financed;, and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 2021 and its other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The

information in this release is provided only as of the date of this release, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

For further information, please contact:

Investor Relations:

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917-680-5608

- Financial Tables Follow –

Consolidated Balance Sheets
(In thousands except share and par value amounts)

	December 31, 2021	December 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 67,325	$ 6,227
Prepaid expenses and other current assets	1,533	1,707
Total Current Assets	68,858	7,934
Property and equipment, net	101	174
Right of use asset	1,383	279
Deposits and other assets	23	23
Total Assets	**$ 70,365**	**$ 8,410**
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable	$ 524	$ 886
Accrued expenses	1,928	925
Accrued employee benefits	978	868
Lease liability	124	287
Total Current Liabilities	3,554	2,966
Lease liability - Long term	1,403	186
Total Liabilities	4,957	3,152
Commitments and Contingencies	—	—
Series A Preferred Stock, $0.001 par value; 10,000,000 shares authorized; 0 and 120,000 issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	—	12,798
Stockholders' Equity (Deficit):		
Series B Preferred Stock, $1,000 par value; 10,000,000 shares authorized, 0 and 3,973 issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	—	2,477
Common stock, $0.001 par value; 200,000,000 shares authorized, 132,044,866 issued and 132,042,538 outstanding at December 31, 2021 and 29,252,253 issued and 29,249,925 outstanding at December 31, 2020	132	29
Additional paid-in capital	336,560	240,821
Accumulated deficit	(271,284)	(248,094)
Total Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	65,408	(4,767)
Non-controlling interest	—	(2,773)
Total Stockholders' Equity (Deficit)	65,408	(7,540)
Total Liabilities and Stockholders' Equity	**$ 70,365**	**$ 8,410**

Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	For the year ended December 31,	
	2021	2020
Operating Costs and Expenses:		

General and administrative	$ 6,474	$ 5,029
Research and development	7,800	5,131
Total Operating Costs and Expenses	14,274	10,160
Loss from Operations	(14,274)	(10,160)
Other Income:		
Interest income	6	44
Total Other Income	6	44
Net Loss	(14,268)	(10,116)
Net Loss Attributable to Non-controlling Interest	(1)	(73)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (14,267)**	**$ (10,043)**
Series A Preferred Stock Dividends	(24)	(254)
Series B Preferred Stock Dividends	(1,496)	(1,380)
Effect of Series A Preferred Stock price adjustment	(7,402)	—
Effect of Warrant exercise price adjustment	—	(880)
Net Loss Attributable to Common Stockholders	**$ (23,189)**	**$ (12,557)**
Net Loss Per Share - Basic and Dilutive	**$ (0.19)**	**$ (0.66)**
Weighted average number of shares outstanding during the period - basic and dilutive	**121,875,042**	**19,011,362**