UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 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 LLC

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 May 16, 2022, Synthetic Biologics, Inc., a Nevada corporation (the "Registrant") issued a press release that included financial information for its quarter ended March 31, 2022. 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 May 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: May 16, 2022

SYNTHETIC BIOLOGICS, INC.

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

Synthetic Biologics Reports First Quarter 2022 Operational Highlights and Financial Results

-Encouraging data further supports the development of novel oncolytic adenovirus (OV) platform; Announced a peer-reviewed publication highlighting positive clinical data on VCN-01 and an upcoming oral presentation on VCN-11, a novel oncolytic adenovirus designed to evade neutralizing antibodies-

- Reported positive safety data on SYN-020 intestinal alkaline phosphatase from the Phase 1 Multiple Ascending Dose clinical trial-

-Formed Scientific Advisory Board and strengthened the leadership team to support transformative clinical development strategy and extension into oncology -

-As of March 31, 2022, Synthetic Biologics reports $56.7 million in cash, which is expected to provide runway through the end of 2023-

-Conference call and webcast to be held today at 8:30 a.m. ET-

Rockville, MD, May 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 March 31, 2022, and provided a corporate update.

Recent Developments:

- *Pipeline updates (OV):* 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 which is intended to improve systemic delivery by enabling the virus to coat itself in albumin and thereby evade neutralizing antibodies (NAbs).
    - In May 2022, announced an upcoming oral presentation on VCN-11 at the 25th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT). The presentation will include preclinical results showcasing the potential of VCN-11 to balance safety, with no major toxicities observed, and effectively target tumors after intravenous re-administration, even in the presence of high level NAbs.
    - In March 2022, announced the peer-reviewed publication of a Phase 1, multicenter, open-label, dose-escalation study investigating the therapeutic potential of intravenous VCN-01 oncolytic adenovirus with or without standard-of-care (SoC) chemotherapy (gemcitabine/nab-paclitaxel) in patients with advanced solid tumors. The data, published in the *Journal for ImmunoTherapy of Cancer*, suggests that treatment with VCN-01 is feasible and has an acceptable safety profile, with encouraging biological and clinical activity. These findings provide valuable dose-finding context and inform the clinical development strategy for VCN-01.
- SYN-020: In May 2022, reported positive safety data from the Phase 1a multiple ascending dose study of SYN-020 in healthy volunteers. Analyses of preliminary data demonstrated that SYN-020 maintained a favorable safety profile and was well-tolerated across all dose levels. There were a few treatment-related adverse events, and all were mild (grade 1) and resolved without medical intervention. Both the previously reported Phase 1 single ascending dose (SAD) study and the current MAD study are intended to support the development of SYN-020 in multiple clinical indications.
- *Corporate Updates*
    - In May 2022, formed a Scientific Advisory Board (SAB) composed of industry leaders in oncolytic viruses and gene therapies. The SAB will work cohesively with the Synthetic Biologics' leadership team to support the Company's transformative clinical development strategy and extension into oncology. The founding members of the SAB are:

        - Chairman: Ramon Alemany, Ph.D., Head of Immunotherapy and Virotherapy Group at Translational Research Laboratory of the Institut Catala d'Oncologia (ICO) and Institut de Investigacio Biomedica de Bellvitage (IDIBELL).
        - Member: Mark S. Blumenkranz, M.D., MMS, is HJ Smead Professor Emeritus in the Department of Ophthalmology at Stanford University.
        - Member: Ennio Antonio Chiocca, M.D., Ph.D., is Harvey W. Cushing Professor of Neurosurgery at Harvard Medical School, Neurosurgeon-in-Chief and Chairman, Department of Neurosurgery and Co-Director, Institute for the Neurosciences at Brigham and Women's Faulkner Hospital.
        - Member: Daniel DiMaio, M.D., Ph.D., is the Waldemar Von Zedtwitz Professor of Genetics and Professor of Molecular Biophysics and Biochemistry, and of Therapeutic Radiology at Yale School of Medicine, as well as a Senior Advisor to the Director, Yale Cancer Center.
        - Member: Tom Dubensky, Ph.D., President of Tempest Therapeutics.
        - Member: Josep Tabernero, M.D., Ph.D., is Head of the Medical Oncology Department at the Vall d'Hebron University Hospital, Director of the Vall d'Hebron Institute of Oncology (VHIO) and Professor of Medicine at UVic.
    - In March 2022, Frank Tufaro, Ph.D., transitioned from Chief Operating Officer of recently acquired VCN Biosciences (VCN) to Chief Operating Officer of Synthetic Biologics. Dr. Tufaro will be responsible for leading strategic operations and optimizing organizational functions. As part of this acquisition, Manel Cascalló, Ph.D., former CEO of VCN, was appointed as General Director of Synthetic Biologic's European Subsidiary.

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 (Q4 2022).

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

SYN-004

- Data read out from the first cohort of the SYN-004 study in allo-HCT patients (H2 2022).

SYN-020

- Planning for the initiation of a Phase 2a study of SYN-020 (H2 2022).

“We are extremely pleased with the continued momentum following the transformative VCN acquisition, and our significant corporate advancements that mark a new phase of strategic growth,” said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. “This is an important phase of Synthetic Biologics’ evolution, and to support our extension into oncology, we strengthened our leadership team and recently formed a Scientific Advisory Board of leading experts composed of key opinion leaders. These distinguished leaders have made groundbreaking scientific advances in their respective fields of oncology, immunology and gene therapy, and we look forward to their counsel as we advance our oncolytic adenovirus development program to address devastating cancers with high unmet need. We are well positioned to deliver on our sharpened clinical development strategy and are poised for an exciting year ahead with the anticipation of multiple clinical studies and pivotal milestones that should continue to drive shareholder value.”

Quarter Ended March 31, 2022 Financial Results

General and administrative expenses increased to $1.7 million for the for the three months ended March 31, 2022, from $1.4 million for the three months ended March 31, 2021. This increase of 17% primarily composed of increased consulting and legal costs related to the VCN acquisition, higher insurance costs, audit fees, and public relations expenses and VCN administrative expenses not included in prior year. The charge related to stock-based compensation expense was $85,000 for the three months ended March 31, 2022, compared to $82,000 the three months ended March 31, 2021.

Research and development expenses increase to $2.6 million for the three months ended March 31, 2022, from approximately $1.1 million for the three months ended March 31, 2021. This increase of 132% is primarily the result of higher manufacturing expense for SYN-020, costs incurred related to our Phase 1a clinical trial of SYN-020 and the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients and VCN research expenses related to VCN-01 not incurred in the prior year. We anticipate research and development expense to increase as we plan for and initiate enrollment for our phase 2 clinical trial for VCN-01 in PDAC, phase 2/3 clinical trial in retinoblastoma, expand GMP manufacturing activities for VCN-01 and SYN-020, and continue with supporting our VCN-11 and other preclinical and discovery initiatives. The charge related to stock-based compensation expense was $28,000 for the three months ended March 31, 2022, compared to $19,000 related to stock-based compensation expense for the three months ended March 31, 2021.

Other expense was $21,068 for the three months ended March 31, 2022 compared to other income of $347 for the three months ended March 31, 2021. Other expense is primarily composed of exchange loss of $22,607, offset by interest income of $1,539. Other income for the three months ended March 31, 2021 is primarily comprised of interest income.

Cash and cash equivalents totaled $56.7 million as of March 31, 2022, a decrease of $10.5 million from December 31, 2021.

Conference Call

Synthetic Biologics will host a conference call at 8:30 a.m. ET today to review first quarter 2022 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: 13729717. 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. The Company's lead candidates are: (1) VCN-01, an oncolytic adenovirus designed to replicate selectively and aggressively within tumor cells, and to degrade the tumor stroma barrier that serves as a significant physical and immunosuppressive barrier to cancer treatment; (2) 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 (3) 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 the potential of VCN-11 to balance safety, the suggestion that treatment with VCN-01 is feasible has an acceptable safety profile, the SAD and MAD studies supporting the development of SYN-020 in multiple clinical indications, 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 (Q4 2022), initiation of a Phase 2/3 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 (H2 2022), planning for the initiation of a Phase 2a study of SYN-020 (H2 2022), being well positioned to deliver on our sharpened clinical development strategy and being poised for an exciting year ahead with the anticipation of multiple clinical studies and pivotal milestones that should continue to drive shareholder value 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 VCN-01 dosing in an investigator sponsored study of brain tumors at the University of Leeds (H1 2022), initiate 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), initiate 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 (Q4 2022), initiate a Phase 2/3 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 (H2 2022), the SAD and MAD studies supporting the development of SYN-020 in multiple clinical indications and planning for the initiation of a Phase 2a study of SYN-020 (H2 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 –

Synthetic Biologics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands except share and par value amounts)

	March 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 56,692	$ 67,325
Prepaid expenses and other current assets	2,863	1,533
Total Current Assets	59,555	68,858
Non-Current Assets		
Property and equipment, net	302	101
Restricted cash	103	
Right of use asset	1,338	1,383
In-process research and development	21,869	—
Goodwill	5,809	—
Deposits and other assets	23	23
Total Assets	**$ 88,999**	**$ 70,365**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,354	$ 524
Accrued expenses	1,535	1,928
Accrued employee benefits	423	978
Contingent consideration, current portion	7,470	—
Loans Payable-current	68	
Operating lease liability	126	124
Total Current Liabilities	10,976	3,554
Non-current Liabilities		
Non-current contingent consideration	4,688	—
Loan Payable - Long term	229	—
Deferred tax liabilities, net	3,728	—
Lease liability - Long term	1,351	1,403
Total Liabilities	20,972	4,957
Commitments and Contingencies		

Stockholders' Equity (Deficit):		
Common stock, $0.001 par value; 200,000,000 shares authorized, 158,440,168 issued and 158,437,840 outstanding at March 31, 2022 and 132,044,866 issued and 132,042,538 outstanding at December 31, 2021	158	132
Additional paid-in capital	343,245	336,560
Accumulated other comprehensive loss	181	—
Accumulated deficit	(275,557)	(271,284)
Total Stockholders' Equity	68,027	65,408
Total Liabilities and Stockholders' Equity	**$ 88,999**	**$ 70,365**

Synthetic Biologics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	For the three months ended March 31,	
	2022	**2021**
Operating Costs and Expenses:		
General and administrative	$ 1,655	$ 1,419
Research and development	2,597	1,118
Total Operating Costs and Expenses	4,252	2,537
Loss from Operations	(4,252)	(2,537)
Other Expense:		
Exchange loss	(23)	—
Interest income	2	—
Total Other Expense	(21)	—
Net Loss	(4,273)	(2,537)
Net Loss Attributable to Non-controlling Interest	—	(1)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (4,273)**	**$ (2,536)**
Series A Preferred Stock Dividends	—	(24)
Effect of Series A Preferred Stock price adjustment	—	(7,402)
Series B Preferred Stock Dividends	—	(1,497)
Net Loss Attributable to Common Stockholders	**$ (4,273)**	**$ (11,459)**
Net Loss Per Share - Basic and Dilutive	$ (0.03)	$ (0.13)
Weighted average number of shares outstanding during the period - Basic and Dilutive	138,201,442	90,807,693
Net Loss	(4,273)	(2,537)
Loss on foreign currency translation	(181)	—
Total comprehensive loss	(4,454)	(2,537)
Comprehensive loss attributable to non-controlling interest	—	(1)
Comprehensive loss attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (4,454)	$ (2,536)