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 10, 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 1.01. Entry into a Material Definitive Agreement.

As previously reported by Synthetic Biologics, Inc. ("Synthetic") in a Current Report on Form 8-K filed by Synthetic with the Securities and Exchange Commission (the "SEC") on December 14, 2021 (the "December 2021 Form 8-K"), Synthetic entered into a Share Purchase Agreement on December 14, 2021 (the "Purchase Agreement"), with VCN Biosciences, S.L., a corporation organized under the laws of Spain ("VCN") and the shareholders of VCN (the "Sellers"), to acquire all the outstanding shares of VCN (the "VCN Shares") from the shareholders of VCN (the "Acquisition"). The Share Purchase Agreement was amended on March 9, 2022 to reallocate to certain key employees and consultants of VCN a portion of the 26,395,303 shares of common stock, $0.001 par value, of Synthetic (the "Closing Shares") to be issued at the closing of the acquisition of VCN.

Item 2.01. Completion of Acquisition or Disposition of Assets.

On March 10, 2022, Synthetic closed the Acquisition (the "Closing") and acquired all the outstanding shares of VCN. As consideration for the purchase of the VCN Shares, at the Closing, Synthetic paid $4,700,000 (the "Closing Cash Consideration") to Grifols Innovation and New Technologies Limited ("Grifols"), the owner of approximately 86% of the equity of VCN, and issued to the remaining Sellers and certain key employees and consultants of VCN the Closing Shares, representing 19.99% of the outstanding shares of Synthetic's common stock on December 14, 2021, the date of the Purchase Agreement. In addition to the consideration described above, under the terms of the Purchase Agreement, Synthetic assumed up to $2,400,000 of existing liabilities of VCN and has agreed to make cash payments to Grifols upon the achievement of certain clinical and commercialization milestones, all as described in more detail in the December 2021 Form 8-K.

The Purchase Agreement contains customary representations, warranties and covenants of the Sellers and Synthetic. Subject to certain customary limitations, the Sellers have agreed to indemnify Synthetic and its officers and directors against certain losses related to, among other things, breaches of their representations and warranties, certain specified liabilities and the failure to perform covenants or obligations under the Purchase Agreement.

In connection with the Acquisition, prior to the Closing Synthetic loaned VCN $425,000 to help finance the costs of certain of VCN's research and development activities and, at the Closing, VCN and Grifols entered into a sublease agreement for the sublease by VCN of the laboratory and office space currently occupied by it as well as a transitional services agreement. As a Purchase Agreement post-Closing covenant, Synthetic has agreed to commit to fund VCN's research and development programs, including but not limited to VCN01 PDAC phase 2 trial, VCN01 RB pivotal trial and necessary G&A within a budgetary plan of approximately $27.8 million.

The foregoing summary of the Purchase Agreement, as amended, does not purport to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement that is filed herewith as Exhibit 2.1 and the amendment thereto that is filed herewith as Exhibit 2.2, both of which are incorporated herein by reference.

The representations, warranties and covenants contained in the Purchase Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to the Purchase Agreement, and may be subject to limitations agreed upon by the contracting parties. Accordingly, the Purchase Agreement is incorporated herein by reference only to provide investors with information regarding the terms of the Purchase Agreement, and not to provide investors with any other factual information regarding Synthetic, VCN or either of their businesses, and should be read in conjunction with the disclosures in Synthetic's periodic reports and other filings with the SEC.

About VCN

VCN is a private, clinical-stage biopharmaceutical company which is developing new agents for the treatment of certain cancers based on oncolytic adenoviruses with high potency and selectivity. VCN's lead product candidate, VCN-01, is an oncolytic adenovirus being studied in clinical trials for cancers with high unmet need, including pancreatic carcinoma and retinoblastoma. Oncolytic viruses have a unique mechanism of action as compared to other cancer drugs and can detect cancer mutations, replicate or self-amply within cancer cells, break down (i.e., lyse) the membranes of the cells thereby killing them and then propagate the oncolytic effect to neighboring cancer cells. The therapeutic effect is therefore amplified within tumors reducing the viral dose needed to reach tumors. Currently, VCN has four exclusive patent licenses in independent technologies developed internally and in collaboration with the Virotherapy Group of the Catalan Institute of Oncology (ICO-IDIBELL) that result in enhanced antitumoral potency of oncolytic adenoviruses.

Item 3.02. Unregistered Sales of Equity Securities.

The information set forth in Item 1.01 and Item 2.01 of this Current Report on Form 8-K is incorporated herein by reference into this Item 3.02 in its entirety. The Closing Shares were issued in a transaction exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(a)(2) thereof and Regulation S thereof ("Regulation S"). The Sellers receiving the shares of Synthetic common stock represented that they each were an "accredited investor," as defined in Regulation D, and were acquiring the securities described herein for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof or are exempt from registration under exemption afforded by Regulation S. Accordingly, the Closing Shares have not been registered under the Securities Act and may not be offered or sold in the United States absent registration or an exemption from registration under the Securities Act and any applicable state securities laws.

Item 7.01. Regulation FD Disclosure.

On March 11, 2022, Synthetic issued the press release attached hereto as Exhibit 99.1 announcing the closing of the Acquisition.

Item 9.01. Financial Statements and Exhibits.

(a) Financial statements of businesses acquired.

The financial statements required by Item 9.01(a) of Form 8-K will be filed with the SEC no later than 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

(b) Pro forma financial information.

The pro forma financial information required by Item 9.01(b) of Form 8-K will be filed with the SEC no later than 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

(d) Exhibits.

Exhibit Number	Description
2.1	Share Purchase Agreement, by and among Synthetic Biologics, Inc., VCN Biosciences, S.L. and the shareholders of VCN Biosciences, S.L., dated December 14, 2021 (incorporated by reference to the Form 8-K filed with the Securities and Exchange Commission on December 14, 2021 (File No. 001-12584)
2.2	Amendment, dated March 9, 2022, to the Share Purchase Agreement, by and among Synthetic Biologics, Inc., VCN Biosciences, S.L. and the shareholders of VCN Biosciences, S.L., dated December 14, 2021
99.1	Press Release issued by Synthetic Biologics, Inc., dated March 11, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are 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 hereunto duly authorized.

Dated: March 11, 2022 SYNTHETIC BIOLOGICS, INC.

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

Exhibit 2.2

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AMENDMENT TO SHARE PURCHASE AGREEMENT

This **AMENDMENT** (the "***Amendment***") is made and entered into as of the 9th day of March, 2022 to the **SHARE PURCHASE AGREEMENT**, dated December 14, 2021 (the "***Agreement***"), by and among Synthetic Biologics, Inc., a Nevada corporation (the "***Purchaser***"), VCN Biosciences, S.L., a corporation organized under the laws of Spain (the "***Company***"), and each of the shareholders of the Company (collectively, the "***Shareholders***"). Capitalized terms used and not defined herein shall have the meanings ascribed to them in the Agreement.

WHEREAS, Section 13.3 of the Agreement provides that prior to the Closing the Agreement may be amended by written agreement among the Purchaser, the Company and the Shareholders.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Section 1.2(a) of the Agreement is hereby deleted in its entirety and replaced with the following:

"At the Closing, the Purchaser shall deliver to (i) Grifols Innovation and New Technologies Limited ("***Grifols***") the Closing Cash Consideration by means of wire transfer of immediately available funds to an account or accounts designated by Grifols; (ii) the creditors of VCN set forth on Schedule 1.2 hereto (the "***VCN Creditors***") evidence of registration with the Purchaser's transfer agent of shares of Purchaser Common Stock in the name of each such creditor, in each case for such number of shares of Purchaser Common Stock set forth opposite such creditors name on Schedule 1.2 hereto; and (iii) the Remaining Shareholders evidence of registration with the Purchaser's transfer agent of shares of Purchaser Common Stock in the name of each Remaining Shareholder, in each case for such number of shares of Purchaser Common Stock set forth opposite such Remaining Shareholder's name on Schedule 1.2 hereto (collectively, the "***Closing Consideration***"); provided, however, it shall be a condition to any issuance of Purchaser Common Stock to the VCN Creditors that Purchaser shall have received from each such creditor a written representation and warranty, in form and substance acceptable to Purchaser, with respect to the matters set forth in Article IV hereof, as applicable to such creditor."

2. The first of sentence of Section 9.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"Unless otherwise mutually agreed in writing between the Purchaser and the Shareholders, the Closing shall take place at the offices of Blank Rome LLP, 1271 Avenue of the Americas, New York, NY 10020, on the date agreed to by the Purchaser and the Shareholders but no later than 8:00 A.M. (Eastern Time) on March 15, 2022."

3. Schedule 1.2 of the Agreement is hereby deleted in its entirety and replaced with Schedule 1.2 attached hereto.

4. All other terms of the Agreement shall remain in full force and effect. The Agreement, as amended by this Amendment, constitutes the entire agreement between the parties with respect to the subject matter thereof.

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5. This Amendment may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile signature shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original, not a facsimile signature.

[Signature Page Follows]

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IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first written above.

SYNTHETIC BIOLOGICS, INC.

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

THE COMPANY:

VCN BIOSCIENCES, S.L.

By: /s/ Manel Cascalló
Name: Manel Cascalló
Title: Chief Executive Officer

SHAREHOLDERS:

By: /s/ Gabriel María Capellá Munar
Name: Gabriel María Capellá Munar

By: /s/ Ramón Alemany
Name: Ramón Alemany

By: /s/ Manel Cascalló

Name: Manel Cascalló

BIO CAPE GROUP, S.L.

By: /s/ Guadalupe Foyo Ballesta
Name: Guadalupe Foyo Ballesta,
Administrator

BIOVAN PATRIMONIAL, S.L.

By: /s/ Margarita Nadal
Name: Margarita Nadal
Administrator

[Signatures continue on next page]

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GRIFOLS INNOVATION AND NEW TECHNOLOGIES, LIMITED

By: /s/ Oscar Calsamiglia Mendlewicz
Name: Oscar Calsamiglia Mendlewicz
Authorized Signatory

Signature page to the Amendment to Share Purchase Agreement

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Schedule 1.2

NAME	SYN SHARES	COUNTRY
VCN Creditors		
Frank Tufaro	806,452	United States
Carmen Blasco	80,644	Spain
Ernest Milian	80,644	Spain
Ana Mato	22,581	Spain
Victoria Maliandi	22,581	Spain
Sonia Celej	22,581	Poland (Tax residence in Spain)
Patricia Alonso	16,129	Spain
Romy Seth	2,470,184	Canada (Tax residence in the United States)
Lacarya Scott	2,470,184	United States
Ashland Securities, LLC	65,071	United States
Shareholders		
Gabriel Maria Capella Munar	5,006,625	Spain
Ramon Alemany Bonastre	5,006,625	Spain
Manuel Maria Cascallo Piqueras	5,006,625	Spain
Bio Cape Grup, S.L. (FFF1)	2,534,059	Spain
BioVCN Patrimonial, S.L. (FFF2)	2,784,318	Spain
TOTAL	**26,395,303**	

Synthetic Biologics Completes Acquisition of VCN Biosciences

- Expands pipeline into oncology with unique, clinical-stage oncolytic viruses optimized for intravenous administration -

-Strong cash position to support multiple inflection points for VCN-01 with the start of a Phase 2 trial in combination with standard-of-care chemotherapy in patients with pancreatic ductal adenocarcinoma and a Phase 2/3 pivotal trial either as an adjunct to chemotherapy or a potential rescue therapy in advanced retinoblastoma pediatric patients-

ROCKVILLE, Md., March 11, 2022 (GLOBE NEWSWIRE) - Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company developing therapeutics designed to treat diseases in areas of high unmet need, today announced that it has completed the acquisition of VCN Biosciences, S.L. (VCN) following the satisfaction of all closing conditions.

VCN is a privately held clinical-stage biotech company focused on developing a new oncolytic adenovirus (OV) platform designed for intravenous (IV) and intravitreal (IVit) 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 acquisition transforms Synthetic Biologics' pipeline with the addition of VCN's lead clinical-stage drug candidate, VCN-01, as well as preclinical stage VCN-11, both of which are next-generation OVs in development for the treatment of cancers with high unmet need. VCN-01 was granted Orphan Drug Designation in 2011 by the European Medicines Agency (EMA) for the treatment of pancreatic ductal adenocarcinoma (PDAC), and in February this year was granted Orphan Drug Designation by the U.S. FDA for the treatment of retinoblastoma (RB). VCN-11 is a modified version of VCN-01 that incorporates a proprietary albumin binding domain in the virus outer shell and was designed to improve systemic delivery by enabling the virus to coat itself with host serum albumin and prevent inactivation by neutralizing antibodies.

"The acquisition of VCN positions us at the forefront of oncolytic virus development and propels the Synthetic Biologics pipeline forward," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "The therapeutic application of OVs has been limited, in part, by a need for local administration. Our OVs are designed for systemic administration to target primary as well as metastatic tumors. Once inside the tumor, our OVs are uniquely engineered to replicate selectively and aggressively within the tumor cells and to break down the tumor stroma through the expression of PH20, a differentiating benefit of VCN-01."

Mr. Shallcross continued, "We are highly encouraged by the promising clinical safety and efficacy data generated to date, and we plan to start a Phase 2 trial of VCN-01 in combination with gemcitabine/Abraxane® standard of care chemotherapy in PDAC patients. The trial will be led by Dr. Manuel Hidalgo Medina, an internationally renowned physician, scientist and academic, with deep expertise in oncology, and a Member of the Board of Directors at Bristol Myers Squibb. Additionally, we plan to initiate a Phase 2/3 pivotal trial of VCN-01 as either an adjunct to chemotherapy or a potential rescue therapy in advanced RB pediatric patients. With a strong cash position and established collaborations with leaders in the field, we are poised to advance a robust multi-regional clinical program and maximize the clinical potential of our innovative product pipeline. We remain committed to driving shareholder value and look forward to providing updates on our progress as we work towards improving the lives of patients."

Transaction Details

As consideration for the purchase of VCN, at the closing of the transaction Synthetic Biologics paid US$4,700,000 to Grifols Innovation and New Technologies Limited, the owner of approximately 86% of the equity of VCN, and issued to the remaining shareholders and certain key employees and consultants of VCN 26,395,303 shares of common stock of Synthetic Biologics, representing 19.99% of the outstanding shares of Synthetic's Biologics common stock on December 14, 2021, the date of the Share Purchase Agreement with VCN and its shareholders. In addition to the consideration described above, under the terms of the Share Purchase Agreement, Synthetic Biologics has also agreed to make the following milestone payments to Grifols Innovation and New Technologies Limited:

Milestone Payments
US$3MM upon VCN-01 US IND Safe to Proceed – PDAC (or other *first* indication)
US$2.75MM upon VCN-01 US IND Safe to Proceed – RB (or other *second* indication)
US$3.25MM upon VCN-01 US first patient dosed– PDAC (or other *first* indication) after receipt of VCN-01 US IND Safe to Proceed for PDAC being informed
US$3.25MM upon VCN-01 US first patient dosed – RB (or other *second* indication) after receipt of VCN-01 US IND Safe to Proceed for RB being informed
US$6MM upon VCN-01 US Phase 2 trial meets the primary endpoint or if a Phase 2 trial is not conducted and only a Phase 3 trial is conducted then upon a Phase 3 being initiated – PDAC (or other *first* indication)
US$8MM upon VCN-01 Pivotal Trial meeting the primary endpoint or upon BLA Submission – RB (or other *second* indication)
US$12MM upon VCN-01 US Phase 3 trial meeting the primary endpoint or upon BLA Submission – PDAC (or other *first* indication)
US$16MM upon VCN-01 BLA Approval – PDAC (or other *first* indication)
US$16MM upon VCN-01 BLA Approval – RB (or other *second* indication)

In addition, Synthetic Biologics agreed as a post- Closing covenant to commit to fund VCN's research and development programs, including but not limited to VCN-01 PDAC Phase 2 trial, VCN-01 RB pivotal trial and necessary G&A within a budgetary plan of approximately US$27.8 million.

A.G.P./Alliance Global Partners served as excusive financial advisor to Synthetic Biologics in connection with the transaction. Tungsten Advisors served as the exclusive financial advisor to VCN Biosciences SL.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is 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) and intravitreal 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 strong cash position supporting multiple inflection points for VCN-01 with the start of a Phase 2 trial in combination with standard-of-care chemotherapy in patients with pancreatic ductal adenocarcinoma and a Phase 2/3 pivotal trial either as an adjunct to chemotherapy or a potential rescue therapy in advanced retinoblastoma pediatric patients, being poised to advance a robust multi-regional clinical program and maximize the clinical potential of Synthetic Biologics' product pipeline, VCN's new oncolytic adenovirus platform triggering tumor cell death, improving access of co-administered cancer therapies to the tumor, and promoting a robust and sustained anti-tumor response by the patient's immune-system, starting a Phase 2 trial of VCN-01 in combination with gemcitabine/Abraxane® standard of care chemotherapy in patients with pancreatic ductal adenocarcinoma and initiating a Phase 2/3 pivotal trial of VCN-01 as either an adjunct to chemotherapy or a potential rescue therapy in advanced RB pediatric patients. 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 the planned Phase 2 trial of VCN-01 in combination with standard-of-care chemotherapy in patients with pancreatic ductal adenocarcinoma 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, and if initiated, the ability to complete them on time and achieve the desired results and benefits continuing 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 and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 2020 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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