

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): December 14, 2021

**SYNTHETIC BIOLOGICS, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of  
incorporation)

**001-12584**

(Commission File No.)

**13-3808303**

(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.

On December 14, 2021, Synthetic Biologics, Inc. (“Synthetic”) entered into a Share Purchase Agreement (“Purchase Agreement”) with VCN Biosciences, S.L., a corporation organized under the laws of Spain (“VCN”) and the shareholders of VCN (the “Sellers”), which provides for the acquisition by SYN (the “Acquisition”) of all the outstanding shares of VCN (the “VCN Shares”) from the shareholders of 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 for which there is no cure, 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-amplify 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.

### Material Terms of the Purchase Agreement

Pursuant to the Purchase Agreement, as consideration for the purchase of the VCN Shares, Synthetic has agreed at the closing of the transactions contemplated by the Purchase Agreement (the “Closing”) to pay \$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 to issue to the remaining Sellers 26,395,303 shares of common stock, \$.001 par value, of Synthetic (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. As additional consideration for the purchase of the VCN Shares held by Grifols, Synthetic has also agreed to make the following milestone payments to Grifols:

---

#### 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)

The Purchase Agreement provides that at the Closing VCN shall have no liabilities of any nature outstanding other than up to \$2,400,000 of liabilities (the “Specified Indebtedness”) which Synthetic will assume, which include certain loans from the Spanish Government and the Catalan Government Agency. In the event VCN’s liabilities at Closing exceed the amount of the Specified Indebtedness, the Closing Cash Consideration will be reduced by the amount of such excess liabilities.

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. The Closing of the transaction is subject to the approval by the Spanish government of Synthetic’s acquisition of VCN under Spain’s Foreign Investment Act and other customary closing conditions.

The Purchase Agreement further provides that prior to Closing Synthetic will loan to VCN up to \$425,000 to help finance the costs of certain of VCN’s research and development activities. In the event that Closing does not take place under certain circumstances, the loan will become due and payable to Synthetic. In addition, at Closing VCN and Grifols will enter 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. Synthetic agreed as a post- Closing covenant 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 27.81 million.

A.G.P/Alliance Global Partners and Griffin Securities, Inc. served as financial advisors to Synthetic’s board of directors and Tungsten Partners LLC served as financial advisor to VCN.

---

The foregoing summary of the Purchase Agreement 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.

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 Securities and Exchange Commission (the "SEC").

#### *Forward-Looking Statements*

This Report contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 27A of the United States Securities Act of 1933, as amended) concerning Synthetic, VCN, the Purchase Agreement and other matters. These statements are based upon management's current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and include statements regarding the proposed Acquisition of VCN by Synthetic, the timing of such acquisition and the various timelines for development of VCN's product candidates. The forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from those reflected in Synthetic's forward-looking statements include, among others, the risk associated with Synthetic's and VCN's ability to satisfy the conditions to consummate the proposed Acquisition, including obtaining necessary governmental approvals, the timing of the closing of the proposed Acquisition, the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Purchase Agreement between the Sellers and Synthetic, unanticipated difficulties or expenditures relating to the proposed Acquisition or development of VCN's drug candidates, the response of business partners and competitors to the announcement of the proposed Acquisition, and/or potential difficulties in employee retention as a result of the announcement and pendency of the proposed Acquisition, whether the combined business of Synthetic and VCN will be successful, Synthetic's 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 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's 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 Synthetics' and VCN's products, developments by competitors that render such products obsolete or non-competitive, Synthetic's and VCN's ability to maintain license agreements, the continued maintenance and growth of Synthetics' and VCN's patent estate, and other factors described in Synthetics' annual report on Form 10-K for the year ended December 31, 2020, subsequent quarterly reports on Form 10-Qs and any other filings we make with the SEC. Synthetic can give no assurance that the conditions to the acquisition will be satisfied. The information in this presentation is provided only as of the date presented, and Synthetic undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

#### **Item 2.03 Creation of a Direct Financial Obligation or an Obligation Under an Off-balance Sheet Arrangement of a Registrant.**

The description of the Purchase Agreement in "Item 1.01 Entry into a Material Definitive Agreement" of this Current Report on Form 8-K is incorporated by reference in its entirety into this Item 2.03.

#### **Item 3.02. Unregistered Sales of Equity Securities.**

The information set forth in Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference into this Item 3.02 in its entirety. The Closing Shares will be issued in a transaction exempt from registration under the Securities Act in reliance on Section 4(a)(2) thereof. 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 will not be 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 December 14, 2021, Synthetic Biologics issued the press release attached hereto as Exhibit 99.1 announcing entering into the Share Purchase Agreement.

The press release is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

---

Item 9.01. - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
<a href="#">2.1*</a>	<a href="#">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</a>
<a href="#">99.1</a>	<a href="#">Press Release issued by Synthetic Biologics, Inc., dated December 14, 2021</a>
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

*\*The schedules to the Share Purchase Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Certain portions of the exhibits to the Share purchase Agreement have been omitted in accordance with Item 601(b)(10) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.*

## 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: December 14, 2021

SYNTHETIC BIOLOGICS, INC.

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

---