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 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 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 7.01. Regulation FD Disclosure.

On May 10, 2022, Synthetic Biologics, Inc. (the "Company") issued a press release announcingpositive safety data from its Phase 1, placebo-controlled, double-blind multiple ascending dose (MAD) clinical trial of SYN-020 intestinal alkaline phosphatase (IAP). The Phase 1 MAD study enrolled 32 healthy adult volunteers into four cohorts with SYN-020 administered orally in doses ranging from 5 mg to 75 mg twice daily for 14 days with a follow-up evaluation at day 35. Each cohort included six subjects who received SYN-020 and two who received placebo. 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. The most common adverse event, constipation, occurred in three out of 24 subjects in the treatment arm and in one out of eight subjects in the placebo arm. No adverse event led to discontinuation of the study drug and there were no serious adverse events. SYN-020 levels were below the limit of quantitation in all plasma samples at all timepoints during the study.

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language 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 8.01. Other Events.

On May 10, 2022, the Company issued a press release announcingpositive safety data from its Phase 1, placebo-controlled, double-blind multiple ascending dose (MAD) clinical trial of SYN-020 intestinal alkaline phosphatase (IAP). The Phase 1 MAD study enrolled 32 healthy adult volunteers into four cohorts with SYN-020 administered

orally in doses ranging from 5 mg to 75 mg twice daily for 14 days with a follow-up evaluation at day 35. Each cohort included six subjects who received SYN-020 and two who received placebo. 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. The most common adverse event, constipation, occurred in three out of 24 subjects in the treatment arm and in one out of eight subjects in the placebo arm. No adverse event led to discontinuation of the study drug and there were no serious adverse events. SYN-020 levels were below the limit of quantitation in all plasma samples at all timepoints during the study.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Synthetic Biologics, Inc., dated May 10, 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 10, 2022

SYNTHETIC BIOLOGICS, INC.

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

Synthetic Biologics Reports Positive Safety Data on SYN-020 Intestinal Alkaline Phosphatase Phase 1 Multiple Ascending Dose Clinical Trial

-Orally administered SYN-020 observed to be well tolerated across all doses in healthy volunteers-

ROCKVILLE, MD – May 10, 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 positive safety data from its Phase 1, placebo-controlled, double-blind multiple ascending dose (MAD) clinical trial of SYN-020 intestinal alkaline phosphatase (IAP). The Phase 1 MAD study enrolled 32 healthy adult volunteers into four cohorts with SYN-020 administered orally in doses ranging from 5 mg to 75 mg twice daily for 14 days with a follow-up evaluation at day 35. Each cohort included six subjects who received SYN-020 and two who received placebo. 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. The most common adverse event, constipation, occurred in three out of 24 subjects in the treatment arm and in one out of eight subjects in the placebo arm. No adverse event led to discontinuation of the study drug and there were no serious adverse events. SYN-020 levels were below the limit of quantitation in all plasma samples at all timepoints during the study. Additional analyses, including fecal levels of SYN-020 and anti-drug antibody levels are on-going.

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. The Company is continuing to evaluate potential lead indications, which may include celiac disease, nonalcoholic fatty liver disease (NAFLD), and radiation enteropathy as well as indications to treat and prevent metabolic and inflammatory disorders associated with aging. This latter group of age-related clinical indications is supported by the Company's collaboration with Massachusetts General Hospital.

"SYN-020 is a promising, versatile asset that has the potential to become a multi-indication therapeutic capable of addressing a considerable market opportunity and unmet need for innovative, new therapies targeting disorders stemming from gastrointestinal (GI) inflammation," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "We will continue to explore the therapeutic potential of SYN-020 across indications including celiac disease, NAFLD, age-related metabolic and inflammatory diseases. We are very encouraged by these positive Phase 1 results and look forward to SYN-020's clinical advancement."

SYN-020 is a recombinant bovine IAP formulated for oral delivery to the small intestine and designed to diminish fat absorption and intestinal inflammation, tighten the gut barrier to mitigate "leaky gut," and promote a healthy microbiome. Despite its broad therapeutic potential, a key hurdle to commercialization has been the high cost of IAP manufacture. Synthetic Biologics has overcome this hurdle and has the ability to produce SYN-020 at a scale and cost viable for clinical and commercial development.

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 intravenous (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.

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 includes statements regarding the Phase 1 SAD study and the current MAD study supporting the development of SYN-020 in multiple clinical indications, continuing to explore the therapeutic potential of SYN-020 across indications, including celiac disease, NAFLD, and age-related metabolic and inflammatory diseases, and the continued development of SYN-020*. 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, Synthetic Biologics' ability to develop SYN-020 in multiple indications, including as a therapeutic for treatment of disorders stemming from gastrointestinal (GI) inflammation, including celiac disease, NAFLD, and age-related metabolic and inflammatory diseases, 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 and 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:
Chris Calabrese
LifeSci Advisors, LLC
ccalabres@lifesciadvisors.com
+1-917-680-5608