

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): June 29, 2021

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, MD 20850
(Address of principal executive offices and zip code)

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

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 7.01 Regulation FD Disclosure.

On June 29, 2021, Synthetic Biologics, Inc. (the “Company”) issued a press release announcing that that patient dosing and observation has been completed in its Phase 1, open label, single-ascending dose (SAD) clinical trial of SYN-020 intestinal alkaline phosphatase (IAP). The Phase 1 SAD study enrolled 24 healthy adult volunteers into four cohorts with SYN-020 given orally as single doses ranging from 5 mg to 150 mg daily. Analyses of preliminary data demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels and no adverse events were attributed to the study drug. No serious adverse events were reported. A second Phase 1 clinical trial intended to evaluate the safety, tolerability and biodistribution of multiple-ascending doses (MAD) of SYN-020 in healthy volunteers is expected to commence during the third quarter of 2021. Topline results from this clinical trial are anticipated during the second quarter of 2022. Both Phase 1 SAD and MAD studies are intended to support the development of SYN-020 in multiple potential clinical indications, including celiac disease, nonalcoholic fatty liver disease, radiation enteropathy, and indications to treat and prevent metabolic and inflammatory disorders associated with aging, which are supported by the Company’s collaboration with Massachusetts General Hospital.

A copy of the press release is furnished 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.

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.

Item 8.01 Other Events

On June 29, 2021, the Company announced that that patient dosing and observation has been completed in its Phase 1, open label, SAD clinical trial of SYN-020 intestinal alkaline phosphatase (IAP). The Phase 1 SAD study enrolled 24 healthy adult volunteers into four cohorts with SYN-020 given orally as single doses ranging from 5 mg to 150 mg daily. Analyses of preliminary data demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels and no adverse events were attributed to the study drug. No serious adverse events were reported. A second Phase 1 clinical trial intended to evaluate the safety, tolerability and biodistribution of multiple-ascending doses of SYN-020 in healthy volunteers is expected to commence during the third quarter of 2021. Topline results from this clinical trial are anticipated during the second quarter of 2022. Both Phase 1 SAD and MAD studies are intended to support the development of SYN-020 in multiple potential clinical indications, including celiac disease, nonalcoholic fatty liver disease, radiation enteropathy, and indications to treat and prevent metabolic and inflammatory disorders associated with aging, which are supported by the Company’s collaboration with Massachusetts General Hospital.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished with this Current Report on Form 8-K:

Exhibit No.	Description
99.1	Press Release issued by Synthetic Biologics, Inc., dated June 29, 2021.

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: June 29, 2021

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross

Name: Steven A. Shallcross

Title: Chief Executive Officer
and Chief Financial Officer
