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 5, 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, 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 2.02 – Results of Operations and Financial Condition.

On May 5, 2021, Synthetic Biologics, Inc., a Nevada corporation (the "Registrant") issued a press release that included financial information for its quarter ended March 31,2021. A copy of the press release is attached as Exhibit 99.1 to this Current 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 5, 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: May 5, 2021

SYNTHETIC BIOLOGICS, INC.

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

Synthetic Biologics Reports 2021 First Quarter Operational Highlights and Financial Results

Initiated Phase 1b/2a Clinical Trial of SYN-004 in Allogeneic HCT Recipients for the Prevention of aGVHD

Initiated Phase 1a Single-Ascending-Dose Clinical Trial of SYN-020 Intestinal Alkaline Phosphatase

Reports $76.9 Million of Cash on Hand to Fund Clinical Programs Through Proof-of-Concept and Extend Operations into 2023

-- Conference Call Today at 4:30 p.m. (ET) --

Rockville, MD, May 5, 2021 – Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need, today provided a clinical programs update and reported financial results for the quarter ended March 31, 2021.

Recent developments:

- Announced enrollment has commenced and three out of a total of four cohorts have been dosed in the first Phase 1a clinical trial of SYN-020 intestinal alkaline phosphatase ("IAP") intended to support development of SYN-020 in multiple indications
- Announced enrollment has commenced and the first patient was dosed in the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant ("HCT") recipients
- Current cash position of approximately $76.9 million
- Received $8.0 million from the exercise of warrants
- Current cash runway provides funding into 2023 and ability to fund Phase 1b/2a clinical trial of SYN-004 as well as SYN-020intestinal alkaline phosphatase ("IAP") through proof-of-concept

Upcoming milestones, pandemic conditions permitting:

- Topline data from the Phase 1a single-ascending-dose ("SAD") study of SYN-020 anticipated during Q3 2021
- Expect to commence second Phase 1a multiple-ascending-dose ("MAD") study of SYN-020 during Q3 2021; topline data anticipated during Q2 2022
- Topline data readout from the first antibiotic cohort of the SYN-004 Phase1b/2a clinical trial is expected during Q4 2021

"During the first quarter of 2021 we remained diligently focused on advancing our portfolio of GI and microbiome-focused clinical programs and were pleased to announce the commencement of clinical trials for our SYN-004 and SYN-020 programs," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "Enrollment in the SYN-004 Phase 1b/2a clinical trial in allogeneic hematopoietic cell transplant (HCT) recipients is underway at the Washington University School of Medicine in St. Louis ("Washington University") and the first patient of the first antibiotic cohort was dosed earlier this year. We believe SYN-004 has the potential to address an important and underserved patient population, and may significantly improve outcomes for allogeneic HCT recipients by preventing downstream complications often associated with disruption of the gut microbiome by intravenous ("IV") beta-lactam antibiotics. If enrollment proceeds as planned, we anticipate announcing topline data from the first antibiotic cohort during the fourth quarter of 2021, pandemic conditions permitting."

Mr. Shallcross continued, "We were also very excited to announce the initiation of a Phase 1a single-ascending-dose clinical trial of our SYN-020 IAP program during the first quarter of 2021. To date, three out of a total of four cohorts have been dosed and we remain on track to report topline data from this study during the third quarter of 2021, pandemic conditions permitting. A second Phase 1a multiple-ascending-dose study is also expected to begin enrollment during the third quarter of 2021 with topline data expected early next year. Both studies are designed to support the advancement of SYN-020 in multiple potential therapeutic indications, including celiac disease, nonalcoholic fatty liver disease ("NAFLD") and age-related metabolic and inflammatory diseases. We are very excited about the potential for this program to be a long-term value driver for our Company and look forward to sharing important updates."

Mr. Shallcross concluded, "While we remain focused on the execution of our clinical development activities, we were also able raise net proceeds of approximately $66 million as well as $8.0 million in proceeds from the cash exercise of warrants, significantly strengthening our balance sheet and financial position. As a result of these activities, our current cash position is approximately $76.9 million. Importantly, our fortified balance sheet will fully fund our SYN-004 and SYN-020 clinical programs through proof-of-concept clinical studies, and help accelerate our other ongoing activities."

Clinical Development and Operational Update

- Announced Washington University has begun enrollment and the first patient was dosed in the first antibiotic cohort of the Company's Phase 1b/2a clinical trial of SYN-004 in allogeneic HCT recipients for the prevention of acute graft-versus-host-disease (aGVHD)
  - The Phase 1b/2a clinical trial comprises a single center, randomized, double-blind, placebo-controlled clinical trial of oral SYN-004 in up to 36 evaluable adult allogeneic HCT recipients,
  - The goal of this clinical trial is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of oral SYN-004 administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever,
  - Study participants will be enrolled into three sequential cohorts and administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 and four will receive placebo,
  - Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee ("DSMC"), which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic,
  - A topline data readout for the first antibiotic cohort is anticipated during the fourth quarter of 2021, pandemic conditions permitting;

- Announced enrollment has commenced and three out of a total of four cohorts have been dosed in a Phase 1a SAD clinical trial of SYN-020 in healthy adult volunteers
  - The Phase 1a SAD study is designed to evaluate safety, tolerability and pharmacokinetics of four single-ascending doses of oral SYN-020 in healthy adult volunteers
  - In all, up to 24 study participants will be enrolled into four cohorts that will run sequentially, all of which will receive oral SYN-020. A topline data readout is anticipated during the third quarter of 2021, pandemic conditions permitting,

- A second Phase 1a clinical trial evaluating multiple-ascending doses of SYN-020 in healthy volunteers is expected to commence during the third quarter of 2021. Topline data is anticipated during the second quarter of 2022, pandemic conditions permitting,
- Both studies are intended to support the development of SYN-020 in multiple potential clinical indications including celiac disease, NAFLD, and indications supported by the Company's collaboration with Massachusetts General Hospital;

- Strengthened balance sheet by raising net proceeds of $66 million from the sale of common stock via the Company's At-The-Market ("ATM") facility and $8.0 million resulting from the cash exercise of a portion of Company's 2018 warrants during Q1 2021
  - As a result of these activities, the Company has extended its cash runway into 2023 and has the ability to fully fund its Phase 1b/2a clinical trial of SYN-004 and planned Phase 1 SAD and MAD clinical trials of SYN-020.

Quarter Ended March 31, 2020 Financial Results

General and administrative expenses increased by 2% to approximately $1.42 million for the three months ended March 31, 2021, from approximately $1.39 million for the three months ended March 31, 2020. This increase is primarily due to higher insurance costs, audit fees, and legal costs offset by a reduction in patent related legal fees, consulting fees and travel expense. The charge related to stock-based compensation expense was $82,000 for the three months ended March 31, 2021, compared to $65,000 the three months ended March 31, 2020.

Research and development expenses decreased by 32% to approximately $1.1 million for the three months ended March 31, 2021, from approximately $1.6 million for the three months ended March 31, 2020. This decrease is primarily the result of lower indirect program costs for the three months ended March 31, 2021, including salary and related expense reductions, a decrease in manufacturing costs for SYN-020 and market research. In addition, as a result of the global COVID-19 pandemic, the Company's development partner (Washington University) reduced their operating capacity during 2021 to include only essential activities as part of their pandemic response, which delayed the start of the Company's clinical trial, resulting in lower clinical trial expenses for the quarter. The research and development costs incurred during the quarter were primarily related to the Company's Phase 1a clinical trial of SYN-020 and the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients. The Company anticipates research and development expense to increase as ongoing clinical trials continue to enroll patients. The charge related to stock-based compensation expense was $19,000 for the three months ended March 31, 2021, compared to $18,000 related to stock-based compensation expense for the three months ended March 31, 2020.

Other income was $347 for the three months ended March 31, 2021, compared to other income of $38,000 for the three months ended March 31, 2020. Other income for the three months ended March 31, 2021 and 2020 is primarily comprised of interest income.

Cash and cash equivalents as of March 31, 2021 totaled $76.9 million, an increase of $70.7 million from December 31, 2020.

Conference Call

Synthetic Biologics will hold a conference call today, Wednesday, May 5 , 2021, at 4:30 p.m. (EST). The dial-in information for the call is as follows, U.S. toll free: 1-888-347-5280 or International: +1 412-902-4280. Participants are asked to dial in 15 minutes before the start of the call to register. The call will also be webcast over the Internet at https://www.webcaster4.com/Webcast/Page/1096/40931. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/40931 , for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need. The Company's lead candidates are: (1) 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 (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.

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 first Phase 1a clinical trial of SYN-020 supporting development of SYN-020 in multiple indications; topline data from the Phase 1a single-ascending-dose ("SAD") study of SYN-020 during Q3 2021, commencing a second Phase 1a multiple ascending-dose ("MAD") study of SYN-020 during Q3 2021 and topline data anticipated during Q2 2022, topline data readout from the first antibiotic cohort of the SYN-004 Phase 1b/2a clinical trial during Q4 2021, SYN-004 having the potential to address an important and underserved patient population, and significantly improving outcomes for allogeneic HCT recipients by preventing downstream complications often associated with disruption of the gut microbiome by intravenous ("IV") beta-lactam antibiotics. If enrollment proceeds as planned, we anticipate announcing topline data from the first antibiotic cohort during the fourth quarter of 2021, pandemic conditions permitting, SYN-020 program being a long-term driver for Synthetic Biologics, the financial footing allowing Synthetic Biologics to continue its operations into 2023 as well as fully fund its SYN-004 and SYN-020 clinical programs through proof-of-concept clinical studies. 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, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, a failure of Synthetic Biologics' clinical trials for SYN-004 and SYN-020 to be completed on time, to provide topline data when anticipated or to achieve desired results and benefits, especially in light of COVID-19, a failure of Synthetic Biologics' clinical trials to continue enrollment as expected or receive anticipated funding, a failure of Synthetic Biologics to successfully develop, market or sell its products, Synthetic Biologics' inability to maintain its material licensing agreements, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products 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:

Synthetic Biologics, Inc. (Corporate and Investors)
Vincent I. Perrone, Director Corporate Communication, (240) 660-2000, info@syntheticbiologics.com

Ogilvy (Media)
Gregory Kelley, Senior Vice President, (404) 836-2302, gregory.kelley@ogilvy.com

- Financial Tables Follow -

Synthetic Biologics, Inc. and Subsidiaries
(in thousands, except share and per share amounts)

Consolidated Balance Sheets

	March 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 76,887	$ 6,227
Prepaid expenses and other current assets	1,749	1,707
Property and equipment, net	156	174
Right of Use Asset	239	279
Deposits and other assets	23	23
Total Assets	$ 79,054	$ 8,410
Liabilities and Stockholder's Deficit		
Total liabilities	$ 2,230	$ 3,152
Series A Convertible Preferred Stock	-	12,798
Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	79,598	(4,767)
Non-controlling interest	(2,774)	(2,773)
Total Liabilities and Stockholders' Equity (Deficit)	$ 79,054	$ 8,410

Condensed Consolidated Statements of Operations

	For the three months ended March 31,	
	2021	2020
Operating Costs and Expenses		
General and administrative	$ 1,419	$ 1,393
Research and development	1,118	1,635
Total Operating Costs and Expenses	2,537	3,028
Loss from Operations	(2,537)	(3,028)
Other Income		
Interest income	-	38
Total Other Income	-	38
Net Loss	(2,537)	(2,990)
Net Loss Attributable to Non-controlling Interest	(1)	(26)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (2,536)	$ (2,964)
Series A Preferred Stock Dividends	(24)	(62)
Effect of Series A Preferred Stock price adjustment	(7,402)	-
Series B Preferred Stock Dividends	(1,497)	(404)
Net Loss Attributable to Common Stockholders	(11,459)	(3,430)
Net Loss Per Share - Basic and Dilutive	$ (0.13)	$ (0.20)
Weighted average number of common shares outstanding - Basic and Dilutive	90,807,693	17,093,920

###