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): August 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 August 5, 2021, Synthetic Biologics, Inc., a Nevada corporation (the "Registrant") issued a press release that included financial information for its quarter ended June 30, 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 August 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: August 5, 2021

SYNTHETIC BIOLOGICS, INC.

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

Exhibit 99.1

Synthetic Biologics Reports Second Quarter 2021 Operational Highlights and Financial Results;
Conference Call to be Held Today at 4:30 PM ET

Phase 1 Single-Ascending Dose Clinical Trial of SYN-020 Demonstrated Favorable Safety Profile and was Well Tolerated at All Dose Levels; A Second Phase 1 Multiple-Ascending Dose Clinical Trial Expected to Commence in Q3 2021

Enrollment in Phase 1b/2a Clinical Trial of SYN-004 in Allogeneic HCT Recipients Proceeding as Planned

Reports $74.3 Million of Cash on Hand to Fund Clinical Programs Through Key Milestones Beyond 2022

Rockville, MD, August 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 second quarter ended June 30, 2021.

Recent Developments:

- Announced completion of patient dosing and observation in the Phase 1, open label, single-ascending dose ("SAD") clinical trial of SYN-020 intestinal alkaline phosphatase ("IAP")
- Continuing enrollment in the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant ("HCT") recipients
- Current cash position of approximately $74.3 million
- Current cash runway expected to provide funding to complete Phase 1b/2a clinical trial of SYN-004, clinical trials of SYN-020 through proof-of-concept, and other key milestones into 2023

Anticipated Milestones:

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

"During the second quarter, we remained focused on the advancement of our portfolio of gastrointestinal and microbiome-focused clinical programs," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "We were pleased to complete patient dosing and observation in the Phase 1 SAD clinical trial of SYN-020 intestinal alkaline phosphatase with preliminary results demonstrating that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to SYN-020. Looking ahead, we intend to commence a second Phase 1 MAD clinical trial of SYN-020 in healthy adult volunteers during the third quarter of 2021 with topline results expected during the second quarter of 2022. Both the Phase 1 SAD and MAD studies are designed to support the advancement of SYN-020 in multiple potential therapeutic indications, including celiac disease, nonalcoholic fatty liver disease ("NAFLD"), radiation enteritis, and age-related metabolic and inflammatory diseases."

Mr. Shallcross continued, "Patient screening and enrollment in the SYN-004 Phase 1b/2a clinical trial in allogeneic HCT recipients remains ongoing at the Washington University School of Medicine in St. Louis ("Washington University"). At this time, enrollment is proceeding as expected and we anticipate announcing topline results from this first of three antibiotic cohorts during the fourth quarter of 2021. We believe SYN-004 has the potential to significantly improve outcomes for allogeneic HCT recipients by preventing downstream complications often caused by disruption of the gut microbiome by intravenous ("IV") beta-lactam antibiotics following conditioning therapy. We are very excited about the potential for our portfolio of clinical development programs to be long-term value drivers for our Company and look forward to sharing important updates as they become available."

Clinical Development and Operational Update

- Announced completion of patient dosing and observation in the Phase 1, open label, single-ascending dose clinical trial of SYN-020
  - 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.
  - 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 evaluating multiple-ascending doses of SYN-020 in healthy volunteers is expected to commence during the third quarter of 2021. Topline data are 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, radiation enteritis, as well as indications supported by the Company's collaboration with Massachusetts General Hospital.

- Enrollment in 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") remains ongoing
  - 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.

- Received notification from the NYSE American that the Company had regained compliance with all of the continued listing standards set forth in Part 10, Section 1003 of the NYSE American Company Guide (the "Company Guide") relating to the Exchange's continued listing requirements.

Quarter Ended June 30, 2021 Financial Results

General and administrative expenses decreased by 2% to approximately $1.26 million for the three months ended June 30, 2021, from approximately $1.29 million for the three months ended June 30, 2020. This decrease is primarily due to lower legal costs and vacation expense offset by higher insurance costs, audit fees and registration fees. The charge related to stock-based compensation expense was $83,000 for the three months ended June 30, 2021, compared to $67,000 for the three months ended June 30, 2020.

Research and development expenses increased by 21% to approximately $1.9 million for the three months ended June 30, 2021, from approximately $1.6 million for the three months ended June 30, 2020. This increase is primarily the result of increased clinical trial expenses as we began dosing patients in the Phase 1b/2a clinical trial of SYN-004 and Phase 1 SAD clinical trial of SYN-020 during the three months ended June 30, 2021, offset by lower indirect program costs for the three months ended June 30, 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, our clinical development partner (Washington University) reduced their operating capacity during 2020 to include only essential activities as part of their pandemic response, which delayed the start of our clinical trial until 2021. We anticipate research and development expense to increase as our ongoing clinical trials continue to enroll patients. The charge related to stock-based compensation expense was $19,000 for the three months ended June 30, 2021, compared to $19,000 related to stock-based compensation expense for the three months ended June 30, 2020.

Other income was $2,000 for the three months ended June 30, 2021, compared to other income of $6,000 for the three months ended June 30, 2020. Other income for the three months ended June 30, 2021 and 2020 is primarily comprised of interest income.

Cash and cash equivalents as of June 30, 2021 totaled $74.3 million, an increase of $68.1 million from December 31, 2020.

Conference Call

Synthetic Biologics will hold a conference call today, Thursday, August 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/1096/41790. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/41790 , 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 current cash runway providing funding to complete the Phase 1b/2a clinical trial of SYN-004, clinical trials of SYN-020 through proof-of-concept, and other key milestones into 2023, the Phase 1 clinical trials of SYN-020 supporting development of SYN-020 in multiple potential clinical indications, commencing a second Phase 1 multiple ascending-dose ("MAD") study of SYN-020 during Q3 2021 and topline data anticipated during Q2 2022, a topline data readout from the first of three antibiotic cohorts of the SYN-004 Phase 1b/2a clinical trial during Q4 2021, SYN-004 having the potential to 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 following conditioning therapy. 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:

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- Financial Tables Follow -

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

Consolidated Balance Sheets

	For the three months ended	
	June 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 74,291	$ 6,227
Prepaid expenses and other current assets	1,341	1,707
Property and equipment, net	132	174
Right of Use Asset	1,468	279
Deposits and other assets	23	23
Total Assets	$ 77,255	$ 8,410
Liabilities and Stockholder's Deficit		
Total liabilities	$ 3,524	$ 3,152
Series A Convertible Preferred Stock	-	12,798
Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	76,505	(4,767)
Non-controlling interest	(2,774)	(2,773)
Total Liabilities and Stockholders' Equity (Deficit)	$ 77,255	$ 8,410

Condensed Consolidated Statements of Operations
(In thousands except share and per share amounts)

	For the three months ended June 30, *(Unaudited)*		For the six months ended June 30, *(Unaudited)*	
	2021	2020	2021	2020
Operating Costs and Expenses				
General and administrative	$ 1,265	1,286	$ 2,685	$ 2,679
Research and development	1,932	1,603	3,049	3,238
Total Operating Costs and Expenses	3,197	2,889	5,734	5,917
Loss from Operations	(3,197)	(2,889)	(5,734)	(5,917)
Other Income				
Interest income	2	6	2	44
Total Other Income, net	2	6	2	44
Net Loss	(3,195)	(2,883)	(5,732)	(5,873)
Net Loss Attributable to Non-controlling Interest	-	(16)	(1)	(42)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (3,195)	$ (2,867)	$ (5,731)	$ (5,831)
Series A Preferred Dividends	-	(63)	(24)	(125)
Effect of Series A Preferred Stock price adjustment	-		(7,402)	
Series B Preferred Dividends	-	(392)	(1,497)	(796)
Net Loss Attributable to Common Stockholders	$ (3,195)	$ (3,322)	$ (14,654)	$ (6,752)
Net Loss Per Share – Basic and Dilutive	$ (0.02)	$ (0.18)	$ (0.13)	$ (0.38)
Weighted average number of common shares outstanding - Basic and Diluted	132,042,538	18,405,884	111,539,024	17,748,688