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, 2020

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 2.02 – Results of Operations and Financial Condition.

On May 5, 2020, Synthetic Biologics, Inc., a Nevada corporation (the "Registrant") issued a press release that included financial information for its quarter ended March 31, 2020. A copy of the press release is attached 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release issued by Synthetic Biologics, Inc., dated May 5, 2020

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, 2020

SYNTHETIC BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by Synthetic Biologics, Inc., dated May 5, 2020

Exhibit 99.1

Synthetic Biologics Reports 2020 First Quarter Operational Highlights and Financial Results

-- Company Updates Guidance and Clinical Development Timeline in Response to the COVID-19 Global Pandemic --

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

Rockville, MD, May 5, 2020 – 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, 2020.

"During the first quarter of 2020, we remained sharply focused on executing our strategy to advance our portfolio of GI and microbiome-focused clinical development programs while responding to the unprecedented global health and economic crisis sparked by the COVID-19 pandemic," said Steven A. Shallcross, Chief Executive and Financial Officer of Synthetic Biologics. "Recommendations by local governments, hospitals and healthcare organizations to concentrate resources towards COVID-19 care are having a material impact on ongoing and planned clinical trials. This includes our ongoing Phase 2b investigator-sponsored clinical trial of SYN-010, intended to treat irritable bowel syndrome with constipation (IBS-C), being conducted out of Cedars-Sinai Medical Center (CSMC), as well as our planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients, which will be conducted by the Washington University School of Medicine in St. Louis (Washington University).Although we have experienced additional delays in enrollment and site visits for our planned and ongoing clinical trials, we believe we have implemented an operational framework which will allow us to navigate this crisis and ultimately deliver on the tangible results and goals we have established for our company."

Mr. Shallcross continued, "During the first quarter, we continued to make significant progress towards the completion of Investigational New Drug (IND)-enabling toxicology studies and assay development that are expected to support the filing of an IND for our SYN-020 intestinal alkaline phosphatase (IAP) program during the second quarter of 2020." Mr. Shallcross concluded, "In response to the efforts undertaken by our clinical development partners to conserve resources for combatting COVID-19, we have been able to reduce our burn rate and further extend our cash runway through at least the first quarter of 2021. We are monitoring the crisis caused by the spread of the COVID-19 closely and remain dedicated to protecting the health and safety of our employees, our clinical development partners and our patients."

Clinical Development and Operational Update

- Received official meeting minutes from the U.S. Food & Drug Administration (FDA) in Q1 2020 following a Type-C meeting held at the Company's request to discuss the development of a Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients
  - The goal of this study is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of 150 mg oral SYN-004 (ribaxamase) administered to allogeneic HCT recipients four times per day who receive an IV beta-lactam antibiotic to treat fever,
  - Study participants will be enrolled into three sequential cohorts administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 (ribaxamase) and four will receive placebo,
  - Due to the unique challenges posed by the global COVID-19 pandemic, Washington University has temporarily limited all non-essential activities, which directly impacts planned clinical trials. As a result, commencement of the planned Phase 1b/2a clinical trial in allogeneic HCT recipients is postponed until the first quarter of 2021, subject to the impact of COVID-19,

- Initiation of the clinical trial remains contingent upon approval of the clinical trial protocol by the Washington University School of Medicine's Institutional Review Board (IRB) and determination that the study is safe-to-proceed by the FDA;

· Enrollment in the Phase 2b investigator-sponsored clinical study of SYN-010 for the treatment of IBS-C continued through most of the first quarter of 2020. However, due to the unique challenges posed by the global COVID-19 pandemic, CSMC has temporarily limited all non-essential activities, which directly impacts ongoing clinical trials
  - As a result, additional enrollment in the Phase 2b investigator-sponsored clinical trial is temporarily suspended until a time when the safety of the Company's employees, the employees of its clinical development partners, and study participants can be assured,
  - Active study participants who did not complete the study prior to the decision to halt all non-essential activities may elect to complete the study as CSMC has taken steps to ensure proper data collection from this group of patients,
  - A data readout is anticipated during the third quarter of 2020, subject to the impact of COVID-19,
  - Cedars-Sinai Medical Center and Synthetic Biologics are co-funding the study. The patent rights covering the use of SYN-010 are owned by Cedars-Sinai Medical Center and are exclusively licensed by Cedars-Sinai Medical Center to Synthetic Biologics;

· Made additional progress towards the completion of IND-enabling toxicology studies and assay development that are expected to support the advancement of SYN-020 (intestinal alkaline phosphatase) into clinical trials targeting areas of significant unmet medical need, including enterocolitis associated with radiation therapy for cancer
  - Anticipate filing a U.S. IND in Q2 2020;

· The Company has further extended its cash runway since its clinical development partners (CSMC, Washington University) have reduced their operating capacity to include only essential activities directed towards combatting COVID-19, which excludes all planned and ongoing clinical trials for the time being;

· As previously disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which was filed with the Securities and Exchange Commission on February 20, 2020, the Company's audited financial statements contained a going concern explanatory paragraph in the audit opinion from its independent registered public accounting firm. This announcement does not represent any change or amendment to the Company's financial statements or to its Annual Report on Form 10-K for the year ended December 31, 2019.

Quarter Ended March 31, 2020 Financial Results

General and administrative expenses increased by 21% to $1.4 million for the three months ended March 31, 2020, from $1.1 million for the three months ended March 31, 2019. This increase is primarily due to increased insurance costs, registration fees, and legal costs. The charge related to stock-based compensation expense was $65,000 for the three months ended March 31, 2020, compared to $65,000 the three months ended March 31, 2019.

Research and development expenses decreased by 32% to $1.6 million for the three months ended March 31, 2020, from $2.4 million for the three months ended March 31, 2019. This decrease is primarily the result of lower indirect program costs for the three months ended March 31, 2020, including salary and related expense reductions resulting from the 2019 headcount reductions and a decrease in manufacturing costs for SYN-020. The research and development costs incurred during the quarter were primarily related to the investigator-sponsored Phase 2b clinical study of SYN-010. We anticipate research and development expense to decrease as a result of the response to the global COVID-19 pandemic by our clinical development partners which has led to the postponement of the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients and a temporary halt in new enrollment in the Phase 2b investigator sponsored clinical trial of SYN-010. The charge related to stock-based compensation expense was $18,000 for the three months ended March 31, 2020, compared to no charge related to stock-based compensation expense for the three months ended March 31, 2019 resulting from the 2018 restructuring.

Other income was $38,000 for the three months ended March 31, 2020, compared to other income of $44,000 for the three months ended March 31, 2019. Other income for the three months ended March 31, 2020 and 2019 is primarily comprised of interest income.

Cash and cash equivalents as of March 31, 2020 totaled $10.1 million, a decrease of $5.0 million from December 31, 2019.

Conference Call

Synthetic Biologics will hold a conference call today, Tuesday, May 5, 2020, 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/1096/34417. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/34417, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a 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 clinical 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 microbiome damage, *C. difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-010, which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company is also advancing SYN-020, an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) 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 commencement of the planned Phase 1b/2a investigator-sponsored clinical study in allogeneic HCT patients in the first quarter of 2021, anticipated data readout for the investigator-sponsored Phase 2b clinical study for SYN-010 during the third quarter of 2020, anticipated IND filing for SYN-020 in the second quarter of 2020, SYN-004's degrading certain commonly used intravenous (IV) beta-lactam antibiotics within the gastrointestinal tract to prevent microbiome damage, C. difficile infection, overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease in allogeneic hematopoietic cell transplant (HCT) recipients, and SYN-010 reducing the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation. 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, and those conducted by investigators, for SYN-004 and SYN-010 to be commenced or completed on time 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, 2019 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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Ogilvy (Media)
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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 ends March 31,	
	2020	**2019**
Assets		
Cash and cash equivalents	$ 10,085	$ 15,045
Prepaid expenses and other current assets	1,084	1,381
Property and equipment, net	309	367
Right of Use Asset	386	419
Deposits and other assets	23	23
Total Assets	$ 11,887	$ 17,235
Liabilities and Stockholder's Deficit		
Total liabilities	$ 3,281	$ 5,748
Series A Convertible Preferred Stock	12,606	12,544
Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	(1,122)	1,821
Non-controlling interest	(2,878)	(2,878)
Total Liabilities and Stockholders' Equity (Deficit)	$ 11,887	$ 17,235

Condensed Consolidated Statements of Operations

	For the three months ended March 31,	
	2020	**2019**
Operating Costs and Expenses		
General and administrative	$ 1,393	$ 1,154
Research and development	1,635	2,418
Total Operating Costs and Expenses	3,028	3,572
Loss from Operations	(3,028)	(3,572)
Other Income		
Interest income	38	44
Total Other Income	38	44
Net Loss	(2,990)	(3,528)
Net Loss Attributable to Non-controlling Interest	(26)	(16)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (2,964)	$ (3,512)
Series A Preferred Stock Dividends	(62)	(61)
Series B Preferred Stock Dividends	(404)	(398)
Net Loss Attributable to Common Stockholders	(3,430)	(3,971)
Net Loss Per Share - Basic and Dilutive	$ (0.20)	$ (0.25)
Weighted average number of common shares outstanding - Basic and Dilutive	17,093,920	15,656,784

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