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): February 27, 2019

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:

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§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 February 27, 2019, Synthetic Biologics, Inc., a Nevada corporation (the "Registrant") issued a press release that included financial information for the year ended December 31, 2018. 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.

Exhibit 99.1 Press Release issued by Synthetic Biologics, Inc., dated February 27, 2019

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: February 27, 2019

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 February 27, 2019

Exhibit 99.1

Synthetic Biologics Reports 2018 Year End Operational Highlights and Financial Results

-- Enrollment is Ongoing in Phase 2b Investigator-Sponsored Clinical Study of SYN-010, for the Treatment of IBS-C; Topline Data Readout Anticipated in 2H 2019 --

-- Conference Call Wednesday, February 27, 2019, at 4:30 p.m. (EST) --

Rockville, MD, February 27, 2019 – Synthetic Biologics, Inc. (NYSE American: SYN), a clinical-stage company developing therapeutics that preserve the microbiome to protect and restore the health of patients, today provided a clinical programs update and reported financial results for the year ended December 31, 2018.

"During the fourth quarter, we remained sharply focused on executing our strategy to advance and demonstrate the significant value of our portfolio of GI and microbiome-focused clinical assets," stated Steven A. Shallcross, Chief Executive and Financial Officer. "We are pleased to report that patient enrollment is continuing for our investigator-sponsored Phase 2b clinical trial of SYN-010, our modified-release formulation of lovastatin lactone designed to treat an underlying cause of irritable bowel syndrome with constipation. We believe data derived from this study will solidify our existing clinical outcomes data, including dose-response, and potentially simplify future registration studies. We anticipate a topline data readout from this study in the second half of 2019."

Mr. Shallcross continued, "During the fourth quarter, we also announced the results of our End-of-Phase 2 meeting with the U.S. Food & Drug Administration (FDA) during which key elements of a Phase 3 clinical program were confirmed to support a marketing application for SYN-004 for the prevention of *Clostridium difficile* infection (CDI). In parallel, we continue to evaluate strategies to pursue a secondary clinical indication for SYN-004 in a specialized patient population which may allow for a more narrow and less costly clinical development pathway. One such indication is the prevention of acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, where protection of the gut microbiome from antibiotic damage may provide a distinct benefit to patient outcomes. Discussions with key opinion leaders who are experts in allogeneic HCT are ongoing, and we look forward to sharing updates and progress for this potential indication."

"With the steps we have taken at the end of the fourth quarter to fortify our long-term financial footing, we have created a strong foundation upon which to execute our strategy to advance and showcase the value of our late stage clinical assets. Our entire organization is excited and committed to achieving the important clinical development milestones we have established for 2019," concluded Mr. Shallcross.

Clinical Development and Operational Update

- Commenced enrollment of Phase 2b investigator-sponsored clinical study of SYN-010, for the treatment of IBS-C,
  - The Phase 2b clinical study is being conducted by the Medically Associated Science and Technology (MAST) Program at Cedars-Sinai Medical Center and is a 12-week, placebo-controlled, double-blind, randomized clinical trial evaluating two dose strengths of oral SYN-010 (21 mg and 42 mg) in approximately 150 patients diagnosed with IBS-C,
  - The primary objective for the study will be to determine the efficacy of SYN-010, measured as an improvement from baseline in the weekly average number of complete spontaneous bowel movements (CSBMs) during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses relative to placebo,

- Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, stool frequency as well as the use of rescue medication relative to placebo,
- Topline data readout anticipated for 2H 2019,
- 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;

· Held an End-of-Phase 2 meeting with FDA and confirmed key elements of the Phase 3 clinical program to support a marketing application for SYN-004 (ribaxamase),
- A single Phase 3 clinical trial may be sufficient for marketing approval for the prevention of antibiotic-mediated CDI,
- The Phase 3 clinical program will entail a single, global, event-driven clinical trial with a fixed maximum number of patients for total enrollment,
- The primary efficacy endpoint will be the reduction in the incidence of CDI at one month after the last drug dose in the ribaxamase treatment group versus placebo,
- A separate co-primary safety endpoint is non-inferiority in mortality rates between the ribaxamase treatment group and placebo at 3 months post-randomization;

· Continued to evaluate a potential secondary indication for SYN-004 (ribaxamase) for the prevention of acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplantation (HCT) recipients,
- Identification of key investigators and the development of clinical protocols and a pre-IND package is ongoing,
- Anticipate initiation of a Phase 1/2 investigator-sponsored clinical study in HCT patients in 2H 2019, contingent upon the identification of a research partner and subsequent Institutional Review Board (IRB) approval;

· Identified potential clinical indications for SYN-020 (intestinal alkaline phosphatase) in areas of unmet medical need including, enterocolitis associated with radiation therapy for cancer and autoimmune enterocolitis associated with checkpoint inhibitor therapy for cancer,
- Preclinical efficacy studies are ongoing,
- Anticipate filing a US IND application in Q4 2019,
- Plan to commence a Phase 1 clinical trial in Q1 2020;

· Strengthened balance sheet by raising gross proceeds of approximately $18.6 million from the closing of a public offering of common stock and Series B Convertible Preferred Stock in support of our lead clinical development activities
- Raised additional net proceeds of approximately $12.2 million from the utilization of the Company's "at-the-market" facility through the end of 2018.

Year Ended December 31, 2018 Financial Results

General and administrative expenses decreased to $5.7 million for the year ended December 31, 2018, compared to $7.5 million for the year ended December 31, 2017. This decrease of 24% is due to the decreased stock-based compensation expense related to forfeitures and share price, along with the reduction of salary, travel and consulting expense, offset by higher registration, investor relations and legal costs. The charge relating to stock-based compensation expense was $1.0 million for the year ended December 31, 2018, compared to $2.0 million for the year ended December 31, 2017.

Research and development expenses decreased to $11.8 million for the year ended December 31, 2018, from $18.8 million for the year ended December 31, 2017. This decrease of 37% is primarily the result of lower SYN-004 (ribaxamase) and SYN-010 program costs for 2018 since no clinical trials were ongoing during the year. The research and development costs incurred during the quarter were primarily related to planning for future Phase 3 (SYN-004) and Phase 2b/3 (SYN-010) clinical programs as we sought to secure the financial resources necessary for the completion of these clinical trials. We anticipate research and development expense to increase due to the ongoing Phase 2b investigator-sponsored clinical trial for SYN-010 and development activities associated with the potential initiation of a Phase 1/2 investigator-sponsored clinical trial for the prevention of aGVHD in HCT recipients for SYN-004. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $1.1 million for the year ended December 31, 2018, compared to $1.4 million for the year ended December 31, 2017.

Other income was $4.2 million for the year ended December 31, 2018, compared to other income of $10.8 million for the year ended December 31, 2017. Other income for the year ended December 31, 2018 is primarily due to non-cash income of $4.1 million from the change in fair value of warrants. The decrease in the fair value of warrants was due to the decrease in our stock price from December 31, 2017.

In connection with the issuance and subsequent conversions of the Series B Convertible Preferred Stock in 2018 and the issuance of the Series A Convertible Preferred Stock in 2017, the Company recognized non-cash deemed dividends of $11.7 million and $6.9 million respectively, for the beneficial conversion feature resulting from the intrinsic value of the Series B and Series A conversion options as of the issuance date.

Cash and cash equivalents on December 31, 2018 were $28.9 million, an increase of $11.8 million from December 31, 2017.

Conference Call

Synthetic Biologics will hold a conference call today, Wednesday, February 27 , 2019, 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/1096/29346. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/29346, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a clinical-stage company developing therapeutics that preserve the microbiome to protect and restore the health of patients. 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 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’s preclinical pursuits include SYN-020, an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases as well as monoclonal antibody therapies for the prevention and treatment of pertussis. 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 belief that data derived from the investigator-sponsored Phase 2b clinical trial of SYN-010 will solidify Synthetic Biologics' existing clinical outcomes data, including dose-response, and potentially simplify future registration studies, anticipated topline data readout from the investigator-sponsored Phase 2b clinical trial of SYN-010 in the second half of 2019, anticipated initiation of a Phase 1/2 investigator-sponsored clinical study in HCT patients in 2H 2019, anticipated increase in research and development expense due to the ongoing Phase 2b investigator-sponsored clinical trial for SYN-010 and development activities associated with the potential initiation of a Phase 1/2 investigator-sponsored clinical trial for the prevention of aGVHD in HCT recipients for SYN-004, anticipated filing of a US IND application for SYN-020 in Q4 2019 and plans to commence a Phase 1 clinical trial for SYN-020 in Q1 2020. 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, 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' most recent Form 10-K 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

	December 31,	
	2018	**2017**
Assets		
Cash and cash equivalents	$ 28,918	$ 17,116
Prepaid expenses and other current assets	593	827
Property and equipment, net	607	872
Deposits and other assets	23	23
Total Assets	$ 30,141	$ 18,838
Liabilities and Stockholder's Equity (Deficit)		
Total liabilities	$ 3,686	$ 10,195
Series A Convertible Preferred Stock	12,296	12,053
Synthetic Biologics, Inc. and Subsidiaries Equity (deficit)	14,159	(3,410)
Total Liabilities and Stockholders' Equity (Deficit)	$ 30,141	$ 18,838

Condensed Consolidated Statements of Operations

	For the years ended December 31,	
	2018	**2017**
Operating Costs and Expenses		
General and administrative	$ 5,727	$ 7,467
Research and development	11,844	18,784
Total Operating Costs and Expenses	17,571	26,251
Loss from Operations	(17,571)	(26,251)
Other Income		
Change in fair value of warrant liability	4,083	10,738
Interest income	67	21
Total Other Income	4,150	10,759
Net Loss	(13,421)	(15,492)
Net Loss Attributable to Non-controlling Interest	(54)	(318)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (13,367)	$ (15,174)
Series A Preferred Stock Dividends	(243)	(6,962)
Series B Preferred Stock Dividends	(11,681)	-
Net Loss Attributable to Common Stockholders	(25,291)	(22,136)
Net Loss Per Share - Basic and Dilutive	$ (4.06)	$ (6.23)
Weighted average number of common shares outstanding - Basic and Dilutive	6,232,442	3,553,316

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