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 8, 2018

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 August 8, 2018, Synthetic Biologics, Inc., a Nevada corporation, (the "Registrant") issued the attached press release that included financial information for the fiscal quarter ended June 30, 2018. 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 99.1	Press Release issued by Synthetic Biologics, Inc., dated August 8, 2018.

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 8, 2018

SYNTHETIC BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by Synthetic Biologics, Inc. dated August 8, 2018

Exhibit 99.1

Synthetic Biologics Reports Second Quarter 2018 Operational Highlights and Financial Results

– SYN-004 End of Phase 2 Meeting with U.S. Food & Drug Administration on Track for Third Quarter of 2018 –

– Conference Call Today, August 8, 2018, at 4:30 p.m. (EDT) –

Rockville, MD, August 8, 2018 – Synthetic Biologics, Inc. (NYSE American: SYN), a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients, today provided an operational update and reported financial results for the three months ended June 30, 2018.

"Following several productive meetings earlier this year, we are pleased to have reached preliminary agreement on key elements of our planned Phase 3 clinical trial for ribaxamase, our first-in-class therapeutic intervention designed to prevent the onset of primary *C. difficile* infection (CDI) by protecting the gut microbiome from antibiotic-mediated dysbiosis. We are in the process of optimizing a protocol synopsis for the Phase 3 clinical trial which we will discuss with the FDA at our end of Phase 2 meeting which is currently planned to take place towards the end of the third quarter" stated Steven A. Shallcross, Interim Chief Executive Officer and Chief Financial Officer.

"We will continue to work closely and collaboratively with the FDA to define a clear and achievable pathway toward gaining marketing approvals. In our ongoing interactions with FDA, what has become clear is their recognition of the unmet need for novel interventions to combat and prevent the proliferation of CDI. With more than 450,000 cases of CDI each year in the U.S., if approved, ribaxamase will be the first intervention specifically designed to prevent CDI associated with the most commonly used IV antibiotics," concluded Shallcross.

Clinical Development and Operational Update

- Announced the Company reached preliminary agreement with the FDA on key elements of a proposed Phase 3 clinical program for SYN-004 (ribaxamase), which is expected to:
    - Comprise a global, event driven clinical trial with a fixed maximum number of patients for total enrollment,
    - Evaluate the potential efficacy and safety of ribaxamase in a broader patient population by the inclusion of additional IV β-lactam antibiotics in addition to ceftriaxone and by enrolling patients with a variety of underlying infections,
    - Evaluate the ability of ribaxamase to reduce the incidence of *Clostridium difficile* infection (CDI) in the ribaxamase treatment group compared to placebo as the primary efficacy endpoint,
    - Evaluate mortality risk as the co-primary safety endpoint which will be separate from the primary efficacy endpoint of reduction in the incidence of CDI,
- Anticipate End-of-Phase 2 meeting with the FDA in 3Q 2018 to solidify the remaining elements of the planned SYN-004 (ribaxamase) Phase 3 clinical trial;
- Plan to initiate SYN-004 (ribaxamase) Phase 3 clinical trial in 2H 2019;

- Continue efforts to solidify clinical infrastructure, including exploring international regulatory and market access structures to support advancement of SYN-010, designed to treat an underlying cause of the symptoms associated with irritable bowel syndrome with constipation (IBS-C);

- Reported supportive data from a second canine animal model demonstrating that when co-administered with oral amoxicillin and oral Augmentin, oral SYN-007 did not interfere with systemic absorption of the antibiotics but did diminish microbiome damage associated with these antibiotics in 2Q 2018.

Quarter Ended June 30, 2018 Financial Results

General and administrative expenses decreased by 13% to $1.4 million for the three months ended June 30, 2018, compared to $1.6 million for the same period in 2017. This decrease is primarily the result of lower salary expense, stock compensation, and related benefits costs incurred during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017 due to the resignation of the Chief Executive Officer, along with the reduction of travel and consulting expense, offset by higher registration, investor relations and legal costs. The charge related to stock-based compensation expense was $264,000 for the three months ended June 30, 2018, compared to $539,000 for three months ended June 30, 2017.

Research and development expenses decreased by 25% to $3.6 million for the three months ended June 30, 2018, from $4.8 million for the three months ended June 30, 2017. This decrease is primarily the result of lower SYN-004 (ribaxamase) and SYN-010 program costs for 2018 since no clinical trials were ongoing during the quarter. 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 seek to secure the financial resources necessary for the completion of these clinical trials. The charge related to stock-based compensation expense was $293,000 for the three months ended June 30, 2018, compared to $331,000 for the same period in 2017.

Other income was $789,000 million for the three months ended June 30, 2018, compared to other income of $2.2 million for the same period in 2017. Other income for the three months ended June 30, 2018 is primarily comprised of non-cash income of $783,000 million from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price from the prior quarter.

Cash and cash equivalents as of June 30, 2018 was $7.1 million, a decrease of $10.0 million from December 31, 2017.

Conference Call

Synthetic Biologics will hold a conference call today, Tuesday, August 8, 2018, at 4:30 p.m. (EDT). 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/1096/26414. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/26414, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 development are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR), 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 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, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU). 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 includes statements regarding our plan to continue to work closely with the FDA to define a clear and achievable pathway toward gaining market approval, expectations as to the elements of the proposed Phase 3 clinical trial for SYN-004; the anticipated timing of the initiation of the end of Phase 2 meeting, which is anticipated to be held during the end of the third quarter of 2018; the plan to initiate SYN-004 Phase 3 clinical trial in 2H 2019, and the potential benefits of SYN-004 and SYN-010. 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, Synthetic Biologics' ability to design a Phase 3 trial with the co-primary endpoints and receive FDA approval for such design; Synthetic Biologics' ability to implement the Phase 3 program as a global, event-driven clinical trial, Synthetic Biologics' ability to initiate the Phase 3 clinical program in the second half of 2019 following an end of Phase 2 meeting with the FDA during the third quarter of 2018, Synthetic Biologics' ability to establish a path forward to develop ribaxamase and conduct a robust, controlled and well-designed clinical trial that may provide sufficient efficacy and safety data to support a pathway towards marketing approval for ribaxamase, Synthetic Biologics' ability to regain compliance with the continued listing standards of the NYSE American by September 2, 2019, Synthetic Biologics' ability to comply with other continued listing requirements of the NYSE American, the ability of its product candidates to demonstrate safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' clinical trials continuing enrollment as expected, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, including approval of proposed trial designs, 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, Synthetic Biologics' ability to achieve acceptance of its product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' products by competitors that render Synthetic Biologics' products obsolete or non-competitive, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to obtain or maintain the capital or grants necessary to fund its research and development activities, a loss of any of Synthetic Biologics' key scientists or management personnel and other factors described in Synthetic Biologics' Form 10-K for the year ended December 31, 2017 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

	June 30, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 7,129	$ 17,116
Prepaid expenses and other current assets	535	827
Property and equipment, net	731	872
Deposits and other assets	23	23
Total Assets	$ 8,418	$ 18,838
Liabilities and Stockholder's Deficit		
Total liabilities	$ 4,672	$ 10,195
Series A Convertible Preferred Stock	12,173	12,053
Synthetic Biologics, Inc. and subsidiaries deficit	(8,427)	(3,410)
Total Liabilities and Stockholders' Deficit	$ 8,418	$ 18,838

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)*	
	2018	**2017**	**2018**	**2017**
Operating Costs and Expenses				
General and administrative	$ 1,431	$ 1,664	$ 3,051	$ 3,734
Research and development	3,572	4,831	6,942	10,891
Total Operating Costs and Expenses	5,003	6,475	9,993	14,625
Loss from Operations	(5,003)	(6,475)	(9,993)	(14,625)
Other Income (Expense)				
Change in fair value of warrant liability	783	2,159	3,483	7,249
Interest income	6	1	15	3
Total Other Income (Expense), net	789	2,160	3,453	7,252
Net Loss	(4,214)	(4,315)	(6,540)	(7,373)
Net Loss Attributable to Non-controlling Interest	(17)	(60)	(26)	(272)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (4,197)	$ (4,255)	$ (6,514)	$ (7,101)
Series A Preferred Dividend	(61)	-	(120)	-
Net Loss Attributable to Common Stockholders	$ (4,258)	$ (4,255)	$ (6,634)	$ (7,101)
Net Loss Per Share – Basic and Dilutive	$ (0.03)	$ (0.03)	$ (0.05)	$ (0.06)
Weighted average number of common shares outstanding – Basic and Diluted	128,918,408	123,005,220	128,743,616	120,241,593

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