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 8, 2019

SYNLOGIC, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-37566 (Commission File Number)

26-1824804 (IRS Employer Identification No.)

301 Binney St., Suite 402
Cambridge, MA
(Address of principal executive offices)

02142 (Zip Code)

Registrant's telephone number, including area code: (617) 401-9975

Not applicable

(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):

Ш	Written	communications	pursuant to	Rule 425	under	the Se	ecurities	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	SYBX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ⊠

If an emerging growth company, indicate by check mark 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, 2019, Synlogic, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release dated August 8, 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.

SYNLOGIC, INC.

By: /s/ Todd Shegog

Date: August 8, 2019

Name: Todd Shegog

Title: Chief Financial Officer

Synlogic Reports Second Quarter 2019 Financial Results and Provides Program Updates

- Strong balance sheet supports clinical advancement of lead and emerging Synthetic Biotic™ programs -
- -Bridging study to evaluate solid oral formulation of SYNB1618 open and recruiting healthy volunteers -
 - Company will host a conference call and webcast at 5:00 pm ET today -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--August 8, 2019--Synlogic, Inc. (NASDAQ:SYBX), a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, today reported its financial results for the second quarter ended June 30, 2019 and provided an update on its programs.

"In the first half of the year we made significant advances in our Synthetic Biotic programs while strengthening our platform capabilities and our balance sheet," said Aoife Brennan, M.B., B.Ch., Synlogic's president and chief executive officer. "We look forward to an equally productive second half of the year as we continue to advance our novel Synthetic Biotic medicines to provide potential therapeutic solutions for patients with unmet medical needs."

Recent Highlights and Updates

- Positive topline clinical data from phenylketonuria (PKU) patient cohorts in Phase 1/2a clinical trial enable next stage of clinical development of new solid formulation of SYNB1618. In July, Synlogic announced positive top-line clinical data demonstrating safety and tolerability of a liquid formulation of SYNB1618 in patients with PKU. Importantly, the data also demonstrated that production of biomarkers related to SYNB1618's engineered ability to consume phenylalanine (Phe) was equivalent in patients and healthy volunteers. Synlogic has initiated a bridging study in healthy volunteers to evaluate the activity and maximum tolerated dose of a solid oral formulation of SYNB1618 manufactured by the company using an improved fermentation process. Full data and a description of the model will be presented at the annual symposium of the Society for the Study of Inborn Errors of Metabolism (SSIEM) in Rotterdam, September 3-6, 2019.
- Expanded collaboration with Ginkgo Bioworks provides expanded synthetic biology capabilities and strengthens Synlogic balance sheet. In June, Synlogic and Ginkgo entered into a long-term strategic platform collaboration. Under the agreement Ginkgo invested \$80.0 million in Synlogic at a premium to market. Synlogic will use Ginkgo's cell programming platform for building and testing thousands of microbial strains to accelerate progression of early preclinical leads to drug candidates optimized for further clinical development. Synlogic paid \$30.0 million to Ginkgo for synthetic biology services to be provided over an initial period of five years which can be extended. Synlogic has exclusive rights to any Synthetic Biotic medicines that it develops as part of the collaboration and to intellectual property covering such products.
- Establishment of clinical collaboration with Roche will enable evaluation of SYNB1891, engineered to express a STING agonist, in combination with PD-L1-blocking checkpoint inhibitor (CPI) atezolizumab (Tecentriq®) in patients with advanced solid tumors. Synlogic remains on track to file an Investigational New Drug application with the U.S. Federal Drug Administration in the second half of 2019 for SYNB1891 to enable the company to initiate an open-label Phase 1 clinical trial to evaluate the candidate as a monotherapy and a combination treatment with atezolizumab.
- Appointment of Scott Plevy, M.D., as Chief Scientific Officer to lead Synlogic's research organization. Dr. Plevy is a gastroenterologist who most recently served as Vice President, Gastroenterology Disease Area Leader and IL-23 Pathway Leader at Janssen Research & Development, LLC, after a successful career in academia. He has a wealth of experience in early-phase clinical trials and performed translational research to advance the understanding of novel immunologic interventions in inflammatory bowel disease, other inflammatory conditions, and microbiome-related diseases.

Second Quarter 2019 Financial Results

As of June 30, 2019, Synlogic had cash, cash equivalents and short and long-term investments of \$149.1 million.

In June 2019, Synlogic issued to Ginkgo 6,340,771 shares of common stock at a purchase price per share of \$9.00, and pre-funded warrants to purchase an aggregate of 2,548,117 shares of common stock at an exercise price of \$9.00 per share, with \$8.99 of such exercise price paid at the closing of the offering. The net proceeds to Synlogic were approximately \$79.9 million.

For the three months ended June 30, 2019, Synlogic reported a consolidated net loss of \$12.3 million, or \$0.45 per share, compared to a consolidated net loss of \$14.6 million, or \$0.59 per share, for the corresponding period in 2018.

Research and development expenses were \$9.7 million for the three months ended June 30, 2019 compared to \$10.9 million for the corresponding period in 2018. The decrease was primarily due to decreased clinical development costs for its SYNB1618 program and a decrease in nonclinical development costs for its programs, partially offset by increased research and development support costs.

General and administrative expenses for the three months ended June 30, 2019 were \$3.7 million compared to \$4.7 million for the corresponding period in 2018. The decrease was primarily due to a decrease in compensation costs and other employee-related expenses.

Revenues were \$0.4 million for the three months ended June 30, 2019, compared to \$0.3 million for the corresponding period in 2018. Revenue for both periods was associated with Synlogic's collaboration with AbbVie to develop Synthetic Biotic medicines for the treatment of irritable bowel disease.

Six-months Results

For the six months ended June 30, 2019, the consolidated net loss was \$25.3 million, or \$0.96 per share, compared to a consolidated net loss of \$25.8 million, or \$1.14 per share, for the corresponding period in 2018.

Total operating expenses were \$27.5 million for the six months ended June 30, 2019, compared to \$27.6 million for the corresponding period in 2018.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast at 5:00 pm ET today, Thursday, August 8, 2019. To access the live webcast, please visit the "Event Calendar" page within the Investors and Media section of the Synlogic website. Alternatively, investors may listen to the call by dialing +1 (844) 815-2882 from locations in the United States or +1 (213) 660-0926 from outside the United States. The conference ID number is 6968273. For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors and Media section of the Synlogic website.

About Synlogic

Synlogic is pioneering the development of a novel class of living medicines, Synthetic Biotic medicines, based on its proprietary drug development platform. Synlogic leverages the tools and principles of synthetic biology to genetically engineer probiotic microbes to perform or deliver critical functions missing or damaged due to disease. The company's two lead programs, SYNB1020 and SYNB1618, target hyperammonemia as a result of liver damage or genetic disease, and PKU, respectively. When delivered orally, Synthetic Biotic medicines can act from the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect, with the potential to significantly improve symptoms of disease for affected patients. In addition, the company is leveraging the broad potential of its platform to create Synthetic Biotic medicines for the treatment of more common diseases, including liver disease, inflammatory and immune disorders, and cancer. Synlogic is collaborating with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease (IBD). For more information, please visit www.synlogictx.com.

Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Synlogic may identify forward-looking statements. Examples of forward-looking statements, include, but are not limited to, statements regarding the strength of Synlogic's balance sheet, the potential of Synlogic's platform to develop therapeutics to address a wide range of diseases including: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; the potential of Synlogic's technology to treat hyperammonemia and phenylketonuria; and the expected timing of Synlogic's anticipated clinical trial initiations. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including: the uncertainties inherent in the preclinical development process; the ability of Synlogic to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in Synlogic's filings with the SEC. The forward-looking statements contained in this press release reflect Synlogic's current views with respect to future events. Synlogic anticipates that subsequent events and developments will cause its views to change. However, while Synlogic may elect to update these forward-looking statements in the future, Synlogic specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Synlogic's view as of any date subsequent to the date hereof.

Synlogic, Inc. Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except share and per share data)			months ended	For the six months ended		
	Jui	ne 30, 2019	June 30, 201	June 30, 2019	June 30, 2018	
Revenue	\$	350	\$ 254	\$ 688	\$ 608	
Operating expenses						
Research and development		9,703	10,872	20,087	19,233	
General and administrative		3,742	4,734	7,393	8,363	
Total operating expenses		13,445	15,606	27,480	27,596	
Loss from operations		(13,095)	(15,352	(26,792)	(26,988)	
Other income (expense), net		751	761	1,502	1,232	
Net loss	\$	(12,344)	\$ (14,591	\$ (25,290)	\$ (25,756)	
Net loss per share attributable to common shareholders - basic and diluted	\$	(0.45)	\$ (0.59	\$ (0.96)	\$ (1.14)	
Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted	2	7,242,514	24,803,379	26,284,262	22,503,802	

Synlogic, Inc.

Condensed Consolidated Balance Sheets Data

(unaudited)

(in thousands)

	June 30, 2019		December 31, 2018		
Assets					
Cash, cash equivalents and short and long-term investments	\$	149,072	\$	122,729	
Fixed assets		13,847		14,841	
Other assets		52,026		2,770	
Total assets	\$	214,945	\$	140,340	
Liabilities and Stockholders' Equity					
Current liabilities	\$	11,291	\$	8,341	
Long-term liabilities		22,831		7,901	
Total liabilities		34,122		16,242	
Total stockholders' equity		180,823		124,098	
Total liabilities and stockholders' equity	\$	214,945	\$	140,340	
Common stock and common stock equivalents:					
Common stock		31,719,719		25,401,479	
Common stock warrants (pre-funded)		2,548,117		<u> </u>	
Common stock and pre-funded stock warrants		34,267,836		25,401,479	

Contacts

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