

**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): **November 13, 2018**

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):

- 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 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 November 13, 2018, Synlogic, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2018. 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 November 13, 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.

SYNLOGIC, INC.

Date: November 13, 2018

By: /s/ Todd Shegog
Name: Todd Shegog
Title: Chief Financial Officer

Synlogic Reports Third Quarter 2018 Financial Results and Provides Program Updates

– Advancement of SYN1891, the first Synthetic Biotic™ immuno-oncology candidate to enable Investigational New Drug Application (IND) filing in 2H 2019 –

– Ongoing clinical trials of SYN1020 and SYN1618 in patients with data expected in 2019 –

– Management to host conference call and webcast at 5:00 pm ET today –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--November 13, 2018--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 third quarter ended September 30, 2018, and provided an update on its programs.

“This is an exciting time for Synlogic, as we continue to explore the breadth of our platform. We have advanced SYN1891, our dual innate immune activator for the treatment of cancer into IND-enabling studies,” said Aoife Brennan, M.B., B.Ch., Synlogic’s president and chief executive officer. “Our two orally administered Synthetic Biotic medicines, SYN1618 for the treatment of phenylketonuria and SYN1020 for the treatment of hyperammonemia, have demonstrated proof of mechanism in healthy volunteers and we look forward to clinical data from the ongoing clinical trials in patients in 2019.”

Recent Highlights

Pipeline

- **Presentation of preclinical data highlighting potential of Synthetic Biotic medicines in immuno-oncology (IO) and declaration of first IO clinical candidate** at the Society for Immunotherapy of Cancer (SITC) annual meeting. Data presented at the meeting demonstrate the platform’s potential for the treatment of cancer and inflammation and specifically highlight the unique advantages of Synlogic’s approach to stimulate the innate immune system. Based on preclinical data Synlogic is advancing SYN1891, a STING-agonist producing synthetic biotic strain, into IND-enabling studies. Synlogic hosted an investor and analyst event at the SITC annual meeting, featuring presentations by key opinion leaders (KOLs), and members of Synlogic management who outlined development plans for SYN1891. A webcast of the event is available on the Synlogic website.
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- **Presentation of preclinical data supporting continued development of SYN1020 for the treatment of liver disease** at the American Association for the Study of Liver Diseases (AASLD) annual meeting. Preclinical data were presented demonstrating dose dependent lowering of blood ammonia by Synthetic Biotic strains designed to consume ammonia and produce arginine in a rat bile duct ligation model confirming earlier preclinical observations in mouse models of liver disease. In addition, data were presented from studies conducted by Synlogic to establish ammonia measurement parameters and ammonia levels in healthy volunteers at clinical sites that are participating in Synlogic's ongoing Phase 1b/2a clinical trial of SYN1020 in patients with cirrhosis and elevated ammonia. Topline data from this clinical trial are now expected in mid-2019 due to slower than expected rates of initiation of clinical trial sites and patient enrollment.
- **Announcement of positive interim data from healthy volunteer (HV) arm of its ongoing Phase 1/2a clinical trial evaluating SYN1618 for the treatment of Phenylketonuria (PKU):** Data established a go-forward dose for the treatment arm in patients with PKU and demonstrated a statistically significant, dose-dependent effect on treatment-associated biomarkers, indicating proof-of-mechanism. Synlogic also published preclinical data identifying these same biomarkers in *Nature Biotechnology*, further supporting SYN1618's continued development. The Company continues to evaluate SYN1618 in patients with PKU in its ongoing Phase 1/2a study and expects to report topline data from this trial in mid-2019.

Corporate

- **Appointed Aoife Brennan, M.B., B.Ch., as president and chief executive officer:** Dr. Brennan had served as interim president and chief executive officer since May 2018 and joined Synlogic as chief medical officer in 2016.

Third Quarter 2018 Financial Results

As of September 30, 2018, Synlogic had cash, cash equivalents, and short-term investments of \$132.6 million.

For the three months ended September 30, 2018, Synlogic reported a consolidated net loss of \$10.7 million, or \$0.43 per share, compared to a consolidated net loss of \$11.9 million, or \$1.66 per share, for the corresponding period in 2017.

Research and development expenses were \$9.9 million for the three months ended September 30, 2018 compared to \$9.0 million for the corresponding period in 2017.

General and administrative expenses for the three months ended September 30, 2018 were \$3.4 million compared to \$3.2 million for the corresponding period in 2017.

Revenues were \$1.8 million for the three months ended September 30, 2018, compared to \$0.1 million for the corresponding period in 2017. The revenue for both periods is associated with Synlogic's collaboration with AbbVie to develop a Synthetic Biotic medicine for the treatment of inflammatory bowel disease. The increase in revenue was primarily the result of the achievement of a \$2.0 million milestone under a September 2018 amendment to the AbbVie agreement of which \$1.8 million was recognized in revenue in the quarter ended September 30, 2018.

Nine-months Results

For the nine months ended September 30, 2018, the consolidated net loss was \$36.5 million, or \$1.56 per share, compared to a consolidated net loss of \$28.7 million, or \$7.87 per share, for the corresponding period in 2017.

Total operating expenses were \$40.9 million for the nine months ended September 30, 2018, compared to \$31.2 million for the corresponding period in 2017. The increase in operating expenses was primarily due to compensation-related expenses associated with increased headcount and increased external costs associated with development of Synlogic's Synthetic Biotic programs.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast today at 5:00 p.m. ET today, Tuesday, November 13, 2018. 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 2674209. 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 beneficial microbes to perform or deliver critical functions missing or damaged due to disease. Synthetic Biotic medicines are designed to act locally and have a systemic effect to address disease in patients. Synlogic's two lead programs, SYN1020 and SYN1618, are orally administered and target hyperammonemia as a result of liver damage or genetic disease, and phenylketonuria, respectively. Synlogic is also developing SYN1891 as an intratumorally administered Synthetic Biotic medicine for the treatment of cancer. In addition, the company is leveraging the broad potential of its platform to create additional Synthetic Biotic medicines for the treatment of liver disease, as well as inflammatory and immune disorders, including Synlogic's collaboration 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 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 and availability of clinical trial data. 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)

	For the three months ended		For the nine months ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Revenue	\$ 1,801	\$ 111	\$ 2,409	\$ 2,333
Operating expenses				
Research and development	9,934	8,955	29,167	22,605
General and administrative	3,401	3,231	11,764	8,634
Total operating expenses	13,335	12,186	40,931	31,239
Loss from operations	(11,534)	(12,075)	(38,522)	(28,906)
Other income (expense), net	786	151	2,018	226
Net loss	<u>\$ (10,748)</u>	<u>\$ (11,924)</u>	<u>\$ (36,504)</u>	<u>\$ (28,680)</u>
Net loss per share attributable to common shareholders - basic and diluted	<u>\$ (0.43)</u>	<u>\$ (1.66)</u>	<u>\$ (1.56)</u>	<u>\$ (7.87)</u>
Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted	<u>25,208,117</u>	<u>7,169,241</u>	<u>23,415,242</u>	<u>3,642,125</u>

Synlogic, Inc.
Condensed Consolidated Balance Sheets Data
(unaudited)

(in thousands)

	September 30, 2018	December 31, 2017
Assets		
Cash, cash equivalents and short-term investments	\$ 132,623	\$ 87,025
Fixed assets	14,887	9,783
Other assets	4,536	2,891
Total assets	<u>\$ 152,046</u>	<u>\$ 99,699</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 8,930	\$ 9,027
Long-term liabilities	8,082	5,634
Total liabilities	17,012	14,661
Total stockholders' equity	135,034	85,038
Total liabilities and stockholders' equity	<u>\$ 152,046</u>	<u>\$ 99,699</u>

CONTACT:

Synlogic

Media Contact:

Courtney Heath, 617-872-2462

courtney@scientpr.com

or

Investor Contact:

Elizabeth Wolffe, Ph.D., 617-207-5509

liz@synlogictx.com