# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

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# 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): **March 12, 2019**

# SYNLOGIC, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-37566** | **26-1824804** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **301 BinneySt., Suite 402**<br>**Cambridge, MA**<br>**(Address of principal executive offices)** | **02142**<br>**(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. ☒

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**Item 2.02 Results of Operations and Financial Condition**

On March 12, 2019, Synlogic, Inc. (the "Company") announced its financial results for the quarter and full year ended December 31, 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 March 12, 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.**

Date: March 12, 2019

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

**Exhibit 99.1**

# Synlogic Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Business Update

## *– Ended 2018 with approximately $123 million in cash and investments, which provides runway through 2020 –*

## *– Clinical trial readouts expected in mid-2019 from two Synthetic Biotic™ medicines and first IND application expected from Synlogic's immuno-oncology platform in second half of 2019 –*

## *– Company will host a conference call and webcast at 8:00 am ET today –*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--March 12, 2019--Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company applying synthetic biology to probiotics to develop novel, living medicines, today reported its financial results for the fourth quarter and full year ended December 31, 2018.

"2019 is an exciting year for Synlogic as we continue to advance out platform and programs," said Aoife Brennan, M.B., Ch.B. Synlogic's president and chief executive officer. "Data expected mid-year from clinical trials of SYNB1020 and SYNB1618, in patients with hyperammonemia and phenylketonuria, respectively, will guide our plans for future development of our Synthetic Biotic medicines in these areas and additional rare metabolic diseases. We are also exploring new applications of our platform as we advance our first immuno-oncology program toward submission of an Investigational New Drug (IND) application and into clinical studies. Furthermore, with our increased capability to manufacture clinical trial material, we are now in a position to advance our programs through development as expeditiously as possible."

**2019 Priorities**
***Pipeline***

- **Presentation of top-line data from Phase 1b/2a study of SYNB1020 in patients with cirrhosis and elevated blood ammonia expected by mid-year.** The double-blind, placebo-controlled study is designed to assess safety and tolerability, the ability of orally administered SYNB1020 to lower blood ammonia as well as its effect on several exploratory measures associated with hyperammonemia in this population. These data will provide valuable information for both platform development and the development path for Synlogic's hyperammonemia program.
- **Presentation of top-line data from study to evaluate SYNB1618 in patients with PKU expected by mid-year.** The second part of this double-blind, placebo-controlled study is designed to assess safety and tolerability of orally administered SYNB1618 in a single dose (N=4) and multiple dose cohort (N=10) of patients with phenylketonuria (PKU). Additional endpoints of the study will explore the production of biomarkers of SYNB1618 activity that are expected to provide information as to the differences in pharmacodynamics of the Synthetic Biotic medicine in patients versus healthy volunteers.
- **Advancement of SYNB1891 immuno-oncology program candidate to enable filing of an IND application in the second half of the year.** SYNB1891 is an intra-tumorally administered Synthetic Biotic medicine engineered to produce cyclic di-AMP (CDA), an agonist of the STING pathway, that is designed to serve as a dual innate activator of the immune system as a potential treatment for solid tumors.
- **Continued progress and refinement of manufacturing and process development.** Synlogic is developing and manufacturing solid oral Synthetic Biotic formulations suitable for Phase 2 clinical trials and beyond.
- **Advancement of new research programs to expand product pipeline.**
- **Presentation and publication of data at major scientific and medical meetings.** Synlogic is committed to publishing and presenting data that demonstrate the breadth of Synlogic's Synthetic Biotic platform.
- **Advancement of collaboration.** On March 6, 2019, Synlogic announced that its collaboration with AbbVie to develop a Synthetic Biotic medicine for the treatment of inflammatory bowel disease (IBD) had advanced into lead optimization triggering a milestone payment to Synlogic. The two companies will work together to develop and enable the selection of a suitable candidate for entry into IND-enabling studies.

*Corporate*

- **Continued strengthening of Synlogic's leadership.** In February 2019, Synlogic announced the appointment of Patricia N. Hurter, Ph.D., Senior Vice President of Pharmaceutical and Preclinical Sciences at Vertex Pharmaceuticals, Inc., to its board of directors. Synlogic is also conducting a search to fill the position of Chief Medical Officer vacated by Dr. Brennan.
- **Continued exploration of additional strategic opportunities.** Synlogic expects to develop additional strategic collaborations to expand the reach of the Synthetic Biotic platform.

**Fourth Quarter 2018 Financial Results**
For the three months ended December 31, 2018, Synlogic reported a consolidated net loss of $11.9 million, or $0.47 per share, compared to a net loss of $11.7 million, or $0.74 per share, for the corresponding period in 2017.

Research and development expenses were $8.9 million for the three months ended December 31, 2018 compared to $7.7 million for the corresponding period in 2017. The increase was primarily due to an increase in compensation-related expenses associated with increased headcount and increases in expenses related to the lease of a larger facility at 301 Binney Street in Cambridge, Massachusetts, which Synlogic occupied in January 2018.

General and administrative expenses for the three months ended December 31, 2018 were $4.0 million compared to $4.3 million for the corresponding period in 2017. The decrease was primarily due to decreases in professional fees such as audit, legal and tax services, partially offset by increases in compensation-related expenses associated with increased headcount and increases in expenses related to the lease of Synlogic's facility at 301 Binney Street.

Revenue was $0.1 million for the three months ended December 31, 2018 and December 31, 2017. Revenue is associated with the payments received for services performed under the Synlogic's collaboration with AbbVie to develop a Synthetic Biotic medicine for the treatment of IBD.

As of December 31, 2018, Synlogic had cash, cash equivalents, and short-term investments of $122.7 million.

**Full Year 2018 Financial Results**
For the year ended December 31, 2018, consolidated net loss was $48.4 million, or $2.03 per share, compared to a consolidated net loss of $40.4 million, or $6.00 per share, for the year ended December 31, 2017. Revenues were $2.5 million for the year ended December 31, 2018, compared to $2.4 million for the same period in 2017. Total operating expenses were $53.8 million for the year ended December 31, 2018, compared to $43.3 million for the same period in 2017. The increase in operating expenses was primarily due to compensation-related expenses associated with increased headcount, increased expenses related to the lease of Synlogic's facility at 301 Binney Street and increased external costs associated with development of Synlogic's Synthetic Biotic programs, including process and formulation development, pre-clinical and clinical studies.

**Conference Call & Webcast Information**
Synlogic will host a conference call and live webcast today at 8:00 a.m. ET today, Tuesday, March 12, 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 2181868. 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, SYNB1020 and SYNB1618, are orally administered and target hyperammonemia as a result of liver damage or genetic disease, and phenylketonuria, respectively. Synlogic is also developing SYNB1891 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: cancer, rare metabolic diseases, liver disease, and inflammatory and immune disorders; 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 cancer, hyperammonemia, and phenylketonuria; and Synlogic's ability to develop and manufacture Synthetic Biotic formulations. 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 and clinical 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) | For the three months ended | | For the year ended | |
|---|---|---|---|---|
| | December 31, 2018 | December 31, 2017 | December 31, 2018 | December 31, 2017 |
| Revenue | $ 111 | $ 111 | $ 2,520 | $ 2,444 |
| Operating expenses | | | | |
| Research and development | 8,867 | 7,736 | 38,034 | 30,341 |
| General and administrative | 3,952 | 4,293 | 15,716 | 12,927 |
| Total operating expenses | 12,819 | 12,029 | 53,750 | 43,268 |
| Loss from operation | (12,708) | (11,918) | (51,230) | (40,824) |
| Other income(expense), net | 777 | 221 | 2,795 | 447 |
| Net loss | $ (11,931) | $ (11,697) | $ (48,435) | $ (40,377) |
| Net loss per share attributable to common shareholders - basic and diluted | $ (0.47) | $ (0.74) | $ (2.03) | $ (6.00) |
| Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted | 25,269,396 | 15,871,223 | 23,882,685 | 6,724,641 |

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

(in thousands)

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and short-term investments | $ 122,729 | $ 87,025 |
| Fixed assets | 14,841 | 9,783 |
| Other assets | 2,770 | 2,891 |
| Total assets | $ 140,340 | $ 99,699 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | $ 8,341 | $ 9,027 |
| Long-term liabilities | 7,901 | 5,634 |
| Total liabilities | 16,242 | 14,661 |
| Total stockholders' equity | 124,098 | 85,038 |
| Total liabilities and stockholders' equity | $ 140,340 | $ 99,699 |

CONTACT:
**MEDIA CONTACT:**
**Synlogic**
Courtney Heath
Phone: 617-872-2462
Email: courtney@scientpr.com

**INVESTOR CONTACT:**
**Synlogic**
Elizabeth Wolffe, Ph.D.
Phone: 617-207-5509
Email: liz@synlogictx.com