# 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, 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):

Uritten 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 August 8, 2018, Synlogic, Inc. (the "Company") announced its financial results for the quarter ended June 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 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.

Date: August 8, 2018

SYNLOGIC, INC.

By: /s/ Todd Shegog

Name: Todd Shegog Title: Chief Financial Officer

#### Synlogic Reports Second Quarter 2018 Financial Results and Provides Program Updates

#### - Data from Phase 1/2 studies of SYNB1618 and SYNB1020 expected by end of 2018 -

#### - On track to advance first immuno-oncology program into IND-enabling studies in fourth quarter of 2018 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--August 8, 2018--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 second quarter ended June 30, 2018 and provided an update on its programs.

"Synlogic's recent progress, including initiation of two clinical trials and multiple presentations of preclinical data, highlight the potential of Synthetic Biotic medicines across a range of diseases," said Aoife Brennan, M.B., B.Ch., Synlogic's interim president and chief executive officer and chief medical officer. "In the second half of 2018, we look to continue this momentum as we advance our clinical pipeline, with data expected from phase 1/2 clinical trials of our two lead programs, SYNB1020 in patients with hyperammonemia due to cirrhosis and SYNB1618 in healthy volunteers. In addition, we look forward to advancing our first immuno-oncology program into IND-enabling studies for the treatment of cancer."

#### Recent Highlights Pipeline

- **Presentation of preclinical data highlighting potential of Synthetic Biotic medicines in immuno-oncology (IO)** at the annual meeting of the Federation of Clinical Immunology Societies (FOCIS 2018), including the platform's broad capabilities to generate candidates that secrete or consume immunologically relevant compounds for the potential treatment of cancer and inflammation. Data presented in two sessions demonstrate that intratumorally injected *E. coli* Nissle was able to colonize and persist in the tumor, and that multiple functions can be engineered into a single bacterial strain. These properties support the continued development of Synthetic Biotic immunotherapies for the treatment of solid tumors, particularly "cold" tumors that may be resistant to current immunotherapies due to their lack of infiltrating immune cells or a highly immunosuppressive tumor microenvironment. Synlogic plans to advance its first immuno-oncology program into IND-enabling studies in the fourth quarter of 2018.
- Presentation of preclinical data supporting continued development of SYNB1618 for the treatment of Phenylketonuria (PKU) in a plenary session at the annual meeting of the American Society for Microbiology (ASM Microbe 2018). The data demonstrate, in a mouse model of PKU and healthy non-human primates, that orally administered SYNB1618 can result in significant decreases in blood phenylalanine levels and dose-responsive pharmacokinetics. Synlogic is currently evaluating SYNB1618 in a Phase 1/2a clinical trial for the management of PKU and expects to report interim data from healthy volunteers before the end of 2018 and full data that includes cohorts of patients with PKU in 2019.
- **Presentation of new preclinical data highlighting beneficial activity of SYNB1020 in animal model of liver disease** at Digestive Disease Week (DDW 2018). The data demonstrate that, in addition to lowering systemic levels of ammonia, administration of SYNB1020 resulted in reduced indicators of liver damage, providing additional support for its continued development for the potential treatment of liver disease. SYNB1020 is currently being evaluated in a Phase 1b/2a clinical trial in patients with elevated ammonia due to cirrhosis, with topline data expected at the end of 2018.

## Corporate

- **Strengthened balance sheet**: As of June 30, 2018, Synlogic had cash, cash equivalents, and short-term investments of \$143.2 million which includes \$28.9 million in net proceeds generated by a registered direct offering completed in April 2018.
- Addition to Russell 3000<sup>®</sup> Index following its annual reconstitution, providing Synlogic increased visibility and exposure to institutional investors.

#### Second Quarter 2018 Financial Results

For the three months ended June 30, 2018, Synlogic reported a consolidated net loss of \$14.6 million, or \$0.59 per share, compared to a consolidated net loss of \$9.4 million, or \$4.70 per share, for the corresponding period in 2017.

Research and development expenses were \$10.9 million for the three months ended June 30, 2018 compared to \$8.5 million for the corresponding period in 2017. The increase was primarily due to an increase in expenses associated with Synlogic's SYNB1618 program including its ongoing Phase 1/2a clinical trial, an increase in compensation and other employee-related expenses associated with increased headcount, partially offset by one-time equity-based and patent-related charges of \$2.1 million associated with Synlogic's MIT-BU license agreement.

General and administrative expenses for the three months ended June 30, 2018 were \$4.7 million compared to \$3.0 million for the corresponding period in 2017. The increase was primarily due to an increase of \$1.2 million in compensation costs associated with the separation of Synlogic's former chief executive officer, as well as compensation and other employee-related expenses associated with increased headcount.

Revenues were \$0.3 million for the three months ended June 30, 2018, compared to \$2.1 million for the corresponding period in 2017. Revenue for both periods was associated with Synlogic's collaboration with AbbVie to develop Synthetic Biotic medicines for the treatment of irritable bowel disease (IBD). The decrease in revenue was primarily the result of a milestone achieved and recognized during the three months ended June 30, 2017.

#### **Six-months Results**

For the six months ended June 30, 2018, the consolidated net loss was \$25.8 million, or \$1.14 per share, compared to a consolidated net loss of \$16.8 million, or \$9.20 per share, for the corresponding period in 2017.

Total operating expenses were \$27.6 million for the six months ended June 30, 2018, compared to \$19.1 million for the corresponding period in 2017. The increase in operating expenses was primarily due to compensation-related expenses associated with increased headcount, increased external costs associated with development of Synlogic's Synthetic Biotic programs including process and formulation development, pre-clinical and clinical studies as well as increased general and administrative expenses as a consequence of becoming a public company.

## **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. Synlogic'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 <u>www.synlogictx.com</u>.

#### **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)  | Fo  | For the three months ended |     |            | For the six months ended |      |            |  |
|   | Jur | 1e 30, 2018                | Jun | e 30, 2017 | June 30, 2018            | Jun  | e 30, 2017 |  |
| Revenue   | \$  | 254                        | \$  | 2,111      | \$ 608                   | 3 \$ | 2,222      |  |
| Operating expenses  |     |                            |     |            |                          |      |            |  |
| Research and development  |     | 10,872                     |     | 8,532      | 19,233                   | 3    | 13,650     |  |
| General and administrative  |     | 4,734                      |     | 3,036      | 8,363                    | 3    | 5,403      |  |
| Total operating expenses  |     | 15,606                     |     | 11,568     | 27,590                   | 6    | 19,053     |  |
| Loss from operations  |     | (15,352)                   |     | (9,457)    | (26,988                  | )    | (16,831)   |  |
| Other income (expense), net   |     | 761                        |     | 69         | 1,232                    | 2    | 75         |  |
| Net loss  | \$  | (14,591)                   | \$  | (9,388)    | \$ (25,756               | )\$  | (16,756)   |  |
|   |     |                            |     |            |                          |      |            |  |
| Net loss per share attributable to common shareholders - basic and diluted  | \$  | (0.59)                     | \$  | (4.70)     | \$ (1.14                 | ) \$ | (9.20)     |  |
| Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted | _   | 24,803,379                 |     | 1,997,228  | 22,503,802               | 2    | 1,821,736  |  |

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

| (in thousands)                                    |               |         |                   |        |  |
|---|---------------|---------|-------------------|--------|--|
|   | June 30, 2018 |         | December 31, 2017 |        |  |
| Assets  |               |         |                   |        |  |
| Cash, cash equivalents and short-term investments | \$            | 143,212 | \$                | 87,025 |  |
| Fixed assets                                      |               | 14,594  |                   | 9,783  |  |
| Other assets                                      |               | 3,267   |                   | 2,891  |  |
| Total assets                                      | \$            | 161,073 | \$                | 99,699 |  |
| Liabilities and Stockholders' Equity              |               |         |                   |        |  |
| Current liabilities                               | \$            | 8,203   | \$                | 9,027  |  |
| Long-term liabilities                             |               | 8,250   |                   | 5,634  |  |
| Total liabilities                                 |               | 16,453  |                   | 14,661 |  |
| Total stockholders' equity                        |               | 144,620 |                   | 85,038 |  |
| Total liabilities and stockholders' equity        | \$            | 161,073 | \$                | 99,699 |  |

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