# **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, 2017

# 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.)** 

200 Sidney St., Suite 320 Cambridge, MA (Address of principal executive offices)

02139

(Zip Code)

(617) 401-9947 Registrant's telephone number, including area code

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:							
☐ 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, 2017, Synlogic, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2017 (the "Press Release"). A copy of the Press Release is furnished as Exhibit 99.1 to this current report on Form 8-K.

The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this current report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this current report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	Press release dated November 13, 2017.

# 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, 2017 By: /s/ TODD SHEGOG

Name: Todd Shegog

Title: Chief Financial Officer

## Synlogic Reports Third Quarter 2017 Financial Results and Recent Progress

- Reported Positive Top-line Results from Phase 1 Clinical Study of SYNB1020 in Healthy Volunteers -
- Received Orphan Drug Designation for SYNB1618, a Synthetic Biotic  $^{TM}$  Medicine for the Treatment of Phenylketonuria -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--November 13, 2017--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 third quarter ended September 30, 2017. As of September 30, 2017, Synlogic had cash, cash equivalents, and short-term investments of \$96.6 million.

"In our first months as a public company, we have achieved significant progress in advancing our pipeline with our recent release of positive data from the first clinical trial of our Synthetic Biotic medicine SYNB1020 for hyperammonemia," said JC Gutiérrez-Ramos, Ph.D., Synlogic's president and chief executive officer. "We are building an organization with the goal of bringing rational drug design and pharmacologically driven drug development to a new class of living medicines. We are focused internally on developing treatments for inborn errors of metabolism and we look forward to advancing our two lead programs into clinical studies in patients in 2018."

#### **Pipeline Highlights**

- Reported positive top-line clinical data from Synlogic's Phase 1 clinical study of SYNB1020, an orally delivered, first-in-class, Synthetic Biotic medicine designed to treat elevated blood ammonia levels (hyperammonemia) in genetic urea cycle disorders (UCD) or in chronic liver disease
  - The trial successfully met its primary objectives, demonstrating safety and tolerability in healthy volunteers and identifying the maximum tolerated dose. SYNB1020 did not colonize and was cleared within the expected timeframe in subjects who had completed follow-up. Viability and evidence of mechanistic activity of the Synthetic Biotic was demonstrated in feces of subjects who received SYNB1020, but not in control subjects. Furthermore, in the multiple ascending dose component of the Phase 1 study, daily dosing of SYNB1020 over 14 days in healthy volunteers enabled identification of a dose-response relationship between SYNB1020 oral administration and changes in a nitrogen endpoint in plasma which was found to be statistically significant in the highest dose cohort compared to placebo
  - The Company plans to initiate a Phase 1b/2a study of SYNB1020 in patients with liver cirrhosis and elevated ammonia in the first half of 2018 and a second Phase 1b/2a study in patients with UCDs.
- Received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for SYNB1618, an orally delivered, Synthetic Biotic medicine designed for treatment of phenylketonuria (PKU), an inborn error of metabolism caused by a mutation of the gene that breaks down the amino acid phenylalanine (Phe).
  - Reserved for treatments of rare diseases affecting fewer than 200,000 people in the U.S., Orphan Drug Designation
    offers FDA assistance in trial design and grants development and commercial incentives, including eligibility for a
    seven-year period of market exclusivity in the U.S., if approved. In 2018, Synlogic plans to initiate a clinical trial to
    evaluate SYNB1618 for the potential treatment of PKU.

#### **Corporate Highlights**

- Completed merger and began trading on the NASDAQ Capital Market under the ticker symbol "SYBX".
  - o On August 28, 2017, Synlogic, Inc. and Mirna Therapeutics, Inc. closed the merger of the two companies.
- Strengthened leadership team with two key additions.
  - Synlogic appointed two experienced executives to key leadership roles: Andrew Gengos as Chief Operating Officer and Head of Corporate Development; and Adam Thomas as Chief Human Resources Officer.

## **Third Quarter 2017 Financial Results**

As of September 30, 2017, Synlogic had cash, cash equivalents, and short-term investments of \$96.6 million and 16.3 million shares issued and outstanding.

For the three months ended September 30, 2017, Synlogic reported a net loss of \$11.9 million for the third quarter of 2017 compared to a net loss of \$5.3 million for the corresponding period in 2016. The increase in net loss for the third quarter was primarily due to increases in research and development expenses as well as increases in compensation-related expenses as Synlogic continues to grow its employee headcount and hire into key positions to support its corporate goals.

Research and development expenses were \$9.0 million for the three months ended September 30, 2017 compared to \$4.1 million in the corresponding period in 2016. The increase was primarily due to an increase in external costs associated with our Phase 1 clinical trial, preclinical studies, formulation development and consulting fees as well as increased internal research costs and increased compensation-related expenses associated with increased headcount.

General and administrative expenses for the three months ended September 30, 2017 were \$3.2 million compared to \$1.3 million for the corresponding period in 2016. The increase was primarily due to increases in expenses related to the reverse merger and becoming a public company including legal, audit, investor relations, and filing fees as well as increases in compensation-related expenses associated with increased headcount.

Revenue was \$0.1 million for each of the three months ended September 30, 2017 and September 30, 2016. Revenue is associated with the upfront, nonrefundable \$2.0 million payment from the AbbVie collaboration, which is being recognized on a straight-line basis over the expected term of the collaboration.

#### **About Synthetic Biotic Medicines**

Synlogic's innovative new class of Synthetic Biotic medicines 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 target a group of rare metabolic diseases – inborn errors of metabolism (IEM). Patients with these diseases are born with a faulty gene, inhibiting the body's ability to break down commonly occurring by-products of digestion that then accumulate to toxic levels and cause serious health consequences. When delivered orally, these medicines can act from the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect. Synthetic Biotic medicines are designed to clear toxic metabolites associated with specific metabolic diseases and have the potential to significantly improve symptoms of disease for affected patients.

## **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's initial pipeline includes Synthetic Biotic medicines for the treatment of rare genetic diseases, such as urea cycle disorders (UCD) and phenylketonuria (PKU). 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 <a href="https://www.synlogictx.com">www.synlogictx.com</a>.

#### **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; the expected timing of Synlogic's anticipated clinical trial initiations; and the benefit of orphan drug status. 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)

	For the three months ended			For the nine months ended				
	Se	ptember 30, 2017	Se	ptember 30, 2016	Se	eptember 30, 2017	Se	ptember 30, 2016
Revenue	\$	111	\$	111	\$	2,333	\$	333
Operating expenses Research and development General and administrative Total operating expenses Loss from operation Other income(expense), net		8,955		4,133		22,605		9,883
		3,231		1,286		8,634		4,555
		12,186		5,419		31,239		14,438
		(12,075) 151		(5,308) 2		(28,906) 226		(14,105) (1)
Net loss	\$	(11,924)	\$	(5,306)	\$	(28,680)	\$	(14,106)
Net loss per share attributable to common shareholders - basic and diluted Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic	\$	(1.66)	\$	-	\$	(7.87)	\$	-
and diluted		7,169,241		-		3,642,125		-
Net loss per share attributable to common unitholders - basic and diluted Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic	\$	-	\$	(3.33)	\$	-	\$	(9.17)
and diluted		-		1,594,265		-		1,538,896

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

(in thousands)	September 30, 2017		December 31, 2016		
Assets					
Cash, cash equivalents and short-term investments	\$	96,572	\$	14,586	
Fixed assets		4,911		3,504	
Other assets		2,987		1,949	
Total assets	\$	104,470	\$	20,039	
Liabilities, Contingently Redeemable Preferred Shares/Units and Equity					
Current liabilities	\$	7,961	\$	4,186	
Deferred revenue, net of current portion		779		1,112	
Other liabilities		165		1,238	
Total liabilities		8,905		6,536	
Total equity and contingently redeemable preferred shares		95,565		13,503	
Total liabilities and equity	\$	104,470	\$	20,039	

# CONTACT:

# **MEDIA CONTACT:**

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