

# Synlogic Reports Third Quarter 2017 Financial Results and Recent Progress

November 13, 2017

- Reported Positive Top-line Results from Phase 1 Clinical Study of SYNB1020 in Healthy Volunteers -
- Received Orphan Drug Designation for SYNB1618, a Synthetic Biotic<sup>TM</sup> Medicine for the Treatment of Phenylketonuria -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 13, 2017-- Synlogic, Inc. (Nasdag: 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 forwardlooking statements. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "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 forwardlooking 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 September 30, September 30 2017 2016		For the nine months ended September 30, September 30, 2017 2016		
Revenue	\$ 111	\$ 111	\$ 2,333	\$ 333	
Operating expenses					
Research and development	8,955	4,133	22,605	9,883	
General and administrative	3,231	1,286	8,634	4,555	
Total operating expenses	12,186	5,419	31,239	14,438	
Loss from operation	(12,075)	(5,308)	(28,906)	(14,105 )	
Other income(expense), net	151	2	226	(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 and diluted	7,169,241	) \$ - -	\$ (7.87 3,642,125	) \$ -	
Net loss per share attributable to common unitholders - basic and diluted	\$ -	\$ (3.33	) \$ -	\$ (9.17	)
Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic 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

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# **MEDIA CONTACT:**

Synlogic

Courtney Heath, 617-872-2462

courtney@scientpr.com

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# INVESTOR CONTACT:

Synlogic

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

liz@synlogictx.com