Synlogic Provides Program and Business Update and Reports Third Quarter 2019 Financial Results

November 12, 2019

–SYNB1618 solid oral bridging study ongoing and SYNB1891 immuno-oncology study open –

– Company ends 3Q2019 with approximately $139 million in cash, cash equivalents and investments supporting projected runway through 2021 –

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 12, 2019-- 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, 2019, and provided an update on its programs and progress.

"We are making good progress towards our goal of evaluating the breadth of therapeutic applications of our Synthetic Biotic platform. Notably, the recent initiation of the first clinical trial of a Synthetic Biotic medicine for the treatment of cancer represents a significant step for Synlogic," said Aoife Brennan, M.B., B.Ch., Synlogic's president and chief executive officer. "We also continue to advance our SYNB1618 program for the treatment of phenylketonuria in an ongoing bridging study to evaluate the tolerability and activity of a solid oral formulation, and we look forward to sharing those data and our plans for the next steps in this program."

Recent Highlights
Pipeline

- **Clearance of Investigational New Drug (IND) application and initiation of SYNB1891 immuno-oncology (IO) clinical study.** Synlogic has initiated a Phase 1 open-label, multicenter, dose escalation trial of its STING-agonist producing bacterial strain, SYNB1891, for the treatment of refractory solid tumors. The study's primary objectives are to evaluate safety and tolerability of escalating doses of intratumorally administered SYNB1891 as a monotherapy. Once a maximum tolerated dose is established, patients will receive escalating dose levels of SYNB1891 in combination with a fixed dose of the checkpoint inhibitor, Atezolizumab, to establish a recommended Phase 2 dose for the combination regimen. Synlogic expects to have data from the monotherapy arm of the study in 2020.
- **Presentation of positive data from Phase 1/2a Study of SYNB1618 in patients with phenylketonuria (PKU) as well as modeling work to estimate target dosing of SYNB1618.** In September, clinical data from a randomized, double-blind, placebo-controlled Phase 1/2a study of SYNB1618, which is being developed for the treatment of PKU were presented at the Annual Symposium of the Society for the Study of Inborn Errors of Metabolism (SSIEM) by Jerry Vockley, M.D. Ph.D., Professor of Pediatrics and Chief of Medical Genetics, University of Pittsburgh, and a principal investigator on the trial. The study's primary objective was to evaluate safety and tolerability and to measure biomarkers of phenylalanine-consuming activity of multiple ascending doses of a liquid formulation of SYNB1618 in healthy volunteers and a single dose level in PKU patient cohorts. SYNB1618 was well tolerated in healthy volunteers and patients with PKU and the data demonstrated equivalent phenylalanine-consumption.
- **Initiation of bridging study of a solid oral formulation of SYNB1618 in healthy volunteers to establish maximum tolerated dose (MTD) for efficacy study in patients with PKU.** Based on data from its Phase 1/2a study of a liquid formulation of SYNB1618, Synlogic initiated a bridging study in healthy volunteers of a new solid oral formulation to establish an MTD that would potentially enable at least a 30% lowering of blood Phe levels in PKU patients based on the company's modeling data. With supporting data from the bridging study, Synlogic expects to advance SYNB1618 into an efficacy study in patients in the first half of 2020.

Corporate

- **Key appointments to Synlogic's leadership and research and development teams**
  - **Richard Riese, M.D. Ph.D., chief medical officer,** joined Synlogic in September and has assumed responsibilities for all clinical and regulatory functions from current president and CEO, Aoife Brennan.
  - **Gregg Beloff, interim chief financial officer,** was appointed in October 2019. Mr. Beloff, who has more than 20 years of experience in the life sciences industry, brings significant expertise in operational management, strategic planning, corporate and business development, fundraising and mergers and acquisitions.

Third Quarter 2019 Financial Results
As of September 30, 2019, Synlogic had cash, cash equivalents, and short- and long-term investments of $138.7 million. The Company anticipates that, based on its current operating plan, its existing cash and cash equivalents will fund company operations through 2021.

For the three months ended September 30, 2019, Synlogic reported a consolidated net loss of $13.3 million, or $0.39 per share, compared to a consolidated net loss of $10.7 million, or $0.43 per share, for the corresponding period in 2018.

Research and development expenses were $10.6 million for the three months ended September 30, 2019 compared to $9.9 million for the corresponding period in 2018. The increase was primarily due to increased clinical development costs for our SYNB1618 program.

General and administrative expenses for the three months ended September 30, 2019 were $3.9 million compared to $3.4 million for the corresponding period in 2018.

Revenues were $0.3 million for the three months ended September 30, 2019, compared to $1.8 million for the corresponding period in 2018. 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 decrease 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.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast today at 5:00 p.m. ET today, Tuesday, November 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 3889667. 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 probiotic microbes to perform or deliver critical functions missing or damaged due to disease. The Company's lead program, SYNB1618, targets PKU. 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 inflammatory and immune disorders, and cancer. Synlogic's first immuno-oncology program, SYNB1891, is in clinical development for the treatment of solid tumors and lymphoma. Synlogic is collaborating 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, including statements regarding Synlogic's plans and expectations for the development of SYNB1618. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, clinical development plans, 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, inborn errors of metabolism, 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; and the expected timing of Synlogic's clinical trials 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 clinical and 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, except share and per share data)	For the three months ended		For the nine months ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Revenue	$ 305	$ 1,801	$ 993	$ 2,409
Operating expenses				
Research and development	10,564	9,934	30,651	29,167

General and administrative	3,879	3,401	11,272	11,764
Total operating expenses	14,443	13,335	41,923	40,931
Loss from operations	(14,138)	(11,534)	(40,930)	(38,522)
Other income (expense), net	853	786	2,355	2,018
Net loss	$ (13,285)	$ (10,748)	$ (38,575)	$ (36,504)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.39)	$ (0.43)	$ (1.33)	$ (1.56)
Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted	34,213,096	25,208,117	28,956,280	23,415,242

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

	September 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and short and long-term investments	$ 138,662	$ 122,729
Fixed assets	13,289	14,841
Other assets	50,458	2,770
Total assets	$ 202,409	$ 140,340
Liabilities and Stockholders' Equity		
Current liabilities	$ 10,337	$ 8,341
Long-term liabilities	23,405	7,901
Total liabilities	33,742	16,242
Total stockholders' equity	168,667	124,098
Total liabilities and stockholders' equity	$ 202,409	$ 140,340

Common stock and common stock equivalents:		
Common stock	32,290,814	25,401,479
Common stock warrants (pre-funded)	2,548,117	—
Common stock	34,838,931	25,401,479

View source version on businesswire.com: https://www.businesswire.com/news/home/20191112005948/en/

Source: Synlogic, Inc.

MEDIA CONTACT:
Caroline Rufo, Ph.D.
MacDougall
Phone: 781-235-3060
Email: crufo@macbiocom.com

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