Synlogic Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

March 12, 2020

- Synlogic ended 2019 with approximately $127 million in cash and investments, which provides runway into 2022 -

- Company will host a conference call at 5:00 pm ET today -

CAMBRIDGE, Mass., March 12, 2020 /PRNewswire/ -- 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 fourth quarter and full year ended December 31, 2019.

"We have built key Synthetic Biotic platform capabilities in synthetic biology, manufacturing and development to enable the efficient generation of therapeutics that have the potential to address unmet medical need in a range of indications from rare metabolic diseases to cancer," said Aoife Brennan, M.B., Ch.B., Synlogic's president and chief executive officer. "Building on our experience in our PKU program we have made steady progress on new programs in enteric hyperoxaluria and maple syrup urine disease and we look forward to providing more detail on these initiatives as well as the underlying engine that powers our pipeline as year progresses."

2020 Priorities

Pipeline

- **Initiation of a Phase 2 clinical trial to evaluate a solid formulation of SYNB1618 in patients with phenylketonuria (PKU) expected in the first half of 2020.** The trial is designed to evaluate safety and tolerability of a solid formulation of SYNB1618 as well as its potential to lower blood phenylalanine (Phe) levels in PKU patients. In addition, the study is expected to provide valuable information to validate predictive pharmacodynamic and preclinical modeling.
- **Evaluation of data expected in 2020 from the monotherapy arm of the Phase 1 clinical study of SYNB1891 in patients with advanced solid tumors or lymphoma.** SYNB1891 is an intra-tumorally administered Synthetic Biotic medicine engineered to produce cyclic di-AMP, 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 or lymphoma. SYNB1891 is being evaluated as a monotherapy in an ongoing Phase 1 open-label, multicenter, dose escalation clinical trial (NCT04167137) in patients with advanced solid tumors or lymphoma. Synlogic expects to have data from the monotherapy arm of this study in 2020. After establishing a maximum tolerated dose for SYNB1891 as monotherapy, Synlogic expects to initiate a second arm of the trial in which subjects will receive escalating dose levels of SYNB1891 in combination with a fixed dose of the checkpoint inhibitor, atezolizumab (Tecentriq®), to establish a recommended dose for the combination regimen.
- **Continued development of patient and commercialization-appropriate presentations of SYNB1618.** Synlogic has developed and manufactured a solid formulation of its Synthetic Biotic SYNB1618 suitable for future clinical trials and continues to evaluate and develop presentations such as enteric-coated capsules and pressed tablets for eventual commercialization.
- **Advancement of new Synthetic Biotic programs in metabolic diseases with high unmet medical need.** Synlogic is conducting preclinical studies of Synthetic Biotic medicines to treat enteric hyperoxaluria (HOX), an acquired metabolic disorder in which patients develop recurrent kidney stones due to elevated urinary oxalate levels and are at an increased risk of kidney failure. In addition, Synlogic is also developing Synthetic Biotic medicines for the treatment of maple syrup urine disease (MSUD), a rare inherited metabolic disease caused by defective enzymes that metabolize branched chain amino acids (BCAAs) which are components of protein. Elevated blood levels of BCAAs can lead to can lead to seizures, coma, and death. There are currently no approved therapies to treat these disorders.
- **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.

Corporate

- **Continued strengthening of Synlogic's leadership.** In January 2020, Synlogic announced the appointment of Michael Burgess, M.B., Ch.B., Ph.D., President, Research & Development, at Turnstone Biologics, to its board of directors. Dr. Burgess is a physician scientist who brings extensive experience in translational drug development from leadership roles at several large Pharma companies including Roche, Bristol-Myers Squibb and Lilly.
- **Continued exploration of additional strategic collaborations.** Synlogic expects to continue to develop strategic collaborations to expand the breadth of its Synthetic Biotic pipeline in therapeutic areas that have high biology risk.

Fourth Quarter 2019 Financial Results

As of December 31, 2019, Synlogic had cash, cash equivalents, and short- and long-term investments of $127.1 million.

For the three months ended December 31, 2019, Synlogic reported a consolidated net loss of $12.8 million, or $0.37 per share, compared to a net loss of $11.9 million, or $0.47 per share, for the corresponding period in 2018.

Research and development expenses were $11.3 million for the three months ended December 31, 2019 compared to $8.9 million for the corresponding period in 2018. The increase in expenses was primarily due to use of synthetic biology services provided under Synlogic's collaboration with Ginkgo and increased clinical activities, including the SYNB1618 bridging study and initiation of the SYNB1891 Phase 1 clinical study.

General and administrative expenses for the three months ended December 31, 2019 were $3.5 million compared to $4.0 million for the corresponding period in 2018.

Revenue was $1.2 million for the three months ended December 31, 2019 compared to $0.1 million for the three months ended December 31, 2018. Revenue is associated with services performed under the Synlogic's collaboration with AbbVie to develop a Synthetic Biotic medicine for the treatment of inflammatory bowel disease (IBD). The increase in revenue for the fourth quarter of 2019 compared to the same period in 2018 was a result of revised estimates of time and effort required to reach certain milestones in the collaboration.

Full Year 2019 Financial Results

For the year ended December 31, 2019, consolidated net loss was $51.4 million, or $1.70 per share, compared to a consolidated net loss of $48.4 million, or $2.03 per share, for the year ended December 31, 2018. Revenues were $2.2 million for the year ended December 31, 2019, compared to $2.5 million for the same period in 2018. Total operating expenses were $56.6 million for the year ended December 31, 2019, compared to $53.8 million for the same period in 2018.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast today at 5:00 p.m. ET today, Thursday, March 12, 2020. 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 4089293. 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. When delivered orally, Synthetic Biotic medicines are designed to function in 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. The Company's lead program in this area, SYNB1618, targets 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 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. 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 initiation, enrollment, timing, progress, release of data from and results of our planned and ongoing clinical trials; 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 various diseases; Synlogic's ability to develop and manufacture Synthetic Biotic formulations; and Synlogic's goals with respect to the development and potential use, if approved, of each of its product candidates. 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, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Revenue	$ 1,230	$ 111	$ 2,224	$ 2,520
Operating expenses				

Research and development	11,253	8,867	41,905	38,034
General and administrative	3,456	3,952	14,728	15,716
Total operating expenses	14,709	12,819	56,633	53,750
Loss from operations	(13,479)	(12,708)	(54,409)	(51,230)
Other income, net	681	777	3,036	2,795
Net loss	$ (12,798)	$ (11,931)	$ (51,373)	$ (48,435)
Net loss per share - basic and diluted	$ (0.37)	$ (0.47)	$ (1.70)	$ (2.03)
Weighted-average common shares used in computing net loss per share - basic and diluted	34,224,070	25,269,396	30,284,068	23,882,685

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share data)

	December 31, 2019	December 31, 2018
Assets		
Cash, cash equivalents, and short and long-term investments	$ 127,073	$ 122,729
Fixed assets	13,021	14,841
Other assets	48,480	2,770
Total assets	$ 188,574	$ 140,340
Liabilities and stockholders' equity		
Current liabilities	$ 8,863	$ 8,341
Long-term liabilities	22,806	7,901
Total liabilities	31,669	16,242
Total stockholders' equity	156,905	124,098
Total liabilities and stockholders' equity	$ 188,574	$ 140,340
Common stock and common stock equivalents		
Common stock	32,266,814	25,401,479
Common stock warrants (pre-funded)	2,548,117	-
Total common stock	34,814,931	25,401,479

View original content to download multimedia:http://www.prnewswire.com/news-releases/synlogic-reports-fourth-quarter-and-full-year-2019-financial-results-and-provides-business-update-301022625.html

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