Synlogic Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

March 25, 2021

-- SYNB8802 advances to Phase 1B Proof of Concept After Proof of Mechanism Demonstrated in Dietary Hyperoxaluria Study --

-- Synlogic ended 2020 with $100.4 million in cash, cash equivalents, and short-term investments, extending projected runway into 2023 --

-- Management to host conference call and webcast at 8:30 a.m. ET today --

CAMBRIDGE, Mass., March 25, 2021 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today reported financial results for the fourth quarter and full year ended December 31, 2020, and provided an update on programs and progress.

"2021 is an incredibly exciting year for the company. We now have demonstrated proof of mechanism in humans from both of our lead metabolic programs, Phenylketonuria (PKU) and Enteric Hyperoxaluria, and expect to have important clinical readouts in patients from both programs later this year," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "We believe there is significant unmet need in PKU and Enteric Hyperoxaluria and that our Synthetic Biotic medicines can address these and other metabolic diseases in ways not possible with other modalities."

"Enteric Hyperoxaluria is a historically underserved area in which dangerously high levels of urinary oxalate cause progressive kidney damage," said Richard Riese, M.D., Synlogic's Chief Medical Officer. "Part A of the Phase 1 study of SYNB8802 in healthy volunteers demonstrates compelling levels of Urinary Oxalate lowering at a well-tolerated dose in Dietary Hyperoxaluria cohorts, and we are thrilled to be advancing this program."

Dr. Riese further stated, "We are also excited to continue to advance the SynPheny-1 Phase 2 study of SYNB1618 for the treatment of PKU, as well as the Phase 1 clinical study of SYNB1891 in solid tumors and lymphomas. Patient interest continues to be robust. We are looking forward to top line results from both trials later in 2021."

2020 Highlights & 2021 Priorities

The Metabolic Portfolio:

Progression of a proof-of-concept Phase 2 clinical trial of SYNB1618 for the treatment of Phenylketonuria (PKU), with data expected in the second half of 2021. SYNB1618 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for PKU.

- Synthetic Biotic medicines offer potential for a safe, tolerable, reversible and oral therapy, which reduces plasma Phe levels by consuming Phe in the GI tract.
- SynPheny-1 is designed to evaluate plasma Phe lowering of a solid oral formulation of SYNB1618 in adult PKU patients who do not benefit from, or do not tolerate, existing therapies such as Kuvan or Palynziq.
- SYNB1934, an evolved Synthetic Biotic medicine in the PKU portfolio, has progressed to IND enabling studies.
    - SYNB1934 consumes Phe in the GI tract and contains a high activity PAL enzyme developed using directed evolution from the SYNB1618 PAL enzyme.
    - SYNB1934 may offer additional Phe lowering capacity, or the ability to dose at lower levels, relative to SYNB1618.
- Synlogic will provide full results of the SYNB1618 Phase 1 study of a solid oral formulation in healthy volunteers at the American College of Medical Genetics (ACMG) meeting in April 2021.

Completion of Part A of the Phase 1 study of SYNB8802 in Healthy Volunteers. Part B in patients with Enteric Hyperoxaluria following Roux-en-Y gastric bypass surgery has been initiated. SYNB8802 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for Enteric Hyperoxaluria. Synlogic has completed dosing of five cohorts in part A, 45 total subjects. Findings include:

- SYNB8802 was generally well tolerated in healthy volunteers. There were no serious or systemic adverse events. The most frequent adverse events were mild or moderate, transient, and GI-related.
- Dietary Hyperoxaluria was successfully induced in Healthy Volunteers.
    - Subjects placed on 600 mg of daily dietary oxalate had urinary oxalate levels of 44.8 mg/24h at baseline.
- Dose responsive changes in urinary oxalate levels were observed with a significant reduction in urinary oxalate relative to placebo across three dose levels.
- A dose of 3e11 live cells administered three times daily with meals was selected as the dose for part B of the study.
- This dose was well-tolerated and resulted in a change from baseline urinary oxalate reduction of 28.6% (90% CI: -42.4 to -11.6), compared to placebo.
- At the end of dosing, the mean 24-hour urinary oxalate level was 40.1 mg for subjects treated with SYNB8802 3e11 live

cells, compared to 58.1 mg for placebo subjects. Upper limit of normal urinary oxalate levels are 45 mg per 24 hours.

Full results of the study will be presented at a future medical meeting. Data from Part B in patients with Enteric Hyperoxaluria following Roux-en-Y gastric bypass surgery is expected in the second half of 2021.

The Immunomodulation Portfolio:

Advancement of SYNB1891 into combination arm dosing with PDL1 checkpoint inhibitor in an ongoing Phase 1 clinical study in patients with advanced solid tumors or lymphoma. SYNB1891 is an intratumorally administered Synthetic Biotic medicine engineered to act as a dual innate and adaptive immune activator.

- SYNB1891 is currently being evaluated in a Phase 1 study that has two parts:
  - Part A is a monotherapy arm that has enrolled five dose cohorts to date. The maximum tolerated dose has not been reached and dose escalation continues.
  - Part A of the study has demonstrated target engagement and activation of the STING pathway.
  - Part B of the study was initiated in December 2020 and combines escalating dose levels of SYNB1891 with a fixed dose of the PD-L1 checkpoint inhibitor atezolizumab to establish a recommended Phase 2 dose for the combination regimen.
  - An update on the study will be shared at the American Association of Cancer Research (AACR) meeting in April 2021.
  - Data from both arms will continue to be reported as appropriate over the course of 2021, with mature combination therapy data expected by the end of the year.

Corporate Update:

- **Synlogic expands Board of Directors.** Synlogic recently appointed Michael Heffernan and Lisa Kelly-Croswell to its Board of Directors.
  - Mr. Heffernan is a seasoned entrepreneur and biopharmaceutical leader with over 25 years of experience building and leading development stage and commercial companies.
  - Ms. Kelly-Croswell is a global Human Resources executive with over 30 years of experience in assignments commonly involving rapid business growth, performance turnarounds and innovation.
- **Synlogic strengthens Leadership Team.**
  - Dr. Caroline Kurtz was promoted to Chief Development Officer. Dr. Kurtz joined Synlogic in October 2016 and is responsible for program leadership and portfolio planning and progression. With over 25 years of experience in the pharmaceutical industry, Dr. Kurtz has led multiple programs through mid and late-stage clinical development.
  - Daniel Rosan was promoted to Senior Vice President and Head of Finance. Mr. Rosan joined Synlogic in March 2020 and has over 20 years of industry experience.
  - Synlogic appointed Dr. Jamie Austin to the role of Incoming Head of Regulatory Affairs. Dr. Austin has over 15 years of industry experience.
- **Synlogic advances strategic partnerships.**
  - Synlogic and the MIT Voigt Lab are collaborating with the Air Force Research Laboratory (AFRL) and the Department of Defense (DoD) to engineer novel investigational medicines to address battle fatigue.
  - Synlogic and Ginkgo Bioworks continue to advance their long-term strategic platform collaboration that provides expanded synthetic biology capabilities to Synlogic.

Fourth Quarter 2020 Financial Results

As of December 31, 2020, Synlogic had cash, cash equivalents and short-term investments of $100.4 million.

For the three months ended December 31, 2020, Synlogic reported a consolidated net loss of $14.6 million, or $0.39 per share, compared to a consolidated net loss of $12.8 million, or $0.37 per share, for the corresponding period in 2019.

Research and development expenses were $11.4 million for the three months ended December 31, 2020 compared to $11.3 million for the corresponding period in 2019.

General and administrative expenses for the three months ended December 31, 2020 were $3.3 million compared to $3.5 million for the corresponding period in 2019.

There was no revenue for the three months ending December 31, 2020 compared to $1.2 million for the three months ended December 31, 2019. Revenue for the prior period was associated with Synlogic's collaboration with AbbVie to develop Synthetic Biotic medicines for the treatment of Inflammatory Bowel Disease, which was terminated in May 2020.

Full Year 2020 Financial Results

For the year ended December 31, 2020, consolidated net loss was $59.2 million, or $1.65 per share, compared to a consolidated net loss of $51.4 million, or $1.70 per share, for the year ended December 31, 2019. Revenues were $0.5 million for the year ended December 31, 2020, compared to $2.2 million for the same period in 2019. Total operating expenses were $61.0 million for the year ended December 31, 2020, compared to $56.6 million for the same period in 2019.

Financial Outlook
Based upon its current operating plan, Synlogic expects to have sufficient cash to be able to fund the base operating plan into 2023.

Conference Call & Webcast Information
Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, Thursday, March 25, 2021. To access the live webcast, please visit the "Event Calendar" page within the Investors and Media section of the Synlogic website. 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 4897219. A replay will be available for 30 days on the Investors and Media section of the Synlogic website.

About PKU
Phenylketonuria (PKU) is an inherited metabolic disease that manifests at birth and is marked by an inability to break down Phe, an amino acid that is commonly found in many foods. Left untreated, high levels of Phe become toxic and can lead to serious neurological and neuropsychological problems affecting the way a person thinks, feels, and acts. Due to the seriousness of these symptoms, infants are screened at birth in many countries to ensure early diagnosis and treatment to avoid intellectual disability and other complications.

About Enteric Hyperoxaluria
Enteric Hyperoxaluria is an acquired metabolic disorder caused by increased absorption of dietary oxalate, which is present in many healthy foods, making it almost impossible to control with diet alone. Enteric Hyperoxaluria often occurs as a result of a primary insult to the bowel, such as inflammatory bowel disease, short bowel syndrome, or as a result of surgical procedures such as Roux-en-Y bariatric weight-loss surgery.

Enteric Hyperoxaluria results in dangerously high levels of urinary oxalate, which causes progressive kidney damage, kidney stone formation, and nephrocalcinosis. Enteric Hyperoxaluria has no approved treatment options.

About Synlogic
Synlogic™ is bringing the transformative potential of synthetic biology to medicine. With a premiere synthetic biology platform that leverages a reproducible, modular approach to microbial engineering, Synlogic designs Synthetic Biotic medicines that target validated underlying biology to treat disease in new ways. Synlogic's proprietary pipeline includes Synthetic Biotics for the treatment of metabolic disorders including Phenylketonuria (PKU) and Enteric Hyperoxaluria. The company is also building a portfolio of partner-able assets in immunology and oncology.

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, 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, metabolic diseases, and inflammatory and immune disorders; our expectations about sufficiency of our existing cash balance; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; 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 year ended	
	December 31, 2020	December 31, 2019	December 31, 2020	December 31, 2019
Revenue	$ —	$ 1,231	$ 545	$ 2,224
Operating expenses				
Research and development	11,407	11,254	47,474	41,905
General and administrative	3,286	3,456	13,537	14,728
Total operating expenses	14,693	14,710	61,011	56,633
Loss from operations	(14,693)	(13,479)	(60,466)	(54,409)
Other income, net	105	681	1,293	3,036
Net loss	$ (14,588)	$ (12,798)	$ (59,173)	$ (51,373)
Net loss per share - basic and diluted	$ (0.39)	$ (0.37)	$ (1.65)	$ (1.70)
Weighted-average common shares used in computing net loss per share - basic and diluted	37,792,966	34,224,070	35,835,744	30,284,068

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)

	December 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents, short and long-term investments	$ 100,444	$ 127,073
Fixed assets	10,776	13,021
Other assets	32,620	48,480
Total assets	$ 143,840	$ 188,574
Liabilities and stockholders' equity		
Current liabilities	$ 8,301	$ 8,863
Long-term liabilities	20,404	22,806
Total liabilities	28,705	31,669
Total stockholders' equity	115,135	156,905
Total liabilities and stockholders' equity	$ 143,840	$ 188,574
Common stock and common stock equivalents		
Common stock	38,183,273	32,266,814
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	40,731,390	34,814,931

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