Synlogic Reports First Quarter Financial Results and Provides Business Update

May 13, 2021

- Proof of concept studies for co-lead metabolic programs SYNB1618 in PKU and SYNB8802 in Enteric Hyperoxaluria on track for 2H 2021 readouts -

- $94.4 million in cash, cash equivalents, and short-term investments as of March 31 plus April financing of $32.6 million (net) enables runway extension to 2H 2023 -

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

CAMBRIDGE, Mass., May 13, 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 first quarter ended March 31, 2021, and provided an update on its clinical and preclinical programs.

"We are building momentum and executing on our plans to demonstrate the clinical potential of our Synthetic Biotic platform in 2021," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "With proof of mechanism established in our two lead metabolic programs and a strengthened balance sheet, we are well positioned to deliver proof of concept readouts for both SYNB1618 in Phenylketonuria (PKU) and SYNB8802 in Enteric Hyperoxaluria later this year."

Quarter Highlights

The Metabolic Portfolio:

Continued development of Synthetic Biotic™medicines for the treatment of PKU.

- Enrollment of the SynPheny-1 Phase 2 trial is on track with data expected in the second half of 2021. SynPheny-1 is designed to evaluate plasma phenylalanine (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® (sapropterin dihydrochloride) or PALYNZIQ® (pegvaliase-pqpz).

- Data on the solid oral formulation of SYNB1618 was presented at the American College of Medical Genetics meeting in April 2021.

- Continued development of SYNB1934, an evolved Synthetic Biotic medicine in the PKU portfolio, which may provide increased Phe lowering efficacy, lower dosing, or both, relative to SYNB1618. SYNB1934 is progressing through IND enabling studies.

SYNB1618 and SYNB1934 are orally administered Synthetic Biotic medicines being developed as potential treatments for PKU. They are intended to address the needs of patients of all age groups through the consumption of Phe in the gastrointestinal (GI) tract, which has the potential to lower blood Phe levels and enable the consumption of more natural protein in the diet.

Demonstration of proof of mechanism of SYNB8802, a Synthetic Biotic medicine being developed for the treatment of Enteric Hyperoxaluria.

- In an ongoing Phase 1 study, SYNB8802 demonstrated safety and urinary oxalate lowering in healthy volunteers consuming a high oxalate diet.

- Urinary oxalate lowering by SYNB8802 was dose-dependent. The 3e11 dose was chosen for further evaluation in the second part of the Phase 1 study in patients with Enteric Hyperoxaluria. This dose was well-tolerated and resulted in a 28.6% (90% CI: -42.4 to -11.6) reduction in urinary oxalate as measured by a change from baseline compared to placebo.

- The second part of the Phase 1 study is continuing with the evaluation of SYNB8802 in patients with Enteric Hyperoxaluria secondary to Roux-en-Y gastric bypass surgery. Data from the second part of the study is anticipated in the second half of 2021.

SYNB8802 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for Enteric Hyperoxaluria. Enteric Hyperoxaluria results in dangerously high urinary oxalate levels causing progressive kidney damage, kidney stone formation, and nephrocalcinosis. Enteric Hyperoxaluria has no approved treatment options. SYNB8802 is designed to consume oxalate in the GI tract to prevent the increased absorption of oxalate in patients with Enteric Hyperoxaluria.

The Immunomodulation Portfolio:

Progression of SYNB1891 in combination arm dosing with PDL1 checkpoint inhibitor in an ongoing Phase 1 clinical study in patients with advanced solid tumors or lymphoma.

- SYNB1891 is currently being evaluated in a Phase 1 study that has two parts:
    - Part A is a monotherapy arm that has enrolled six dose cohorts to date. The maximum tolerated dose has not been reached and dose escalation continues.
    - Part B is a combination arm and dosing has been completed in two cohorts to date with SYNB1891 and the PD-L1 checkpoint inhibitor atezolizumab to establish a recommended Phase 2 dose for the combination regimen.
- Data from this study was presented at the American Association of Cancer Research meeting in April 2021.

SYNB1891 is an intratumorally administered Synthetic Biotic medicine engineered to act as a dual innate and adaptive immune activator. Data from both arms of the Phase 1 study will continue to be reported over the course of 2021, with mature combination therapy data expected by the end of the year.

Corporate Update:

Synlogic strengthens Balance Sheet.

- On April 20th, subsequent to the end of the first quarter, Synlogic completed an underwritten public offering of 11.5 million shares. Net proceeds from the offering were $32.6 million, bringing Synlogic's cash balance to approximately $127 million.

Synlogic advances strategic partnerships and expands manufacturing capabilities.

- Synlogic plans to expand its manufacturing footprint by more than 50% to support continued advancement of its pipeline and late-phase development of its lead metabolic programs.
    - Synlogic will invest to expand fermentation and lyophilization capacity to support scale up efforts, enabling potential late stage development of SYNB1618 and SYNB8802.
    - Construction and build out anticipated to take place in the second half of 2021.
- 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 with multiple undisclosed metabolic programs now in preclinical stages of development.

First Quarter 2021 Financial Results

As of March 31, 2021, Synlogic had cash, cash equivalents and short-term investments of $94.4 million.

For the three months ended March 31, 2021, Synlogic reported a consolidated net loss of $15.0 million, or $0.36 per share, compared to a consolidated net loss of $15.8 million, or $0.46 per share, for the corresponding period in 2020.

Research and development expenses were $11.2 million for the three months ended March 31, 2021 compared to $12.7 million for the corresponding period in 2020.

General and administrative expenses for the three months ended March 31, 2021 were $3.9 million compared to $3.8 million for the corresponding period in 2020.

There was no revenue for the three months ended March 31, 2021 compared to $0.1 million for the corresponding period in 2020. 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.

Financial Outlook

Based upon its current operating plan, balance sheet as of March 31st, 2021 and proceeds from the recent public offering in April 2021, Synlogic expects to have sufficient cash to be able to fund the base operating plan into the second half of 2023.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, Thursday, May 13, 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 2526209. A replay will be available for 30 days on the Investors and Media section of the Synlogic website.

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; 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	
	March 31, 2021	**March 31, 2020**
Revenue	$ —	$ 100
Operating expenses		
Research and development	11,180	12,677
General and administrative	3,851	3,821
Total operating expenses	15,031	16,498
Loss from operations	(15,031)	(16,398)
Other income, net	60	570
Net loss	$ (14,971)	$ (15,828)
Net loss per share - basic and diluted	$ (0.36)	$ (0.46)
Weighted-average common shares used in computing net loss per share - basic and diluted	41,545,050	34,233,688

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)	**March 31, 2021**	**December 31, 2020**
Assets		
Cash, cash equivalents, short and long-term investments	$ 94,352	$ 100,444
Fixed assets	10,174	10,776
Other assets	31,219	32,620
Total assets	$ 135,745	$ 143,840
Liabilities and stockholders' equity		
Current liabilities	$ 6,986	$ 8,301
Long-term liabilities	$ 19,709	20,404
Total liabilities	26,695	28,705
Total stockholders' equity	$ 109,050	115,135
Total liabilities and stockholders' equity	$ 135,745	$ 143,840
Common stock and common stock equivalents		
Common stock	40,873,526	38,183,273
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	43,421,643	40,731,390

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