



Synlogic Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

March 17, 2022

- Phenylketonuria (PKU) program on track for Phase 3 trial initiation in H2 2022 –

- Clinical readouts anticipated for PKU program in H1 2022 and in homocystinuria and enteric hyperoxaluria in H2 2022 –

- \$136.6 million in cash, cash equivalents and marketable securities support projected runway into 2024 –

- Conference call and webcast at 8:30 a.m. ET today –

CAMBRIDGE, Mass., March 17, 2022 (GLOBE NEWSWIRE) -- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage biotechnology company developing medicines for metabolic and immunological diseases through its proprietary approach to synthetic biology, today reported financial results for the fourth quarter and full year ending December 31, 2021 and provided an update on pipeline programs.

"2021 was a transformational year for Synlogic highlighted by proof of concept for our lead program in phenylketonuria (PKU)," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "Despite the devastating burden of this disease, a large majority of people living with PKU remain in need of an efficacious, safe, oral medication. We look forward to sharing Phase 2 data in the first half of this year as we continue plans to initiate Phase 3 later this year. We are also excited for clinical data readouts from our homocystinuria (HCU) and enteric hyperoxaluria programs, as well as research progress including our ongoing collaborations with Ginkgo Bioworks and Roche."

Recent Portfolio Highlights

SYNB1618 and SYNB1934: In Development for the Treatment of PKU

- PKU is a rare metabolic disease that can result in irreversible cognitive and neurological damage. Approximately 75% of people with PKU remain untreated, reflecting limitations of current therapies. SYNB1618 and SYNB1934 are non-systemically absorbed, oral drug candidates being studied for both adjunctive and monotherapy treatment of PKU.
- In September 2021, Synlogic reported positive interim results from the Phase 2 SynPheny-1 study for SYNB1618, with clinically meaningful and statistically significant reduction of plasma Phe levels in patients with PKU. Based on this achieved proof of concept, the Company began preparations for Phase 3 development.
- In parallel, Synlogic added an arm to the Phase 2 Synpheny-1 study for SYNB1934, a next-generation drug candidate for PKU designed for greater potency in Phe reduction. This additional arm in Synpheny-1 followed positive results with SYNB1934 in healthy volunteer studies.
- In H1 2022, Synlogic expects to announce additional data from the Synpheny-1 study and, based on those findings, which of the two candidates will proceed to Phase 3 and potential commercialization.

SYNB1353: In Development for the Treatment of HCU

- In November 2021, Synlogic and Ginkgo Bioworks announced the nomination of SYNB1353, a drug candidate designed to consume methionine for the treatment of HCU. Like PKU, HCU is an inherited rare metabolic disease caused by an inborn error of metabolism that results in significant disease burden, including intellectual disability and thromboembolism.
- During 2022, the Company plans to submit an investigational new drug application (IND), initiate clinical trials and, in H2 2022, report Phase 1 healthy volunteer data for SYNB1353.

SYNB8802: In Development for the Treatment of Enteric Hyperoxaluria

- Enteric hyperoxaluria, a leading cause of recurrent kidney stones, is a chronic, progressive disease that can lead to chronic kidney disease (CKD) and end-stage renal disease (ESRD), and for which there is currently no FDA-approved treatment.
- Synlogic demonstrated proof of mechanism for SYNB8802 in enteric hyperoxaluria in 2021, and it is currently being evaluated in patients who have undergone Roux-en-Y gastric bypass surgery, with proof-of-concept data from this study expected in 2022.

Preclinical Pipeline

- Synlogic plans to advance research programs to address metabolic and immunologic diseases, including wholly owned programs targeting inflammatory bowel disease and hyperuricemia (gout), diseases for which the Synthetic Biotic clinical profile of orally-administered, non-systemically absorbed biotherapeutics is particularly compelling.
- The Company's research collaboration with Roche to develop a Synthetic Biotic for the treatment of inflammatory bowel

disease continues to progress.

- Synlogic and Ginkgo continue to advance their long-term strategic platform collaboration with multiple undisclosed metabolic and immunology programs now in preclinical development.

Anticipated Upcoming Milestones

Rare Metabolic Diseases

- SYNB1618 and SYNB1934 for PKU
 - Phase 2 SynPheny-1 study data H1 2022
 - Phase 3 trial initiation H2 2022
- SYNB1353 for homocystinuria (HCU)
 - Data from Phase 1 trial in healthy volunteers H2 2022

Enteric Hyperoxaluria

- SYNB8802 for enteric hyperoxaluria
 - Data from Phase 1b trial in patients with Roux-en-Y gastric bypass 2022

Corporate Updates

Earlier this month, the company announced the appointment of Michael Jensen as Chief Financial Officer. Mr. Jensen brings extensive and diversified experience within global pharmaceutical and medical device companies to Synlogic, spanning analytics, financial management, information systems, and operations. Mr. Jensen was formerly the CFO of Intrinsic Therapeutics.

Fourth Quarter 2021 Financial Results

As of December 31, 2021, Synlogic had cash, cash equivalents, and marketable securities of \$136.6 million.

Revenue was \$0.6 million for the three months ended December 31, 2021. Revenue in 2021 was associated with the ongoing research collaboration with Roche for the discovery of a novel Synthetic Biotic medicine for the treatment of IBD. There was no revenue for the three months ended December 31, 2020.

Research and development expenses were \$11.9 million for the three months ended December 31, 2021, compared to \$11.4 million for the corresponding period in 2020.

General and administrative expenses for the three months ended December 31, 2021 were \$3.9 million compared to \$3.3 million for the corresponding period in 2020.

For the three months ended December 31, 2021, Synlogic reported a consolidated net loss of \$15.1 million, or \$0.21 per share, compared to a consolidated net loss of \$14.6 million, or \$0.39 per share, for the corresponding period in 2020.

Full Year 2021 Financial Results

Revenues were \$1.8 million for the year ended December 31, 2021, compared to \$0.5 million for the same period in 2020. Revenue in 2021 was associated with the ongoing research collaboration with Roche for the discovery of a novel Synthetic Biotic medicine for the treatment of IBD. Revenue in 2020 was due to the prior collaboration with AbbVie, which was terminated in May 2020. Operating expenses were \$62.5 million for the year ended December 31, 2021, compared to \$61.0 million for the same period in 2020. For the year ended December 31, 2021, consolidated net loss was \$60.6 million, or \$1.09 per share, compared to a consolidated net loss of \$59.2 million, or \$1.65 per share, for the year ended December 31, 2020.

Financial Outlook

Based upon its current operating plan and balance sheet as of December 31, 2021, Synlogic expects to have sufficient cash to be able to fund operations into 2024.

Investor Conference Presentation

Today, Synlogic will participate in Oppenheimer's 32nd Annual Healthcare Conference. Dr. Brennan will present virtually at 10:40 am ET.

A live webcast of the presentation will be accessible under the "[Event Calendar](#)" in the Investors & Media section of the Company's website. An archived version will also be available after the presentation on the Synlogic website.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, March 17, 2022. 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 1719849. A replay will be available for 30 days on the Investors and Media section of the Synlogic website.

About Synlogic

Synlogic is a clinical-stage biotechnology company developing medicines through its proprietary approach to synthetic biology. Synlogic's pipeline includes its lead program in phenylketonuria (PKU), which has demonstrated proof of concept with plans to start a pivotal, Phase 3 study in the second half of 2022, and additional novel drug candidates designed to treat homocystinuria (HCU) and enteric hyperoxaluria. The rapid advancement of these potential biotherapeutics, called Synthetic Biotics, has been enabled by Synlogic's proprietary, reproducible, target-specific drug design. Synlogic uses

programmable, precision genetic engineering of well-characterized probiotics to exert localized activity for therapeutic benefit, with a focus on metabolic and immunologic diseases. Synlogic is also working with Roche in a research collaboration focused on the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease and with Ginkgo Bioworks to include additional undisclosed preclinical assets, combining Synlogic's approach to Synthetic Biotics with Ginkgo's Codebase and Foundry services. For additional information 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, 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," "on track," "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 approach to Synthetic Biotics to develop therapeutics to address a wide range of diseases including 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 Biotics; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; our research and other collaborations; and the expected timing of Synlogic's clinical trials of SYN1618, SYN1934, SYN1353 and SYN8802 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 Securities and Exchange Commission. 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 years ended	
	December 31		December 31	
	2021	2020	2021	2020
Revenue	\$ 592	\$ —	\$ 1,754	\$ 545
Operating expenses				
Research and development	11,873	11,407	47,127	47,474
General and administrative	3,864	3,286	15,392	13,537
Total operating expenses	15,737	14,693	62,519	61,011
Loss from operations	(15,145)	(14,693)	(60,765)	(60,466)
Other income, net	56	105	204	1,293
Net loss	\$ (15,089)	\$ (14,588)	\$ (60,561)	\$ (59,173)
Net loss per share - basic and diluted	\$ (0.21)	\$ (0.39)	\$ (1.09)	\$ (1.65)
Weighted-average common shares used in computing net loss per share - basic and diluted	71,945,538	37,792,966	55,329,711	35,835,744

Synlogic, Inc. Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share data)

	December 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents, & marketable securities	\$ 136,629	\$ 100,444
Fixed assets	9,088	10,776
Other assets	29,019	32,620
Total assets	\$ 174,736	\$ 143,840

Liabilities and stockholders' equity

Current liabilities	\$ 10,080	\$ 8,301
Long-term liabilities	17,390	20,404
Total liabilities	<u>27,470</u>	<u>28,705</u>
Total stockholders' equity	<u>147,266</u>	<u>115,135</u>
Total liabilities and stockholders' equity	\$ 174,736	\$ 143,840
Common stock and common stock equivalents		
Common stock	69,698,844	38,183,273
Common stock warrants (pre-funded)	<u>2,548,117</u>	<u>2,548,117</u>
Total common stock	72,246,961	40,731,390

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Source: Synlogic, Inc.