Synlogic Reports Fourth Quarter and Full Year 2022 Financial Results and Corporate Updates

March 29, 2023

– Phenylketonuria (PKU) program on track for Phase 3 trial initiation in first half of 2023 –

– Rare Pediatric Disease Designation granted for SYNB1934 for PKU and SYNB1353 for homocystinuria (HCU) –

- Platform presentation and two poster presentations at SIMD Annual Meeting –

– $77.6 million in cash, cash equivalents and marketable securities support projected runway into second half of 2024 –

CAMBRIDGE, Mass., March 29, 2023 (GLOBE NEWSWIRE) -- Synlogic, Inc. (Nasdaq: SYBX), the leading company advancing therapeutics based on synthetic biology, today reported financial results for the fourth quarter and full year ending December 31, 2022 and provided a business update.

“Last year was a tremendous year for Synlogic and our Synthetic Biotic platform given our three positive clinical readouts in three different diseases in the fourth quarter alone,” said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. “We are on track to initiate Synpheny-3, the pivotal Phase 3 study for SYNB1934 in PKU, our lead program, and we were thrilled to present three data presentations – including Phase 2 PKU data as a platform presentation – at the SIMD Annual Meeting.”

Fourth Quarter 2022 and Recent Highlights

- Received positive opinion on orphan designation from the European Medicines Agency (EMA) for SYNB1934 for PKU
- Presentation of data from both the Phase 2 Synpheny-1 study in PKU and the Phase 1 study with SYNB1353 for HCU at the Society for Inherited Metabolic Disorders (SIMD) 44th Annual Meeting
- Received Rare Pediatric Disease Designation (RPDD) from the U.S. Food and Drug Administration (FDA) for both:
  - SYNB1934 for PKU
  - SYNB1353 for HCU
- Announced positive top-line Phase 2 data for PKU; advancing SYNB1934 to Phase 3
- Demonstrated proof of mechanism for SYNB1353 for HCU, based on a top-line data from a Phase 1 study using a methionine meal challenge in healthy volunteers
- Proof of concept achieved with Phase 1b top-line data for SYNB8802 for enteric hyperoxaluria

Anticipated Upcoming Milestones

- Initiation of Phase 3 clinical trial of SYNB1934 for PKU in the first half of 2023
- Advancing SYNB1353 to Phase 2 study in patients with HCU
- Presentation of data from Phase 1b studies of SYNB8802, in development for enteric hyperoxaluria
- Progression of preclinical pipeline programs, including partnerships

Corporate Updates

In January 2023, the company announced the appointment of Dr. Dave Hava as Head of Research and Development. Through the integration of the company’s research and development teams, Dr. Hava oversees the advancement of clinical stage programs in addition to progressing our collaboration with Roche and select preclinical programs. Dr. Hava joined Synlogic in 2020, as Chief Scientific Officer, and continues to assume this position within the company.

Fourth Quarter 2022 Financial Results

As of December 31, 2022, Synlogic had cash, cash equivalents, and short-term marketable securities of $77.6 million.

Revenue was $0.1 million for the three months ended December 31, 2022, compared to $0.6 million for the corresponding period in 2021. Revenue in both periods was associated with the ongoing research collaboration with Roche for the discovery of a novel Synthetic Biotic medicine for the treatment of IBD.

Research and development expenses were $13.6 million for the three months ended December 31, 2022, compared to $11.9 million for the corresponding period in 2021.

General and administrative expenses for the three months ended December 31, 2022 were $3.8 million compared to $3.9 million for the corresponding period in 2021.

For the three months ended December 31, 2022, Synlogic reported a consolidated net loss of $16.7 million, or $0.24 per share, compared to a consolidated net loss of $15.1 million, or $0.21 per share, for the corresponding period in 2021.

Full Year 2022 Financial Results

Revenues were $1.2 million for the year ended December 31, 2022, compared to $1.8 million for the same period in 2021. Revenue in both periods was associated with the ongoing research collaboration with Roche for the discovery of a novel Synthetic Biotic medicine for the treatment of IBD. Operating expenses were $68.6 million for the year ended December 31, 2022, compared to $62.5 million for the same period in 2021. For the year ended December 31, 2022, consolidated net loss was $66.1 million, or $0.92 per share, compared to a consolidated net loss of $60.6 million, or $1.09 per share, for the year ended December 31, 2021.

Financial Outlook

Based upon its current operating plan and balance sheet as of December 31, 2022, Synlogic expects to have sufficient cash to be able to fund operations into the second half of 2024.

About Synlogic

Synlogic is the leading company advancing therapeutics based on 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 first half of 2023, and additional novel drug candidates designed to treat homocystinuria (HCU), enteric hyperoxaluria and gout. The rapid advancement of these potential biotherapeutics, called Synthetic Biotics, has been enabled by Synlogic's 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 immunological diseases. In addition to its clinical programs, Synlogic has a research collaboration with Roche on the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease or IBD. Synlogic has also developed two drug candidates through a research collaboration with Ginkgo Bioworks: SYNB1353, designed to consume methionine for the potential treatment of HCU, and SYNB2081, designed to lower uric acid for the potential treatment of gout. 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," "look forward," "estimate," "expect," "intend," on track," "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 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; and the expected timing of Synlogic's clinical trials of SYNB1934, SYNB1353, SYNB8802 and SYNB2081 and availability of clinical trial data. Actual results could differ materially from those contained in any forward-looking statements 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 U.S. 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.

Media Contact: media@synlogictx.com

Investor Relations: investor@synlogictx.com

Synlogic, Inc.
Condensed Consolidated Statements of Operations
(unaudited)

(in thousands,except share and per share data)

	For the three months ended December 31		For the years ended December 31	
	2022	2021	2022	2021
Revenue	$ 106	$ 592	$ 1,180	$ 1,754
Operating expenses				
Research and development	13,639	11,873	52,044	47,127
General and administrative	3,770	3,864	16,555	15,392
Total operating expenses	17,409	15,737	68,599	62,519
Loss from operations	(17,303)	(15,145)	(67,419)	(60,765)
Other income, net	607	56	1,272	204
Net loss	$ (16,696)	$ (15,089)	$ (66,147)	$ (60,561)

Net loss per share - basic and diluted	$ (0.24)	$ (0.21)	$ (0.92)	$ (1.09)
Weighted-average common shares used in computing net loss per share - basic and diluted	70,742,634	71,945,538	71,725,479	55,329,711

Synlogic, Inc.
Condensed Consolidated Balance Sheets

(in thousands, except share data)

	December 31, 2022	December 31, 2021
Assets		
Cash, cash equivalents, & marketable securities	$ 77,629	$ 136,629
Property and equipment, net	7,323	9,088
Other assets	25,913	29,019
Total assets	$ 110,865	$ 174,736
Liabilities and stockholders' equity		
Current liabilities	$ 12,122	$ 10,080
Long-term liabilities	16,133	17,390
Total liabilities	28,255	27,470
Total stockholders' equity	$ 82,610	$ 147,266
Total liabilities and stockholders' equity	$ 110,865	$ 174,736
Common stock and common stock equivalents		
Common stock	66,736,251	69,698,844
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	69,284,368	72,246,961

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Source: Synlogic, Inc.