Synlogic Reports First Quarter 2023 Financial Results and Provides Business Update

May 11, 2023

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

- Recent milestones include receipt of Rare Pediatric and Orphan Drug Designations from the FDA, and orphan designation from the EMA for SYNB1934 as a potential treatment for PKU -

CAMBRIDGE, Mass., May 11, 2023 (GLOBE NEWSWIRE) -- Synlogic, Inc. (Nasdaq: SYBX), the leading company advancing therapeutics based on synthetic biology, today reported financial results for the first quarter ended March 31, 2023, and provided an update on its pipeline programs.

“We continue to advance the SYNB1934 program towards initiation of our pivotal study, Synpheny-3, in the first half of the year, focused on our opportunity to transform the medical management of PKU,” said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. “The quarter also included recognition of Synthetic Biotics as novel biotherapeutics for rare metabolic diseases more broadly, as both our PKU and homocystinuria (HCU) programs were spotlighted at the leading medical congress for inborn errors of metabolism.”

First Quarter 2023 and Recent Business Highlights

- Received Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) from the U.S. Food and Drug Administration (FDA) for SYNB1934 for PKU
- Received positive opinion on orphan designation from the European Medicines Agency (EMA) for SYNB1934 for PKU
- Announced full data from both the Phase 2 Synpheny-1 study in PKU and the Phase 1 study in HCU at the Society for Inherited Metabolic Disorders (SIMD) 44th Annual Meeting

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
- Progression of preclinical pipeline programs, including partnerships

First Quarter 2023 Financial Results

As of March 31, 2023, Synlogic had cash, cash equivalents and short-term investments of $57.4 million.

Revenue was $0.2 million for each of the three months ended March 31, 2023 and March 31, 2022. Revenue in both periods was primarily associated with the ongoing research collaboration with Roche for the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease.

For the three months ended March 31, 2023, Synlogic reported a consolidated net loss of $15.6 million, or $0.23 per share, compared to a consolidated net loss of $15.7 million, or $0.22 per share, for the corresponding period in 2022.

Research and development expenses were $12.5 million for the three months ended March 31, 2023, compared to $11.7 million for the corresponding period in 2022.

General and administrative expenses were $4.0 million for the three months ended March 31, 2023, compared to $4.3 million for the corresponding period in 2022.

Financial Outlook

Based upon its current operating plan and balance sheet as of March 31, 2023, Synlogic expects to have sufficient cash to be able to fund operations into the second half of 2024.

Upcoming Investor and Industry Conference Participation

Synlogic leadership will attend the Jefferies Global Healthcare Conference being held June 7-9, 2023, in New York City.

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," “prepare” 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.

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

(in thousands except share and per share data)	For the three months ended March 31	
	2023	**2022**
Revenue	$ 174	$ 244
Operating expenses		
Research and development	12,450	11,738
General and administrative	3,967	4,271
Total operating expenses	16,417	16,009
Loss from operations	(16,243)	(15,765)
Other income, net	621	68
Net loss	$ (15,622)	$ (15,697)
Net loss per share - basic and diluted	$ (0.23)	$ (0.22)
Weighted-average common shares used in computing net loss per share - basic and diluted	69,070,211	71,969,007

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)	**March 31, 2023**	**December 31, 2022**
Assets		
Cash, cash equivalents, & marketable securities	$ 57,368	$ 77,629
Property and equipment, net	6,885	7,323
Other assets	29,190	25,913
Total assets	$ 93,443	$ 110,865
Liabilities and stockholders' equity		
Current liabilities	$ 9,737	$ 12,122
Long-term liabilities	14,994	16,133
Total liabilities	24,731	28,255
Total stockholders' equity	$ 68,712	$ 82,610

Total liabilities and stockholders' equity	$ 93,443	$ 110,865
Common stock and common stock equivalents		
Common stock	68,041,856	66,736,251
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	70,589,973	69,284,368

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