Synlogic Reports Third Quarter 2022 Financial Results and Provides Business Update

November 10, 2022

Top-line Phase 2 data for phenylketonuria (PKU) demonstrated robust plasma Phe reduction and high response rate; Phase 3 study initiation planned for H1 2023

Clinical readouts for SYNB1353 for homocystinuria (HCU) and SYNB8802 for enteric hyperoxaluria (EH) expected in 2022

$91.7 million in cash, cash equivalents and short-term investments support projected runway into 2024

CAMBRIDGE, Mass., Nov. 10, 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 third quarter ended September 30, 2022 and provided an update on its pipeline programs.

“We’re thrilled with the recently announced results of our Phase 2 Synpheny-1 study in phenylketonuria (PKU), which demonstrates the potential to provide a transformative treatment option for patients,” said Aoife Brennan, M.B. Ch.B, Synlogic President and Chief Executive Officer. “These data also validate our platform and approach to drug development, and we are looking forward to additional readouts from our programs for homocystinuria (HCU) and enteric hyperoxaluria (EH) later this year.”

Anticipated Upcoming Milestones

- Initiate the Phase 3 trial for SYNB1934 in PKU in H1 2023 with Phase 3 readiness activities currently underway.
- Share data from the Phase 1 trial in healthy volunteers for SYNB1353 for HCU in 2022.
- Share proof of concept data for SYNB8802 for EH in 2022.

Recent Business Highlights

- Announced positive top-line data from the Phase 2 Synpheny-1 study of SYNB1934 and SYNB1618 in PKU.
- Confirmed that SYNB1934 will progress to the Phase 3 registrational study expected to begin in H1 2023.
- Earned a research milestone for the achievement of prespecified success criteria under the research collaboration agreement with Roche for the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease (IBD).

Third Quarter 2022 Financial Results

As of September 30, 2022, Synlogic had cash, cash equivalents and short-term investments of $91.7 million.

Revenue for the three months ended September 30, 2022 was $0.7 million compared to $0.9 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 for the treatment of IBD.

For the three months ended September 30, 2022, Synlogic reported a consolidated net loss of $17.9 million, or $0.25 per share, compared to a consolidated net loss of $16.0 million, or $0.29 per share, for the corresponding period in 2021.

Research and development expenses were $14.6 million for the three months ended September 30, 2022 compared to $13.4 million for the corresponding period in 2021.

General and administrative expenses were $4.4 million for the three months ended September 30, 2022 compared to $3.6 million for the corresponding period in 2021.

Financial Outlook

Based upon its current operating plan and balance sheet as of September 30, 2022, Synlogic expects to have sufficient cash to be able to fund operations into 2024.

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 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 (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 SYNB1618, 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		For the Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Revenue	$ 678	$ 916	$ 1,074	$ 1,162
Operating expenses				
Research and development	14,610	13,355	38,405	35,254
General and administrative	4,402	3,616	12,785	11,528
Total operating expenses	19,012	16,971	51,190	46,782
Loss from operations	(18,334)	(16,055)	(50,116)	(45,620)
Other income, net	422	39	665	148
Net loss	$ (17,912)	$ (16,016)	$ (49,451)	$ (45,472)
Net loss per share - basic and diluted	$ (0.25)	$ (0.29)	$ (0.69)	$ (0.91)
Weighted-average common shares used in computing net loss per share - basic and diluted	72,108,113	55,336,936	72,061,935	49,730,231

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)	September 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents, & marketable securities	$ 91,656	$ 136,629
Property and equipment, net	7,901	9,088
Other assets	28,680	29,019
Total assets	$ 128,237	$ 174,736
Liabilities and stockholders' equity		
Current liabilities	$ 11,602	$ 10,080
Long-term liabilities	16,207	17,390
Total liabilities	27,809	27,470
Total stockholders' equity	100,428	147,266
Total liabilities and stockholders' equity	$ 128,237	$ 174,736
Common stock and common stock equivalents		
Common stock	70,285,495	69,698,844
Common stock warrants (pre-funded)	2,548,117	2,548,117

Total common stock	72,833,612	72,246,961

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