Synlogic Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 9, 2023

- Underwritten public offering of $21.0 million and earned $2.5 million milestone payment from Roche have extended cash runway into the first half of 2025 -

- Progress of the Synpheny-3 pivotal trial in phenylketonuria (PKU) supports enrollment completion in 2024, with top-line data in the first half of 2025 -

- Company received Fast Track Designation from the FDA for labafenogene marselecobac (SYNB1934) as a potential treatment for PKU -

CAMBRIDGE, Mass., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage biotechnology company advancing novel, oral, non-systemically absorbed biotherapeutics to transform the care of serious diseases, today reported financial results for the third quarter ended September 30, 2023, and provided a corporate update.

"This quarter brought us important progress on multiple fronts, including the closing of a financing which extended our cash runway into the first half of 2025," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "We are pleased with our progress in Synpheny-3, our ongoing pivotal study in PKU, which is also expected to readout in the first half of 2025, and we are grateful to our investigators and their staff at our clinical trial sites, as well as the PKU community for their continued support and partnership as we execute this landmark trial."

Recent Business Highlights

- Closing of $21.0 million underwritten public offering, extending the Company's cash runway into the first half of 2025.
- Progress with Synpheny-3, the pivotal study of labafenogene marselecobac for PKU, with operations across the United States and Canada, with additional countries expected before year-end 2023 and in early 2024.
- Receipt of Fast Track Designation from the FDA for labafenogene marselecobac for the treatment of phenylketonuria.
- Publication of Synpheny-1 Phase 2 study results for the PKU program in the journal *Nature Metabolism.*
- Presentation of Synpheny-1 Phase 2 study results by lead investigator Dr. Jerry Vockley of the University of Pittsburgh at the 37th E.S.PKU Conference 2023.
- Granting of an important US Patent (US Pat. No. 11,766,463), specifically covering the mutant PAL enzyme expressed by labafenogene marselecobac and extending the patent term exclusivity for SYNB1934 to 2041.
- Earning of $2.5 million milestone payment 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).

Anticipated Milestones for Synpheny-3 Pivotal Study in PKU

- Data safety monitoring board review of initial subset of data in the first half of 2024, potentially supporting study expansion to include 12- to 18-year-olds.
- Completion of full study enrollment in the second half of 2024.
- Release of top-line data in the first half of 2025.

Upcoming Scientific & Industry Presentations

- Caroline Kurtz, Ph.D., Chief Development Officer at Synlogic, will present *"Development of labafenogene marselecobac (SYNB1934), an engineered probiotic designed for the treatment of phenylketonuria (PKU)*," on Thursday, November 16th at the 20th Orphan Drugs & Rare Diseases Global Congress 2023 Americas, held in Boston on November 16th and 17th.
- David Lubkowicz, M.S., Head, Strain Engineering & Characterization and HCU Program Lead at Synlogic, will present *"Improvements of SYNB1353, an Engineered Bacteria for the Treatment of Homocystinuria Lead to Increased in Vitro and In Vivo Degradation of Methionine,"* at the International Conference on Microbiome Engineering 2023, held in Berkley, California on December 8th to 10th.

Third Quarter 2023 Financial Results and Financial Outlook

As of September 30, 2023, Synlogic had cash, cash equivalents and short-term investments of $33.4 million, not inclusive of the October financing of $19.6 million (net), and an additional $2.5 million earned from the Roche research collaboration milestone announced in November.

Revenue for the three months ended September 30, 2023 was $0.4 million compared to $0.7 million for the corresponding period in 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 September 30, 2023, Synlogic reported a consolidated net loss of $12.1 million, or $2.57 per share, compared to a

consolidated net loss of $17.9 million, or $3.73 per share, for the corresponding period in 2022.

Research and development expenses were $9.6 million for the three months ended September 30, 2023, compared to $14.6 million for the corresponding period in 2022.

General and administrative expenses were $3.4 million for the three months ended September 30, 2023, compared to $4.4 million for the corresponding period in 2022.

Based upon its current operating plan and inclusive of the net cash proceeds from the October financing and milestone payment from Roche, Synlogic expects to have sufficient cash to be able to fund operations further into the first half of 2025.

About Synlogic

Synlogic is a clinical-stage biotechnology company advancing novel, oral, non-systemically absorbed biotherapeutics to transform the care of serious diseases in need of new treatment options. The Company's late-stage pipeline is focused on rare metabolic diseases, led by labafenogene marselecobac (SYNB1934), currently being studied as a potential treatment for phenylketonuria (PKU) in Synpheny-3, a global, pivotal Phase 3 study. Additional product candidates address diseases including homocystinuria (HCU), enteric hyperoxaluria, gout, and cystinuria. This pipeline is fueled by the Synthetic Biotic platform, which applies precision genetic engineering to well-characterized probiotics. This enables Synlogic to create GI-restricted, oral medicines designed to consume or modify disease-specific metabolites – an approach well suited for PKU and HCU, both inborn errors of metabolism, as well as other disorders in which the disease–specific metabolites transit through the GI tract, providing validated targets for these Synthetic Biotics. Research activities include a partnership with Roche focused on inflammatory bowel disease (IBD), and a collaboration with Ginkgo Bioworks in synthetic biology, which has contributed to two pipeline programs to date. For more information, please visit www.synlogictx.com or follow us on Twitter, LinkedIn, Facebook or Instagram.

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," "focused on," "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 labafenogene marselecobac (previously known as 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 September 30		For the Nine Months Ended September 30	
	2023	2022	2023	2022
Revenue	$ 393	$ 678	$ 602	$ 1,074
Operating expenses				
Research and development	9,616	14,610	33,831	38,405
General and administrative	3,400	4,402	11,291	12,785
Total operating expenses	13,016	19,012	45,122	51,190
Loss from operations	(12,623)	(18,334)	(44,520)	(50,116)
Other income, net	548	422	1,784	665
Loss before income taxes	(12,075)	(17,912)	(42,736)	(49,451)
Income tax expense	(3)	-	(12)	-
Net loss	$ (12,078)	$ (17,912)	$ (42,748)	$ (49,451)
Net loss per share - basic and diluted	$ (2.57)	$ (3.73)	$ (9.17)	$ (10.29)
Weighted-average common shares used in computing net loss per share - basic and diluted	4,699,847	4,807,207	4,662,444	4,804,127

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)

	September 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents, & marketable securities	$ 33,415	$ 77,629
Property and equipment, net	5,949	7,323
Other assets	26,890	25,913
Total assets	$ 66,254	$ 110,865
Liabilities and stockholders' equity		
Current liabilities	$ 9,144	$ 12,122
Long-term liabilities	13,706	16,133
Total liabilities	22,850	28,255
Total stockholders' equity	43,404	82,610
Total liabilities and stockholders' equity	$ 66,254	$ 110,865
Common stock and common stock equivalents		
Common stock	4,598,297	4,449,082
Common stock warrants (pre-funded)	169,874	169,874
Total common stock	4,768,171	4,618,956

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