



Synlogic Reports Third Quarter Financial Results and Provides Business Update

November 10, 2021

- Interim analysis of Phase 2 SynPheny-1 study demonstrated proof of concept in phenylketonuria. Program to advance to Phase 3 development -

- Research milestone in inflammatory bowel disease collaboration with Roche achieved -

- \$150.1 million in cash, cash equivalents and short-term investments supports projected runway into 2024 -

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

CAMBRIDGE, Mass., Nov. 10, 2021 /PRNewswire/ -- Synlogic, Inc. ([Nasdaq: SYBX](#)), a clinical-stage company bringing the transformative potential of synthetic biology to medicine, today reported financial results for the third quarter ended September 30, 2021 and provided an update on clinical programs.

"We are very pleased to be moving our Phenylketonuria (PKU) program into late-phase clinical development with the goal of bringing forward a clinically meaningful and differentiated medicine to the PKU community. The positive interim analysis from the Phase 2 SynPheny-1 study gives us confidence as we prepare to launch a Phase 3 program in PKU in 2022," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "We continue to advance oral metabolic programs in other areas of high unmet need as well as drive our research engine forward, including achieving an important early milestone in our IBD collaboration with Roche. The Synthetic Biotic™ platform is proving to be a potent and rapid source of novel therapeutic candidates."

Recent Portfolio Highlights

Metabolic Portfolio

Phenylketonuria (PKU): Proof of concept of SYN1618 achieved in an interim analysis. Full study results of both SYN1618 and SYN1934, and advancement of Phase 3 program, expected in 2022.

- In September, the Company reported SYN1618 demonstrated proof of concept in PKU patients, with a clinically meaningful and statistically significant reduction of plasma phenylalanine (Phe) levels in an interim analysis of the Phase 2 SynPheny-1 study.
 - SYN1934, an optimized strain of SYN1618, further demonstrated a two-fold increase in biomarkers of Phe metabolism compared to SYN1618 in a head-to-head healthy volunteer study.
 - The Phase 2 SynPheny-1 study has been amended to incorporate SYN1934, with results expected in the first half of 2022.
- Synlogic is preparing to start a Phase 3 program with the preferred strain based on the SynPheny-1 study data in phenylketonuria (PKU) in 2022.
- Further data on the Synlogic PKU program will be presented at the 14th International Congress of Inborn Errors of Metabolism (ICIEM) meeting to be held in Sydney, Australia and virtually on November 21 – 24, 2021.

Enteric Hyperoxaluria: Proof of concept data of SYN8802 anticipated in 2022.

- In April, the Company reported that SYN8802 demonstrated proof of mechanism in Part A of an ongoing Phase 1 study, with robust and dose-dependent evidence of urinary oxalate lowering in healthy volunteers given a high oxalate diet.
 - Part B of the study is continuing to evaluate of SYN8802 in patients with enteric hyperoxaluria secondary to Roux-en-Y gastric bypass surgery, with data expected next year.
- Further data on SYN8802 and enteric hyperoxaluria were presented at the American Urological Association 2021 Annual Meeting and the American Society of Nephrology Kidney Week 2021, including real-world evidence demonstrating a relationship between higher urinary oxalate levels and increased incidence of chronic kidney disease.

Homocystinuria (HCU): Synlogic and Ginkgo announced that SYN1353 for the treatment of homocystinuria has been advanced into IND-enabling studies, with entry into the clinic expected in 2022.

- SYN1353 was developed using Synlogic's Synthetic Biotic platform incorporating components of Ginkgo Bioworks' codebase. Synlogic holds worldwide development and commercialization rights.
- Further data on this program will be presented at the 14th International Congress of Inborn Errors of Metabolism (ICIEM)

meeting to be held in Sydney, Australia and virtually on November 21 – 24, 2021.

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

Immunomodulation Portfolio

Achievement of preclinical milestone in research collaboration with Roche

- In June 2021, Synlogic and Roche entered into a research collaboration agreement for the discovery of a novel Synthetic Biotic medicine for the treatment of inflammatory bowel disease (IBD), addressing an undisclosed novel target in IBD.
- During the third quarter, Synlogic achieved a prespecified research milestone and earned the first milestone payment due under the terms of the collaboration.

Phase 1 study of SYNB1891 in combination with PD-L1 checkpoint inhibitor patients with advanced solid tumors or lymphoma has completed enrollment.

- Results will be presented at the Society for Immunotherapy of Cancer 2021 annual meeting to be held in Washington, D.C. and virtually on November 10 – 14, 2021.
- No further studies are planned for SYNB1891 at this time.

Corporate Updates

Synlogic strengthens balance sheet and builds leadership team

- In September, Synlogic completed an underwritten public offering of 17.3 million shares, resulting in net proceeds to Synlogic of approximately \$48.4 million.
- Synlogic appointed Molly Harper to the newly created position of Chief Business Officer. Ms. Harper will provide strategic leadership to the commercial, corporate development and business development functions, and lead the planning and commercialization of Synlogic's growing pipeline.

Third Quarter 2021 Financial Results

As of September 30, 2021, Synlogic had cash, cash equivalents, and short-term investments of \$150.1 million.

For the three months ended September 30, 2021, Synlogic reported a consolidated net loss of \$16.0 million, or \$0.29 per share, compared to a consolidated net loss of \$13.2 million, or \$0.36 per share, for the corresponding period in 2020.

Research and development expenses were \$13.4 million for the three months ended September 30, 2021 compared to \$10.5 million for the corresponding period in 2020.

General and administrative expenses for the three months ended September 30, 2021 were \$3.6 million compared to \$3.0 million for the corresponding period in 2020.

Revenue was \$0.9 million for the three months ended September 30, 2021. There was no revenue for the three months ended September 30, 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.

Financial Outlook

Based upon its current operating plan and balance sheet as of September 30, 2021 Synlogic expects to have sufficient cash to be able to fund operations into 2024.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, Wednesday, November 10, 2021. 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 5450919. A replay will be available for 30 days on the Investors and Media section of the Synlogic website.

About Synlogic

Synlogic™ is bringing the transformative potential of synthetic biology to medicine. With a premier synthetic biology platform that leverages a reproducible, modular approach to microbial engineering, Synlogic designs Synthetic Biotic medicines that target validated underlying biology to treat disease in new ways. Synlogic's proprietary pipeline includes Synthetic Biotics for the treatment of metabolic disorders including Phenylketonuria (PKU) and Enteric Hyperoxaluria. The company is also building a portfolio of partner-able assets in immunology and oncology. More information about Synlogic's programs and pipeline can be found at <https://www.synlogictx.com>.

About SYNB1618 and SYNB1934

SYNB1618 and SYNB1934 are orally administered Synthetic Biotic medicines being developed as potential treatments for phenylketonuria (PKU). They are intended to address the needs of patients of all age groups through the consumption of Phe in the gastrointestinal tract, which has the potential to lower blood Phe levels and enable the consumption of more natural protein in the diet.

About SYNB8802

SYNB8802 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for enteric hyperoxaluria. SYNB8802 is designed to consume oxalate in the GI tract to prevent the increased absorption of oxalate in enteric hyperoxaluria patients.

About SYNB1353

SYNB1353 is a novel medicine in development for the treatment of diseases of methionine metabolism including homocystinuria (HCU). SYNB1353 was developed using Synlogic's Synthetic Biotic platform incorporating components of Ginkgo Bioworks' codebase. Synlogic holds worldwide development and commercialization rights to SYNB1353.

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," "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 platform to develop therapeutics to address a wide range of diseases including: cancer, 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 Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; and the expected timing of Synlogic's clinical trials 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 nine months ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenue	\$ 916	\$ —	\$ 1,162	\$ 545
Operating expenses				
Research and development	13,355	10,481	35,254	36,067
General and administrative	3,616	2,956	11,528	10,250
Total operating expenses	16,971	13,437	46,782	46,317
Loss from operations	(16,055)	(13,437)	(45,620)	(45,772)
Other income, net	39	215	148	1,187
Net loss	\$ (16,016)	\$ (13,222)	\$ (45,472)	\$ (44,585)
Net loss per share - basic and diluted	\$ (0.29)	\$ (0.36)	\$ (0.91)	\$ (1.27)
Weighted-average common shares used in computing net loss per share - basic and diluted	55,336,936	36,297,780	49,730,231	35,174,203

Synlogic, Inc. Condensed Consolidated Balance Sheets (unaudited)

(in thousands, except share data)	September 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents, and short-term investments	\$ 150,054	\$ 100,444
Fixed assets	\$ 9,625	10,776
Other assets	\$ 30,857	32,620
Total assets	\$ 190,536	\$ 143,840
Liabilities and stockholders' equity		
Current liabilities	\$ 10,591	\$ 8,301
Long-term liabilities	\$ 18,363	20,404
Total liabilities	28,954	28,705
Total stockholders' equity	\$ 161,582	115,135
Total liabilities and stockholders' equity	\$ 190,536	\$ 143,840

Common stock and common stock equivalents		
Common stock	69,707,541	38,183,273
Common stock warrants (pre-funded)	<u>2,548,117</u>	<u>2,548,117</u>
Total common stock	72,255,658	40,731,390

 View original content: <https://www.prnewswire.com/news-releases/synlogic-reports-third-quarter-financial-results-and-provides-business-update-301420323.html>

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