Synlogic Reports Second Quarter 2023 Financial Results and Provides Business Update

August 10, 2023

Recent milestones include initiation of the pivotal Phase 3 trial, Synpheny-3, and receipt of Fast Track designation for labafenogene marselecobac as a potential treatment for PKU

CAMBRIDGE, Mass., Aug. 10, 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 second quarter ended June 30, 2023, and provided an update on its pipeline programs.

"With our pivotal Phase 3 study, Synpheny-3, now underway, we are focused on trial execution and ensuring access, inclusion and an optimal experience for the patients who participate in this landmark study of a potential breakthrough in the management of PKU," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "We were also pleased to share important regulatory milestones for the product candidate this quarter, including receipt of the FDA's Fast Track designation, reenforcing the great medical need for this investigational medicine, and the World Health Organization (WHO)'s approval of the international non-proprietary name (INN) for SYNB1934: labafenogene marselecobac."

Second Quarter 2023 and Recent Business Highlights

- Announced initiation of Synpheny-3, the global, pivotal Phase 3 study of efficacy and safety of labafenogene marselecobac (previously known as SYNB1934), as a treatment for patients with PKU (n=150)
- Received Fast Track designation from the U.S. Food and Drug Administration (FDA) for labafenogene marselecobac as a potential treatment for PKU
- WHO acceptance of the international non-proprietary name (INN) of labafenogene marselecobac for the drug candidate previously known as SYNB1934
- Presented data from multiple programs at 2023 Synthetic Biology: Engineering, Evolution & Design (SEED) conference

Second Quarter 2023 Financial Results and Financial Outlook

As of June 30, 2023, Synlogic had cash and cash equivalents of $46.3 million.

Revenue for the three months ended June 30, 2023 was $35 thousand compared to $152 thousand 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 June 30, 2023, Synlogic reported a consolidated net loss of $15.0 million, or $0.21 per share, compared to a consolidated net loss of $15.8 million, or $0.22 per share, for the corresponding period in 2022.

Research and development expenses were $11.8 million for the three months ended June 30, 2023, compared to $12.1 million for the corresponding period in 2022.

General and administrative expenses were $3.9 million for the three months ended June 30, 2023, compared to $4.1 million for the corresponding period in 2022.

Based upon its current operating plan and balance sheet as of June 30, 2023, Synlogic expects to have sufficient cash to be able to fund operations further into the second half of 2024.

Investor Conference Participation

Synlogic leadership will participate in The H.C. Wainwright Global Investment Conference, being held September 11-13, 2023 in-person in New York City. Participation will include both investor meetings and a company presentation. A live webcast of the presentation, if available, will be accessible under the "Event Calendar" in the Investors & Media section of the Synlogic website. An archived version will be available afterwards at the same location.

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 (previously known as 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)	Three Months Ended June 30		Six Months Ended June 30	
	2023	2022	2023	2022
Revenue	$ 35	$ 152	$ 209	$ 396
Operating expenses				
Research and development	11,765	12,057	24,215	23,795
General and administrative	3,924	4,112	7,891	8,383
Total operating expenses	15,689	16,169	32,106	32,178
Loss from operations	(15,654)	(16,017)	(31,897)	(31,782)
Other income, net	615	175	1,236	243
Loss before income taxes	(15,039)	(15,842)	(30,661)	(31,539)
Income tax expense	(9)	-	(9)	-
Net loss	$ (15,048)	$ (15,842)	$ (30,670)	$ (31,539)
Net loss per share - basic and diluted	$ (0.21)	$ (0.22)	$ (0.44)	$ (0.44)
Weighted-average common shares used in computing net loss per share - basic and diluted	70,219,442	72,106,224	69,651,392	72,038,460

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)	June 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents & marketable securities	$ 46,261	$ 77,629
Property and equipment, net	6,398	7,323
Other assets	26,625	25,913
Total assets	$ 79,284	$ 110,865
Liabilities and stockholders' equity		
Current liabilities	$ 9,632	$ 12,122
Long-term liabilities	14,878	16,133

Total liabilities	24,510	28,255
Total stockholders' equity	54,774	82,610
Total liabilities and stockholders' equity	$ 79,284	$ 110,865
Common stock and common stock equivalents		
Common stock	68,613,862	66,736,251
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	71,161,979	69,284,368

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