Synlogic Reports Second Quarter Financial Results and Provides Business Update

August 12, 2021

- Proof of concept studies for co-lead metabolic programs SYNB1618 in PKU and SYNB8802 in Enteric Hyperoxaluria on track for 2H 2021 readouts -

- Immunomodulation portfolio expanded via strategic research collaboration in IBD -

- Synlogic ends 2Q 2021 with $115.5 million in cash, cash equivalents and investments supporting projected runway into 2H 2023 -

- Management to host conference call and webcast at 8:30 a.m. ET today -

CAMBRIDGE, Mass., Aug. 12, 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 second quarter ended June 30, 2021, and provided an update on its clinical and preclinical programs.

"We are executing across our co-lead metabolic programs and advancing towards proof of concept readouts of our Synthetic Biotic™ medicines for the treatment of Phenylketonuria and Enteric Hyperoxaluria," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "With a next-generation strain in a Phase 1 study for the treatment of Phenylketonuria, a strategic collaboration in place to expand our IBD pipeline and an advancing pre-clinical pipeline of metabolic disease programs, we have a robust set of potential therapies that could provide meaningful benefit to patients. We look forward to communicating results and next steps over the coming months."

Quarter Highlights

The Metabolic Portfolio:

Proof of concept data of SYNB1618 for the treatment of Phenylketonuria (PKU) anticipated in second half of 2021, Phase 1 study of SYNB1934 initiated.

- The SynPheny-1 Phase 2 trial of SYNB1618 continues to progress.
  - SynPheny-1 is designed to evaluate plasma phenylalanine (Phe) lowering of a solid oral formulation of SYNB1618 in adult PKU patients who do not benefit from, or do not tolerate, existing therapies.
- In July, the Company initiated a Phase 1 study of SYNB1934, a next-generation strain designed for the treatment of PKU, to evaluate safety, tolerability and head-to-head comparison of Phe-consumption biomarkers between SYNB1934 and SYNB1618.
  - SYNB1934, an evolved strain of SYNB1618 in the PKU portfolio, has the potential to provide increased benefit to patients living with PKU.
  - Preclinical *in vivo* and *in vitro* studies demonstrated a greater than 2-fold improvement in the ability of SYNB1934 to consume and break down Phe compared to SYNB1618.
- Papers published in the journals *Nature Metabolism* and *Communications Biology* detail findings from a first-in-human study of SYNB1618 and the development of a mechanistic model to predict the function of Synthetic Biotic medicines in healthy volunteers and PKU patients.
  - Data from the first-in-human study of SYNB1618 showed dose-responsive, non-saturated increases in gastrointestinal consumption of Phe by SYNB1618.
  - These data add to the growing body of scientific research demonstrating the therapeutic potential of Synthetic Biotic medicines for the treatment of PKU.

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

Proof of concept data of SYNB8802 for the treatment of Enteric Hyperoxaluria anticipated in second half of 2021.

- SYNB8802 demonstrated proof of mechanism in Part A of an ongoing Phase 1 trial, with evidence of urinary oxalate lowering in a Dietary Hyperoxaluria model in healthy volunteers given a high oxalate diet.
  - Urinary oxalate lowering by SYNB8802 was robust and dose-dependent.
  - The 3e11 dose is undergoing evaluation in Part B of the study in patients with Enteric Hyperoxaluria.
  - This dose was well-tolerated and resulted in a 28.6% (90% CI: -42.4 to -11.6) reduction in urinary oxalate as measured by a change from baseline compared to placebo.
- Part B of the study is continuing with the evaluation of SYNB8802 in patients with Enteric Hyperoxaluria secondary to

Roux-en-Y gastric bypass surgery.
- Data on the development of SYNB8802 was presented at the Synthetic Biology: Engineering, Evolution & Design (SEED) conference in June 2021.

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.

Enteric Hyperoxaluria results in dangerously high urinary oxalate levels causing progressive kidney damage, kidney stone formation, and nephrocalcinosis. Enteric Hyperoxaluria has no approved treatment options. Approximately 100,000 patients in the US suffer from chronic and recurrent kidney stones as a result of severe Enteric Hyperoxaluria.

The Immunomodulation Portfolio:

Progression of SYNB1891 in combination arm dosing with PD-L1 checkpoint inhibitor in Phase 1 study in patients with advanced solid tumors or lymphoma.

- SYNB1891 is currently being evaluated in a Phase 1 study that has two parts: Part A is a monotherapy arm that has enrolled six dose cohorts to date. Part B is a combination arm with SYNB1891 and the PD-L1 checkpoint inhibitor atezolizumab that has enrolled two dose cohorts to date.
    - The study is ongoing. Mature combination therapy data is expected by the end of the year.

SYNB1891 is an investigational drug for the intra-tumoral treatment of solid tumors and lymphoma, composed of an engineered Synthetic Biotic strain of E. coli Nissle that produces cyclic di-AMP (CDA), a stimulator of the STING (STimulator of INterferon Genes) pathway.

Advancement of preclinical programs in Inflammatory Bowel Disease.

- In June, 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). Under the terms of the agreement, Synlogic and Roche will collaborate to develop a Synthetic Biotic medicine addressing an undisclosed novel target in IBD.
- Data on novel Synthetic Biotic approaches for the treatment of IBD was presented at Digestive Disease Week (DDW) in May 2021.

Corporate Update:

Synlogic strengthens Balance Sheet and advances synthetic biology capabilities.

- In April, Synlogic completed an underwritten public offering of 11.5 million shares, resulting in net proceeds to Synlogic of approximately $32.6 million.
- Synlogic and Ginkgo Bioworks continue to advance their long-term strategic platform collaboration that provides expanded synthetic biology capabilities to Synlogic with multiple undisclosed metabolic programs now in preclinical stages of development. Additional information on these programs will be provided over the course of the year.

Second Quarter 2021 Financial Results

As of June 30, 2021, Synlogic had cash, cash equivalents, and short-term investments of $115.5 million.

For the three months ended June 30, 2021, Synlogic reported a consolidated net loss of $14.5 million, or $0.28 per share, compared to a consolidated net loss of $15.5 million, or $0.44 per share, for the corresponding period in 2020.

Research and development expenses were $10.7 million for the three months ended June 30, 2021 compared to $12.9 million for the corresponding period in 2020.

General and administrative expenses for the three months ended June 30, 2021 were $4.1 million compared to $3.5 million for the corresponding period in 2020.

Revenue was $0.2 million for the three months ended June 30, 2021, compared to $0.4 million for the corresponding period in 2020. Revenue for the three months ended June 30, 2021 was due to the collaboration with Roche, for the discovery of a novel Synthetic Biotic medicine for treatment of inflammatory bowel disease (IBD). Under the terms of the agreement, Synlogic and Roche will collaborate to develop a Synthetic Biotic medicine addressing an undisclosed novel target in IBD. Revenue for the three months ended June 30, 2020 was due to the prior collaboration with AbbVie to develop Synthetic Biotic medicines for the treatment of inflammatory bowel disease, which was terminated in May 2020.

Financial Outlook

Based upon its current operating plan and balance sheet as of June 30, 2021 Synlogic expects to have sufficient cash to be able to fund the base operating plan into the second half of 2023.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, Thursday, August 12, 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 7586239. 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 premiere 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.

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 SEC. 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 six months ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Revenue	$ 246	$ 445	$ 246	$ 545
Operating expenses				
Research and development	10,719	12,909	21,899	25,586
General and administrative	4,061	3,473	7,912	7,294
Total operating expenses	14,780	16,382	29,811	32,880
Loss from operations	(14,534)	(15,937)	(29,565)	(32,335)
Other income, net	49	402	109	972
Net loss	$ (14,485)	$ (15,535)	$ (29,456)	$ (31,363)
Net loss per share - basic and diluted	$ (0.28)	$ (0.44)	$ (0.63)	$ (0.91)
Weighted-average common shares used in computing net loss per share - basic and diluted	52,049,424	34,967,761	46,876,216	34,604,738

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)

	June 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents, and short-term investments	$ 115,462	$ 100,444
Fixed assets	$ 9,928	10,776
Other assets	$ 31,494	32,620
Total assets	$ 156,884	$ 143,840
Liabilities and stockholders' equity		
Current liabilities	$ 9,633	$ 8,301
Long-term liabilities	$ 19,173	20,404
Total liabilities	28,806	28,705
Total stockholders' equity	$ 128,078	115,135
Total liabilities and stockholders' equity	$ 156,884	$ 143,840
Common stock and common stock equivalents		
Common stock	52,375,344	38,183,273
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	54,923,461	40,731,390

View original content:https://www.prnewswire.com/news-releases/synlogic-reports-second-quarter-financial-results-and-provides-business-update-301353948.html

SOURCE Synlogic, Inc.

Media Contact, Christen Baglaneas, Synlogic, Inc., Phone: 617-401-9152, Email: christen.baglaneas@synlogictx.com; Investor Contact, Daniel Rosan, Synlogic, Inc., Phone: 617-401-9152, Email: dan.rosan@synlogictx.com