



Synlogic Reports Third Quarter 2020 Financial Results and Provides Business Update

November 5, 2020

- Synlogic ends 3Q2020 with \$102.0 million in cash, cash equivalents and investments supporting projected runway into 2022

- Phase 2 study of SYN1618 and Phase 1 study of SYN8802 initiated -

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

CAMBRIDGE, Mass., Nov. 5, 2020 /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 Sept. 30, 2020, and provided an update on programs and progress.

"We are gaining momentum across our three clinical stage programs as we head into the end of the year," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "We are ahead of schedule in moving SYN8802—our investigational Synthetic Biotic for the treatment of Enteric Hyperoxaluria—into the clinic and initiated the Phase 2 SynPheny-1 study in PKU patients. On the corporate side, we have strengthened our leadership team with the addition of Dr. David Hava as Chief Scientific Officer. With a strong cash runway, we have the resources to execute on our key clinical milestones over the next 12 months, extending our lead as the premier platform for engineered Synthetic Biotic medicines."

"We are thrilled with the recent progress moving two programs forward in the clinic. Initiation of the Phase 2 SynPheny-1 study of SYN1618 puts us on track to see data in PKU patients around the middle of next year," said Richard Riese, M.D., Synlogic's Chief Medical Officer. "The SynPheny-1 study will provide, for the first-time, data on the ability of SYN1618 to lower blood Phe in a meaningful way for the 70% of PKU patients who are not served by existing oral therapies."

Dr. Riese further stated, "Our second metabolic program, SYN8802 for Enteric Hyperoxaluria, has the potential to improve kidney health in an area of underappreciated need. Enteric Hyperoxaluria patients have no approved therapies to control dangerously high levels of urinary oxalate. We have initiated the Phase 1 trial and are looking forward to rapidly advancing SYN8802 through clinical development."

2020 Priorities & Highlights

The Metabolic Portfolio:

- **Initiation of a Phase 2 clinical trial to evaluate SYN1618 in patients with Phenylketonuria (PKU), with data expected in the middle of 2021.** SYN1618 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for PKU.
 - Based on feedback from patients and caregivers Synlogic believes both current and emerging treatment options will continue to leave too many patients behind.
 - Synthetic Biotic medicines offer potential for a safe, tolerable, reversible and oral therapy, which controls Phe levels by consuming Phe in the GI tract.
 - Clinical sites have been activated across the United States and Synlogic expects to dose the first patient in the Phase 2 SynPheny-1 study of SYN1618 by year-end.
 - SynPheny-1 is designed to evaluate plasma Phe lowering of a solid oral formulation of SYN1618 in adult PKU patients who do not benefit from, or do not tolerate, existing therapies such as Kuvan or Palynziq.
 - In addition, the study is expected to provide valuable information to validate predictive pharmacodynamic and preclinical modeling.
- **Advancement of SYN8802 for the treatment of Enteric Hyperoxaluria.** Synlogic is developing SYN8802 to treat Enteric Hyperoxaluria.
 - SYN8802 has commenced a Phase 1 clinical study. The first healthy volunteer cohort was dosed in November 2020.
 - Synlogic presented a poster at the American Society of Nephrology's (ASN) 2020 Kidney Week Virtual Event on SYN8802, which demonstrated:
 - In both nonhuman primate and mouse models of acute Hyperoxaluria, SYN8802 significantly reduced oxalate levels.
 - Proprietary in-silico simulations of predicted human exposure suggest SYN8802 has the potential to achieve between 20% and 50% urinary oxalate lowering in patients at doses that have been well tolerated in prior trials of Synthetic Biotic medicines.

The Immunomodulation Portfolio:

- **Continuation of the monotherapy arm of the Phase 1 clinical study of SYN1891 in patients with advanced solid tumors or lymphoma.** SYN1891 is currently in Phase 1 clinical development in patients with advanced solid tumors or lymphoma.

- Enrollment in the Phase 1 trial continues per plan.
- Synlogic expects to share an update on the initial dose cohorts of the monotherapy arm of the Phase 1 clinical study before the end of the year, per plan.
- Initiation of the combination arm of the Phase 1 clinical study, with the anti-PD-1 antibody Tecentriq (atezolizumab), is expected in the first half of 2021.

Corporate Profile:

- **Synlogic strengthens Leadership Team.** Synlogic appointed Dr. David Hava, Ph.D., as Chief Scientific Officer.
 - Dr. Hava brings over a decade of senior experience in research and development to Synlogic, including deep academic expertise in pillars of synthetic biology. Dr. Hava is an experienced drug hunter who has brought multiple programs from ideation into and through the clinic and has led numerous successful partnerships. Before joining Synlogic, Dr. Hava served as CSO at Metera Pharmaceuticals. He has also served as CSO at Pulmatrix Inc., where he led the Research and Development organization in the company's development of their delivery platform. Dr. Hava earned his Ph.D. in Molecular Biology and Microbiology at Tufts University and he completed his postdoctoral training at Harvard Medical School studying immunology and host-pathogen interactions.

Third Quarter 2020 Financial Results

As of September 30, 2020, Synlogic had cash, cash equivalents and short-term investments of \$102.0 million.

For the three months ended Sept. 30, 2020, Synlogic reported a consolidated net loss of \$13.2 million or \$0.36 per share, compared to a consolidated net loss of \$13.3 million or \$0.39 per share, for the corresponding period in 2019.

Research and development expenses were \$10.5 million for the three months ended September 30, 2020 compared to \$10.6 million for the corresponding period in 2019.

General and administrative expenses for the three months ended September 30, 2020 were \$3.0 million compared to \$3.9 million for the corresponding period in 2019.

There was no revenue for the three months ending September 30, 2020 and \$0.3 million for the three months ending September 30, 2019. Revenue for the prior period was associated with Synlogic's collaboration with AbbVie to develop Synthetic Biotic medicines for the treatment of irritable bowel disease, which was terminated in May 2020.

Financial Outlook

Based upon its current operating plan, Synlogic expects to have a projected cash runway into 2022.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, Thursday, Nov. 5, 2020. 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 8557525. 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 (HOX). The company is also building a portfolio of partner-able assets in immunology and oncology.

About PKU

Phenylketonuria (PKU) is an inherited metabolic disease that manifests at birth and is marked by an inability to break down Phe, an amino acid that is commonly found in many foods. Left untreated, high levels of Phe become toxic and can lead to serious neurological and neuropsychological problems affecting the way a person thinks, feels, and acts. Due to the seriousness of these symptoms, infants are screened at birth in many countries to ensure early diagnosis and treatment to avoid intellectual disability and other complications.

About Enteric Hyperoxaluria

Enteric Hyperoxaluria (HOX) is an acquired metabolic disorder caused by increased absorption of dietary oxalate, which is present in many healthy foods, making it almost impossible to control with diet alone. Enteric Hyperoxaluria often occurs as a result of a primary insult to the bowel, such as inflammatory bowel disease, short bowel syndrome, or as a result of surgical procedures such as Roux-en-Y bariatric weight-loss surgery.

Enteric Hyperoxaluria results in dangerously high levels of urinary oxalate, which causes progressive kidney damage, kidney stone formation, and nephrocalcinosis. Enteric Hyperoxaluria has no approved treatment options.

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; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; 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 nine months ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Revenue	\$ —	\$ 305	\$ 545	\$ 993
Operating expenses				
Research and development	10,481	10,564	36,067	30,651
General and administrative	2,956	3,879	10,250	11,272
Total operating expenses	13,437	14,443	46,317	41,923
Loss from operations	(13,437)	(14,138)	(45,772)	(40,930)
Other income, net	215	853	1,187	2,355
Net loss	\$ (13,222)	\$ (13,285)	\$ (44,585)	\$ (38,575)
Net loss per share - basic and diluted	\$ (0.36)	\$ (0.39)	\$ (1.27)	\$ (1.33)
Weighted-average common shares used in computing net loss per share - basic and diluted	36,297,780	34,213,096	35,174,203	28,956,280

Synlogic, Inc.
Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share data)

	September 30, 2020	December 31, 2019
Assets		
Cash, cash equivalents, and short and long-term investments	\$ 101,966	\$ 127,073
Fixed assets	11,418	13,021
Other assets	34,968	48,480
Total assets	\$ 148,352	\$ 188,574
Liabilities and stockholders' equity		
Current liabilities	\$ 6,738	\$ 8,863
Long-term liabilities	21,117	22,806
Total liabilities	27,855	31,669
Total stockholders' equity	120,497	156,905
Total liabilities and stockholders' equity	\$ 148,352	\$ 188,574
Common stock and common stock equivalents		
Common stock	34,672,052	32,266,814
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	37,220,169	34,814,931

View original content: <http://www.prnewswire.com/news-releases/synlogic-reports-third-quarter-2020-financial-results-and-provides-business-update-301166732.html>

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