UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 4, 2020

SYNLOGIC, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-37566 (Commission File Number)

26-1824804 (IRS Employer Identification No.)

301 Binney St., Suite 402 Cambridge, MA (Address of principal executive offices)

02142 (Zip Code)

Registrant's telephone number, including area code: (617) 401-9975

Not applicable (Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SYBX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ⊠

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \boxtimes

Item 2.02 Results of Operations and Financial Condition

On November 4, 2020, Synlogic, Inc. (the "Company") announced the initiation of a Phase 1 study of SYNB8802 for the treatment of Enteric Hyperoxaluria. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On November 5, 2020, Synlogic, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2020. The full text of the press release and subsequent presentation issued in connection with the announcement is furnished as Exhibit 99.2 and 99.3, respectively, to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1, 99.2, and 99.3) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing

Item 9.01 Financial Statements and Exhibits.

(d)

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Press Release dated November 4 2020
Press Release dated November 5 2020
Presentation dated November 5 2020
Cover Page Interactive Data File (embedded within the Inline XBRL document) 99.1 99.2 99.3 104

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SYNLOGIC, INC.

Date: November 5, 2020

By: Name:

/s/ Gregg Beloff Gregg Beloff Interim Chief Financial Officer Title:

Synlogic Initiates Phase 1 Study of SYNB8802 for the Treatment of Enteric Hyperoxaluria

CAMBRIDGE, Mass., Nov. 4, 2020 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today announced it has treated the first healthy volunteer in its Phase 1 study of the investigational Synthetic Biotic medicine SYNB8802 for the treatment of Enteric Hyperoxaluria (HOX).

"We are thrilled to be moving SYNB8802 into the clinic ahead of schedule," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "Leveraging our Synthetic Biotic platform allowed us to move rapidly from candidate declaration to the initiation of the Phase 1 study in under nine months. Patients with dangerously high urinary oxalate levels today have few options, and we will move this program forward with a sense of urgency to meet their needs."

Enteric Hyperoxaluria 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. There are no approved treatment options.

SYNB8802 is an engineered non-pathogenic strain of E. coli (Nissle), using Synlogic's Synthetic Biotic platform, designed to consume oxalate in the GI tract and lower urinary oxalate levels, potentially reducing kidney damage due to Enteric Hyperoxaluria. SYNB8802 is administered orally.

Synlogic recently presented preclinical data on SYNB8802 at the American Society of Nephrology's (ASN) Kidney Week 2020. Key findings:

- SYNB8802 consumes oxalate and produces formate, a metabolite of oxalate, in vitro.
- In both nonhuman primate and mouse models of acute Hyperoxaluria, SYNB8802 significantly reduced oxalate levels at six hours relative to vehicle alone.
- Proprietary in-silico simulations of predicted human exposure suggest SYNB8802 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 Phase 1 clinical study will provide for a rapid proof of concept read out by focusing on both an initial healthy volunteer cohort as well as a cohort of patients with Enteric Hyperoxaluria after Roux-n-Y gastric bypass surgery," said Richard Riese, M.D., Synlogic's Chief Medical Officer. "This post-gastric bypass population provides an optimal cohort to assess the ability of SYNB8802 to lower urinary oxalate. We look forward to providing further updates as the study progresses."

The Phase 1 clinical study has two parts: Part A is a multiple ascending dose study in healthy volunteers; Part B is a placebo controlled, cross-over design study in patients with Enteric Hyperoxaluria following Roux-n-Y gastric bypass surgery. SYNB8802 will be assessed for safety and tolerability, and the potential to reduce urinary oxalate. Synlogic anticipates data from the study will be available in 2021.

Learn more about Synlogic's programs and pipeline by visiting https://www.synlogictx.com/.

About Synlogic

SynlogicTM 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

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," "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, and inflammatory and immune disorders; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop nove 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 state

CONTACT: Media Contact: Betsy Yates, MacDougall, 912-695-7081, synlogic@macbiocom.com | Investor Contact: Daniel Rosan, Synlogic, Inc., 617-207-5509, dan.rosan@synlogictx.com

Synlogic Reports Third Quarter 2020 Financial Results and Provides Business Update

- Synlogic ends 3Q2020 with \$102.0 million in cash, cash equivalents and investments supporting projected runway into 2022 -
- Phase 2 study of SYNB1618 and Phase 1 study of SYNB8802 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 SYNB8802—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 SYNB1618 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 SYNB1618 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, SYNB8802 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 SYNB8802 through clinical development."

2020 Priorities & Highlights

The Metabolic Portfolio:

- Initiation of a Phase 2 clinical trial to evaluate SYNB1618 in patients with Phenylketonuria (PKU), with data expected in the middle of 2021. SYNB1618 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for PKU.
 - o Based on feedback from patients and caregivers Synlogic believes both current and emerging treatment options will continue to leave too many patients behind.
 - o 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 SYNB1618 by year-end.
 - SynPheny-1 is designed to evaluate plasma Phe lowering of a solid oral formulation of SYNB1618 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 SYNB8802 for the treatment of Enteric Hyperoxaluria. Synlogic is developing SYNB8802 to treat Enteric Hyperoxaluria.
 - SYNB8802 has commenced a Phase 1 clinical study. The first healthy volunteer cohort was dosed in November 2020.
 - o Synlogic presented a poster at the American Society of Nephrology's (ASN) 2020 Kidney Week Virtual Event on SYNB8802, which demonstrated:
 - In both nonhuman primate and mouse models of acute Hyperoxaluria, SYNB8802 significantly reduced oxalate levels.
 - Proprietary in-silico simulations of predicted human exposure suggest SYNB8802 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 SYNB1891 in patients with advanced solid tumors or lymphoma. SYNB1891 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

SynlogicTM 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.

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Synlogic, Inc. Condensed Consolidated Statements of Operations

	For the three months ended			For the nine months ended			
September 30, 2020		September 30, 2019		September 30, 2020		September 30, 2019	
\$	_	\$	305	\$	545	\$	993
	10,481		10,564		36,067		30,651
	2,956		3,879		10,250		11,272
	13,437		14,443		46,317		41,923
	(13,437)		(14,138)		(45,772)		(40,930)
	215		853		1,187		2,355
\$	(13,222)	\$	(13,285)	\$	(44,585)	\$	(38,575)
\$	(0.36)	\$	(0.39)	\$	(1.27)	\$	(1.33)
	36,297,780		34,213,096		35,174,203		28,956,280
	\$	\$ 10,481 2,956 13,437 (13,437) 215 \$ (13,222) \$ (0.36)	September 30, 2020 Septem \$ — \$ 10,481 2,956	September 30, 2020 September 30, 2019 \$ 305 10,481 10,564 2,956 3,879 13,437 14,443 (13,437) (14,138) 215 853 \$ (13,222) \$ \$ (0.36) \$ \$ (0.39)	For the three months ended September 30, 2020 September 30, 2019 September 30, 2019	For the three months ended For the nine of September 30, 2020 September 30, 2020 September 30, 2020 \$ \$ \$ 305 \$ \$ \$ 36,067 2,956 3,879 10,250 13,437 14,433 46,317 (13,437) (14,138) (45,772) 215 853 1,187 \$ (13,222) \$ (13,285) \$ (44,585)	September 30, 2020 September 30, 2019 September 30, 2020 Septemb

Synlogic, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share data)				
	Septem	ber 30, 2020	Decem	nber 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

CONTACT: Media Contact: Caroline Rufo, Ph.D., MacDougall, Phone: 781-235-3060, Email: crufo@macbiocom.com; Investor Contact: Daniel Rosan, Synlogic, Inc., Phone: 617-207-5509, Email: dan.rosan@synlogictx.com



Forward Looking Statements

This presentation 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 presentation regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forwardlooking statements. In addition, when or if used in this presentation, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, the approach we are taking to discover and develop novel therapeutics using synthetic biology; statements regarding the potential of our platform to develop therapeutics to address a wide range of diseases, including: metabolic diseases, inflammatory and immune disorders, and cancer; the future clinical development of Synthetic Biotic medicines; the potential of our technology to treat phenylketonuria and cancer; the expected timing of our anticipated clinical trial initiations and availability of clinical data; the benefit of orphan drug and fast track status; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials; the results of our collaborations; and the difficulty in predicting the time and cost of development of our product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the uncertainties inherent in the preclinical development process; our ability to protect our intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in our filings with the SEC. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in our quarterly report on Form 10-Q filed with the SEC on May 8, 2020, and in any subsequent filings we make with the SEC. The forward-looking statements contained in this presentation reflect our current views with respect to future events. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our view as of any date subsequent to the date hereof.



Opening Remarks

Dr. Aoife Brennan MB CHB

President & CEO

synlogic



3rd Quarter Highlights: Execution Across the Portfolio

Metabolic Programs

Rapidly progressed metabolic programs

- SYNB1618 in PKU Phase 2
 SynPheny-1 study initiated
- IND for SYNB8802 in Enteric
 Hyperoxaluria opened and Phase
 1 study initiated

Immunomodulation

Immunomodulation in immunology and oncology

 SYNB1891 monotherapy continues to enroll: study update expected late 2020

Advanced exploratory work in IBD

We are the premier Synthetic Biology platform engineering bacterial Synthetic Biotic medicines



Synlogic Entering Data Rich Period In The Clinic



Significant Clinical Readouts Within Our Current Cash Window

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3rd Quarter 2020 Summary Results

Balance Sheet (unaudited)

Cash, Cash Equivalents, and Short & Long Term Marketable Securities

30 Sept 2020	30 June 2020
\$102.0 M	\$109.1M

Statement of Operations (unaudited)
R&D Expenses
G&A Expenses
Net Loss
Net loss per share – basic and diluted*
Weighted Average Shares Outstanding *

Three Months Ended				
30 Sept 2020	30 Sept 2019			
\$10.5 M	\$10.6 M			
\$3.0 M	\$3.9 M			
\$(13.2 M)	\$(13.3M)			
\$(0.36)	\$(0.39)			
36.3 M	34.2 M			

Strong Cash Position With Runway Into 2022

 ${\sf SYNIOGIC} \quad * \ {\sf weighted} \ {\sf average} \ {\sf shares} \ {\sf used} \ {\sf in} \ {\sf computing} \ {\sf net} \ {\sf loss} \ {\sf per} \ {\sf shares} \ {\sf -basic} \ {\sf and} \ {\sf diluted}$



Progress in Metabolic Programs

Dr. Richard Riese, MD, PhD Chief Medical Officer



Phenylketonuria (PKU)

Emerging treatment options will continue to leave many patients behind

SYNB1618 demonstrates potential to lower Phe in PKU patients

Phase 2 Phe-lowering trial initiated



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Synlogic's Approach to Phenylketonuria (PKU)





Synthetic Biotic Mechanism of Action

Consume Phe in the GI Tract



Reduce Phe in the blood

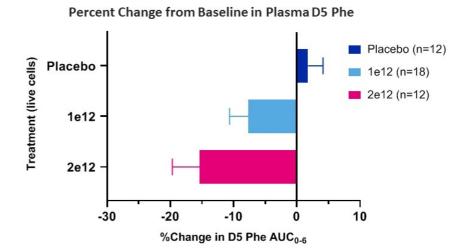


SYNB1618 was able to consume Phe in healthy volunteers Synlogic has initiated a Phase 2 Study in PKU patients (SynPheny-1)



SYNB1618 in the Clinic: Solid Oral HV Data Demonstrates Phe Lowering

- D5-labeled Phe and biomarkers of strain activity measured at baseline and after treatment
- Finding: SYNB1618 consumes
 Phe in the GI tract based on
 biomarkers in a dose
 dependent manner

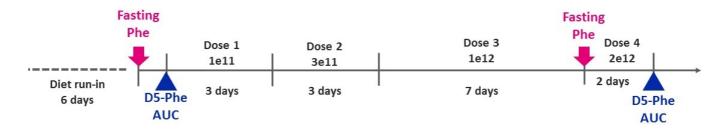


SYNB1618 Mechanism Confirmed: Accessed D5-Phe Tracer in Gut & Lowered Plasma D5-Phe

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SynPheny-1 Phase 2 Proof of Concept Study in PKU





- Demonstrate Phe Lowering in PKU Patients
 - Plasma Phe lowering in fasted state at 1 x 10¹² live cells over 7 days
 - Post meal D5-Phe AUC lowering at 2 x 10¹² live cells (not impacted by diet)
- Validate PD Model
 - · Understand relationship of strain specific biomarkers with plasma Phe lowering
- Safety and Tolerability

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Patient-Centered Clinical Trial Design & Execution





Directly informed by patient feedback on executing trials in the COVID era



Flexible design allowing home-based or office-based visits



 $Rigorous\ \&\ personalized\ diet\ control\ to\ ensure\ consistent\ Phe\ intake, including\ 6-day\ run-in$



Dose ramp to improve tolerability & compliance



Enteric Hyperoxaluria

Enteric Hyperoxaluria results in significant kidney damage with no available treatment options

SYNB8802 has the potential to meaningfully lower urinary oxalate levels

SYNB8802 Phase 1 clinical study initiated ahead of schedule



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Synlogic's Approach to Enteric Hyperoxaluria

Dietary Sources of Oxalate



Synthetic Biotic Mechanism of Action

Consume Oxalate in the GI Tract



Reduce Oxalate in the urine

Enteric Hyperoxaluria Program Status

SYNB8802 was able to consume oxalate in multiple animal models

Synlogic has initiated a Phase 1 Study in healthy volunteers

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Enteric Hyperoxaluria: Phase 1 Design Provides PoC Opportunity

Phase 1a Healthy Volunteers

Phase 1b Enteric Hyperoxaluria Patients

Multiple Ascending Dose

- High oxalate & low calcium diet run-in
- Primary: Safety & tolerability
- Secondary: Microbial kinetics of strain
- Exploratory: Change in plasma and urine biomarkers

Cross-over

- TID dosing
- N = 20 patients (Roux-en Y gastric bypass)
- UOx >70 mg/day

Roux-en-y gastric bypass population provides opportunity to demonstrate urinary oxalate lowering in disease state

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Concluding Remarks

Dr. Aoife Brennan MD CHB

President & CEO

synlogic



Available For Questions



Aoife Brennan, MD CHB President & CEO



Richard Riese, MD PhD CMO



David Hava, PhD CSO



Antoine Awad, COO



Gregg Beloff, JD MBA Interim CFO

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