

**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 10, 2021

SYNOLOGIC, 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.

Item 2.02 Results of Operations and Financial Condition

On November 10, 2021, Synlogic, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2021. The full text of the press release and the subsequent presentation issued in connection with the announcement is furnished as Exhibit 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 and 99.2) 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) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 10, 2021.
99.2	Presentation dated November 10, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: November 10, 2021

Synlogic, Inc.

By: /s/ Gregg Beloff

Name: Gregg Beloff

Title: Interim Chief Financial Officer



Synlogic Reports Third Quarter Financial Results and Provides Business Update

- 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. (PR Newswire) November 10, 2021 – 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 SYNBI891 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 SYNBI891 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 SYN1618 and SYN1934

SYN1618 and SYN1934 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 SYN8802

SYN8802 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for enteric hyperoxaluria. SYN8802 is designed to consume oxalate in the GI tract to prevent the increased absorption of oxalate in enteric hyperoxaluria patients.

About SYN1353

SYN1353 is a novel medicine in development for the treatment of diseases of methionine metabolism including homocystinuria (HCU). SYN1353 was developed using Synlogic's Synthetic Biotic platform incorporating components of Ginkgo Bioworks' codebase. Synlogic holds worldwide development and commercialization rights to SYN1353.

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.

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MEDIA CONTACT:
 Bill Berry
 Berry & Company Public Relations
 Phone: 212-253-8881
 Email: bberry@berrypr.com

INVESTOR CONTACT:
 Daniel Rosan
 Synlogic, Inc.
 Phone: 617-401-9152
 Email: dan.rosan@synlogictx.com

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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)	<u>September 30, 2021</u>	<u>December 31, 2020</u>
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)	2,548,117	2,548,117
Total common stock	72,255,658	40,731,390

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Exhibit 99.

Bringing the Transformative Power of Synthetic Biology to Medicine

Q3 Financial Results & Business Update
10 November 2021



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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 forward-looking 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 November 10, 2021, 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



Multiple high value indications accessible with Synthetic Biotic Medicines

Metabolic programs

Phenylketonuria (PKU)

SYNB1618 strain achieved prespecified 20% Phe lowering target in PKU patients in interim analysis

SYNB1934 strain demonstrated two-fold greater activity than SYNB1618 in healthy volunteers

Other Inborn Errors of Metabolism

SYNB1353 progressing to IND-enabling studies for treatment of homocystinuria

Enteric Hyperoxaluria

SYNB8802 achieved proof of mechanism in Phase 1A in dietary hyperoxaluria induced in healthy volunteers

Dose dependent consumption of oxalate in the GI tract shown

Phase 1B patient data expected 2022 in patients with enteric hyperoxaluria

Immunology

Solid Tumors

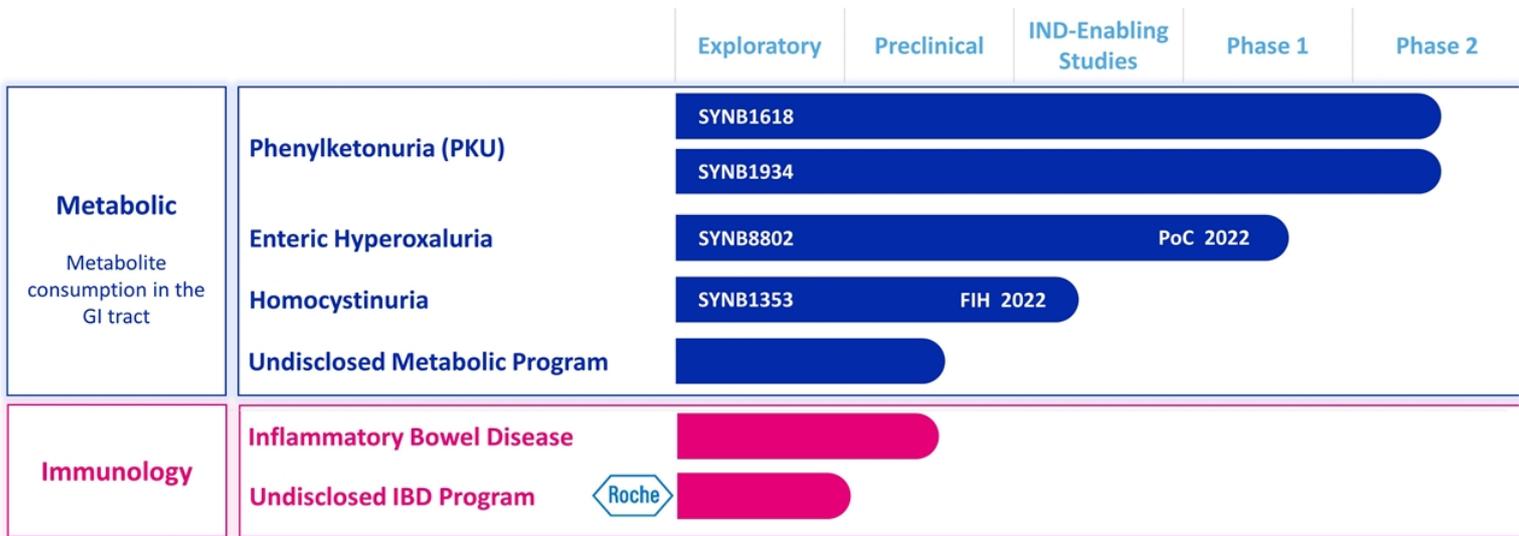
SYNB1891 combination study with PD-1 has completed enrollment. No further studies planned at this time

Inflammatory Bowel Disease

Advancing research collaboration with Roche on novel IBD target; achieved first milestone

Clinical benefit of the Synthetic Biotic platform demonstrated

Robust pipeline moving forward



Progress against our strategy

PKU	Demonstrated plasma Phe lowering in patients with classical PKU	
PKU	Demonstrated higher potency of next generation strain in humans	
HOX	Progressed Phase 1B study	
IBD	Achieved first Roche research collaboration milestone	
Other Metabolic	Advanced third oral metabolic program, SYN1353 for the treatment of HCU, into IND-enabling studies	

Synthetic Biotic Medicines: Differentiated Potential in PKU

Molly Harper
Chief Business Officer

synlogic



PKU: Significant Disease Burden, Need for New Treatment Options



➤ Inherited defects in PAH enzyme impairs ability to metabolize Phe

➤ Phe build-up can cause irreversible neurological damage and neurocognitive defects

➤ Neurocognitive risk remains:

- 8X risk for intellectual disabilities¹
- 70% had significant neuropsych comorbidity (50% had multiple)²

➤ >70% of adults with PKU are not actively treated by metabolic clinics³

¹ Bilder et al. 2017; ² Levy et al. 2020 ³ Berry et al. 2013

Current options leave behind the majority that live with PKU



sapropterin

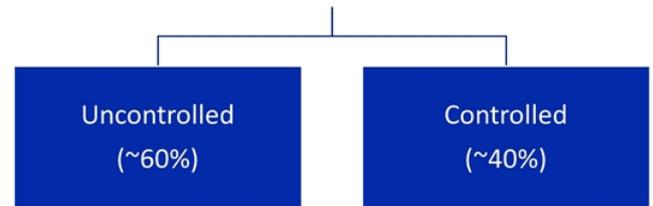
- 30% response rate¹
- 10% mean fasting Phe reduction for all-comers²
- Adult daily pill burden can exceed 10 tablets³



pegvaliase-pqpz

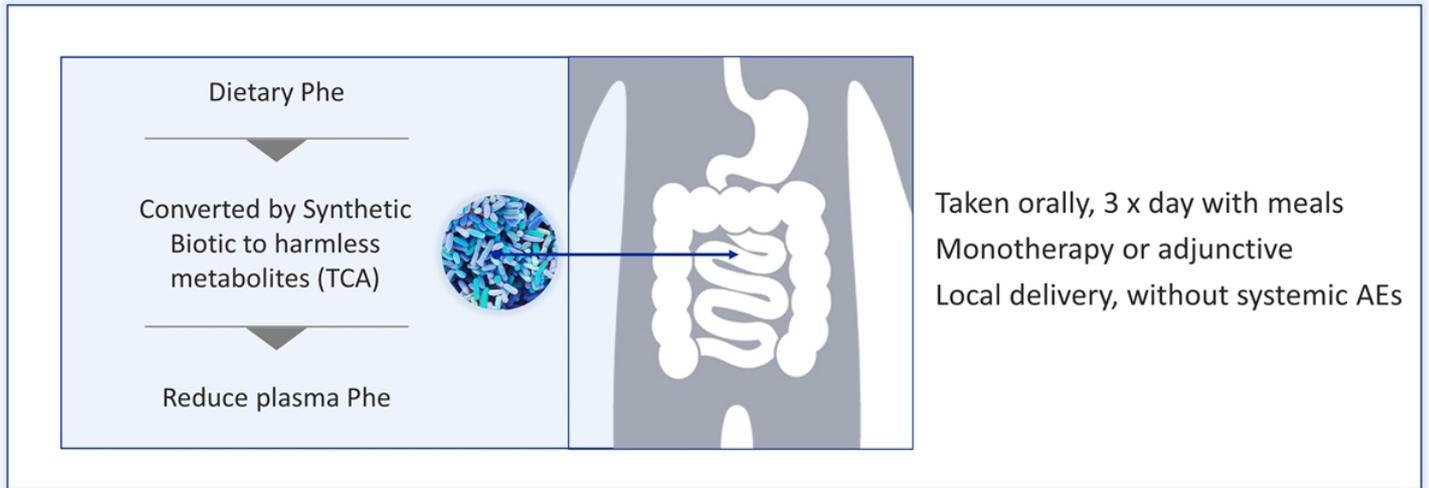
- Self-injection, daily
- 6-12 month titration
- Boxed warning: anaphylaxis “at any time during treatment”
- Restricted REMS
- Only approved for adults⁴

US PKU Population:
~17,000⁵



90% of patients and caregivers express need for greater natural protein intake⁽⁶⁾

Synthetic Biotic™ Medicines are designed for PKU

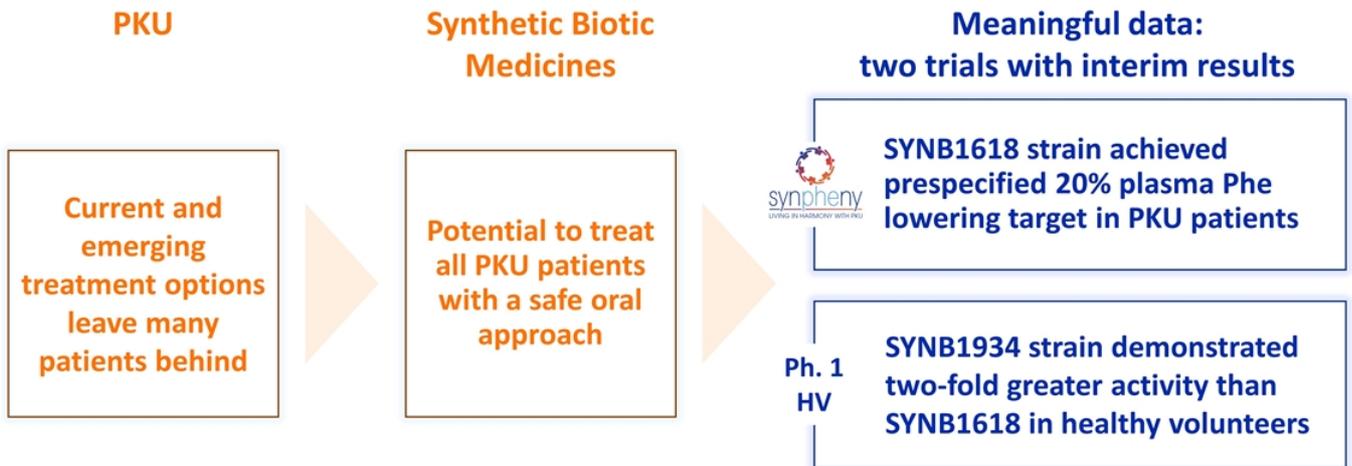


Interim Analysis of SYN1618 SynPheny-1 Phase 2 Study in PKU

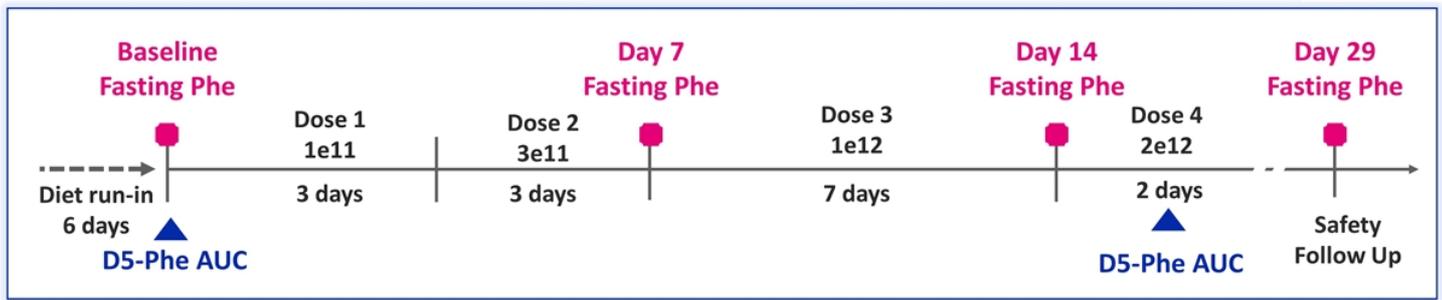


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Synthetic Biotic Medicines: a novel approach in Phenylketonuria (PKU)



SYNB1618 Phase 2 SynPheny-1 study in PKU: Design



Population

- IA of 8 subjects receiving SYNB1618
- Adult PKU patients, plasma Phe levels $\geq 600 \mu\text{mol/L}$
- Stable diet
- No use of Kuvan or Palynziq in SYNB1618 arm

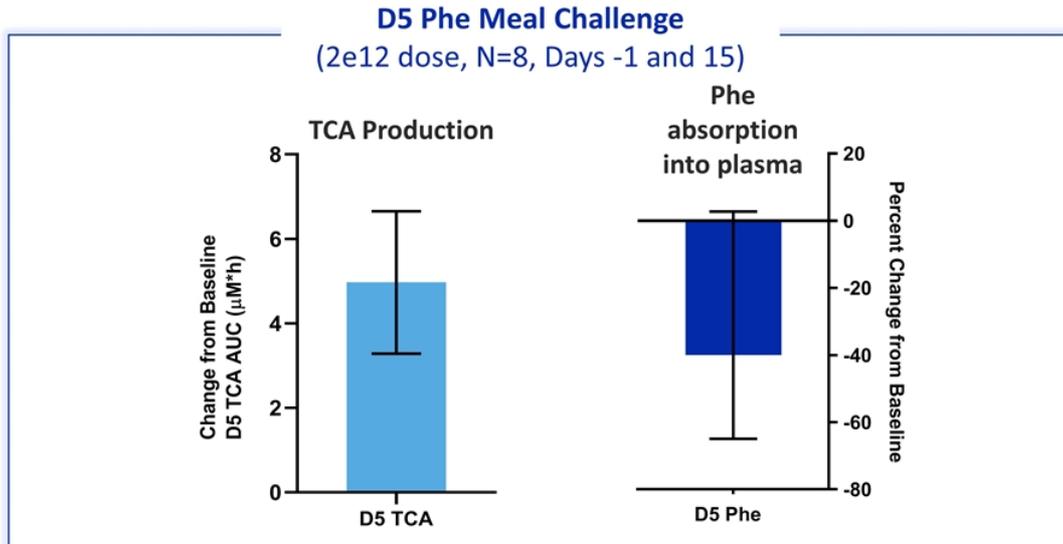
Endpoints

- Fasting Plasma Phe levels (day -1, 7, 14, 29)
- ▲ Labelled D5-Phe 24hr AUC, change from baseline after meal challenge (day -1, 15)

Diet Control

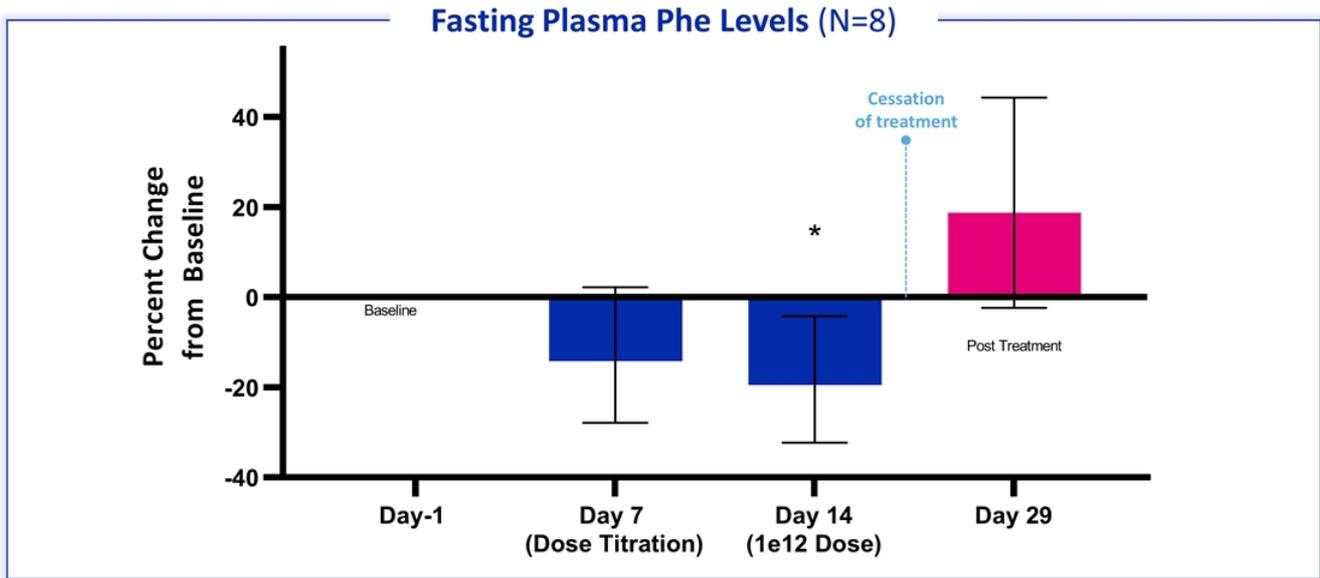
- 6-day diet run in
- Individualized diet plan to match baseline Phe intake
- Stable study diet: diet run-in through 2 weeks post treatment

SYNB1618 metabolized Phe into TCA and prevented Phe absorption after meal challenge



4 of 8 patients experienced >40% D5-Phe lowering after meal challenge

SYNB1618 reduced fasting plasma Phe levels

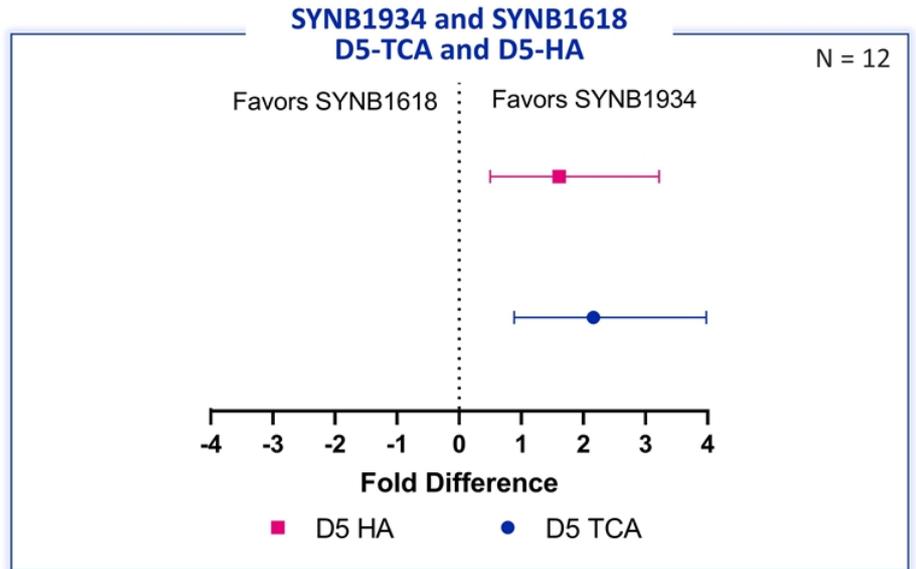


4 of 8 patients experienced >30% reduction in fasting Plasma Phe at Day 7 or Day 14

SYNB1934 demonstrated two-fold improvement over SYNB1618 in biomarkers of Phe metabolism

SYNB1934

- Developed from SYNB1618 using directed evolution
- Evaluated in a head-to-head study in healthy volunteers
- Potential for increased Phe lowering and flexibility to optimize clinical profile
- Moving into a new arm of the Phase 2 SynPheny study



SYNB1934 to be evaluated in new arm of SynPheny-1 study



Healthy volunteers

PKU Patients

SYNB1618
1e12 dose

7%

D5-Phe reduction post-meal

20%

Fasting plasma Phe

SYNB1934
1e12 dose

27%

D5-Phe reduction post-meal

*Expectation of improved
clinical profile*

Enteric Hyperoxaluria (HOX)

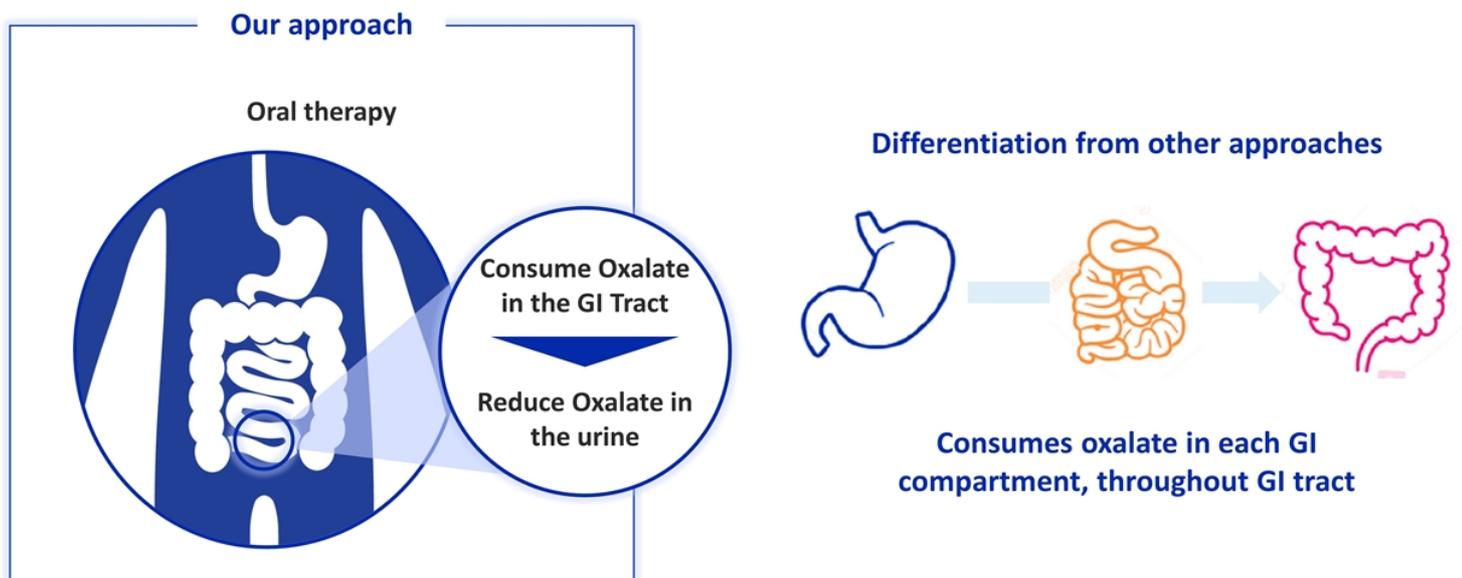
Enteric Hyperoxaluria results in significant, irreversible, and progressive kidney damage

SYNB8802 proof of mechanism established: potential for best-in-class urinary oxalate lowering

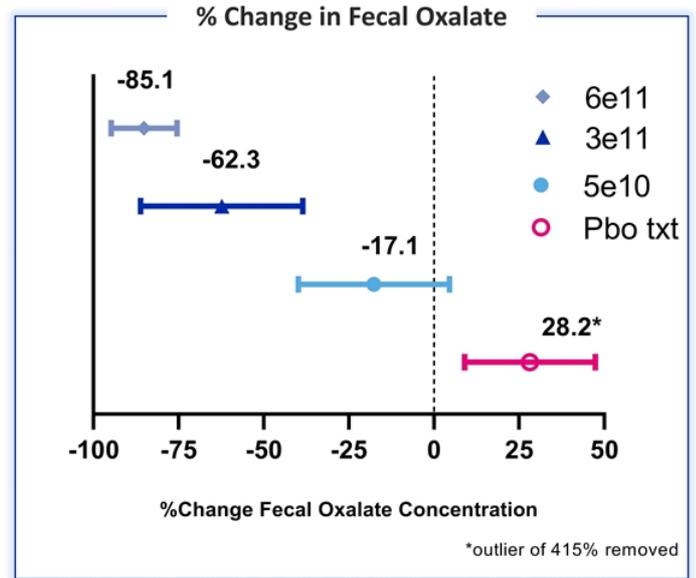
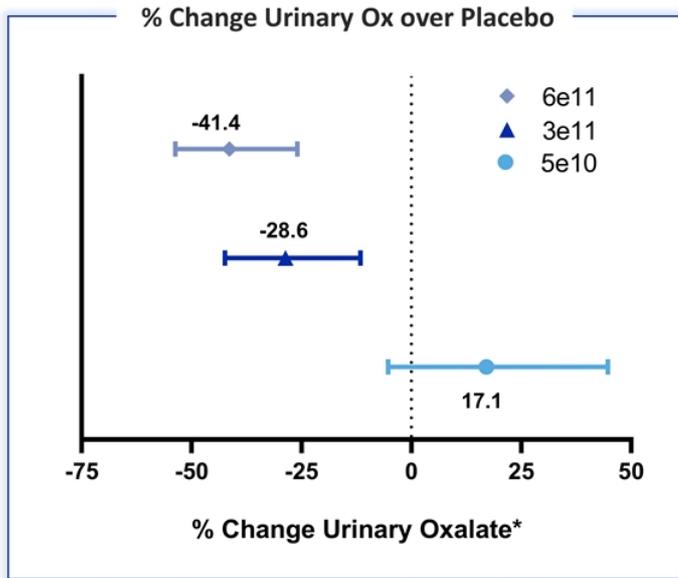
Proof of concept data expected 2022



An innovative approach in an area of high unmet medical need



Ph 1B Proof of Concept in Enteric Hyperoxaluria patients (Roux-en-Y population) initiated

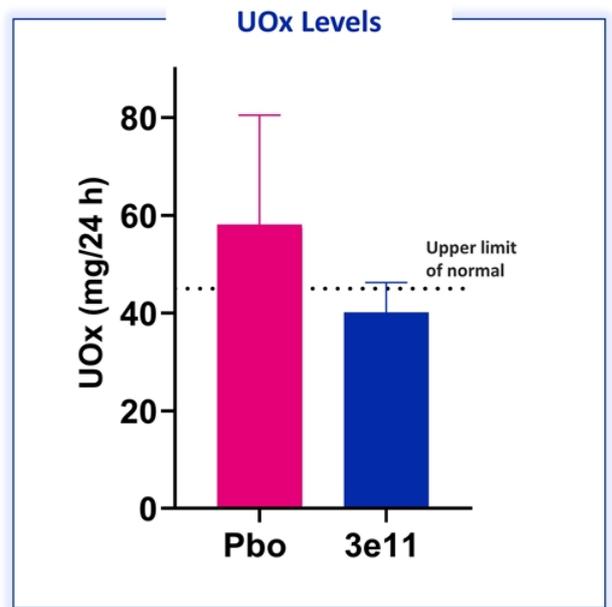
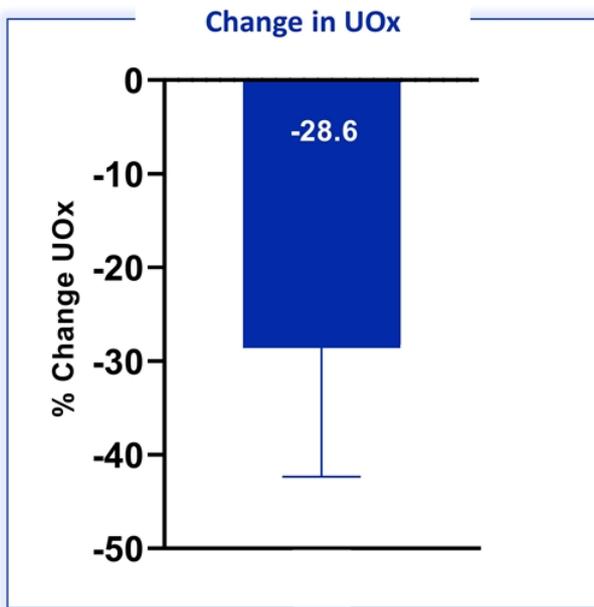


Consistent evidence of oxalate consumption across endpoints in dietary hyperoxaluria in healthy volunteers



* LS mean change over Placebo, +/- 90% CI, all days baseline and treated

SYNB8802 3e11 live cells dose advancing to Ph1B in patients



Clinically meaningful lowering of urinary oxalate demonstrated at a well tolerated dose

Third Quarter, 2021

Summary Results

Balance Sheet (unaudited)

Cash, Cash Equivalents, and Marketable Securities

30 September 2021

\$150.1 M

31 December 2020

\$100.4 M

Statement of Operations (unaudited)

R&D Expenses

\$13.4 M

\$10.5 M

G&A Expenses

\$3.6 M

\$3.0 M

Net Loss

\$16.0 M

\$13.2 M

Net loss per share – basic and diluted*

\$0.29

\$0.36

*Weighted Average Shares Outstanding**

55.3 M

36.3 M

Concluding Remarks

Dr. Aoife Brennan
MD CHB

President & CEO

synlogic



Synlogic continues to deliver meaningful data

		2021	H1 2022	H2 2022
PKU	Ph2 SynPheny proof of concept read-out	SYNB1618 Delivered	SYNB1934	
	SYNB1934 Head to Head data in HV	SYNB1934 Delivered		
	Start of pivotal program			SYNB1618 or SYNB1934
Enteric Hyperoxaluria	Ph1A study in HV read-out	SYNB8802 Delivered		
	Ph1B proof of concept read-out		SYNB8802	
Homocystinuria	Ph1 initiation			SYNB1353

Robust portfolio with significant milestones over the next 18 months

Available For Questions



Aoife Brennan, MB ChB
President & CEO



Molly Harper
Chief Business Officer



Dave Hava, PhD
Chief Scientific Officer



Antoine Awad
Chief Operating Officer



Daniel Rosan
Head of Finance & Investor
Relations



Caroline Kurtz, PhD
Chief Development
Officer



Gregg Beloff, JD MBA
Interim CFO