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): March 17, 2022

SYNLOGIC, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37566**	**26-1824804**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

301 Binney St., Suite 402 **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(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 March 17, 2022, Synlogic, Inc. (the "Company") announced its financial results for the quarter and full year ended December 31, 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 March 17, 2022.
99.2	Presentation dated March 17, 2022.
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: March 17, 2022

Synlogic, Inc.

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

Synlogic Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

- Phenylketonuria (PKU) program on track for Phase 3 trial initiation in H2 2022 –

- Clinical readouts anticipated for PKU program in H1 2022 and in homocystinuria and enteric hyperoxaluria in H2 2022 –

- $136.6 million in cash, cash equivalents and marketable securities support projected runway into 2024 –

- Conference call and webcast at 8:30 a.m. ET today –

Cambridge, Mass. March 17, 2022 – Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage biotechnology company developing medicines for metabolic and immunological diseases through its proprietary approach to synthetic biology, today reported financial results for the fourth quarter and full year ending December 31, 2021 and provided an update on pipeline programs.

"2021 was a transformational year for Synlogic highlighted by proof of concept for our lead program in phenylketonuria (PKU)," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "Despite the devastating burden of this disease, a large majority of people living with PKU remain in need of an efficacious, safe, oral medication. We look forward to sharing Phase 2 data in the first half of this year as we continue plans to initiate Phase 3 later this year. We are also excited for clinical data readouts from our homocystinuria (HCU) and enteric hyperoxaluria programs, as well as research progress including our ongoing collaborations with Ginkgo Bioworks and Roche."

Recent Portfolio Highlights

SYNB1618 and SYNB1934: In Development for the Treatment of PKU

- PKU is a rare metabolic disease that can result in irreversible cognitive and neurological damage. Approximately 75% of people with PKU remain untreated, reflecting limitations of current therapies. SYNB1618 and SYNB1934 are non-systemically absorbed, oral drug candidates being studied for both adjunctive and monotherapy treatment of PKU.
- In September 2021, Synlogic reported positive interim results from the Phase 2 SynPheny-1 study for SYNB1618, with clinically meaningful and statistically significant reduction of plasma Phe levels in patients with PKU. Based on this achieved proof of concept, the Company began preparations for Phase 3 development.

- In parallel, Synlogic added an arm to the Phase 2 Synpheny-1 study for SYNB1934, a next-generation drug candidate for PKU designed for greater potency in Phe reduction. This additional arm in Synpheny-1 followed positive results with SYNB1934 in healthy volunteer studies.
- In H1 2022, Synlogic expects to announce additional data from the Synpheny-1 study and, based on those findings, which of the two candidates will proceed to Phase 3 and potential commercialization.

SYNB1353: In Development for the Treatment of HCU

- In November 2021, Synlogic and Ginkgo Bioworks announced the nomination of SYNB1353, a drug candidate designed to consume methionine for the treatment of HCU. Like PKU, HCU is an inherited rare metabolic disease caused by an inborn error of metabolism that results in significant disease burden, including intellectual disability and thromboembolism.
- During 2022, the Company plans to submit an investigational new drug application (IND), initiate clinical trials and, in H2 2022, report Phase 1 healthy volunteer data for SYNB1353.

SYNB8802: In Development for the Treatment of Enteric Hyperoxaluria

- Enteric hyperoxaluria, a leading cause of recurrent kidney stones, is a chronic, progressive disease that can lead to chronic kidney disease (CKD) and end-stage renal disease (ESRD), and for which there is currently no FDA-approved treatment.
- Synlogic demonstrated proof of mechanism for SYNB8802 in enteric hyperoxaluria in 2021, and it is currently being evaluated in patients who have undergone Roux-en-Y gastric bypass surgery, with proof-of-concept data from this study expected in 2022.

Preclinical Pipeline

- Synlogic plans to advance research programs to address metabolic and immunologic diseases, including wholly owned programs targeting inflammatory bowel disease and hyperuricemia (gout), diseases for which the Synthetic Biotic clinical profile of orally-administered, non-systemically absorbed biotherapeutics is particularly compelling.
- The Company's research collaboration with Roche to develop a Synthetic Biotic for the treatment of inflammatory bowel disease continues to progress.

- Synlogic and Ginkgo continue to advance their long-term strategic platform collaboration with multiple undisclosed metabolic and immunology programs now in preclinical development.

Anticipated Upcoming Milestones

Rare Metabolic Diseases

- SYNB1618 and SYNB1934 for PKU
  - Phase 2 SynPheny-1 study data — H1 2022
  - Phase 3 trial initiation — H2 2022
- SYNB1353 for homocystinuria (HCU)
  - Data from Phase 1 trial in healthy volunteers — H2 2022

Enteric Hyperoxaluria

- SYNB8802 for enteric hyperoxaluria
  - Data from Phase 1b trial in patients with Roux-en-Y gastric bypass — 2022

Corporate Updates

Earlier this month, the company announced the appointment of Michael Jensen as Chief Financial Officer. Mr. Jensen brings extensive and diversified experience within global pharmaceutical and medical device companies to Synlogic, spanning analytics, financial management, information systems, and operations. Mr. Jensen was formerly the CFO of Intrinsic Therapeutics.

Fourth Quarter 2021 Financial Results

As of December 31, 2021, Synlogic had cash, cash equivalents, and marketable securities of $136.6 million.

Revenue was $0.6 million for the three months ended December 31, 2021. 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. There was no revenue for the three months ended December 31, 2020.

Research and development expenses were $11.9 million for the three months ended December 31, 2021, compared to $11.4 million for the corresponding period in 2020.

General and administrative expenses for the three months ended December 31, 2021 were $3.9 million compared to $3.3 million for the corresponding period in 2020.

For the three months ended December 31, 2021, Synlogic reported a consolidated net loss of $15.1 million, or $0.21 per share, compared to a consolidated net loss of $14.6 million, or $0.39 per share, for the corresponding period in 2020.

Full Year 2021 Financial Results

Revenues were $1.8 million for the year ended December 31, 2021, compared to $0.5 million for the same period in 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. Revenue in 2020 was due to the prior collaboration with AbbVie, which was terminated in May 2020. Operating expenses were $62.5 million for the year ended December 31, 2021, compared to $61.0 million for the same period in 2020. For the year ended December 31, 2021, consolidated net loss was $60.6 million, or $1.09 per share, compared to a consolidated net loss of $59.2 million, or $1.65 per share, for the year ended December 31, 2020.

Financial Outlook

Based upon its current operating plan and balance sheet as of December 31, 2021, Synlogic expects to have sufficient cash to be able to fund operations into 2024.

Investor Conference Presentation

Today, Synlogic will participate in Oppenheimer's 32nd Annual Healthcare Conference. Dr. Brennan will present virtually at 10:40 am ET.

A live webcast of the presentation will be accessible under the "Event Calendar" in the Investors & Media section of the Company's website. An archived version will also be available after the presentation on the Synlogic website.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, March 17, 2022. 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 1719849. A replay will be available for 30 days on the Investors and Media section of the Synlogic website.

About Synlogic

Synlogic is a clinical-stage biotechnology company developing medicines through its proprietary approach to synthetic biology. Synlogic's pipeline includes its lead program in phenylketonuria (PKU), which has demonstrated proof of concept with plans to start a pivotal, Phase 3 study in the second half of 2022, and additional novel drug candidates designed to treat homocystinuria (HCU) and enteric hyperoxaluria. The rapid advancement of these potential biotherapeutics, called Synthetic Biotics, has been enabled by Synlogic's proprietary, reproducible, target-specific drug design. Synlogic uses programmable, precision genetic engineering of well-characterized probiotics to exert localized activity for therapeutic benefit, with a focus on metabolic and immunologic diseases. Synlogic is also working with Roche in a research collaboration focused on the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease and with Ginkgo Bioworks to include additional undisclosed preclinical assets, combining Synlogic's approach to Synthetic Biotics with Ginkgo's Codebase and Foundry services. For additional information visit 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," "on track," "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 approach to Synthetic Biotics to develop therapeutics to address a wide range of diseases including 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 Biotics; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; our research and other collaborations; and the expected timing of Synlogic's clinical trials of SYNB1618, SYNB1934, SYNB1353 and SYNB8802 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.

Synlogic, Inc.
Condensed Consolidated Statements of Operations
(unaudited)

(in thousands,except share and per share data)

	For the three months ended December 31		For the years ended December 31	
	2021	2020	2021	2020
Revenue	$ 592	$ —	$ 1,754	$ 545
Operating expenses				
Research and development	11,873	11,407	47,127	47,474
General and administrative	3,864	3,286	15,392	13,537
Total operating expenses	15,737	14,693	62,519	61,011
Loss from operations	(15,145)	(14,693)	(60,765)	(60,466)
Other income, net	56	105	204	1,293
Net loss	$ (15,089)	$ (14,588)	$ (60,561)	$ (59,173)
Net loss per share—basic and diluted	$ (0.21)	$ (0.39)	$ (1.09)	$ (1.65)
Weighted-average common shares used in computing net loss per share—basic and diluted	71,945, 538	37,792,966	55,329,711	35,835,744

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)

	December 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents, & marketable securities	$ 136,629	$ 100,444
Fixed assets	9,088	10,776
Other assets	29,019	32,620
Total assets	$ 174,736	$ 143,840
Liabilities and stockholders' equity		
Current liabilities	$ 10,080	$ 8,301
Long-term liabilities	17,390	20,404
Total liabilities	27,470	28,705
Total stockholders' equity	147,266	115,135
Total liabilities and stockholders' equity	$ 174,736	$ 143,840
Common stock and common stock equivalents		
Common stock	69,698,844	38,183,273
Common stock warrants (pre-funded)	2,548,117	2,548,117
Total common stock	72,246,961	40,731,390

MEDIA CONTACT:

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

INVESTOR CONTACT:

Andrew Funderburk
Kendall Investor
Phone: 617-401-9152
Email: afunderburk@kendallir.com

synlogic

Transforming Medicine through Synthetic Biology

Q4 and Full Year 2021 Financial Results & Business Update

March 17, 2022

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 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 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 SYNB1618, SYNB1934, SYNB1353 and SYNB8802 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..

Opening Remarks

Dr. Aoife Brennan
MB CHB

President & CEO

synlogic

Multiple Anticipated Milestones as PKU Program Approaches Phase 3

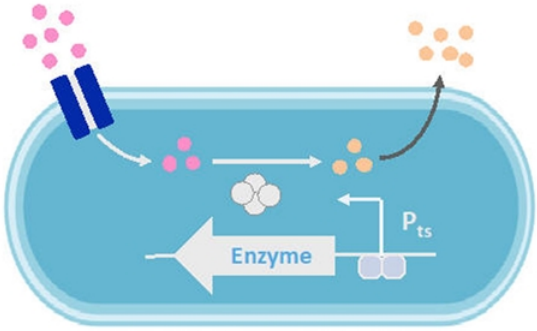
2021

PKU	Proof of concept from Phase 2 interim analysis with lead candidate
PKU	Next generation candidate showed greater potency
HCU	2nd rare metabolic disease drug candidate entered pre-IND studies
HOX	Achieved proof of mechanism in healthy volunteers
IBD	Established Roche collaboration, achieved first research milestone

2022

PKU Phase 2 data	H1 2022
PKU Phase 3 initiation	H2 2022
HCU Phase 1 data from healthy volunteers	H2 2022
Enteric hyperoxaluria proof of concept	2022

Synthetic Biotics: A New Paradigm of Biotherapeutics



Programable, precision **genetic engineering** + Well-characterized **probiotic chassis**

- **Targets validated biology** in metabolic and immunological diseases
- **Safe** *chassis*, with >100 years of human experience
- **Orally-administered** convenience
- **Reversible** via rapid GI clearance
- Addressing **rare and common** diseases

PKU: Unique Opportunity for Value Creation

Significant unmet medical need - 75% of patients remain untreated

De-risked path to registration

Well-connected patient population at concentrated sites of care

Differentiated profile established in POC

Phase 3 initiation in H2 2022 expected

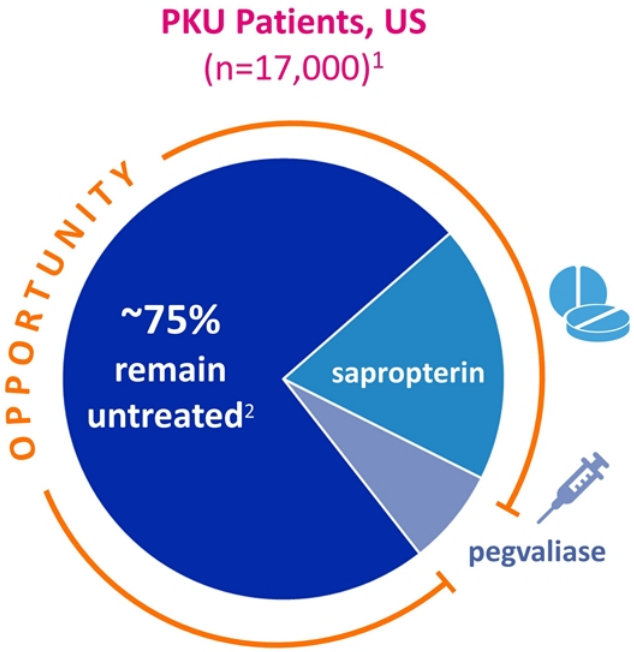
synlogic PKU = phenylketonuria

PKU Opportunity

Molly Harper
Chief Business Officer

synlogic

Limitations of Current Options Create Need for A New Approach in PKU



*Responsive to BH4 (tetrahydrobiopterin) = molecule that the body produces to act as a cofactor with PAH, the enzyme that is impaired in PKU. Sapropterin is a synthetic form of BH4.
NPKUA; 2. Patient numbers for sapropterin, pegvaliase derived from Biomarin financials and disclosures YE 2020; 3. Synlogic Market Research 2021 and Levy 2020 4. U.S. Prescribing Information for Palynziq; REMS = Risk Evaluation and Mitigation Strategy

Potentially Transformative Product Profile

Designed and Differentiated for PKU

- ✓ **Efficacy**
- ✓ **Safety**
- ✓ **Oral administration**
- ✓ **Monotherapy or Adjunctive Use**

synlogic

.Sources: Synlogic PKU Program Update, September 20, 20211, Synlogic Market Research 4Q 2021

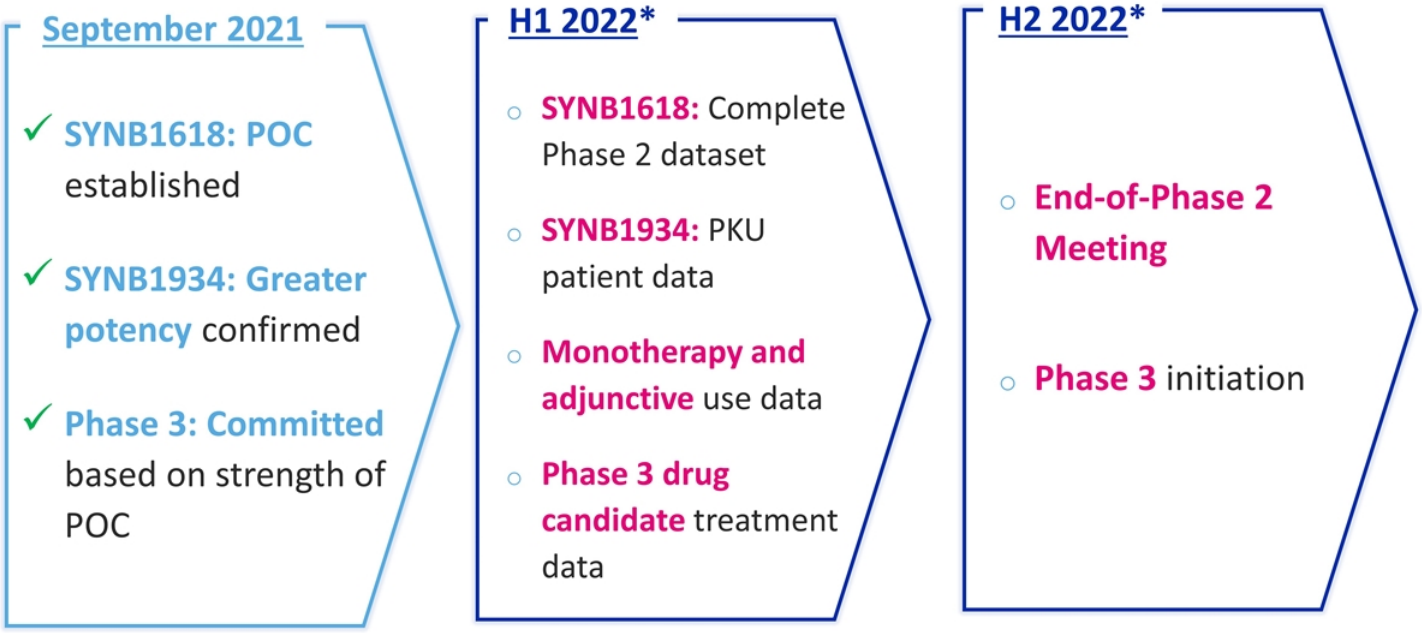
PKU Clinical Development

Dr. Aoife Brennan
MB CHB

President & CEO

synlogic

With POC Established, PKU Program Has Path to Phase 3 in 2022



synlogic

* Anticipated Milestones

Regulatory Path De-Risked at Multiple Levels

Disease
- Precedents in two FDA-approved drugs

Platform

Synthetic Biotics

Drug Candidate

SYNB1618/SYNB1934

Enteric Hyperoxaluria, Homocystinuria and Preclinical Programs

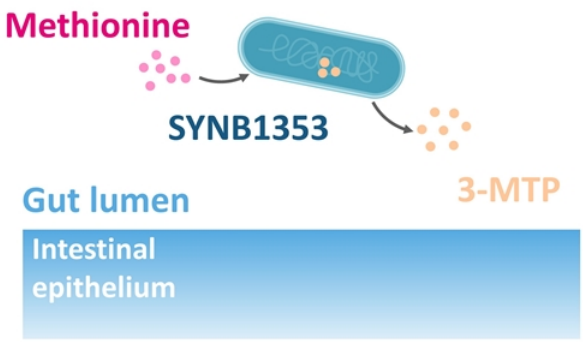
Dave Hava, PhD
Chief Scientific Officer

synlogic

SYNB1353 for HCU: 2nd Rare Metabolic Disease Program

SYNB1353: Methionine-Consuming Drug Candidate for HCU

- **Significant disease burden**
- **Builds on PKU success**
- **Strong synergies with PKU**



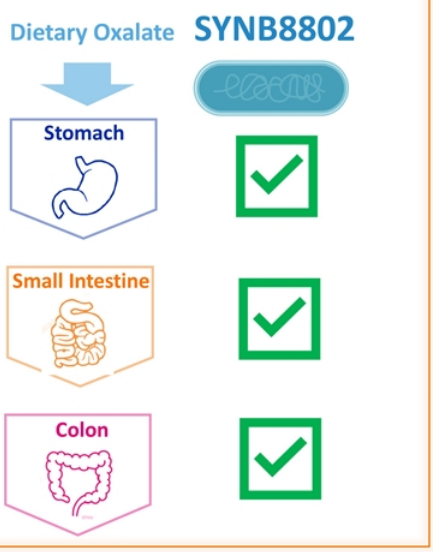
CBS = cystathionine beta-synthase

1. Development of an Investigational Methionine-consuming Synthetic Biotic Medicine (SYNB1353) for the Treatment of Homocystinuria, International Congress of Inborn Errors of Metabolism, November 23, 2021

SYNB8802 for Enteric Hyperoxaluria: On Track for POC in 2022

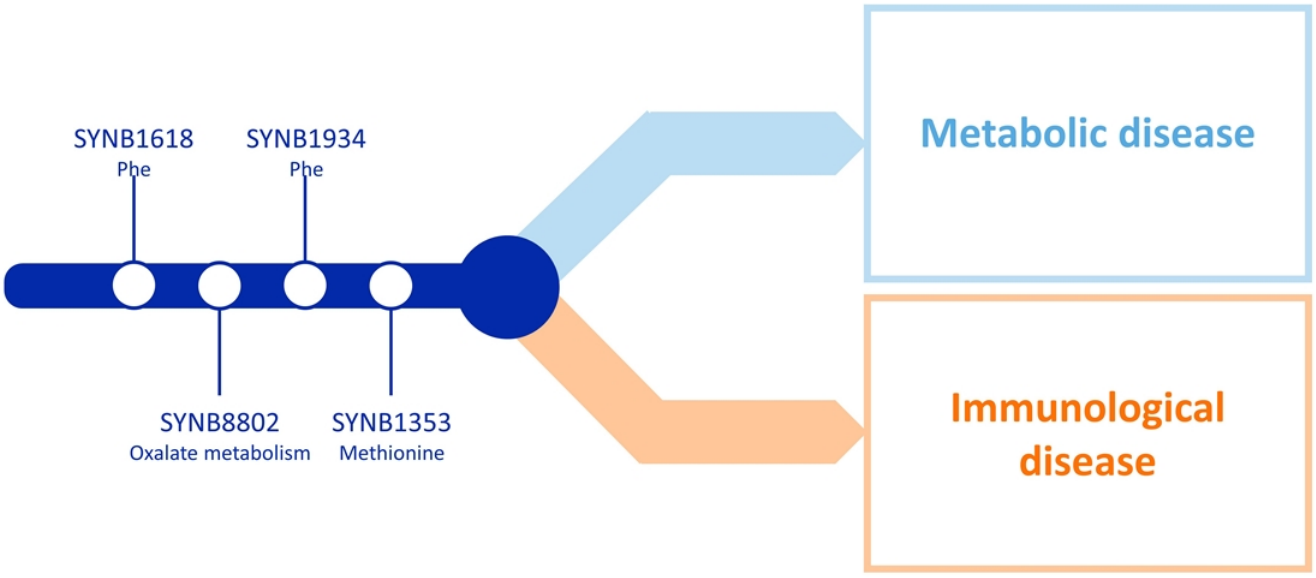
Acute Crises, Long-Term Damage

Consumes Oxalate Across GI Tract



GI = gastrointestinal, CKD = chronic kidney disease, ESRD = end stage renal disease

Platform's Progress Has Enabled Research Programs in New Areas



Strength of Partners Reflects Platform Progress and Potential

IND = Investigational New Drug

Financial Summary

Michael Jensen
Chief Financial Officer

synlogic

Fourth Quarter and Year End 2021

Summary Results

Balance Sheet (unaudited)	31 December 2021	31 December 2020
Cash, Cash Equivalents, and Marketable Securities	$136.6 M	$100.4 M

	Three Months Ended		For the Year Ended	
Financial Performance (unaudited)	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Revenue	$0.6 M	-	1.8 M	0.5 M
R&D Expenses	$11.9 M	$11.4 M	$47.1 M	$47.5 M
G&A Expenses	$3.9 M	$3.3 M	$15.4 M	$13.5 M
Net Loss	$(15.1 M)	$(14.6 M)	$(60.6 M)	$(59.2 M)
Net Loss per share – basic and diluted*	$(0.21)	$(0.39)	(1.09)	(1.65)
*Weighted Average Shares Outstanding**	*71.9 M*	*37.8 M*	*55.3 M*	*35.8 M*

* weighted average shares used in computing net loss per shares - basic and diluted

Concluding Remarks

Dr. Aoife Brennan
MB CHB

President & CEO

synlogic

Multiple Expected Near-Term Milestones

PKU Phase 2 data readout	H1 2022
PKU Phase 3 initiation	H2 2022
HCU Phase 1 data from healthy volunteers	H2 2022
Enteric hyperoxaluria proof of concept	2022

Strong balance sheet: $136.6m* with projected runway into 2024

synlogic * As of December 31, 2021

Available For Questions

Aoife Brennan, MB ChB
President & CEO

Molly Harper
Chief Business Officer

Dave Hava, PhD
Chief Scientific Officer

Michael Jensen
Chief Financial Officer

Antoine Awad
Chief Operating Officer

