

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): August 6, 2020

**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 144-12 under the Exchange Act (17 CFR 240.144-12)  
 Pre-commencement communications pursuant to Rule 144-2(b) under the Exchange Act (17 CFR 240.144-2(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 August 6, 2020, Synlogic, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2020. The full text of the press release and 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

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

99.1 [Press Release dated August 6 2020](#)

99.2 [Presentation dated August 6 2020](#)

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**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: August 6, 2020

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

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## Synlogic Reports Second Quarter 2020 Financial Results and Provides Business Update

- Synlogic ends 2Q2020 with \$109.1 million in cash, cash equivalents and investments supporting projected runway into 2022 -

- Company continues to advance multiple clinical stage Synthetic Biotic medicines -

- Management to host conference call and webcast at 8:00 am ET today -

CAMBRIDGE, Mass., Aug. 6, 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 second quarter ended June 30, 2020, and provided an update on programs and progress.

"Our team at Synlogic continues to achieve our clinical programs and platform milestones, driving the advancement of our portfolio of novel Synthetic Biotic medicines," said Aoife Brennan, M.B. Ch.B., Synlogic's president and chief executive officer. "We are on track to initiate the Phase 2 study of SYN1618 in Phenylketonuria and the monotherapy arm of our Phase 1 trial of SYN1891 in solid tumors continues to progress as planned. With the advancement of our pipeline and a cash runway into 2022, we are well positioned to meet our objectives and bring these novel Synthetic Biotic medicines to patients."

"We have rapidly advanced SYN8802 in Enteric Hyperoxaluria, which leads to dangerously high levels of urinary oxalate and for which patients have few treatment options today," said Richard Riese, M.D., Synlogic's chief medical officer. "We look forward to an IND filing and moving SYN8802 into the clinic in early 2021."

### 2020 Priorities & Highlights

- **Initiation of a Phase 2 clinical trial to evaluate SYN1618 in patients with phenylketonuria (PKU).** SYN1618 is an orally administered Synthetic Biotic medicine being developed as a potential treatment for PKU.
  - Synlogic expects to initiate the Phase 2 clinical trial of SYN1618 in the second half of 2020, per plan.
  - The Phase 2 trial is designed to evaluate safety and tolerability of a solid formulation of SYN1618 as well as its potential to lower blood phenylalanine levels in PKU patients.
  - In addition, the study is expected to provide valuable information to validate predictive pharmacodynamic and preclinical modeling.
- **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 data from the monotherapy arm of the Phase 1 clinical study before the end of the year
- **Advancement of SYN8802 for the treatment of enteric hyperoxaluria**
  - Synlogic is developing SYN8802 to treat enteric hyperoxaluria. SYN8802 has moved into IND-enabling studies.
  - Enteric hyperoxaluria is an acquired metabolic disorder in which patients develop recurrent kidney stones due to elevated urinary oxalate levels and are at an increased risk of kidney failure.
- **Synlogic regains all rights to develop Synthetic Biotic medicines for all effectors targeting IBD**
  - On May 21, Synlogic announced the termination of its collaboration with AbbVie.
  - Upon termination, Synlogic regained all rights to develop IBD Synthetic Biotic medicines for all effectors targeting IBD. This allows Synlogic to fully leverage its expertise in strain engineering, quantitative biology, regulatory, and manufacturing to expand its wholly owned GI-based program portfolio to include IBD.
  - Synlogic further regains the rights to partner its IBD programs.
- **First virtual R&D event**
  - On May 27, Synlogic's Executive Team presented an in-depth review of our Synthetic Biotic medicines platform and programs for the treatment of metabolic diseases, inflammatory and immune disorders, and cancer. The team was joined by guest speaker David S. Goldfarb, Professor of Medicine and Physiology and Clinical Chief, Division of Nephrology at NYU School of Medicine; Chief, Nephrology at NY Harbor VA Medical Center, for an overview of enteric hyperoxaluria.
  - The R&D event materials and replay can be found in the Presentations & Publications section of the Synlogic website
- **Synlogic expands Leadership Team and announces senior management promotions**
  - Synlogic promoted Antoine (Tony) Awad to the position of Chief Operating Officer.
  - Tony joined Synlogic in December 2018 as Head of Technical Operations. He brings over 15 years of experience in the biotechnology and pharmaceutical industry with substantial experience in the development and manufacturing of novel therapeutics from pre-IND studies through global commercialization. Prior to joining Synlogic, Tony served as Senior Vice President of CMC and Operations at Abpro Therapeutics and L.E.A.F. Pharmaceuticals and served in roles of increasing responsibility at Ipsen Biosciences and Merrimack Pharmaceuticals. Tony is a graduate of Boston University and holds degree in biochemistry and molecular biology, and conducted graduate research at Boston University School of Dental Medicine.
  - Synlogic also announced the appointment of Andrew Marsh as Head of Clinical Operations.
  - Andrew brings over 15 years of experience across an array of therapeutic areas, including rare diseases and oncology, and has executed initial IND through registrational human clinical studies. Prior to joining Synlogic he served as Ra Pharmaceuticals' Head of Clinical Development. Andrew is a graduate of Boston University and holds a degree in biomedical engineering. He will be responsible for Clinical Operations, Biometrics, and Clinical Bioanalytics.

### Second Quarter 2020 Financial Results

As of June 30, 2020, Synlogic had cash, cash equivalents, and short-term investments of \$109.1 million.

For the three months ended June 30, 2020, Synlogic reported a consolidated net loss of \$15.5 million, or \$0.44 per share, compared to a consolidated net loss of \$12.3 million, or \$0.45 per share, for the corresponding period in 2019.

Research and development expenses were \$12.9 million for the three months ended June 30, 2020 compared to \$9.7 million for the corresponding period in 2019.

General and administrative expenses for the three months ended June 30, 2020 were \$3.5 million compared to \$3.7 million for the corresponding period in 2019.

Revenues were \$0.4 million for both the three months ended June 30, 2020 and June 30, 2019, respectively. Revenue for both periods was associated with Synlogic's prior collaboration with AbbVie to develop Synthetic Biotic medicines for the treatment of irritable bowel disease.

### 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 today at 8:00 a.m. ET today, Thursday, 6 August 2020. To access the live webcast, please visit the "Event Calendar" page within the Investors and Media section of the Synlogic website.

Alternatively, 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 5673797. For those unable to participate in the conference call or webcast, 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

### 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, 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; the timing and progress of our Phase 1 clinical trial of SYN1891 in patients with advanced solid tumors or lymphoma; and the potential benefits of SYN1891. 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)	<u>For the three months ended</u>		<u>For the six months ended</u>	
	<u>June 30, 2020</u>	<u>June 30, 2019</u>	<u>June 30, 2020</u>	<u>June 30, 2019</u>
Revenue	\$ 445	\$ 350	\$ 545	\$ 688
Operating expenses				
Research and development	12,909	9,703	25,586	20,087
General and administrative	3,473	3,742	7,294	7,393
Total operating expenses	<u>16,382</u>	<u>13,445</u>	<u>32,880</u>	<u>27,480</u>
Loss from operations	(15,937)	(13,095)	(32,335)	(26,792)
Other income, net	402	751	972	1,502
Net loss	<u>\$ (15,535)</u>	<u>\$ (12,344)</u>	<u>\$ (31,363)</u>	<u>\$ (25,290)</u>
Net loss per share - basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.45)</u>	<u>\$ (0.91)</u>	<u>\$ (0.96)</u>
Weighted-average common shares used in computing net loss per share - basic and diluted	<u>34,967,761</u>	<u>27,242,514</u>	<u>34,604,738</u>	<u>26,284,262</u>

**Synlogic, Inc.**  
**Condensed Consolidated Balance Sheets**  
(unaudited)

(in thousands, except share data)	<u>June 30, 2020</u>	<u>December 31, 2019</u>
	<b>Assets</b>	
Cash, cash equivalents, and short and long-term investments	\$ 109,136	\$ 127,073
Fixed assets	12,055	13,021
Other assets	<u>38,202</u>	<u>48,480</u>
Total assets	<u>\$ 159,393</u>	<u>\$ 188,574</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities	\$ 6,058	\$ 8,863
Long-term liabilities	<u>21,663</u>	<u>22,806</u>
Total liabilities	<u>27,721</u>	<u>31,669</u>
Total stockholders' equity	<u>\$ 131,672</u>	<u>156,905</u>
Total liabilities and stockholders' equity	<u>\$ 159,393</u>	<u>\$ 188,574</u>
<b>Common stock and common stock equivalents</b>		
Common stock	34,145,111	32,266,814
Common stock warrants (pre-funded)	<u>2,548,117</u>	<u>2,548,117</u>
Total common stock	36,693,228	34,814,931

Media Contact: Caroline Rufo, Ph.D., MacDougall, Phone: 781-235-3060 Email: crufo@macbiocom.com Investor Contact: Daniel Rosan, Synlogic, Inc., Phone: (617) 401-9975, Email: dan.rosan@synlogictx.com

# synlogic

**Designed For Life**

Q2 Financial Results & Business Update  
6 August 2020

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## Forward Looking Statements

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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 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





## 2<sup>nd</sup> Quarter Highlights

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- We are building **the premier Synthetic Biology** platform to **engineer bacterial Synthetic Biotic medicines** that benefit patients in new ways
- **Team, technology and portfolio** to succeed: appointed Antoine Awad as COO
- Rapidly progressed **metabolic programs**
  - **SYNB1618 PKU** Phase 2 *synPHEny* FPI expected late 2020
  - Advanced IND for **SYNB8802 in Enteric Hyperoxaluria**: FIH expected early 2021
- **Immunomodulation** in immunology and oncology
  - **SYNB1891** monotherapy continues to enroll: data expected late 2020
- Regained rights to **IBD**
- Continued careful capital stewardship & strong cash position

## Advancing The Pipeline

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**Emerging treatment options in PKU will continue to leave many patients behind**

**SYNB1618 demonstrates potential to lower Phe in PKU patients**

**Phase 2 Phe-lowering trial starting in 2H 2020**

***Next generation strain in development***

## Advancing The Pipeline

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**Emerging treatment options in PKU will continue to leave many patients behind**

**SYNB1618 demonstrates potential to lower Phe in PKU patients**

**Phase 2 Phe-lowering trial starting in 2H 2020**  
*Next generation strain in development*

**SYNB1891 (Synthetic Biotic for intratumoral injection) continues to enroll monotherapy cohorts**

**SYNB1891 will provide clinical data from monotherapy cohorts in 2020**

**SYNB1891 has potential for improved efficacy relative to other STING approaches**

# Upcoming Milestones

Synlogic Entering Data Rich Period In The Clinic

Expected Milestone	2020			2021		
	early	mid	late	early	mid	late
<b>SYNB1618</b> PKU			■		■	
Initiate Ph.2 study in PKU patients			■			
Ph.2 Phe-lowering read-out					■	
<b>SYNB8802</b> HOX		■		■		
Initiate IND-enabling studies	■					
Initiate Ph.1 study in HV and Patients				■		
Ph.1 Patient Read-out					■	
<b>SYNB1891</b> I/O			■	■		■
Ph.1 Monotherapy read-out			■			
Initiate Ph.1 combination study arm				■		
Ph.1 Combination therapy read-out						■

Significant Clinical Catalysts Over The Next 6-12 Months

## 2<sup>nd</sup> Quarter 2020 Summary Results

### Balance Sheet (unaudited)

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

30 June 2020

\$109.1M

31 Mar 2020

\$114.3 M

### Statement of Operations (unaudited)

R&D Expenses

G&A Expenses

Net Loss

Net Loss Per Share \*

### Three Months Ended

30 June 2020

\$12.9 M

\$3.5 M

\$(15.5) M

\$(0.44)

30 June 2019

\$9.7 M

\$3.7 M

\$(12.3) M

\$(0.45)

**Strong Cash Position With Runway Into 2022**

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

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# Focus On Enteric Hyperoxaluria

Dr. Richard Riese, MD, PhD  
Chief Medical Officer



# Enteric Hyperoxaluria: Overview

## Dietary Sources of Oxalate



## Risk Factors

- IBD
- Roux-en-Y Gastric Bypass
- Short Bowel Syndrome
- Chronic Pancreatitis

## Clinical Manifestations







Nephrocalcinosis, Stones, and Risk of Chronic Kidney Disease

**Dietary Sources of Oxalate Are Difficult To Avoid, Putting Patients at Risk for Poor Kidney Outcomes**



## Hyperoxaluria: Primary vs. Enteric

	Primary Hyperoxaluria	Enteric Hyperoxaluria
<b>Pathology</b>	Family of autosomal recessive monogenic disorders in which liver enzyme deficiency results in endogenous oxalate overproduction	Pathogenic hyperabsorption of dietary oxalate, often accompanies bowel disease or bariatric surgery
<b>Urinary Oxalate Levels</b>	90 – 500 mg / 24 hrs (up to 10x normal)	45 – 130 mg / 24 hrs (up to 3x normal)
<b>Onset</b>	Pediatric	Adult
<b>Clinical Mgmt</b>	Limited nutrition options; nephrocalcinosis; dialysis; transplant; pyridoxine	Limited nutrition options; treatment of kidney stones as they occur; nephrocalcinosis; dialysis
<b>U.S. Epidemiology</b>	~5,000 – 8,000	200,000 – 250,000
<b>Key Players</b>	 	 

## SYNB8802 Poised To Enter The Clinic

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Enteric Hyperoxaluria manifests in dangerously high urinary oxalate levels, putting patients with pre-existing bowel disease at 3-4x higher risk of CKD \*



Differentiated profile - engineered to absorb oxalate from throughout the GI tract



Two preclinical models, mouse and NHP, provide evidence of urinary oxalate lowering



Precedented clinical development and regulatory path with urinary oxalate as a critical endpoint



Proof of concept achievable in Phase 1B Roux-n-Y gastric bypass population

# Enteric Hyperoxaluria

Our Next Step To Synthetic Biotic Medicines

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**High unmet medical need  
with no available  
therapeutic options**

**Efficient clinical  
development: PoC  
achievable in Phase 1b**

**SYNB8802 has potential to  
meaningfully reduce  
urinary oxalate levels**

# Concluding Remarks

Dr. Aoife Brennan  
MD CHB

President & CEO

synlogic



## Available For Questions

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**Aoife Brennan, MD CHB**  
President & CEO



**Antoine Awad**  
COO



**Richard Riese, MD PhD**  
CMO



**Gregg Beloff, JD MBA**  
Interim CFO



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