

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): May 8, 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 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 May 8, 2020, Synlogic, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2020. 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.

The information in this Current Report on Form 8-K (including Exhibit 99.1) 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 May 8, 2020](#)

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: May 8, 2020

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

Synlogic Reports First Quarter 2020 Financial Results and Provides Business Update

–Cash and investments of \$114 million provide runway into 2022 –

–Company will host virtual R&D event highlighting progress in its Synthetic Biotic platform and programs on Wednesday, May 27, 2020 –

– Company will host a conference call at 8:00 am ET today –

CAMBRIDGE, Mass., May 8, 2020 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, today reported its financial results for the first quarter ended March 31, 2020.

"In the first quarter, we continued to advance our programs and enhance our Synthetic Biotic platform capabilities in synthetic biology, manufacturing and development. While the coronavirus pandemic necessitated we update a number of our development plans, I am very grateful to our dedicated employees who have enabled us to continue to execute on our strategy under challenging circumstances," said Aoife Brennan, M.B., Ch.B., Synlogic's president and chief executive officer. "We look forward to showcasing our deep platform capabilities and expanding program portfolio at our upcoming virtual R&D event on May 27th, which will include more details on one of our newest and rapidly advancing programs in enteric hyperoxaluria."

2020 Priorities

Pipeline

- **Initiation of a Phase 2 clinical trial to evaluate a solid formulation of SYN1618 in patients with phenylketonuria (PKU).** SYN1618 is an orally administered Synthetic Biotic medicine that is being developed as a treatment for PKU.
 - Synlogic intends to continue to work with sites to complete preparatory work, however as a result of the coronavirus pandemic it does not expect to be able to enroll subjects into its Phase 2 clinical trial of SYN1618 until it is safe for patients to enter clinical trial sites.
 - 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.
- **Evaluation of data from the monotherapy arm of the Phase 1 clinical study of SYN1891 in patients with advanced solid tumors or lymphoma.** SYN1891 is an intra-tumorally administered Synthetic Biotic medicine engineered to produce cyclic di-AMP, an agonist of the STING pathway, that is designed to serve as a dual innate activator of the immune system as a potential treatment for solid tumors or lymphoma. SYN1891 is being evaluated as a monotherapy in an ongoing Phase 1 open-label, multicenter, dose escalation clinical trial (NCT04167137) in patients with advanced solid tumors or lymphoma.
 - While this clinical trial and most clinical sites have remained open and enrolled patients have continued on study, Synlogic expects slower enrollment of new patients as a result of the coronavirus pandemic, which has the potential to impact the availability of data in 2020.
- **Continued development of patient and commercialization-appropriate drug presentations of SYN1618.**
 - Synlogic has developed and manufactured a solid formulation of its Synthetic Biotic SYN1618 that it plans to use in future clinical trials and continues to evaluate and develop different drug presentations (e.g. capsule, pressed pill, sachet) for eventual commercialization.
- **Advancement of new Synthetic Biotic programs in metabolic diseases with high unmet medical need.**
 - Synlogic is conducting preclinical studies of Synthetic Biotic medicines to treat enteric hyperoxaluria, 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 expects to move a clinical candidate in its enteric hyperoxaluria program into IND-enabling studies in 2020.
 - In addition, Synlogic is also developing Synthetic Biotic medicines for the treatment of other metabolic diseases, including maple syrup urine disease (MSUD), a rare inherited metabolic disease caused by defective enzymes that metabolize branched chain amino acids (BCAAs) which are components of protein.
- **Publication and presentation of data demonstrating the breadth and potential of its Synthetic Biotic platform.**
 - On March 8th, *Nature Communications* published a Perspective authored by Synlogic scientists entitled, "Developing a new class of engineered live bacterial therapeutics to treat human diseases." The paper, which highlights the considerations for the design and development of engineered live bacteria, including Synthetic Biotic medicines, is available on the Synlogic website on the Presentations and Publications page of the Investors and Media section.
- **On May 27th, 2020 Synlogic will host its first virtual R&D event**
 - The webcast event will highlight the Company's progress in developing its platform capabilities and pipeline of rare metabolic disease programs for internal prosecution and programs in immunomodulation for potential partnering. Dr. David Goldfarb, Professor of Medicine and Physiology at NYU School of Medicine, Clinical Chief of the Nephrology Division at NYU Langone Health, and Chief of the Nephrology Section and Director of the Hemodialysis Unit at the New York VA Medical Center in Manhattan will also present an overview of enteric

hyperoxaluria. A link to the live webcast will be available on Synlogic's website on the News & Events page of the Investors and Media section.

First Quarter 2020 Financial Results

As of March 31, 2020, Synlogic had cash, cash equivalents, and short-term investments of \$114.2 million.

For the three months ended March 31, 2020, Synlogic reported a consolidated net loss of \$15.8 million, or \$0.46 per share, compared to a net loss of \$12.9 million, or \$0.51 per share, for the corresponding period in 2019.

Research and development expenses were \$12.7 million for the three months ended March 31, 2020 compared to \$10.4 million for the corresponding period in 2019. The increase in expenses was primarily due to use of synthetic biology services provided under Synlogic's collaboration with Ginkgo and increased clinical activities associated with the SYN1618 bridging study and the SYN1891 Phase 1 clinical trial.

General and administrative expenses for the three months ended March 31, 2020 were \$3.8 million compared to \$3.7 million for the corresponding period in 2019.

Revenue was \$0.1 million for the three months ended March 31, 2020 compared to \$0.3 million for the three months ended March 31, 2019. Revenue is associated with services performed under the Synlogic's collaboration with AbbVie to develop a Synthetic Biotic medicine for the treatment of IBD.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast today at 8:00 a.m. ET today, Friday, May 8, 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 6869043. 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 pioneering the development of a novel class of living medicines, Synthetic Biotic™ medicines, based on its proprietary drug development platform. Synlogic leverages the tools and principles of synthetic biology to genetically engineer beneficial microbes to perform or deliver critical functions missing or damaged due to disease. When delivered orally, Synthetic Biotic medicines are designed to function in the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect, with the potential to significantly improve symptoms of disease for affected patients. The Company's lead program in this area, SYN1618, targets PKU. In addition, the Company is leveraging the broad potential of its platform to create Synthetic Biotic medicines for the treatment of more common diseases, including inflammatory and immune disorders, and cancer. Synlogic's first immuno-oncology program, SYN1891, is in clinical development for the treatment of solid tumors and lymphoma. Synlogic is collaborating with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease (IBD). For more information, please 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, 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, rare metabolic diseases, liver disease, and inflammatory and immune disorders; the initiation, enrollment, timing, progress, release of data from and results of our planned and ongoing clinical trials; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; the potential of Synlogic's technology to treat various diseases; Synlogic's ability to develop and manufacture Synthetic Biotic formulations; Synlogic's goals with respect to the development and potential use, if approved, of each of its product candidates; and statements regarding the impact of coronavirus on Synlogic's product candidates, clinical trials development and business operations. 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 preclinical and clinical development process; the ability of Synlogic to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in Synlogic's filings with the SEC. The forward-looking statements contained in this press release reflect Synlogic's current views with respect to future events. Synlogic anticipates that subsequent events and developments will cause its views to change. However, while Synlogic may elect to update these forward-looking statements in the future, Synlogic specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Synlogic's view as of any date subsequent to the date hereof.

Synlogic, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands except share and per share data)

For the three months ended

March 31, 2020

March 31, 2019

Revenue	\$	100	\$	338
Operating expenses				
Research and development		12,677		10,384
General and administrative		3,821		3,651
Total operating expenses		16,498		14,035
Loss from operations		(16,398)		(13,697)
Other income, net		570		751
Net loss	\$	(15,828)	\$	(12,946)
Net loss per share - basic and diluted	\$	(0.46)	\$	(0.51)
Weighted-average common shares used in computing net loss per share - basic and diluted		34,233,688		25,293,791

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
Assets		
Cash, cash equivalents, and short and long-term investments	\$ 114,249	\$ 127,073
Fixed assets	\$ 12,661	13,021
Other assets	\$ 44,225	48,480
Total assets	<u>\$ 171,135</u>	<u>\$ 188,574</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 6,819	\$ 8,863
Long-term liabilities	\$ 22,199	22,806
Total liabilities	<u>29,018</u>	<u>31,669</u>
Total stockholders' equity	<u>\$ 142,117</u>	<u>156,905</u>
Total liabilities and stockholders' equity	<u>\$ 171,135</u>	<u>\$ 188,574</u>
Common stock and common stock equivalents		
Common stock	32,459,394	32,266,814
Common stock warrants (pre-funded)	<u>2,548,117</u>	<u>2,548,117</u>
Total common stock	35,007,511	34,814,931



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