

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): April 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 8.01 Other Events.**

On April 10, 2021, Synlogic, Inc. (the “Company”) issued a press release titled “Synlogic Presents Data from SYN1891 Phase 1 Trial at American Association for Cancer Research (AACR) Annual Meeting”.

On April 13, 2021, the Company issued a press release titled “Synlogic Presents Data Demonstrating Activity of a Solid Oral Formulation of SYN1618 at American College of Medical Genetics (ACMG) Annual Meeting”.

Copies of the Company’s press releases are filed as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated April 10, 2021</a>
99.2	<a href="#">Press Release dated April 13, 2021</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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: April 13, 2021

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

## Synlogic Presents Data from SYNBI891 Phase 1 Trial at American Association for Cancer Research (AACR) Annual Meeting

- Data demonstrates activation of STING pathway in patients -
- Combination arm of Phase 1 study of SYNBI891 ongoing -

CAMBRIDGE, Mass., April 10, 2021 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today presented data on SYNBI891 for the treatment of solid tumors and lymphoma during the American Association for Cancer Research (AACR) annual meeting, April 10-15, 2021.

The presentation, "Intratumoral injection of SYNBI891, a Synthetic Biotic designed to activate the innate immune system, demonstrates target engagement in humans including intratumoral STING activation," was delivered by Dr. Filip Janku, Associate Professor, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center. The presentation recording will be available throughout the duration of the conference.

SYNBI891 is an investigational drug being evaluated in an ongoing Phase 1 clinical trial for the treatment of solid tumors and lymphoma. SYNBI891 is composed of an engineered Synthetic Biotic strain of *E. coli* Nissle that produces cyclic di-AMP (CDA), a stimulator of the STING (STimulator of INterferon Genes) pathway. This mechanism can play a critical role in the initiation of an anti-tumor immune response via activation of APCs and presentation of tumor antigens. Findings from the monotherapy cohorts include:

- SYNBI891 is safe and well-tolerated as an intratumoral injection in a heterogenous population.
  - No dose limiting toxicities or SYNBI891-related infections
- Dose levels through  $1e7$  live cells demonstrate target engagement as assessed by dose-dependent increases in serum cytokines, upregulation of ISGs and presence of tumor infiltrating lymphocytes.
- Evidence of durable stable disease was seen in 2 patients and was associated with upregulation genes tied to immune activation and increased intratumoral lymphocytes.

These data support continued dose escalation in the monotherapy and combination arms. The combination arm of the study combines escalating dose levels of SYNBI891 with a fixed dose of a PD-L1 checkpoint inhibitor antibody to establish a recommended Phase 2 dose for the combination regimen.

Data from both arms will continue to be reported over the course of 2021, with mature combination therapy data expected by the end of the year.

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

### About SYNBI891

SYNBI891 is an investigational drug for the intra-tumoral treatment of solid tumors and lymphoma, composed of an engineered Synthetic Biotic strain of *E. coli* Nissle that produces cyclic di-AMP (CDA), a stimulator of the STING (STimulator of INterferon Genes) pathway. This mechanism can play a critical role in the initiation of an anti-tumor immune response via activation of APCs and presentation of tumor antigens. The bacterial chassis of SYNBI891 also stimulates the innate immune system by several other mechanisms, including via Toll-like receptors (TLRs), potentially adding to the magnitude of the overall immune response. While SYNBI891 has been engineered with safety features that are designed to prevent its replication unless supplemented with specific nutrients, the bacteria remain active for several days within the injected tumor to stimulate a local immune response. SYNBI891 is being evaluated in a Phase 1 clinical trial (NCT04167137).

### 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. 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; 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 of SYN1891 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

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## Synlogic Presents Data Demonstrating Activity of a Solid Oral Formulation of SYN1618 at American College of Medical Genetics (ACMG) Annual Meeting

- SYN1618 demonstrates proof of mechanism and phenylalanine (Phe) consumption in GI tract of healthy volunteers -
- SYN1618 Phase 2 study in patients with PKU ongoing -

CAMBRIDGE, Mass., April 13, 2021 Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today presented data from the Phase 1 study of SYN1618 for the treatment of Phenylketonuria (PKU) during the American College of Medical Genetics (ACMG) annual meeting, being held virtually April 13-16, 2021.

The poster presentation, "Randomized, Placebo-Controlled Study of Lyophilized Formulation of SYN1618 in Healthy Adult Volunteers," was delivered by Dr. Marja Puurunen, Synlogic's Senior Medical Director. The presentation recording will be available throughout the duration of the conference.

PKU is an inherited metabolic disease that manifests at birth and is marked by an inability to break down phenylalanine, an amino acid that is commonly found in many foods. Left untreated, PKU can lead to serious neurological and neuropsychological problems.

SYN1618 is an oral investigational Synthetic Biotic medicine designed to break down phenylalanine in the GI tract as a potential treatment for patients with PKU. A solid oral lyophilized powder formulation was evaluated in a Phase 1 study in healthy volunteers. In this study, the safety, tolerability and pharmacodynamics of multiple doses of SYN1618 were assessed. Findings reported today include:

- The solid oral formulation of SYN1618 was well tolerated and metabolically active in the human GI tract.
- SYN1618 reduced the increase of plasma D5-Phe following an oral dose of the tracer in a dose-dependent manner in healthy volunteers.
- SYN1618 demonstrated evidence of activity in the fasted state i.e. without protein intake, suggesting an ability to metabolize non-dietary Phe in the GI tract.

These data support the further clinical development of this therapy for the treatment of PKU. SYN1618 continues to advance in a proof of concept Phase 2 clinical trial in adults with PKU, SynPheny, with data expected in the second half of 2021.

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

### About PKU

Phenylketonuria (PKU) is an inherited metabolic disease that manifests at birth and is marked by an inability to break down phenylalanine (Phe), an amino acid that is commonly found in many foods. Left untreated, high levels of Phe become toxic and can lead to serious neurological and neuropsychological problems affecting the way a person thinks, feels, and acts. Due to the seriousness of these symptoms, infants are screened at birth in many countries to ensure early diagnosis and treatment to avoid intellectual disability and other complications.

### About SYN1618

SYN1618 is an investigational oral drug for the treatment of Phenylketonuria (PKU) composed of an engineered Synthetic Biotic designed to lower plasma phenylalanine (Phe) levels by consuming Phe in the GI tract. A solid oral lyophilized formulation of SYN1618 was found to be safe and well-tolerated, and consumes Phe in the GI tract of healthy volunteers. Synlogic has initiated a Phase 2 study in PKU patients (NCT04534842).

### About Synlogic

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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 of SYN1618 and availability of clinical trial data including Phase 2 data of SYN1618 for the treatment of PKU. 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.

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