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): July 15, 2021

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 8.01 Other Events.

On July 15, 2021, Synlogic, Inc. (the "Company") issued a press release titled "Synlogic Announces Initiation of Phase 1 Study of SYNB1934, a Next-Generation Strain for the Treatment of Phenylketonuria (PKU)".

A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated July 15, 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.

SYNLOGIC, INC.

Date: July 15, 2021

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

Synlogic Announces Initiation of Phase 1 Study of SYNB1934, a Next-Generation Strain for the Treatment of Phenylketonuria (PKU)

– SYNB1934, an evolved strain of SYNB1618, has the potential to provide increased benefit to patients living with PKU –

– SYNB1934 Phase 1 Study to evaluate safety, tolerability and head-to-head comparison of biomarkers of Phe-consumption between SYNB1934 and SYNB1618 –

– SYNB1618 Phase 2 Study in patients with PKU ongoing with data readout expected in 2H 2021 –

Cambridge, Mass. (PR Newswire) July 15, 2021 – Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today announced that it has initiated the Phase 1 clinical trial of SYNB1934, an investigational Synthetic Biotic™ medicine for the treatment of Phenylketonuria (PKU).

“We are delighted to have so quickly advanced SYNB1934 into the clinic, strengthening our PKU portfolio and our potential to provide a meaningful new therapeutic option for patients living with PKU,” said Aoife Brennan, M.B. Ch.B., Synlogic’s President and Chief Executive Officer. “We are on track to report results from our Phase 2 clinical trial of SYNB1618 in the second half of 2021 and look forward to providing additional updates as we advance our PKU portfolio.”

“SYNB1618 and SYNB1934 are orally administered Synthetic Biotic medicines intended to address the needs of PKU patients of all age groups and genotypes through the consumption of Phe in the gastrointestinal tract,” said Richard Riese, M.D., Synlogic’s Chief Medical Officer. “Our orally available and fully reversible Synthetic Biotic medicines have the potential to lower blood Phe levels, and potentially enable the consumption of more natural dietary protein. We aspire to bring forward the most compelling medicine possible to meet the needs of the significant number of patients who do not benefit from, or do not tolerate, existing therapies.”

SYNB1934 is a strain that has been evolved from SYNB1618, which is currently being evaluated in a Phase 2 clinical study. SYNB1934 has the potential to provide increased phenylalanine (Phe) lowering efficacy for patients living with PKU. Preclinical *in vivo* and *in vitro* studies demonstrated a greater than 2-fold improvement in the ability of SYNB1934 to consume and break down Phe compared to SYNB1618, based on production of Phe metabolites.

The Phase 1 multiple ascending dose study of SYNB1934 will evaluate the safety, tolerability and Phe consumption activity of SYNB1934, including a head-to-head comparison with SYNB1618 in healthy volunteers using biomarkers of Phe consumption. Based on the data from the head-to-head comparison, as well as results of the ongoing Phase 2 study of SYNB1618 in patients with PKU, Synlogic plans to select one therapeutic strain for late stage development. Data from the Phase 1 study is expected by the end of 2021.

Data on the solid oral formulation of SYNB1618 was presented at the American College of Medical Genetics meeting in April 2021, and data on the development of SYNB1934 was presented at the Synthetic Biology: Engineering, Evolution & Design (SEED) conference in June 2021.

Patients can learn more about the SynPheny-1 study (NCT04534842) by visiting https://pkuresearchstudy.com. More information about Synlogic's programs and pipeline can be found at 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 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 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, metabolic diseases, 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. 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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