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): October 24, 2017

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.)**

200 Sidney St., Suite 320 **Cambridge, MA**	**02139**
(Address of principal executive offices)	**(Zip Code)**

(617) 401-9947
Registrant's telephone number, including area code

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:

☐ 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))

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 October 24, 2017, Synlogic, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has granted Orphan Drug Designation to SYNB1618, the Company's preclinical-stage drug candidate for the treatment of phenylketonuria, an inborn error of metabolism caused by a mutation in the gene that breaks down the amino acid phenylalanine. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated October 24, 2017.

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: October 24, 2017

By: /s/ Todd Shegog
Name: Todd Shegog
Title: Chief Financial Officer

Media Contact:
Synlogic
Courtney Heath
Phone: 617-872-2462
Email: courtney@scientpr.com

Investor Contact:
Synlogic
Elizabeth Wolffe, Ph.D.
Phone: 617-207-5509
Email: liz@synlogictx.com

Synlogic Receives Orphan Drug Designation for SYNB1618, a Synthetic Biotic™ Medicine for the Treatment of Phenylketonuria

Cambridge, Mass. (Business Wire) October 24, 2017 – Synlogic (Nasdaq: SYBX), a clinical stage company applying synthetic biology to probiotics to develop novel living medicines, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to SYNB1618, Synlogic's preclinical-stage drug candidate for the treatment of phenylketonuria (PKU) , an inborn error of metabolism (IEM) caused by a mutation in the gene that breaks down the amino acid phenylalanine (Phe). Phe accumulation in the blood and brain can lead to neurocognitive abnormalities and treatment currently requires severe dietary protein restriction.

SYNB1618, an orally administered medicine, is designed to complement the missing function in patients with PKU by providing alternative metabolic pathways to consume Phe. Synlogic plans to file an investigational new drug application (IND) with the FDA for SYNB1618 for the potential treatment of PKU in early 2018.

"We believe our Synthetic Biotic medicines could transform the treatment of PKU," said Aoife Brennan, M.B., B.Ch., Synlogic's chief medical officer. "Consequently, we were pleased to receive the FDA's orphan drug designation which validates our approach and represents an important step toward achieving our goal of bringing novel treatments to the patients and families affected by this challenging disease."

The FDA's Orphan Drug Program offers orphan status to drugs and biologics that are intended for the treatment of rare diseases affecting fewer than 200,000 people in the U.S. The designation provides development and commercial incentives for designated compounds and medicines, including eligibility for a seven-year period of market exclusivity in the U.S. after product approval, FDA assistance in clinical trial design and an exemption from FDA user fees.

About PKU

Phe is an essential amino acid that enters the body as a component of dietary protein and can be toxic if its levels accumulate in the blood and brain. PKU is caused by a defect in the gene encoding phenylalanine hydroxylase (PAH), a liver enzyme that metabolizes Phe. Current disease management of PKU involves strict dietary protein restriction with the consumption of Phe-free protein supplements. The only currently approved medication, Kuvan®, is indicated for a subgroup of patients and does not eliminate the need for ongoing dietary management. Life-long Phe control is challenging due to the highly restrictive nature of the diet and patients typically experience worsening neurological function depending on the severity of their genetic mutation and their treatment compliance. PKU is diagnosed at birth, and the National PKU Alliance estimates that there are currently 16,500 people living with the disorder in the U.S.

About Synthetic Biotic Medicines

Synlogic's innovative new class of Synthetic Biotic medicines leverages the tools and principles of synthetic biology to genetically engineer probiotic microbes to perform or deliver critical functions missing or damaged due to disease. The company's two lead programs target a group of rare metabolic diseases – inborn errors of metabolism (IEM). Patients with these diseases are born with a faulty gene, inhibiting the body's ability to break down commonly occurring by-products of digestion that then accumulate to toxic levels and cause serious health consequences. When delivered orally, these medicines can act from the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect. Synthetic Biotic medicines are designed to clear toxic metabolites associated with specific metabolic diseases and have the potential to significantly improve symptoms of disease for affected patients.

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's initial pipeline includes Synthetic Biotic medicines for the treatment of rare genetic diseases, such as urea cycle disorders (UCD) and phenylketonuria (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 liver disease, inflammatory and immune disorders, and cancer. 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: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; 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 phenylketonuria; the expected timing of Synlogic’s anticipated IND application and clinical trial; and the benefit of orphan drug status. 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 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.

###