UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): **June 7, 2017**

Synergy Pharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35268**	**33-0505269**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	IRS Employer Identification No.)

420 Lexington Avenue, Suite 2012
New York, NY 10170
(Address of principal executive offices)

Registrant's telephone number, including area code: **(212) 297-0020**

(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 communication 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 as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). 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 June 7, 2017, Synergy Pharmaceuticals Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's supplemental New Drug Application (sNDA) for TRULANCE™ (plecanatide) for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). The Prescription Drug User Fee Act (PDUFA) date is January 24, 2018. The press release is attached as Exhibit 99.1 to this report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Synergy Pharmaceuticals Inc. Press Release dated June 7, 2017.

SIGNATURE

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.

Dated: June 7, 2017

SYNERGY PHARMACEUTICALS INC.

By: /s/ Gary S. Jacob
Gary S. Jacob, Ph.D.
President and Chief Executive Officer

Exhibit 99.1

NEWS RELEASE

Synergy Pharmaceuticals Announces Acceptance of Supplemental New Drug Application (sNDA) for TRULANCE™ (Plecanatide) for the Treatment of Adults with Irritable Bowel Syndrome with Constipation (IBS-C)

NEW YORK — June 07, 2017 — Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the company's supplemental New Drug Application (sNDA) for TRULANCE™ (plecanatide) for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). The Prescription Drug User Fee Act (PDUFA) date is January 24, 2018.

TRULANCE is a once-daily tablet approved by the FDA for the treatment of adults with chronic idiopathic constipation (CIC) and is currently being evaluated for the treatment of adults with IBS-C. The recommended dosage of TRULANCE for CIC is 3 mg taken orally, once daily, with or without food at any time of the day.

"This acceptance by the FDA is an important step forward for Synergy, building on the recent FDA approval and launch of TRULANCE for adults with CIC, and signaling the next step in our efforts to bring TRULANCE to the many millions of people living with IBS-C," said Gary S. Jacob, Ph.D., Chairman and CEO, Synergy Pharmaceuticals Inc. "This milestone is a testament to our entire team's passion to the continued research and development of TRULANCE, which, if approved, represents an additional, much needed new treatment option for this complex disorder."

The application is based on data from two randomized, 12-week, double-blind, placebo-controlled Phase 3 studies evaluating the efficacy and safety of TRULANCE for the treatment of adults with IBS-C. Across the two trials, more than 2,100 patients received a once-daily tablet of TRULANCE (3 mg or 6 mg doses) or placebo.

In these studies, TRULANCE 3 mg and 6 mg doses met the primary endpoint showing statistical significance in the percentage of patients who were Overall Responders compared to placebo during the 12-week treatment period (Study 1: 30.2% in 3 mg and 29.5% in 6 mg dose groups compared to 17.8% in placebo; $p<0.001$ for 3 mg and $p<0.001$ for 6 mg; Study 2: 21.5% in 3 mg and 24.0% in 6 mg dose groups compared to 14.2% in placebo; $p=0.009$ for 3 mg and $p<0.001$ for 6 mg).

An Overall Responder, as defined by the U.S. Food and Drug Administration (FDA), is a patient who fulfills both $\geq$ 30% reduction in worst abdominal pain and an increase of $\geq$ 1 complete spontaneous bowel movement (CSBM) over baseline, in the same week, for at least 50% of the 12 treatment weeks. This is the current primary endpoint required for FDA approval in IBS-C.

In both studies, the most common adverse event was diarrhea (Study 1 = 3.2% at 3 mg and 3.7% at 6 mg compared to 1.3% at placebo; Study 2 = 5.4% at 3 mg and 4.3% at 6 mg compared to 0.6% at placebo).

Indications and Usage

TRULANCE is a guanylate cyclase-C (GC-C) agonist indicated in adults for the treatment of chronic idiopathic constipation (CIC).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS
Trulance™ is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.

Contraindications

- Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Risk of Serious Dehydration in Pediatric Patients

- Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
- Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile

mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients.
- If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

Adverse Reactions

- In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (5% vs 1% placebo).

Please click here for Full Prescribing Information.

About Irritable Bowel Syndrome with Constipation (IBS-C)

Irritable bowel syndrome (IBS) is a chronic gastrointestinal disorder characterized by recurrent abdominal pain and associated with two or more of the following: related to defecation, associated with a change in the frequency of stool, or associated with a change in the form (appearance) of the stool. IBS can be subtyped by the predominant stool form: constipation

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(IBS-C), diarrhea (IBS-D) or mixed (IBS-M). Those within the IBS-C subtype experience hard or lumpy stools more than 25 percent of the time they defecate, and loose or watery stools less than 25 percent of the time. It is estimated that the prevalence of IBS-C in the U.S. adult population is approximately 4 to 5 percent, although this number can vary as patients may fluctuate between the three subtypes of IBS.

About TRULANCE™

TRULANCE™ (plecanatide) is a once-daily tablet approved for adults with CIC and is being evaluated for IBS-C. With the exception of a single amino acid substitution for greater binding affinity, TRULANCE is structurally identical to uroguanylin, a naturally occurring and endogenous human GI peptide. Uroguanylin activates GC-C receptors in a pH-sensitive manner primarily in the small intestine, stimulating fluid secretion and maintaining stool consistency necessary for regular bowel function.

About Synergy Pharmaceuticals

Synergy is a biopharmaceutical company focused on the development and commercialization of novel GI therapies. The company has pioneered discovery, research and development efforts on analogs of uroguanylin, a naturally occurring and endogenous human GI peptide, for the treatment of GI diseases and disorders. Synergy's proprietary GI platform includes one commercial product TRULANCE and a second lead product candidate, dolcanatide. For more information, please visit www.synergypharma.com.

Forward-Looking Statement

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Synergy Pharmaceuticals Inc. under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast," "estimated," "expected," and "intend," among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the development, launch, introduction and commercial potential of TRULANCE; growth and opportunity, including peak sales and the potential demand for TRULANCE, as well as its potential impact on applicable markets; market size; substantial competition; our ability to

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continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; dependence upon third parties; our financial performance and results, including the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical trials discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Synergy's most recent periodic reports filed with the Securities and Exchange Commission, including Synergy's Form 10-K for the year ended December 31, 2016. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Synergy does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

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