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**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): **May 7, 2017**

**Synergy Pharmaceuticals Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**001-35268**  
(Commission  
File Number)

**33-0505269**  
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.

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**Item 8.01 Other Events.**

On May 7, 2017, Synergy Pharmaceuticals Inc. (the "Company") issued a press release announcing new insights that highlighted the frustrations many patients with chronic idiopathic constipation (CIC) feel with managing their condition. The press release is attached as Exhibit 99.1 to this report on Form 8-K and is incorporated herein by reference.

In addition on May 7, 2017, the Company announced that it will present new data from an analysis of patients with moderate to very severe bloating at baseline who participated in two Phase 3 studies evaluating TRULANCE™ (plecanatide) for the treatment of adults with CIC. These data were recognized by the American Gastroenterology Association (AGA) as a Poster of Distinction and will be presented at Digestive Disease Week (DDW), May 6-9, 2017, in Chicago. The press release is attached as Exhibit 99.2 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 May 7, 2017.  
99.2 Synergy Pharmaceuticals Inc. Press Release dated May 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: May 8, 2017

SYNERGY PHARMACEUTICALS INC.

By: /s/ Gary S. Jacob

Gary S. Jacob, Ph.D.

President and Chief Executive Officer

NEWS RELEASE



**Synergy Presents New Insights at Digestive Disease Week (DDW) Examining Patient and Physician Perceptions and Experiences with Chronic Idiopathic Constipation (CIC)**

*Results from the BURDEN-CIC Study highlight the condition's impact and show need for additional CIC treatment options.*

**NEW YORK — May 7, 2017** — Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) today announced new insights that highlighted the frustrations many patients with chronic idiopathic constipation (CIC) feel with managing their condition. Detailed results from the BURDEN-CIC Study (Better Understanding and Recognition of the Disconnects, Experiences and Needs of Patients with Chronic Idiopathic Constipation) were presented today at Digestive Disease Week (DDW), in Chicago. Findings are based on results from an online survey of more than 1,200 patients and 325 healthcare providers (HCPs).

**Patients are significantly impacted by their CIC, but feel resigned to their condition.** Surveyed patients noted their lives are significantly impacted by CIC in terms of participation in daily activities and measurable loss in productivity:

- More than 40% of patients reported being frustrated with CIC and more than a third (39%) reported that they are “accepting” of their condition.
- Patients report that productivity is impacted approximately five out of every 30 days each month, and personal activities are impacted about four of every 30 days of the month.

**Patients feel a lack of symptom relief and treatment satisfaction.** Among those surveyed, both HCPs (78%) and patients (59%) are not satisfied or not completely satisfied with current branded Rx treatment options available for the treatment of CIC:

- For HCPs, inadequate response to therapy, non-compliance, and side effects were noted as the top challenges with current treatments.

- For patients, efficacy and side effects were noted as two reasons for dissatisfaction with current treatment options, with 84% of patients stating his or her CIC is not fully relieved by current prescription treatments.

Both HCPs and patients said diarrhea is an unacceptable side effect with current CIC treatments:

- More than one-third (34%) of HCPs indicate that managing treatment-related diarrhea is a key challenge with current prescription treatments.
- More than half (54%) of patients that experienced diarrhea because of his or her prescription medication discontinued their treatment.
- Approximately 82% of HCPs and 70% of patients do not agree that diarrhea is an acceptable treatment outcome.

“The BURDEN-CIC Study sheds light on the dissatisfaction and frustration many patients and HCPs experience when managing CIC, which poses a significant challenge due to its wide range of symptoms,” said Lucinda A. Harris, M.D., Mayo Clinic. “Though HCPs are acknowledging patients’ discontent, there is a clear need for HCPs and patients living with CIC to have more productive conversations about the patient’s health and treatment options.”

**About the BURDEN-CIC Study**

The BURDEN-CIC Study (Better Understanding and Recognition of the Disconnects, Experiences, and Needs of Patients with Chronic Idiopathic Constipation) participants consisted of more than 1,200 patients who met CIC criteria (mean age, 48 years; 70 percent of respondents were female) and completed the 45-minute, 68-question, IRB-approved online questionnaire. The study also evaluated, through a 30-minute, 32-item questionnaire, more than 325 healthcare providers who treat patients with CIC.

**About Chronic Idiopathic Constipation (CIC)**

CIC affects approximately 14 percent of the global population, disproportionately affecting women and older adults. People with CIC have persistent symptoms of difficult-to-pass and infrequent bowel movements. In addition to physical symptoms including abdominal bloating and discomfort, CIC can adversely affect an individual’s quality of life, including increasing stress levels and anxiety.

**About Synergy Pharmaceuticals Inc.**

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 treatment of GI diseases and disorders. For more information, please visit [www.synergypharma.com](http://www.synergypharma.com).

## **Forward-Looking Statement**

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “planned,” “believe,” “forecast,” “estimated,” “expected,” and “intend,” among others. These forward-looking statements are based on Synergy’s current expectations and actual results could differ materially. 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, substantial competition; our ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing efforts and dependence upon third parties; 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 Annual Report on Form 10-K for the year ended December 31, 2016 and other periodic reports filed with the Securities and Exchange Commission. 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.

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## **Company Contact:**

Gem Hopkins  
VP, Investor Relations and Corporate Communications  
212-584-7610  
ghopkins@synergypharma.com

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**Synergy Pharmaceuticals to Present TRULANCE™ (Plecanatide) Phase 3 Data at Digestive Disease Week (DDW) for the Treatment of Adults with Chronic Idiopathic Constipation (CIC) with Moderate to Very Severe Bloating**

*New data highlight results for CIC patients with moderate to very severe bloating.*

**NEW YORK — May 7, 2017** — Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) announced today that the company will present new data from an analysis of patients with moderate to very severe bloating at baseline who participated in two Phase 3 studies evaluating TRULANCE™ (plecanatide) for the treatment of adults with chronic idiopathic constipation (CIC). These data were recognized by the American Gastroenterology Association (AGA) as a Poster of Distinction and will be presented at Digestive Disease Week (DDW), May 6-9, 2017, in Chicago.

TRULANCE is a once-daily tablet approved by the Food and Drug Administration (FDA) for the treatment of adults with 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.

Over 12 weeks, patients with CIC and moderate, severe or very severe bloating symptoms at baseline and were treated with TRULANCE 3 mg or 6 mg doses achieved a significantly greater efficacy responder rate—the primary endpoint defined by the FDA for regulatory approval in CIC—in this analysis compared to placebo (18.8% for 3 mg and 16.3% for 6 mg compared to 9.5% for placebo). Efficacy responders were defined as patients who had at least three complete spontaneous bowel movements (CSBMs) in a given week and an increase of at least one CSBM over baseline in the same week for at least nine weeks out of the 12-week treatment period, including at least three of the last four weeks. The symptom of bloating among these patients also showed statistically significant improvements for TRULANCE 3 mg and 6 mg compared to placebo. Improvements in abdominal bloating scores were statistically significant after one week and continued throughout the 12-week treatment period.

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“People living with chronic idiopathic constipation often experience a range of symptoms that can make it more difficult to manage this disorder, including moderate to very severe bloating,” said Satish S.C. Rao, M.D., Ph.D., Professor of Medicine, Division Chief Fellowship Program Director and Director, Digestive Health Center at Augusta University. “The data presented today is consistent with the efficacy and safety results seen from previously published results for TRULANCE in CIC.”

In both studies, the most common adverse event was diarrhea (4.1% at 3 mg and 4.5% at 6 mg compared to 0.7% for placebo). Discontinuation rates were low across both groups (3.6% at 3 mg and 4.5% at 6 mg compared to 2.4% for placebo) and discontinuations due to diarrhea were infrequent (1.0% at 3 mg and 1.6% at 6 mg compared to 0.2% for 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  $\geq 2\%$  and greater than in the placebo group) was diarrhea (5% vs 1% placebo).

**Please click here for Full Prescribing Information.**

## About Chronic Idiopathic Constipation (CIC)

CIC affects approximately 14 percent of the global population, disproportionately affecting women and older adults. People with CIC have persistent symptoms of difficult-to-pass and infrequent bowel movements. In addition to physical symptoms including abdominal bloating and discomfort, CIC can adversely affect an individual's quality of life, including increasing stress levels and anxiety.

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## 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](http://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 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

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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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