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 10, 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 2.02 Results of Operations and Financial Condition.

On May 10, 2017, Synergy Pharmaceuticals Inc. (the "Company") issued a press release announcing financial results for the three months ended March 31, 2017 and other matters described in the press release. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Synergy Pharmaceuticals Inc. Press Release dated May 10, 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 10, 2017

SYNERGY PHARMACEUTICALS INC.

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

Exhibit 99.1

Synergy Pharmaceuticals Reports First Quarter 2017 Financial Results and Business Update

NEW YORK, May 10, 2017 —Synergy Pharmaceuticals Inc. (NASDAQ:SGYP), a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies, today reported its financial results and business update for the three months ended March 31, 2017.

"The first three months of this year have been among the most significant in the company's history and are highlighted by several important milestones that demonstrate our continued commitment to scientifically driven innovation and providing novel treatment options for patients and healthcare providers," said Gary S. Jacob, PhD, Chairman and Chief Executive Officer of Synergy Pharmaceuticals Inc. "Following the early FDA approval of TRULANCE for the treatment of adults with CIC in January, our commercial team initiated TRULANCE promotion on March 20th and we are very pleased with the encouraging feedback from patients and key prescribers, as well as the early uptake of TRULANCE after only a few weeks of marketing. In addition, we have made tremendous progress moving conversations forward with payers and will continue all efforts to increase access for patients. While it is still early in the launch, everything we are seeing reinforces the significant opportunity for TRULANCE to treat adults with CIC over the coming years. Looking ahead, we will continue to focus on the TRULANCE launch in CIC, while working with the FDA to broaden the product label with the IBS-C indication. We look forward to updating you on our progress in the coming months."

Gary Gemignani, Synergy's newly appointed EVP and Chief Financial Officer added, "I am honored to have joined Synergy at this pivotal juncture where I see significant opportunity to capitalize on the strong foundation we have in place to drive further growth. Synergy controls 100% of the worldwide rights to TRULANCE, a high value asset that is now generating revenues and has secured a long lifespan that we will be able to maximize. We remain focused on having a disciplined approach to capital allocation to support appropriate investments that will ensure the long-term success of TRULANCE. I look forward to working with Gary and the team as we continue to pursue growth, strengthen our balance sheet and drive shareholder value."

First Quarter 2017 and Recent Highlights

TRULANCE™ (plecanatide) CIC Update

- In January 2017, the United States Food and Drug Administration (FDA) approved TRULANCE for the treatment of adults with CIC. In clinical trials, TRULANCE helped improve stool consistency and provide more regular bowel movements. TRULANCE is the only prescription medication for CIC that can be taken once-daily, with or without food, at any time of the day. In addition, TRULANCE is the only prescription medication for CIC available in a unique calendar pack that was preferred by the majority of patients versus a traditional pill bottle.

TRULANCE IBS-C Development Update

- In March 2017, we submitted a sNDA for TRULANCE for the treatment of adults with IBS-C. We expect a 10-month review period from the submission date of March 24, 2017. The application is based on data from two of the largest Phase 3 IBS-C clinical trials to date, which evaluated more than 2,100 patients. In both 12-week studies, TRULANCE met the primary endpoint and showed statistical significance in the percentage of patients who were Overall Responders compared to placebo. The FDA has defined an Overall Responder as a patient who achieves $\geq$ 30% reduction in worst abdominal pain and an increase of $\geq$ 1 complete spontaneous bowel movement (CSBM) from baseline, in the same week, for at least 50% of the 12 treatment weeks.

TRULANCE IP Update

- On April 12, 2017, we announced that the United States Patent and Trademark Office (USPTO) has issued three new patents covering TRULANCE. The first patent relates to the method for manufacturing TRULANCE and will expire March 1, 2032. The two other patents relate to formulations and methods of using TRULANCE for treating chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) at 3mg or 6 mg dose; both of these patents will expire September 15, 2031.

TRULANCE Commercial Launch Update

Driving Awareness of TRULANCE and Stimulating Trial and Adoption

- Our sales force of approximately 250 is fully deployed across the U.S. and now educating approximately 27,000 high prescribers about TRULANCE.
  - The targeted prescriber base includes gastroenterologists, primary care physicians, nurse practitioners and physician assistants that currently account for approximately 70% of the total branded prescriptions, according to QuintilesIMS.
  - To date, our sales force has reached over 80% of the prescribers in the top three deciles.
    - According to QuintilesIMS analog research, we are exceeding expectations in terms of penetration and adoption curves with top decile prescribers after one month of launch.
    - Since launch, approximately 50% of TRULANCE prescriptions are coming from other branded prescription products and 50% are new patients.
- Over 300,000 7-day sample packs of TRULANCE have been distributed to the field force, to-date.
- Initiated peer-to-peer educational programs with approximately 140 gastroenterologists now educating local gastroenterologists, primary care physicians and other health care professionals on patient, disease and product-specific information to enable appropriate use of TRULANCE.

- Launched a comprehensive print and digital media plan to drive awareness of TRULANCE and stimulate trial and adoption among target prescribers.
- Presented new TRULANCE data and insights from the BURDEN-CIC study at DDW 2017.
  - Presented six abstracts, including one late-breaker oral presentation highlighting TRULANCE data from the two Phase 3 IBS-C trials. Two of the abstracts were recognized by the American Gastroenterology Association (AGA) as Posters of Distinction.
  - Presented new insights from the BURDEN-CIC study that examined patient and physician perceptions and experiences with CIC. The results highlight the condition's impact and show the need for additional CIC treatment options.

Ensuring Market Access

- To-date, approximately 60% of adult CIC patients with commercial insurance have unrestricted access to TRULANCE.
- The TRULANCE "Savings-to-Go" program helps to ensure an average copay of $25 per prescription for over 95% of patients with commercial insurance.
- The TRULANCE Access Support Services Program provides healthcare providers and patients additional assistance for certain managed care plans that require prior authorizations.
- Medicare Part D and Medicaid discussions are ongoing and progressing well.

Activating and Supporting the Rx Ready Patient

- Launched consumer media campaigns to support the product launch and drive awareness of the TRULANCE brand and the current unmet needs of patients with CIC.
  - TRULANCE Branded Campaign:
    Point-of-care promotion: targeting ~20,000 offices.
    Web sponsorships and display advertisements generated over 36 million impressions, to-date.
    Search engine marketing initiatives generated over 65,000 clicks, to-date.
    Over 100,000 visits to the Trulance.com consumer site, to-date.
  - "Confront Constipation" Campaign:
    Disease awareness initiative designed to increase the understanding and improve the dialogue between patients, prescribers, and other health care providers on managing CIC.
    Campaign has generated 28 original media placements and over 300 million media impressions, to-date.
    Over 60,000 downloads of the Poop Troop emoji keyboard, to-date.

Financial Results

- As of March 31, 2017, we had approximately $139.3 million of cash and cash equivalents on hand as compared to approximately $82.4 million cash and cash equivalents as of December 31, 2016.
- Net cash used in operating activities was $63.5 million in the three months ended March 31, 2017, as compared to $27.6 million in the three months ended March 31, 2016. This increase is primarily attributable to the buildout of the commercial organization and costs related to the launch of TRULANCE, including the building of inventory.
- We had net deferred revenues of $4.3 million during the three months ended March 31, 2017 as we first began distributing our product in March of 2017. We expect that these revenues will be recognized in future periods.
- Net sales in the first quarter of 2017 were approximately $0.1 million as we first began distributing our product in late March of 2017.
- Cost of goods sold in the first quarter of 2017 was approximately $1.8 million.
- Research and development expenses in the first quarter of 2017 were approximately $19.1 million, as compared to $21.2 million in the first quarter of 2016. This decrease in research and development expenses was due primarily to lower spending on CIC clinical studies.
- Selling, general and administrative expenses were approximately $41.9 million in the first quarter of 2017, as compared to approximately $6.4 million in the first quarter of 2016. This increase is primarily attributable to the buildout of the commercial organization and costs related to the launch of TRULANCE.
- On February 6, 2017, we closed on a registered direct offering of approximately 20.3 million shares of our common stock with net proceeds of approximately $121.6 million.
- As of March 31, 2017, the principal balance on our Notes was $18.6 million as compared to $23.5 million at December 31, 2016.
- We had 224.9 million and 202.7 million common shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively, which reflects primarily an increase in the issuance of shares from the common stock offering noted above and the first quarter conversions of the Notes.
- Net loss in the first quarter of 2017 was $64.6 million, as compared to a net loss of $59.9 million incurred in the first quarter of 2016.

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 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.

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.

TRULANCE Important Safety Information

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.

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 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.

Synergy Pharmaceutical Inc.
Condensed Consolidated Balance Sheets

($ in thousands)	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Cash, cash equivalents and available for sale securities	$ 139,262	$ 82,387
Accounts receivable	6,319	—
Inventories	9,647	5,640
Prepaid expenses and other current assets	8,038	889
Total Current assets	163,266	88,916
Other assets	976	936
Total assets	$ 164,242	$ 89,852
Liabilities and Stockholders' Equity		
Total Current Liabilities	$ 43,489	$ 29,430
Senior Convertible Notes, net	16,771	22,665
Derivative financial instruments — warrants	94	216
Total Liabilities	60,354	52,311
Total Stockholders' Equity	103,888	37,541
Total Liabilities and Stockholders' Equity	$ 164,242	$ 89,852

Condensed Consolidated Statement of Operations
($ in thousands except share and per share data)
(unaudited)

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Revenues	$ 98	$ —
Cost of goods sold	1,805	—
Gross profit	(1,707)	—
Costs and Expenses:		
Research and development	19,129	21,175
Selling, general and administrative	41,891	6,375
Loss from Operations	(62,727)	(27,550)
Other Expenses:		
Interest and investment expense, net	(790)	(7,036)
Debt conversion expense	(1,209)	(25,615)
Change in fair value of financial instruments	122	260
Total Other Expenses	(1,877)	(32,391)
Net Loss	$ (64,604)	$ (59,941)
Net Loss per Common Share, Basic and Diluted	$ (0.30)	$ (0.51)
Weighted Average Common Shares Outstanding	215,484,670	117,626,669

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