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): **November 8, 2018**

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 November 8, 2018, Synergy Pharmaceuticals Inc. (the "Company") issued a press release announcing financial results for the three months ended September 30, 2018 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 November 8, 2018.

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: November 8, 2018

SYNERGY PHARMACEUTICALS INC.

By: /s/ Troy Hamilton
Troy Hamilton
Chief Executive Officer

Exhibit 99.1

Synergy Pharmaceuticals Reports Third Quarter 2018 Financial Results and Business Update

NEW YORK, November 8, 2018 —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 September 30, 2018.

Third Quarter 2018 and Recent Highlights

TRULANCE® (plecanatide)

- 63,085 TRULANCE 30-count packs were dispensed in the third quarter of 2018, a 104.7% increase versus 30,825 in the prior year quarter, per IQVIA.
- 23,560 TRULANCE new prescriptions were filled in the third quarter of 2018, a 46.4% increase versus 16,089 in the prior year quarter, per IQVIA.
- Since the launch on March 20, 2017, 250,684 TRULANCE 30-count packs have been dispensed and normalized prescription volume has increased 38.4% on average quarter-over-quarter, per IQVIA.

Financial Results

- TRULANCE U.S. net sales were $11.1 million in the third quarter of 2018, a 122.0% increase compared to $5.0 million in the third quarter of 2017.
- Synergy received an upfront payment of $10.1 million (net of China withholding tax and VAT) upon closing a licensing agreement with Luoxin Pharmaceutical Group Co., Ltd., Shandong for TRULANCE in mainland China, Hong Kong and Macau in August 2018. As of September 30, 2018, the upfront payment was recorded as deferred revenue since no performance obligations had been satisfied.
- Total operating expenses were $36.8 million in the third quarter of 2018, a 27.8% decrease compared to $51.0 million in the third quarter of 2017.
- Total adjusted operating expenses (non-GAAP) were $33.8 million in the third quarter of 2018, a 28.2% decrease compared to $47.1 million in the third quarter of 2017.
- Synergy reported a net loss of $34.5 million, or $0.14 per share, for the third quarter of 2018 compared to a net loss of $48.9 million, or $0.22 per share in the third quarter of 2017.
- Cash and cash equivalents were approximately $45.6 million at the end of the third quarter of 2018.

2018 Outlook

- On October 25, 2018, Synergy announced that it is seeking to renegotiate its term loan agreement with CRG Servicing LLC (“CRG”) and has forgone drawing down on any additional amounts pursuant to its term loan agreement. To-date the Company has been unable to further amend the agreement with respect to the financial, revenue and minimum liquidity covenants. Synergy is continuing discussions with CRG and has twice received temporary waivers on the minimum market cap covenant, which is set to expire on November 12, 2018 absent further extension. The Company is currently pursuing alternatives that better align with its business, but there is no assurance that the Company can secure CRG’s consent or otherwise achieve a transaction to refinance or otherwise repay CRG on commercially reasonable terms, in which case the Company could default under the term loan agreement and may have to pursue or otherwise accelerate strategic alternatives, including the possibility of seeking bankruptcy protection to protect stakeholder value in the event other options are not reasonably executable. Further updates on alternatives will be provided when available.
- As previously announced, TRULANCE uptake in 2018 has been slower than anticipated due to a highly competitive market access environment and slower than anticipated overall market growth. As a result, based on the Company’s current updated forecasts, Synergy is projecting TRULANCE total net sales for 2018 to be between $42.0 million to $47.0 million, which would be below the minimum revenue covenant of $61.0 million set forth in its term loan agreement with CRG. The Company has continued to evaluate opportunities to reduce cash expenditures to better align with anticipated revenues and available capital. In addition, Synergy has remained committed to the continued evaluation of all strategic opportunities to enhance shareholder value and there is no set timetable for completing this process. Synergy has engaged

financial and legal advisors to assist Synergy in evaluating these strategic alternatives. Additional information about the Company's strategic review and go-forward plan will be provided at the appropriate time.

About Synergy Pharmaceuticals

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

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 (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.

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 TRULANCE®

TRULANCE® (plecanatide) is a once-daily tablet approved for adults with CIC or 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.

Indications and Usage

TRULANCE (plecanatide) 3 mg tablets is indicated in adults for the treatment of Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C).

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 four placebo-controlled clinical trials for CIC and IBS-C. Severe diarrhea was reported in 0.6% of TRULANCE-treated CIC patients, and in 1% of TRULANCE-treated IBS-C 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).
- In the two combined IBS-C clinical trials, the most common adverse reaction in TRULANCE-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (4.3% vs 1% placebo).

Please also see the full Prescribing Information, including Box Warning, for additional risk information.

Forward-Looking Statements

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; the possibility that we may need to seek bankruptcy protection or pursue strategic alternatives that could result in leaving our current stockholders with little or no financial ownership of the Company; 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, 2017 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.

Company Contact:

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Synergy Pharmaceutical Inc.
Condensed Consolidated Balance Sheets
(unaudited)

($ in thousands)	September 30, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 45,647	$ 136,986
Accounts receivable	9,222	6,491
Inventories	21,530	17,214
Prepaid expenses and other current assets	5,259	4,469
Total Current Assets	81,658	165,160
Other assets	1,381	1,446
Total Assets	$ 83,039	$ 166,606
Liabilities and Stockholders' (Deficit)		
Other current liabilities	$ 38,355	$ 38,147
Senior convertible notes, net	17,834	—
Term Loan, net	101,739	—
Total Current Liabilities	157,928	38,147
Senior convertible notes, net	—	17,302
Term Loan, net	—	98,660
Derivative financial instruments — warrants	9,767	17,582
Other long-term liabilities	11,588	433
Total Liabilities	179,283	172,124
Total Stockholders' Deficit	(96,244)	(5,518)
Total Liabilities and Stockholders' Deficit	$ 83,039	$ 166,606

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Net sales	$ 11,105	$ 5,008	$ 31,945	$ 7,420
Cost of goods sold	3,922	1,722	11,511	5,001
Gross profit	7,183	3,286	20,434	2,419
Costs and Expenses:				
Research and development	2,904	5,876	9,140	46,346
Selling, general and administrative	33,887	45,110	108,647	140,083
Total Operating Expenses	36,791	50,986	117,787	186,429
Loss from Operations	(29,608)	(47,700)	(97,353)	(184,010)
Other Income (Expense):				
Interest expense, net	(3,369)	(1,226)	(9,697)	(2,361)
State R&D tax credits	—	—	30	—
Debt conversion expense	—	—	—	(1,209)
Change in fair value of derivative instruments - warrants	(433)	55	7,815	216
Total Other Expense	(3,802)	(1,171)	(1,852)	(3,354)
Loss before taxes	(33,410)	(48,871)	(99,205)	(187,364)
Tax expense	(1,133)	—	(1,133)	—
Net Loss	$ (34,543)	$ (48,871)	$ (100,338)	$ (187,364)
Net Loss per Common Share, Basic and Diluted	$ (0.14)	$ (0.22)	$ (0.41)	$ (0.84)
Weighted Average Common Shares Outstanding, Basic and Diluted	247,994,922	224,954,941	247,221,231	221,854,099

Synergy Pharmaceuticals Inc.

Non-GAAP Financial Measures

Adjusted research and development expenses, adjusted selling, general and administrative expenses, and adjusted total operating expenses are not measures of financial performance under accounting principles generally accepted in the United States ("GAAP") and should not be construed as substitutes for, or superior to, GAAP research and development expenses, GAAP selling, general and administrative expenses and GAAP total operating expenses as a measure of financial performance. However, management uses both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage the Company's operations and to better understand its business. Further, management believes the addition of non-GAAP financial measures provides meaningful supplementary information to, and facilitates analysis by, investors in evaluating the Company's financial performance, results of operations and trends. The Company's calculations of adjusted research and development expenses, adjusted selling, general and administrative expenses and adjusted operating expenses, may not be comparable to similarly designated measures reported by other companies, since companies and investors may differ as to what type of events warrant adjustment.

The following table reconciles reported research and development expenses to adjusted research and development expenses (adjusted R&D):

(Unaudited; $ in thousands)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017
Research and development expenses	$ 2,904	$ 5,876
Adjusted to deduct:		
Stock based compensation expense	459	477
Adjusted research and development expenses	$ 2,445	$ 5,399

The following table reconciles reported selling, general and administrative expenses to adjusted selling, general and administrative expenses (adjusted SG&A):

(Unaudited; $ in thousands)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017
Selling, general and administrative expenses	$ 33,887	$ 45,110
Adjusted to deduct:		
Stock based compensation expense	2,525	3,411
Adjusted selling, general and administrative expenses	$ 31,362	$ 41,699

The following table reconciles reported total operating expenses to adjusted operating expenses (adjusted OPEX):

(Unaudited; $ in thousands)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017
Total operating expenses	$ 36,791	$ 50,986
Adjusted to deduct:		
Stock based compensation expense	2,984	3,888
Adjusted operating expenses	$ 33,807	$ 47,098