
**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): **August 9, 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.

Item 2.02 Results of Operations and Financial Condition.

On August 9, 2017, Synergy Pharmaceuticals Inc. (the "Company") issued a press release announcing financial results for the three months ended June 30, 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 August 9, 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: August 9, 2017

SYNERGY PHARMACEUTICALS INC.

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

Synergy Pharmaceuticals Reports Second Quarter 2017 Financial Results and Business Update

- TRULANCE™ (plecanatide) U.S. net sales of \$2.3 million in second quarter of 2017
- Total TRULANCE monthly prescription volume has increased on average more than 182% month-over-month since launch in March 2017
- TRULANCE supplemental new drug application (sNDA) for irritable bowel syndrome with constipation (IBS-C) accepted for FDA review - PDUFA date of January 24, 2018

NEW YORK, August 9, 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 June 30, 2017. Synergy will host a conference call and webcast at 4:30 p.m. Eastern Time on Thursday, September 7, 2017 to discuss its corporate and financial strategy, and provide a general business update. Further details about this conference call can be found below.

“The first half of 2017 was a truly transformative period for Synergy, as we transitioned into a commercial organization and launched our first product, TRULANCE, in the U.S. for the treatment of adults with chronic idiopathic constipation (CIC),” said Gary S. Jacob, Ph.D., Chairman and CEO of Synergy Pharmaceuticals Inc. “We are pleased with the execution of our commercial strategy, and the strong initial demand for TRULANCE, reinforcing the need for new treatment options for patients suffering from CIC. And we are making significant progress in ensuring broad access to TRULANCE, highlighted by a number of favorable early decisions from key national payers.”

“During the second quarter, we also made significant progress towards broadening the TRULANCE label with the FDA acceptance of our sNDA for the treatment of adults with IBS-C,” continued Dr. Jacob. “These achievements put Synergy on excellent footing as we look to drive further long-term growth and value for the TRULANCE brand.”

Gary Gemignani, Synergy’s EVP and Chief Financial Officer added, “We believe Synergy is well-positioned to efficiently capitalize on the substantial opportunity we have in front of us with our core, high value asset, TRULANCE. We are currently evaluating financing options that will provide flexibility and allow us to continue to execute on our business objectives, which we are confident will ultimately maximize shareholder value. We are pleased with our progress on this front and look forward to providing further updates in the near-term.”

Second Quarter 2017 and Recent Highlights

TRULANCE (plecanatide) Commercial Launch Update

Driving Awareness of TRULANCE and Stimulating Trial and Adoption

- Since our launch of TRULANCE on March 20, 2017, our commercial team continues to introduce TRULANCE to more than 27,000 gastroenterologists, primary care physicians, nurse practitioners and physician assistants that represent approximately 70% of the branded prescription business. As of June 30, 2017, we had reached 66% of our targeted prescriber base and over 90% of the high volume prescribers (deciles 8-10). According to QuintilesIMS data as of June 30, 2017:
 - More than 12,600 TRULANCE prescriptions have been filled and total monthly prescription volume has increased on average more than 182% month-over-month during that period.
 - More than 32% of all high prescribers had written a TRULANCE prescription during that period with an average increase for all prescribers of approximately 140% month-over-month.
 - TRULANCE achieved 6.8% new-to-brand prescription (NBRx) total market share and 12% NBRx market share among gastroenterologists.
 - As of June 30, 2017, more than half of new TRULANCE prescriptions filled since launch were coming from new patients not previously on a branded prescription treatment and 45% were patients that converted from other branded prescription treatments.

Ensuring Market Access

- As of June 30, 2017, over 61% of adult CIC patients with commercial insurance will have unrestricted access to TRULANCE for 2017 based on the top 20 pharmacy benefit managers (PBMs) and payers. Additionally, approximately 95% of people with commercial insurance had access to TRULANCE for a co-pay of \$25 or less through the TRULANCE Savings-to-Go-Program.
- We have secured a 2018 managed care contract with CVS Caremark, which manages approximately 50 million commercial lives in the U.S., that will place TRULANCE on formulary without restriction (non-preferred) for its Commercial Template Clients or Employer Groups, representing approximately 24 million lives. We are in contract discussions with CVS Caremark for the remaining commercial lives.
- TRULANCE is currently available through Express Scripts (ESI), which manages approximately 80 million total lives in the U.S., and this commercial formulary status will continue for the remainder of 2017. ESI recently released its 2018 National Preferred Formulary List and introduced 64 new drug exclusions, including TRULANCE. This change only affects access to the ESI National Formulary for non-custom clients, representing approximately 22 million lives, effective January 1, 2018. TRULANCE will remain available to ESI lives covered under the National Preferred Formulary via the “Non-Formulary Exception Request” prior authorization process, for which we currently have a support program in place to ensure patient access. ESI also manages a

larger book of business with its Custom Clients, representing approximately 49 million lives. We are still in active discussions with ESI to determine 2018 formulary status for individual plans under their Custom Clients book of business.

- We are in active contract negotiations with other PBMs and payers for 2018 coverage to ensure our goal of broad access to TRULANCE.
- Med D and Medicaid discussions are ongoing and we expect several major accounts to include TRULANCE on formulary in 2018.

Sales Force Update

- As planned and with the continued progress of the launch, we have initiated the process to transition our Publicis Touchpoint contract sales representatives over to Synergy in preparation of our anticipated approval of TRULANCE in the IBS-C indication this coming January.

TRULANCE IBS-C Development Update

- The FDA has accepted for review our sNDA for TRULANCE for the treatment of adults with IBS-C. The Prescription Drug User Fee Act (PDUFA) date is January 24, 2018.

Financial Results

Revenues

- Net sales were \$2.3 million in the second quarter of 2017, pursuant to the product launch on March 20, 2017. The Company also recorded approximately \$1.5 million in net deferred revenues on its balance sheet, which it expects to recognize in future periods. The Company currently recognizes revenue based on patient demand (prescription sales).

Expenses

- Research and development expenses (“R&D”) were approximately \$22.3 million for the second quarter of 2017 compared to approximately \$26.6 million for the second quarter of 2016. This decrease was primarily due to the cost of validation batches as well as pre-commercial inventory build being classified as R&D in 2016.
 - Selling, general and administrative (“SG&A”) expenses were approximately \$50.7 million for the second quarter of 2017 compared to approximately \$10.2 million for the second quarter of 2016. These increased expenses primarily reflect the cost of marketing and promotional activities to support the product launch of TRULANCE on March 20, 2017. These costs include an approximately \$23.1 million increase in marketing and sales expenses, an increase of \$4.7 million in employee compensation and benefits costs, and an increase of \$11.5 million in stock compensation expense (\$9.3 million related to the modification of Change of Control and terminated employee stock options). There are no remaining Change of Control options outstanding as of June 30, 2017.
 - Cost of goods sold (COGs) were approximately \$2.9 million for the second quarter of 2017. COGs for the quarter are primarily related to technical operations overhead costs.
 - Net interest expense was approximately \$0.3 million in the second quarter of 2017, related to the \$200 million convertible debt financing executed in November 2014. As of June 30, 2017, the Company had approximately \$18.6 million in total debt outstanding compared to approximately \$79.2 million a year ago.
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Net Loss

- Synergy reported a net loss of approximately \$73.9 million for the three months ended June 30, 2017, compared to a net loss of approximately \$38.6 million for the three months ended June 30, 2016. This increase was a result of the operating items discussed above.

Cash Position

- Net cash used in operating activities were approximately \$57.3 million in the second quarter of 2017 compared to approximately \$63.5 million in the first quarter of 2017.
- As of June 30, 2017, we had approximately \$82 million cash and cash equivalents compared to approximately \$82.4 million cash and cash equivalents as of December 31, 2016.

Conference Call on Thursday, September 7, 2017:

Synergy will host a conference call at 4:30 p.m. Eastern Time on Thursday, September 7, 2017 to discuss its corporate and financial strategy, and provide a general business update. The dial-in number to access the call is (877) 407-3987 (U.S. and Canada) or (412) 902-0039 (International). To access the webcast, please visit the Investors section of Synergy’s website at www.synergypharma.com.

A taped replay of the conference call will also be available beginning approximately 2 hours after the call’s conclusion, and will remain available through September 21, 2017. The replay may be accessed by dialing (877) 660-6853 (U.S. and Canada) or (201) 612-7415 (International) and entering conference ID number 13668774. A replay of the webcast will also be available on the Investors section of Synergy’s website at www.synergypharma.com.

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.
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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
(unaudited)

(\$ in thousands)	June 30, 2017	December 31, 2016
Assets		
Cash and cash equivalents	\$ 81,960	\$ 82,387
Accounts receivable	1,782	—
Inventories	11,853	5,640
Prepaid expenses and other current assets	8,368	889
Total Current assets	103,963	88,916
Other assets	936	936
Total assets	\$ 104,899	\$ 89,852
Liabilities and Stockholders' Equity		
Total Current Liabilities	\$ 44,581	\$ 29,430
Senior Convertible Notes, net	16,948	22,665
Derivative financial instruments — warrants	55	216
Total Liabilities	61,584	52,311
Total Stockholders' Equity	43,315	37,541
Total Liabilities and Stockholders' Equity	\$ 104,899	\$ 89,852

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

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Net sales	\$ 2,314	\$ —	\$ 2,412	\$ —
Cost of goods sold	2,890	—	4,695	—
Gross profit	(576)	—	(2,283)	—
Costs and Expenses:				
Research and development	22,314	26,611	41,443	47,786
Selling, general and administrative	50,693	10,249	92,584	16,624
Loss from Operations	(73,583)	(36,860)	(136,310)	(64,410)
Other Expenses:				
Interest and investment expense, net	(345)	(1,673)	(1,135)	(8,709)
Debt conversion expense	—	—	(1,209)	(25,615)
Change in fair value of derivative financial instruments - warrants	39	(23)	161	237
Total Other Expenses	(306)	(1,696)	(2,183)	(34,087)
Net Loss	\$ (73,889)	\$ (38,556)	\$ (138,493)	\$ (98,497)
Net Loss per Common Share, Basic and Diluted	\$ (0.33)	\$ (0.23)	\$ (0.63)	\$ (0.69)
Weighted Average Common Shares Outstanding	224,948,622	168,127,144	220,269,223	143,017,970

Company Contact:

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