

March 1, 2018



Synergy Pharmaceuticals Reports Fourth Quarter and Full Year 2017 Financial Results and Business Update

- *TRULANCE® U.S. net sales were \$9.4 million in the fourth quarter, totaling \$16.8 million for 2017*
- *2017 total prescription volume increased 70% on average month-over-month since launch*
- *Successfully amended CRG debt facility to provide enhanced financial and strategic flexibility*

NEW YORK--(BUSINESS WIRE)-- 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 full year and the three months ended December 31, 2017.

"2017 was a transformative year for Synergy with the FDA approval and launch of our first product, TRULANCE, which saw impressive early adoption and uptake in our first few quarters as a commercial organization and resulted in solid operating results for 2017," said Troy Hamilton, Chief Executive Officer of Synergy Pharmaceuticals Inc. "Strong customer demand was recognized by payors with TRULANCE coverage more than doubling its access on the largest commercial plans since launch. During 2017, we also successfully submitted a sNDA for TRULANCE that led to the second FDA approval in IBS-C in January 2018, expanding our opportunity to bring this important new treatment option to more patients in need."

"As we execute the long-term growth strategy of our business, we are continuing to prioritize investments in key areas that deliver the highest return and growth to the company's top-line," added Mr. Hamilton. "We are continuing to explore all strategic and business development opportunities that align with our core mission to deliver long-term value to our patients, customers and shareholders. The licensing deal we just entered into with Cipher Pharmaceuticals for TRULANCE in Canada is just the first example of our commitment to provide the potential benefit of TRULANCE to patients globally. To this end, we are pleased to announce the amendment of our CRG term loan agreement to provide enhanced strategic and financial flexibility. We are very encouraged by what we accomplished in 2017 as we established a strong foundation for future growth and success."

Fourth Quarter 2017 and Recent Highlights

- TRULANCE U.S. net sales were \$9.4 million in the fourth quarter of 2017, totaling \$16.8 million for the full year 2017.
- Total TRULANCE prescription volume in the fourth quarter of 2017 included 42,486 TRULANCE 30-count packs, per IQVIA. For the full year 2017, more than 88,360 TRULANCE 30-count packs were dispensed, increasing 70% on average month-over-month since launch on March 20, 2017, per IQVIA.
- On January 25, 2018, we announced that the U.S. Food and Drug Administration (FDA) approved TRULANCE® (plecanatide) 3 mg tablet for the once-daily treatment of irritable bowel syndrome with constipation (IBS-C) in adults. This is the second indication for TRULANCE, which was first approved for the treatment of adults with chronic idiopathic constipation (CIC) in January 2017.
- Since launch, TRULANCE commercial coverage has more than doubled to over 85% of all lives covered as of the end of February 2018. In addition, TRULANCE coverage on Medicare Part D and Managed Medicaid plans has grown to over 54% of lives covered.
- In February 2018, we completed our field force integration plan by successfully transitioning our former contract sales representatives over to Synergy to coincide with our IBS-C approval and launch.
- On February 27, 2018 we entered into a definitive licensing agreement with Cipher Pharmaceuticals under which we granted Cipher the exclusive right to develop, market, distribute and sell TRULANCE in Canada. Under the terms of the licensing agreement, Synergy received an upfront payment of \$5.0 million and is eligible for an additional milestone payment, as well as royalties from product sales in Canada. We are continuing to evaluate other potential ex-US business development opportunities for TRULANCE.

Financial Results

- As of December 31, 2017, we had approximately \$137.0 million of cash and cash equivalents on hand as compared to approximately \$82.4 million of cash and cash equivalents as of December 31, 2016.
- Net cash used in operating activities was \$212.9 million in the year ended December 31, 2017, as compared to \$129.8 million in the year ended December 31, 2016.
- Research and development expenses in the fourth quarter of 2017 were approximately \$2.0 million, as compared to \$16.4 million in the fourth quarter of 2016. These decreased expenses were primarily a result of reduced clinical trial spend associated with TRULANCE as well as pre-commercial inventory costs which are recorded as cost of goods sold in 2017.
- Selling, general and administrative expenses were approximately \$41.8 million in the fourth quarter of 2017, as compared to approximately \$26.0 million in the fourth quarter of 2016. These increased expenses primarily reflect the cost of our commercial organization to launch TRULANCE.
- On November 13, 2017, we entered into an underwriting agreement to issue and sell

21,705,426 shares of our common stock together with accompanying warrants ("Warrants") to purchase an aggregate of 21,705,426 shares of Common Stock in an underwritten offering. The net proceeds from the Offering were approximately \$52.2 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

- As of December 31, 2017 the principal balance on our senior secured term loan ("Term Loan") was \$103.2 million. In February 2018 we amended the Term Loan agreement. The amended Term Loan provides for future borrowings of \$25 million, \$25 million and \$50 million on or before June 30, 2018, September 30, 2018 and December 31, 2018, respectively. Additionally, the total amount of the commitment was reduced from \$300 million to \$200 million (excluding PIK loans) and the Minimum Market Capitalization covenant of \$300 million was revised to be 200% of the outstanding principal amount of loan (excluding PIK loans).
- We had 246.7 million and 202.7 million common shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively, which reflects primarily an increase in the issuance of shares from the conversion of Notes, and equity offerings in January and November 2017.
- Net loss in the fourth quarter of 2017 was \$37.0 million, as compared to a net loss of \$59.9 million incurred in the fourth quarter of 2016.

Fourth Quarter Conference Call and Webcast

Synergy will host a conference call and webcast to discuss its financial and operating results for the fourth quarter and full year ending December 31, 2017 today at 4:30 p.m. Eastern Time. Participants may access the conference call by dialing 877-407-3978 (US and Canada) or 412-902-0039 (International). Please let the operator know you would like to join the Synergy Pharmaceuticals call.

To access the webcast as well as a PDF copy of the presentation, please visit the Investors section of Synergy's website at www.synergypharma.com. An audio replay of the conference call will also be available beginning approximately two hours after the call's conclusion, and will remain available through March 15, 2018. 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

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 $\geq 2\%$ 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 $\geq 2\%$ 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; 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.

**Synergy Pharmaceutical Inc.
Consolidated Balance Sheets**

(\$ in thousands)	<u>December 31, 2017</u>	<u>December 31, 2016</u>
Assets		
Cash and cash equivalents	\$ 136,986	\$ 82,387
Accounts receivable	6,491	—
Inventories	17,214	5,640
Prepaid expenses and other current assets	4,469	889
Total Current assets	<u>165,160</u>	<u>88,916</u>
Other assets	1,446	936
Total assets	<u>\$ 166,606</u>	<u>\$ 89,852</u>
Liabilities and Stockholders' (Deficit)/Equity		
Total Current Liabilities	\$ 38,147	\$ 29,430
Senior convertible notes, net	17,302	22,665
Long term debt, net	98,660	—
Derivative financial instruments – warrants	17,582	216
Other long term liabilities	433	—
Total Liabilities	<u>172,124</u>	<u>52,311</u>
Total Stockholders' (Deficit)/Equity	<u>(5,518)</u>	<u>37,541</u>
Total Liabilities and Stockholders' (Deficit)/Equity	<u>\$ 166,606</u>	<u>\$ 89,852</u>

Synergy Pharmaceutical Inc.
Consolidated Statement of Operations

(\$ in thousands except share and per share data)	Three Months Ended December 31, 2017 (unaudited)	Three Months Ended December 31, 2016 (unaudited)	Year Ended December 31, 2017	Year Ended December 31, 2016
Net Sales	\$ 9,400	\$ —	\$ 16,820	\$ —
Cost of goods sold	3,820	—	8,811	—
Gross profit	5,580	—	8,009	—
Costs and Expenses:				
Research and development	1,990	16,406	48,346	87,056
Selling, general and administrative	41,779	25,992	181,862	58,230
Loss from Operations	(38,189)	(42,398)	(222,199)	(145,286)
Other Income/(Loss):				
Interest expense, net	(2,909)	(3,007)	(5,270)	(13,390)
Debt conversion expense	—	(14,543)	(1,209)	(40,158)
State R&D tax credits	—	126	—	121
Change in fair value of financial instruments	4,124	(45)	4,340	106
Total Other Income/(Loss)	1,215	(17,469)	(2,139)	(53,321)
Net Loss	\$ (36,974)	\$ (59,867)	\$ (224,338)	\$ (198,607)
Net Loss per Common Share, Basic and Diluted	\$ (0.16)	\$ (0.31)	\$ (1.00)	\$ (1.21)
Weighted Average Common Shares Outstanding	235,924,350	190,093,786	225,439,121	164,437,548

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