August 7, 2018

Synergy Pharmaceuticals Reports Second Quarter 2018 Financial Results and Business Update

- *TRULANCE® second quarter net sales up over 40% versus prior quarter*
- *TRULANCE added to Express Scripts 2019 National Preferred Formulary List*
- *Synergy secures ex-US licensing deal for TRULANCE in China - providing $12 million upfront payment and potential for future milestone and escalating royalty payments*

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 three months ended June 30, 2018.

"The Synergy team continues to demonstrate strong execution towards our 2018 key business priorities of optimizing the value of TRULANCE, ensuring a strong financial foundation and continuing to explore all business development opportunities," said Troy Hamilton, Chief Executive Officer of Synergy Pharmaceuticals Inc. "In terms of optimizing TRULANCE, we reported strong quarter-over-quarter growth with net sales increasing 43% in the second quarter. In addition, today we announced a major coverage win with Express Scripts, helping us to enhance and expand our current coverage, improve patient access and support sales growth. Lastly, since the beginning of the year we've successfully executed on two ex-US licensing transactions for TRULANCE as well as a collaboration with the National Cancer Institute (NCI) to advance development of our second pipeline asset, dolcanatide, underscoring our commitment to pursuing a wide variety of value-enhancing strategic and business development opportunities. While we are very pleased with these partnerships, we are still actively assessing other potential opportunities that align with our ultimate objective of maximizing value for Synergy shareholders. We remain committed to being as transparent as possible during this ongoing strategic review and expect to provide another update in the near term. I want to thank the entire Synergy team, our customers and shareholders for their continued support during this dynamic period."

“We were pleased with solid topline growth of over 40% in the second quarter versus the prior quarter, resulting in $20.8 million in total net sales for the six months ended June 30, 2018," said Gary Gemignani, EVP and Chief Financial Officer of Synergy Pharmaceuticals Inc. "As we move into the second half of the year, we will continue to balance our commitment to topline growth with the efficient management of our bottom line, as highlighted by the 44% reduction in total adjusted operating expenses we achieved year-

over-year. We are evaluating opportunities to further optimize our operating efficiencies and intend to update our 2018 total adjusted OPEX guidance as part of our ongoing strategic review."

Second Quarter 2018 and Recent Highlights

Optimizing the Value of TRULANCE

- On August 7, 2018, Synergy announced that Express Scripts, a leading U.S. pharmacy benefit manager, will add TRULANCE to its 2019 National Preferred Formulary List, effective January 1, 2019.
- Total TRULANCE normalized prescription volume in the second quarter of 2018 included approximately 55,000 TRULANCE 30-count packs, up over 24% versus the first quarter, and resulting in over 90% average quarterly growth since the product's launch on March 20, 2017, per IQVIA.
- TRULANCE new prescription volume showed nearly 25% average quarterly growth since launch through June 30, 2018, per IQVIA.
- Total number of unique healthcare practitioners prescribing TRULANCE reached over 14,000 in the second quarter of 2018, increasing more than 20% over the first quarter, and resulting in 60% average quarterly growth since launch, per IQVIA.

Ensuring a Strong Financial Foundation

Financial Results

- TRULANCE net sales were $12.3 million in the second quarter of 2018, increasing 43% over the first quarter of 2018, and resulting in $20.8 million in total net sales for the six months ended June 30, 2018. TRULANCE was first approved by the FDA for chronic idiopathic constipation (CIC) in January 2017 and Synergy initiated U.S. sales and marketing efforts on March 20, 2017. TRULANCE was approved by the FDA for a second indication in irritable bowel syndrome with constipation (IBS-C) in January 2018.
- Total operating expenses were $37.5 million in the second quarter of 2018 compared to $74.3 million in total operating expenses in the second quarter of 2017.
- Total adjusted operating expenses (non-GAAP) were $34.0 million in the second quarter of 2018, a 44% decrease compared to $61.0 million in total adjusted operating expenses (non-GAAP) in the second quarter of 2017.
- Synergy reported a net loss of $29.7 million, or $0.12 per share, for the second quarter of 2018 compared to a net loss of $73.9 million, or $0.33 per share in the second quarter of 2017.
- Cash and cash equivalents were approximately $61.2 million at the end of the second quarter. Synergy has the ability to access up to an additional $100 million in 2018 under its Term Loan Agreement with CRG LP, subject to the satisfaction of certain borrowing conditions.

Exploring All Strategic and Business Development Opportunities

Collaborations & Partnerships

- On August 7, 2018, Synergy announced a license agreement with Luoxin Pharmaceutical Group Co., Ltd., Shandong (Luoxin) providing Luoxin exclusive rights to develop and commercialize TRULANCE for the treatment of adults with chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) in mainland China, Hong Kong and Macau. Under the terms of the agreement, Synergy will receive an upfront payment of $12 million. Synergy is also eligible, in the event that certain regulatory and commercial milestones are met, to receive additional payments of up to $56 million in aggregate. In addition, Synergy is eligible to receive tiered royalty payments on aggregate net sales.
- Synergy's Canadian partner, Cipher Pharmaceuticals, remains on-track to file a New Drug Submission for TRULANCE in IBS-C with Health Canada in the second half of 2018. The regulatory review period is approximately one-year from the submission date. Under the terms of the licensing agreement, Synergy is eligible for a milestone payment upon regulatory approval in Canada, as well as royalties from product sales in Canada.
- The National Cancer Institute (NCI) has initiated a NCI-funded and managed clinical biomarker study to evaluate the potential of dolcanatide, Synergy's second uroguanylin analog, to prevent colorectal cancer. The study will assess the colorectal bioactivity of dolcanatide in healthy volunteers and will inform the feasibility and design of a larger study. This is the first clinical biomarker study evaluating the potential benefit of using a uroguanylin analog in colorectal cancer prevention.

2018 Financial Guidance / Strategic Review Update

- Synergy intends to provide an update to shareholders on its ongoing strategic review, including any anticipated related impact on operating expenses, in the third quarter of 2018.

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; 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.
Condensed Consolidated Balance Sheets
(unaudited)

($ in thousands)	June 30, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 61,233	$ 136,986
Accounts receivable	8,511	6,491
Inventories	17,609	17,214
Prepaid expenses and other current assets	7,772	4,469
Total Current Assets	95,125	165,160
Other assets	1,480	1,446
Total Assets	$ 96,605	$ 166,606
Liabilities and Stockholders' (Deficit)		
Total Current Liabilities	$ 33,598	$ 38,147
Senior convertible notes, net	17,657	17,302
Long term debt, net	100,327	98,660
Derivative financial instruments – warrants	9,334	17,582
Other long-term liabilities	379	433
Total Liabilities	161,295	172,124
Total Stockholders’ Deficit	(64,690)	(5,518)
Total Liabilities and Stockholders’ Deficit	$ 96,605	$ 166,606

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

	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Net sales	$ 12,254	$ 2,314	$ 20,840	$ 2,412
Cost of goods sold	3,885	1,643	7,589	3,279
Gross profit	8,369	671	13,251	(867)
Costs and Expenses:				
Research and development	2,844	22,069	6,236	40,470
Selling, general and administrative	34,615	52,185	74,760	94,973
Total Operating Expenses	37,459	74,254	80,996	135,443
Loss from Operations	(29,090)	(73,583)	(67,745)	(136,310)
Other Income/(Expense):				
Interest expense, net	(3,205)	(345)	(6,328)	(1,135)
State R&D tax credits	—	—	30	—
Debt conversion expense	—	—	—	(1,209)
Change in fair value of derivative instruments - warrants	2,604	39	8,248	161
Total Other Income/(Expense)	(601)	(306)	1,950	(2,183)
Net Loss	$ (29,691)	$ (73,889)	$ (65,795)	$ (138,493)
Net Loss per Common Share, Basic and Diluted	$ (0.12)	$ (0.33)	$ (0.27)	$ (0.63)
Weighted Average Common Shares Outstanding	246,990,080	224,948,622	246,827,974	220,269,223

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 June 30, 2018	**Three Months Ended June 30, 2017**
Research and development expenses	$ 2,844	$22,069
Adjusted to deduct:		
Stock based compensation expense	504	(80)
Adjusted research and development expenses	$ 2,340	$22,149

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 June 30, 2018	Three Months Ended June 30, 2017
Selling, general and administrative expenses	$34,615	$ 52,185
Adjusted to deduct:		
Stock based compensation expense	2,924	13,378
Adjusted selling, general and administrative expenses	$31,691	$ 38,807

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

(Unaudited; $ in thousands)

	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017
Total operating expenses	$37,459	$ 74,254
Adjusted to deduct:		
Stock based compensation expense	3,428	13,298
Adjusted operating expenses	$34,031	$ 60,956

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