May 10, 2018

Synergy Pharmaceuticals Reports First Quarter 2018 Financial Results and Business Update

- *TRULANCE only CIC/IBS-C Rx brand to grow in total and new Rx volume quarter-over-quarter, per IQVIA*
- *Synergy lowers 2018 adjusted operating expense* (non-GAAP) *guidance*
- *Initiated strategic partnership with the National Cancer Institute (NCI) to collaborate on study to evaluate dolcanatide's potential to prevent colorectal cancer*
- *Conducting ongoing review of strategic business development options focused on maximizing shareholder value*

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 March 31, 2018.

"The first quarter of 2018 was all about executing on our three key business priorities of optimizing the value of TRULANCE, ensuring a strong financial foundation, and continuing to explore all strategic business development opportunities," said Troy Hamilton, Chief Executive Officer of Synergy Pharmaceuticals Inc. "With TRULANCE, we saw continued growth in prescriptions, market share and its prescriber base and with the IBS-C launch in late February, we have the opportunity to continue to drive further sales growth. In addition, we continued to efficiently manage our operating expenses by prioritizing key investments in areas of high return, such as expanding market access. Finally, we amended our debt agreement to allow for more flexible access to capital as we are pursuing strategic options that align with our core mission to deliver exceptional value to our patients, customers and shareholders. Overall, our progress against our key business priorities during the first quarter reflect our commitment to maximizing shareholder value while also maintaining our focus on providing safe and effective treatment options for patients living with chronic GI conditions."

First Quarter 2018 and Recent Highlights

Optimizing the Value of TRULANCE

- 44,177 TRULANCE 30-count packs were dispensed in the first quarter of 2018, resulting in a total of 132,628 TRULANCE 30-count packs dispensed since the product's launch on March 20, 2017, per IQVIA.

- TRULANCE was the only prescription brand for CIC and IBS-C to show positive total and new prescription volume growth in the first quarter over the prior quarter, per IQVIA.
- In the nine weeks since the launch of the IBS-C indication in late February, TRULANCE prescription volume grew 24% versus the prior nine weeks or nearly five times the branded CIC and IBS-C prescription market growth rate, per IQVIA.
- The total number of unique healthcare practitioners prescribing TRULANCE since launch reached nearly 12,000 in the first quarter of 2018, increasing more than 20% over the prior quarter, per IQVIA.
- TRULANCE currently has over 70% payer coverage across all segments including commercial, Medicare Part D and Managed Medicaid.

Ensuring a Strong Financial Foundation

Financial Results

- Reported TRULANCE net sales were $8.6 million in the first quarter of 2018 compared to net sales of $9.4 million during the fourth quarter of 2017. TRULANCE first quarter net sales of $8.6 million increased by 18% compared to fourth quarter of 2017 adjusted net sales (non-GAAP) of $7.3 million.
- Reported total operating expenses were $43.5 million in the first quarter of 2018 compared to total operating expenses of $43.8 million during the fourth quarter of 2017.
- Total adjusted operating expenses (non-GAAP) were $40.6 million in the first quarter of 2018 compared to $41.1 million in total adjusted operating expenses (non-GAAP) in the fourth quarter of 2017.
- In February 2018, Synergy amended its Term Loan agreement with CRG to provide more financial flexibility while the company continues to evaluate various strategic options. Synergy has the ability to access up to an additional $100 million in 2018 in three tranches.
- Synergy received $5.0 million in non-refundable upfront payments related to the TRULANCE Canadian licensing agreement with Cipher Pharmaceuticals completed in February 2018. This payment was recorded as deferred revenue for the quarter and will be recognized as revenue upon meeting future contractual obligations. Under the terms of the licensing agreement, Synergy is eligible for an additional milestone payment upon regulatory approval in Canada, as well as royalties from Trulance product sales in Canada.
- Synergy reported a net loss of $36.1 million, or $0.15 per share, for the first quarter of 2018.
- Cash and cash equivalents were approximately $98.7 million at the end of the first quarter.

2018 Financial Guidance

- As a result of ongoing efforts to improve cost efficiency measures, Synergy is lowering projected total adjusted operating expense (non-GAAP) guidance for 2018 to be in the range of $165 million - $175 million versus previously guided $175 million - $185 million.

Exploring All Strategic and Business Development Opportunities

Collaborations & Partnerships

- Synergy initiated a partnership with the National Cancer Institute (NCI) to collaborate on a NCI-funded and managed clinical biomarker study to evaluate dolcanatide's potential 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. The advancement of Synergy's proprietary uroguanylin analog, dolcanatide, into this clinical trial builds on Synergy and NCI scientists' pioneering work showing the important role of uroguanylin in the complex biology of colorectal cancer.
- Synergy's Canadian partner, Cipher Pharmaceuticals, is currently in discussions with Health Canada and plans to file a New Drug Submission for TRULANCE in IBS-C in the second half of 2018. The regulatory review period is approximately one-year from the submission date.

Ongoing Strategic Review

- Synergy continues to engage in an ongoing review of strategic business opportunities focused on maximizing shareholder value. This review process includes, but is not limited to, potential US and ex-US partnerships, licensing, and merger and acquisition transactions. Synergy expects to provide further updates on or before it reports second quarter 2018 results.

First-Quarter Conference Call & Webcast

Synergy will host a conference call and webcast today at 4:30 p.m. Eastern Time to discuss first quarter 2018 results. 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 May 24, 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 ≥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)	March 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 98,658	$ 136,986
Accounts receivable	7,414	6,491
Inventories	16,175	17,214
Prepaid expenses and other current assets	8,924	4,469
Total Current Assets	131,171	165,160
Other assets	1,475	1,446
Total Assets	$ 132,646	$ 166,606
Liabilities and Stockholders' (Deficit)		
Total Current Liabilities	$ 42,490	$ 38,147
Senior convertible notes, net	17,480	17,302
Long term debt, net	98,965	98,660
Derivative financial instruments – warrants	11,938	17,582
Other long-term liabilities	406	433
Total Liabilities	171,279	172,124
Total Stockholders’ Deficit	(38,633)	(5,518)
Total Liabilities and Stockholders’ Deficit	$ 132,646	$ 166,606

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

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Net sales	$ 8,586	$ 98
Cost of goods sold	3,704	1,636
Gross profit	4,882	(1,538)
Costs and Expenses:		
Research and development	3,392	18,401
Selling, general and administrative	40,145	42,788
Total Operating Expenses	43,537	61,189
Loss from Operations	(38,655)	(62,727)
Other Income/(Expense):		
Interest expense, net	(3,123)	(790)
State R&D tax credits	30	—
Debt conversion expense	—	(1,209)
Change in fair value of derivative instruments - warrants	5,644	122
Total Other Income/(Expense)	2,551	(1,877)
Net Loss	$ (36,104)	$ (64,604)
Net Loss per Common Share, Basic and Diluted	$ (0.15)	$ (0.30)
Weighted Average Common Shares Outstanding	246,664,067	215,484,670

Synergy Pharmaceuticals Inc.

Non-GAAP Financial Measures

Adjusted net sales, 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 net sales, 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 net sales, 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 net sales to adjusted net sales:

(Unaudited; $ in thousands)

	Three Months Ended March 31, 2018	Three Months Ended December 31, 2017
Net sales	$ 8,586	$ 9,400
Adjusted to deduct:		
Recognition of net sales which were deferred as of September 30, 2017	—	2,057
Adjusted net sales	$ 8,586	$ 7,343

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

(Unaudited; $ in thousands)

	Three Months Ended March 31, 2018	Three Months Ended December 31, 2017
Research and development expenses	$ 3,392	$ 1,990
Adjusted to deduct:		
Stock based compensation expense	671	516
Adjusted research and development expenses	$ 2,721	$ 1,474

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 March 31, 2018	Three Months Ended December 31, 2017
Selling, general and administrative expenses	$ 40,145	$ 41,779
Adjusted to deduct:		
Stock based compensation expense	2,288	2,117
Adjusted selling, general and administrative expenses	$ 37,857	$ 39,662

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

(Unaudited; $ in thousands)

	Three Months Ended March 31, 2018	Three Months Ended December 31, 2017
Total operating expenses	$ 43,537	$ 43,769
Adjusted to deduct:		
Stock based compensation expense	2,959	2,633
Adjusted operating expenses	$ 40,578	$ 41,136

View source version on businesswire.com:
https://www.businesswire.com/news/home/20180510006233/en/

Synergy Pharmaceuticals Inc.
Gem Hopkins, 212-584-7610
VP, Investor Relations and Corporate Communications
ghopkins@synergypharma.com

Source: Synergy Pharmaceuticals Inc.