

November 9, 2015



# Synergy Pharmaceuticals Reports Third Quarter 2015 Financial Results and Business Update

NEW YORK-- 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 and nine months ended September 30, 2015.

“The Synergy team continues to successfully execute on our key pipeline and corporate objectives,” said Gary S. Jacob, Chairman and CEO of Synergy. “Our strong year-to-date performance has resulted in a significant increase in value for our shareholders, enabling us to strengthen our balance sheet and financial position by reducing our debt by over 20%. We anticipate the next year will be marked by a number of value-enhancing opportunities, including our first planned NDA filing with plecanatide for CIC this coming January, pivotal results from our two ongoing phase 3 IBS-C trials, and a second NDA filing with plecanatide for IBS-C, all while building an agile commercial organization as we prepare for a potential U.S. launch with plecanatide in early 2017. The team remains focused on flawless execution across all areas of our business and we look forward to a very exciting 2016.”

## Summary of Key Development Programs, Updates and Anticipated Milestones

### Plecanatide

- On July 30, 2015 we announced positive top-line data from the second of two pivotal phase 3 clinical trials evaluating the efficacy and safety of two different plecanatide treatment doses (3.0 mg and 6.0 mg), taken as a tablet once-a-day, in 1,337 adult patients with chronic idiopathic constipation (CIC). Both plecanatide doses met the study’s primary and key secondary endpoint and were safe and well-tolerated. The most common adverse event was diarrhea, which only occurred in 3.2% of patients in 3.0 mg and 4.5% of patients in 6.0 mg dose groups compared to 1.3% in placebo. Discontinuations due to diarrhea were infrequent (1.1% in 3.0 mg and 1.1% in 6.0 mg dose groups compared to 0.4% in placebo).
- We are continuing to focus on preparation of our first plecanatide new drug application (NDA) for CIC and intend to file with the U.S. Food and Drug Administration (FDA) in January 2016.
- We are continuing to enroll patients with CIC into our ongoing open-label, long-term safety trial with plecanatide. Patients who completed either of the two 12-week phase 3 CIC trials were allowed to enroll and receive either 3.0 mg or 6.0 mg

plecanatide for one year or more. The objective of this trial is to evaluate the long-term safety and tolerability of plecanatide in patients with CIC.

- We are continuing to advance our two pivotal phase 3 clinical trials with plecanatide for irritable bowel syndrome with constipation (IBS-C). Like the CIC program, we are evaluating the efficacy and safety of 3.0 mg and 6.0 mg plecanatide tablets, taken once-daily, in patients with IBS-C. Each phase 3 IBS-C trial is being conducted in the U.S. and expected to enroll approximately 1,050 adult patients with IBS-C.
- We anticipate top-line data from the first phase 3 IBS-C trial with plecanatide in 1H 2016. We expect top-line data from the second phase 3 IBS-C trial in 2H 2016. We intend to file our second NDA with plecanatide in the IBS-C indication by year-end 2016.
- We continue to build our commercial expertise with the appointments of Timothy Callahan and Richard Daly to our Board of Directors and Troy Hamilton as our Chief Commercial Officer. This expanded leadership team is now fully engaged in building our commercial expertise with a clear and focused commercial strategy for our eventual U.S. launch with plecanatide.

#### Dolcanatide

- We are continuing to advance our ongoing phase 1b exploratory study of dolcanatide in patients with mild-to-moderate ulcerative colitis. The double-blind, placebo-controlled, four-week study is being conducted in the United States and is expected to enroll approximately 24 patients.

#### **Financial Results**

- As of September 30, 2015 we had \$142.0 million of cash, cash equivalents and available-for-sale securities on hand as compared to \$196.4 million as of December 31, 2014.
- Our cash used in operating activities during the three months ended September 30, 2015 averaged \$7.2 million per month. Our cash used in operating activities during the six months ended June 30, 2015 averaged \$8.2 million per month. This decrease during the third quarter is a result of a decrease in research and development expenses related to our two plecanatide phase 3 CIC clinical trials.
- From July 1, 2015 through September 30, 2015, approximately \$18.8 million in aggregate principal amount of the Senior Convertible Notes was converted into approximately 6.0 million shares of our common stock. These conversions decreased the principal amount of the Notes to approximately \$159.0 million as of September 30, 2015 from approximately \$178.0 million as of June 30, 2015. Our year-to-date note conversions of \$41.0 million reduce interest expense by approximately \$3.1 million per annum. All conversions were noteholder initiated with no inducement from the company.
- From July 1, 2015 through September 30, 2015, warrants to purchase 189,412 shares of common stock were exercised, yielding proceeds of \$1.0 million, at a weighted average exercise price of \$5.34 per share.

- From July 1, 2015 through September 30, 2015, employee stock options to purchase 248,387 shares of common stock were exercised yielding proceeds of \$1.1 million, at a weighted average exercise price of \$4.34 per share.

## **About Synergy Pharmaceuticals Inc.**

Synergy is a biopharmaceutical company focused on the development and commercialization of novel GI therapies. Our proprietary GI platform includes two fully-owned, late-stage clinical assets - plecanatide and dolcanatide. We designed both plecanatide and dolcanatide to be pharmacologically superior versions of the naturally occurring human GI peptide, uroguanylin, which is an important regulator for digestive fluid movement and gut health. Plecanatide is our first-generation uroguanylin analog being developed for CIC and IBS-C. Taken as a tablet once-a-day, plecanatide is designed to mimic the natural role of uroguanylin by working locally in the upper GI tract to activate and regulate fluid movement required for normal bowel function. In the summer of 2015, we announced positive phase 3 data from two plecanatide clinical trials for CIC. Dolcanatide is our next-generation uroguanylin analog currently being evaluated for the treatment of ulcerative colitis. Dolcanatide is designed to have enhanced resistance to proteolysis in intestinal fluid relative to uroguanylin and yet still retain the same physiologic characteristics as natural uroguanylin. In November 2014, we announced positive data with dolcanatide from our phase 2 clinical trial for opioid-induced constipation (OIC). For more information, please visit [www.synergypharma.com](http://www.synergypharma.com).

## **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 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 Form 10-K for the year ended December 31, 2014 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 Pharmaceuticals Inc.  
Condensed Consolidated Balance Sheets**

<b>(\$ in thousands)</b>	<b>September 30, 2015 (unaudited)</b>	<b>December 31, 2014 (unaudited)</b>
<b>Assets</b>		
Cash, cash equivalents and available for sale securities	\$ 142,001	\$ 196,367
Prepaid expenses and other current assets	1,147	3,836
Total Current Assets	<u>143,148</u>	<u>200,203</u>
Other Assets	809	805
Total Assets	<u><u>\$ 143,957</u></u>	<u><u>\$ 201,008</u></u>
<b>Liabilities and Stockholders' Deficit</b>		
Total Current Liabilities	\$ 19,758	\$ 18,331
Senior Convertible Notes – net	150,735	187,664
Derivative financial instruments – warrants	533	172
Total Liabilities	<u>171,026</u>	<u>206,167</u>
Total Stockholders' Deficit	<u>(27,069)</u>	<u>(5,159)</u>
Total Liabilities and Stockholders' Deficit	<u><u>\$ 143,957</u></u>	<u><u>\$ 201,008</u></u>

**Condensed Consolidated  
Statement of Operations**

(\$ in thousands except share and per share data)  (unaudited)	Three Months ended September 30, 2015	Three Months ended September 30, 2014	Nine Months ended September 30, 2015	Nine Months ended September 30, 2014
<b>Revenues</b>	\$ --	\$ --	\$ --	\$ --
Costs and Expenses:				
Research and development	20,424	20,946	58,147	58,724
Selling, general and administrative	2,728	2,506	14,727	7,963
Loss from Operations	(23,152)	(23,452)	(72,874)	(66,687)
Other (expense)/income				
Interest (expense) and investment income-net	(4,291)	19	(13,815)	47
State R&D tax credits	--	--	--	83
Change in fair value of derivative instruments - warrants	1,446	425	(364)	1,404
Total Other (Expense)/Income	(2,845)	444	(14,179)	1,534
<b>Net Loss</b>	<b>\$ (25,997)</b>	<b>\$ (23,008)</b>	<b>\$ (87,053)</b>	<b>\$ (65,153)</b>
Net Loss per common share, basic and diluted	\$ (0.23)	\$ (0.24)	\$ (0.85)	\$ (0.70)
Weighted Average Common Shares Outstanding	111,328,339	94,738,048	102,838,814	93,631,115

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