

February 25, 2016



# Synergy Pharmaceuticals Reports 2015 Fourth Quarter, Full-Year 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 fourth quarter and the year ended December 31, 2015.

“The last 12 months have been a transformative period with many significant achievements and milestones for the Synergy organization, our shareholders and most importantly, for patients,” said Gary S. Jacob, Chairman and Chief Executive Officer of Synergy Pharmaceuticals. “We reported positive results in two pivotal phase 3 trials with our lead compound plecanatide in chronic idiopathic constipation (CIC) and recently filed our first NDA with the FDA for this often debilitating condition. In addition, we recently reported positive phase 1b data for our second compound dolcanatide in mild-to-moderate ulcerative colitis, expanding the utility of our proprietary uroguanylin-based technology platform beyond functional GI disorders into inflammatory bowel disease. Finally, we recently announced our collaboration with BIND Therapeutics to explore the potential to further broaden the therapeutic applications of our technology into GI cancer.”

“Moving forward, we expect top-line data from our two pivotal phase 3 trials with plecanatide in irritable bowel syndrome with constipation (IBS-C) and intend to file our second NDA for this condition by the end of this year. I am very proud of what our organization has accomplished over the past year and want to take this opportunity to thank the Synergy team for their commitment, enthusiasm and focus on flawless execution as we continue to build the Synergy success story together,” added Dr. Jacob.

## Fourth Quarter 2015 and Recent Highlights

### **Plecanatide**

#### CIC Clinical Program Update

- On January 29, 2016, we announced that we had filed with the FDA our first NDA for plecanatide in CIC. The plecanatide NDA for CIC is supported by positive results from two phase 3 clinical trials which we completed in 2015. If approved, we plan to launch plecanatide with the CIC indication in the first quarter of 2017.
- We have completed patient enrollment in our ongoing open-label, long-term safety trial with plecanatide for CIC. 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, once-daily, 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.

### IBS-C Clinical Program Update

- We are continuing to advance our two pivotal phase 3 clinical trials with plecanatide for IBS-C. Each randomized, 12-week, double-blind placebo-controlled trial is evaluating the efficacy and safety of 3.0 mg and 6.0 mg plecanatide treatment doses, taken as a tablet once-a-day, in approximately 1,050 adult patients with IBS-C.
- We expect to report top-line results from the first phase 3 IBS-C trial with plecanatide in the first half of this year and we anticipate top-line results from the second phase 3 IBS-C trial in the second half of this year. We intend to file our second NDA with plecanatide in the IBS-C indication by year-end 2016.

### Plecanatide CIC Launch Planning & Preparation

- We are continuing launch planning and preparation efforts for our anticipated FDA approval of plecanatide for CIC the first quarter of 2017. Along with our two commercially oriented board members, chief commercial officer and chief financial officer, we have established a highly experienced and strategic team to lead key areas of commercial operations, marketing, sales, market access, medical affairs and technical operations, including supply chain management. We are actively engaged in highly focused and efficient prelaunch activities to prepare the market, our organization and plecanatide for a successful 2017 launch.

### **Dolcanatide**

- On January 11, 2016, we announced positive phase 1b data with dolcanatide in a double-blind, placebo-controlled, four-week study evaluating 28 patients with mild-to-moderate ulcerative colitis. Analysis of the data indicated clear signals of improvement in dolcanatide-treated patients compared with placebo-treated patients. Dolcanatide was also safe and well-tolerated. We are currently evaluating how best to move dolcanatide forward in clinical development to treat ulcerative colitis.

### **Collaboration with BIND Therapeutics**

- On February 16, 2016, we announced that we have entered into a research collaboration agreement with BIND Therapeutics to engineer ACCURINS® decorated with our proprietary uroguanylin analogs to explore the potential targeting of guanylate cyclase-C (GC-C) receptors expressed on tumors, specifically GI malignancies. Upon achievement of proof-of-concept, we anticipate expanding the collaboration to enhance the potential effect of uroguanylin-based ACCURINS® by incorporating therapeutic payloads.

### **Corporate and Financials**

- Our cash, cash equivalents and available-for-sale securities balance as of December 31, 2015 was \$111.8 million, as compared to \$196.4 million on December 31, 2014.

- Net cash provided by financing activities was \$16.4 million during the year ended December 31, 2015, as compared to \$217.1 million provided during the year ended December 31, 2014.
- Net cash used in operating activities during the year ended December 31, 2015 was \$101.0 million as compared to \$89.1 million of cash used in operating activities during the year ended December 31, 2014.
- Net loss for the year ended December 31, 2015 was \$117.5 million or \$1.11 per share as compared to \$95.7 million or \$1.02 per share for the year ended December 31, 2014.
- Net loss for the quarter ended December 31, 2015 was \$30.4 million, or \$0.27 per share, as compared to \$30.6 million or \$0.32 per share, for the quarter ended December 31, 2014.
- Research and development expenses for the year ended December 31, 2015 decreased by approximately \$5.3 million to approximately \$78.0 million from approximately \$83.3 million for the year ended December 31, 2014. This decrease in research and development expenses was largely attributable to a reduction in dolcanatide clinical trial activities.
- Selling, general and administrative expenses for the year ended December 31, 2015 increased approximately \$10.8 million to approximately \$21.8 million for 2015 from approximately \$11.0 million for 2014. These increased expenses were primarily the result of higher employee stock based compensation and an increase in expenses related to commercial and supply chain activities.
- From January 1, 2015 through December 31, 2015, \$41.0 million of aggregate principal amount of our Notes issued in 2014 was converted into approximately 13.2 million shares of our common stock. This brings the principal balance of the Notes to \$159.0 million at December 31, 2015 as compared to \$200.0 million at December 31, 2014. All conversions were noteholder initiated with no inducement or solicitation on the part of the Company.
- As of February 24, 2016, we had 44 full-time employees, as compared to 35 full-time employees on February 24, 2015.

We had 113.7 million and 96.6 million common shares issued and outstanding at December 31, 2015 and 2014, respectively which increase primarily reflects conversions of the Notes.

**Synergy Pharmaceuticals Inc.**  
**Consolidated Balance Sheets**

(\$ in thousands)	December 31, 2015	December 31, 2014
	<u>          </u>	<u>          </u>
<b>Assets</b>		
Cash, cash equivalents and available for sale securities	\$ 111,750	\$ 196,367
Prepaid expenses and other current assets	3,305	3,836
Total Current assets	<u>115,055</u>	<u>200,203</u>
Other assets	874	805
Total assets	<u><u>\$ 115,929</u></u>	<u><u>\$ 201,008</u></u>
<b>Liabilities and Stockholders' Deficit</b>		
Total Current Liabilities	\$ 19,579	\$ 18,331
Senior Convertible Notes – net	151,241	187,664
Derivative financial instruments – warrants	322	172
Total Liabilities	<u>171,142</u>	<u>206,167</u>
Total Stockholders' Deficit	<u>(55,213)</u>	<u>(5,159)</u>
Total Liabilities and Stockholders' Deficit	<u><u>\$ 115,929</u></u>	<u><u>\$ 201,008</u></u>

**Synergy Pharmaceuticals Inc.**  
**Consolidated Statement of Operations**

(\$ in thousands except share and per share data)	Three Months ended December 31, 2015	Three Months ended December 31, 2014	Year ended December 31, 2015	Year ended December 31, 2014
Revenues	\$ --	\$ --	\$ --	\$ --
Costs and Expenses:				
Research and development	19,881	24,550	78,028	83,274
Selling, general and administrative	7,066	3,041	21,794	11,004
Loss from Operations	<u>(26,947)</u>	<u>(27,591)</u>	<u>(99,822)</u>	<u>(94,278)</u>
Other Loss:				
Interest and investment income (expense) - net	(3,469)	(2,922)	(17,284)	(2,875)
State R&D tax credits	--	--	--	83
Change in fair value of derivative instruments - warrants	<u>(30)</u>	<u>(42)</u>	<u>(394)</u>	<u>1,362</u>
Total Other Loss	<u>(3,499)</u>	<u>(2,964)</u>	<u>(17,678)</u>	<u>(1,430)</u>
Net Loss	<u>\$ (30,446)</u>	<u>\$ (30,555)</u>	<u>\$ (117,500)</u>	<u>\$ (95,708)</u>
Net Loss per Common Share, Basic and Diluted	\$ (0.27)	\$ (0.32)	\$ (1.11)	\$ (1.02)
Weighted Average Common Shares Outstanding	113,678,306	96,190,332	105,570,960	94,276,178

**About Synergy Pharmaceuticals Inc.**

Synergy is a biopharmaceutical company focused on the development and commercialization of novel GI therapies. Our proprietary GI platform is based on uroganylin and includes two lead product candidates – plecanatide and dolcanatide. Plecanatide is our first uroganylin analog currently being evaluated for use as a once-daily tablet for two functional GI disorders, chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Plecanatide is a 16-amino acid peptide that is structurally identical to uroganylin with the exception of a single amino acid change. Plecanatide is designed to mimic the function of uroganylin by working locally in the upper GI tract to stimulate digestive fluid movement and support regular bowel function. Dolcanatide is our second uroganylin analog currently being explored for inflammatory bowel disease (IBD). Dolcanatide is designed to be an analog of uroganylin

with enhanced resistance to standard digestive breakdown by proteases in the intestine. 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, 2015 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.

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