

May 11, 2015



# Synergy Pharmaceuticals Reports 2015 First Quarter Results and Business Update

- *Completed enrollment in both phase 3 clinical trials with plecanatide for chronic idiopathic constipation (CIC) - pivotal data readouts expected in 2Q and 3Q 2015*
- *Continued to advance plecanatide phase 3 program for irritable bowel syndrome with constipation (IBS-C) – first pivotal data readout expected in 4Q 2015*
- *Company on-track for first NDA filing with plecanatide for CIC in 4Q 2015*

NEW YORK-- Synergy Pharmaceuticals Inc. (NASDAQ:SGYP), a biopharmaceutical company focused on the development of novel treatments for gastrointestinal diseases and disorders, today reported its financial results and business update for the first quarter ended March 31, 2015.

“We have made significant progress during the first quarter, highlighted by key advancements in our plecanatide phase 3 CIC and IBS-C clinical trials,” said Gary S. Jacob, Ph.D., Chairman and CEO of Synergy Pharmaceuticals Inc. “Both phase 3 programs are progressing as expected, and we remain on track to report important milestones in the coming months, the most imminent being top-line data results from our two phase 3 CIC clinical trials.”

“2015 is a pivotal year for Synergy and I am confident we are well-positioned to achieve our clinical objectives, and will remain focused on advancing these programs, as well as filing our first NDA with plecanatide for CIC by year-end,” added Dr. Jacob.

## First Quarter 2015 and Recent Highlights

### Plecanatide

- On January 8, 2015 and January 29, 2015 Synergy announced the completion of patient enrollment in the first and second of two pivotal phase 3 CIC trials, respectively, which are evaluating the safety and efficacy of two plecanatide doses (3.0 and 6.0 mg). Each randomized, 12-week, double-blind, placebo-controlled phase 3 trial is assessing plecanatide, once-daily oral tablet, in approximately 1350 adult patients with CIC. Synergy plans to announce top-line data results from the first phase 3 CIC trial in 2Q 2015 and top-line data results from the second phase 3 CIC trial are expected in 3Q 2015. The company plans to file its first new drug application (NDA) with the FDA for plecanatide in the CIC indication in December 2015.
- Synergy continues to progress its pivotal phase 3 clinical development program with

plecanatide for irritable bowel syndrome with constipation (IBS-C). The company is currently enrolling patients in the first phase 3 IBS-C trial and it plans to initiate the second phase 3 IBS-C trial in the first half of this year. The phase 3 IBS-C program is evaluating the efficacy and safety of plecanatide 3.0 and 6.0 mg doses, consistent with the ongoing phase 3 CIC program. Each randomized, 12-week, double-blind, placebo-controlled phase 3 trial is expected to enroll approximately 1,050 patients with IBS-C. IBS-C patients successfully completing either of the trials will be offered enrollment into a long a long-term safety trial in order to support the ongoing long-term safety database for the CIC indication. The company plans to announce top-line data results from the first phase 3 IBS-C trial in 4Q 2015 and the second phase 3 IBS-C trial is expected to readout in the first half of 2016. Synergy plans to file an NDA with plecanatide in the IBS-C indication in the second half of 2016.

### SP-333

- Synergy continues to advance its ongoing phase 1b exploratory study of SP-333 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.
- A pre-clinical abstract on SP-333 has been accepted for poster presentation during the 2015 Digestive Disease Week (DDW) annual meeting being held in Washington, DC. The presentation entitled, “Oral Treatment with SP-333, an Analog of Uroguanylin, Effectively Relieves Morphine and Methadone-Induced Constipation in Rats Through a Novel Mechanism Involving Activation of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)” [Sa1393], is scheduled for Saturday, May 16<sup>th</sup> from Noon to 2:00 p.m. (EDT).

### Financials

- Our cash, cash equivalents and available-for-sale securities balance as of March 31, 2015 was \$178.6 million, as compared to \$196.4 million on December 31, 2014.
- Net cash provided by financing activities was \$5.4 million during the three months ended March 31, 2015, as compared to \$22.0 million of cash provided during the three months ended March 31, 2014. This cash provided was entirely attributable to sales of our common stock under our Controlled Equity Sales (“at-the-market” or “ATM”) Agreement with Cantor Fitzgerald & Co.
- Net cash used in operating activities during the three months ended March 31, 2015 was \$23.1 million as compared to \$19.9 million of cash used in operating activities during the three months ended March 31, 2014.
- Net loss for the three months ended March 31, 2015 was \$27.4 million or \$0.28 per share as compared to \$16.2 million or \$0.18 per share for the three months ended March 31, 2014.
- Interest expense on the Senior Convertible Debentures of \$3.75 million and related amortization of deferred financing cost of \$0.6 million totaled \$0.05 of net loss per share during the three months ended March 31, 2015, whereas we had no such

expense during the three months ended March 31, 2014.

- We had 98.0 million and 92.1 million common shares issued and outstanding at March 31, 2015 and 2014, respectively. This increase reflects the sale of common stock pursuant to our ATM program.

### **About Synergy Pharmaceuticals Inc.**

Synergy is a biopharmaceutical company focused on the research and development of novel therapies for the treatment of gastrointestinal (GI) diseases and disorders.

Synergy's proprietary platform technology is based on the naturally occurring human GI peptide, uroguanylin, a key regulator of normal GI physiology. The company's first uroguanylin analogue, plecanatide, is in pivotal phase 3 clinical trials for chronic idiopathic constipation and irritable bowel syndrome with constipation. Synergy's next-generation uroguanylin analogue, SP-333, has successfully completed a phase 2 study for opioid-induced constipation and is currently being explored for ulcerative colitis. 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**

(\$ in thousands)	<u>March 31, 2015</u> (unaudited)	<u>December 31, 2014</u>
Assets		
Cash, cash equivalents and short term available for sale securities	\$ 178,628	\$ 196,367
Prepaid expenses and other current assets	3,649	3,836
Total Current Assets	<u>182,277</u>	<u>200,203</u>
Other Assets	12,555	13,141
Total Assets	<u>\$ 194,832</u>	<u>\$ 213,344</u>
Liabilities and Stockholders' Deficit		
Total Current Liabilities	\$ 19,130	\$ 18,331
Senior Convertible Notes	200,000	200,000
Derivative financial instruments –warrants	440	172
Total Liabilities	<u>219,570</u>	<u>218,503</u>
Total Stockholders' Deficit	<u>(24,738)</u>	<u>(5,159)</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 194,832</u>	<u>\$ 213,344</u>

**Condensed Consolidated Statement of Operations**

(\$ in thousands except share and per share data) (unaudited)	<u>Three Months ended</u> <u>March 31,</u> <u>2015</u>	<u>Three Months ended</u> <u>March 31,</u> <u>2014</u>
Revenues	\$ --	\$ --
Costs and Expenses:		
Research and development	17,788	13,299
General and administrative	4,606	3,178
Loss from Operations	<u>(22,804)</u>	<u>(16,477)</u>
Amortization of deferred Financing costs	(617)	--
Interest Income(Expense) - net	(3,700)	29
Change in Fair Value of Financial Instruments	<u>(268)</u>	<u>223</u>
Total Other Income/(Loss)	<u>(4,585)</u>	<u>252</u>
<b>Net Loss</b>	<u>\$ (27,389)</u>	<u>\$ (16,225)</u>
Net Loss per common share, basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.18)</u>
Weighted Average Common Shares Outstanding	96,683,525	92,056,124

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Source: Synergy Pharmaceuticals Inc.