May 10, 2016

Synergy Pharmaceuticals Reports First Quarter 2016 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 months ended March 31, 2016.

“2016 is off to a strong and promising start for Synergy, highlighted by the U.S. Food and Drug Administration (FDA) acceptance of our first new drug application (NDA) for plecanatide in chronic idiopathic constipation (CIC),” said Gary S. Jacob, Chairman and Chief Executive Officer of Synergy Pharmaceuticals. “We continued to expand the utility and value of our uroguanylin-based platform technology while significantly strengthening our overall financial position. Moving forward, we believe we are well positioned to successfully execute on key pre-launch activities and will continue to evaluate all strategic options to ensure a successful launch of plecanatide early next year. Meanwhile, we expect top-line data from our two pivotal phase 3 trials with plecanatide in irritable bowel syndrome with constipation (IBS-C) in the third quarter and intend to file our second NDA in IBS-C by the end of this year. Our first quarter results demonstrate our profound commitment to optimizing the value of plecanatide and dolcanatide and bringing these important new treatment options to patients suffering from GI diseases.”

First Quarter 2016 and Recent Highlights

Synergy’s Uroguanylin Based GI Platform

Our proprietary GI platform is based on uroguanylin, a naturally occurring human GI peptide, and includes two lead product candidates – plecanatide and dolcanatide. Plecanatide is our first uroguanylin analog currently being evaluated for the treatment of CIC and IBS-C. Dolcanatide is our second uroguanylin analog currently being explored for the treatment of ulcerative colitis (UC). We discovered, are developing and control worldwide rights to our uroguanylin based GI platform.

Plecanatide CIC Development Update

- On January 29, 2016, we filed our first NDA with the FDA for plecanatide in CIC. The NDA has been accepted for FDA review and the Prescription Drug User Fee Act (PDUFA) target action date is January 29, 2017. The plecanatide NDA in CIC is supported by two double-blind placebo-controlled phase 3 trials and one open-label long term safety study. A total of more than 2,700 patients with CIC received a once-daily dose of either plecanatide or placebo across the two placebo-controlled trials.

Additionally, over 3,500 patients were exposed to plecanatide in the CIC clinical development program.

Plecanatide IBS-C Development Update

- We are presently evaluating plecanatide in two pivotal phase 3 trials in patients with IBS-C. Each randomized, 12-week, double-blind placebo-controlled trial is assessing the efficacy and safety of plecanatide (3.0 and 6.0mg), taken as a tablet once-a-day, in approximately 1,050 patients with IBS-C. The primary endpoint for both trials is the percentage of patients who are Overall Responders during the 12-week treatment period. An Overall Responder, as defined by the FDA, is a patient who is a weekly responder (i.e. meets both a 30% abdominal pain intensity reduction and stool frequency increase criteria in the same week) for at least 6 of the 12 treatment weeks. Plecanatide has previously met this endpoint in a phase 2b IBS-C trial that was completed in 2014. We expect top-line data results from the two ongoing phase 3 IBS-C trials in the third quarter of this year. We intend to file our second NDA for plecanatide in IBS-C by the end of this year.

Dolcanatide UC Development Update

- On January 11, 2016, we announced positive proof-of-concept data with dolcanatide in patients with ulcerative colitis. This was a phase 1b double-blind, placebo-controlled, four-week study evaluating 28 patients with mild-to-moderate ulcerative colitis. We are presently evaluating how best to move dolcanatide forward in clinical development for the treatment of ulcerative colitis.

Plecanatide Launch Readiness Update

- Our team is actively engaged in key pre-launch activities to develop and execute on a comprehensive and efficient launch strategy that we believe will ensure plecanatide is well positioned for success. We are currently focused on three key areas: product readiness, market readiness and organizational readiness. Activities supporting these three key priorities include ensuring a thorough supply chain plan, using market and customer insights to develop successful branding, positioning and communication platforms, evaluating all salesforce and market access strategic options, continuing KOL engagement and other medical affairs-driven initiatives, as well as attracting key talent throughout the organization who are highly experienced in launch preparation and execution.

Financial Results

- As of March 31, 2016 we had $84.2 million of cash, cash equivalents and available-for-sale securities on hand as compared to $111.8 million as of December 31, 2015.
- On May 5, 2016 we announced an $89.8 million registered direct offering of our common stock to certain institutional investors at a price of $3.00 per share. The net proceeds from the offering, after deducting estimated offering expenses, were approximately $89.7 million. The offering closed on May 6, 2016.
- Net cash used in operating activities was $27.6 million in the first quarter of 2016, as

compared to $23.1 million in the first quarter of 2015.

- Research and development expenses in the first quarter of 2016 were $21.2 million, as compared to $18.2 million in the first quarter of 2015. This increase in research and development expenses was due primarily to greater spending on IBS-C studies and fees related to our NDA filing, offset partially by a reduction in CIC clinical trial expenses.
- Selling, general and administrative expenses were $6.4 million in the first quarter of 2016, as compared to approximately $4.6 million in the first quarter of 2015. These increased expenses were primarily a result of new selling and marketing spend in preparation of our anticipated commercial launch next year.
- On March 28, 2016 we announced the closing of separate, privately-negotiated exchanges with certain holders of $79.8 million aggregate principal amount of our 7.50% Convertible Senior Notes (“Notes”) due 2019, representing approximately 50% of the outstanding aggregate principal amount of the Notes, for 35.3 million shares of our common stock. Subsequent to this exchange, the principal balance of the Notes at March 31, 2016 was $79.2 million as compared to $159.0 million at December 31, 2015. The annual interest expense reduction attributable to the Notes exchanged is $6.0 million per annum.
- Net loss in the first quarter of 2016 was $59.9 million, or $0.51 per share, as compared to a net loss of $27.4 million, or $0.28 per share, incurred in the first quarter of 2015. This increase in net loss was primarily a result of the debt conversion expense attributable to our convertible notes exchange transaction, which amounted to $25.6 million, or $0.22 per share.

About Synergy Pharmaceuticals Inc.

Synergy is a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. Our proprietary GI platform is based on uroguanylin and includes two lead product candidates – plecanatide and dolcanatide. Plecanatide is our first uroguanylin analog currently being evaluated for use as a once-daily tablet for two functional GI disorders, CIC and IBS-C. Plecanatide is a 16-amino acid peptide that is structurally similar to uroguanylin, a naturally occurring human GI peptide, with the exception of a single amino acid change. Plecanatide is designed to replicate the function of uroguanylin by working locally in the upper GI tract to stimulate digestive fluid movement and support regular bowel function. Dolcanatide is our second uroguanylin analog currently being explored for inflammatory bowel disease. Dolcanatide is designed to be an analog of uroguanylin with enhanced resistance to standard digestive breakdown by proteases in the intestine. For more information, please visit 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 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 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.

Synergy Pharmaceuticals Inc.
Condensed Consolidated Balance Sheets

($ in thousands)	**March 31, 2016 (unaudited)**	**December 31, 2015**
Assets		
Cash, cash equivalents and short term available for sale securities	$ 84,155	$ 111,750
Prepaid expenses and other current assets	3,361	3.305
Total Current Assets	87,516	115,055
Other Assets	877	874
Total Assets	$ 88,393	$ 115,929
Liabilities and Stockholders' Deficit		
Total Current Liabilities	$ 19,264	$ 19,579
Senior Convertible Notes	75,565	151,241
Derivative financial instruments –warrants	62	322
Total Liabilities	94,891	171,142
Total Stockholders’ Deficit	(6,498)	(55,213)
Total Liabilities and Stockholders' Deficit	$ 83,393	$ 115,929

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

	Three Months ended March 31, 2016	Three Months ended March 31, 2015
Revenues	$ --	$ --
Costs and Expenses:		
Research and development	21,175	18,198
Selling, general and administrative	6,375	4606
Loss from Operations	(27,550)	(22,804)
Interest income (expense) - net	(7036)	(4,317
Debt conversion expense	(25,615)	--
Change in Fair Value of Financial Instruments	260	(268)
Total Other (Loss)	(32,391)	(4,585)
Net Loss	$ (59,941)	$ (27,389)
Net Loss per common share, basic and diluted	$ (0.51)	$ (0.28)
Weighted Average Common Shares Outstanding	117,626,669	96,683,525

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