August 8, 2016

Synergy Pharmaceuticals Reports Second 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 June 30, 2016.

“Our exciting transformation from a purely research and development company into a fully integrated commercial organization continues unabated as we successfully advance and execute against our key strategic priorities,” said Gary S. Jacob, Chairman and Chief Executive Officer of Synergy Pharmaceuticals Inc. “These priorities are guided by our overarching mission to optimize the value of plecanatide and maximize shareholder value.”

“The rest of 2016 promises to be an exciting time as we expect top-line results in our two phase 3 IBS-C trials with plecanatide. We are especially pleased with our ongoing dialogue with the FDA, including the results of our recent mid-cycle review meeting. Building the right commercial strategy and having the ability to successfully execute on the launch plan requires a strong team and we are fortunate to be attracting talented leaders with relevant experience from across our industry. I am very proud of the Synergy organization which is committed to a successful launch of plecanatide and bringing this important new treatment option to patients suffering from CIC and IBS-C,” added Dr. Jacob.

Second Quarter 2016 and Recent Highlights

Research & Development

Plecanatide CIC Development Update

- The Food and Drug Administration (FDA) has completed its mid-cycle review meeting of the plecanatide new drug application (NDA) in chronic idiopathic constipation (CIC). To date, no significant issues have been identified. Additionally, the FDA informed us that at this time there are no plans for an advisory committee meeting in connection with its review of the plecanatide NDA in CIC. The plecanatide NDA in CIC is supported by two double-blind placebo-controlled phase 3 trials and one open-label long term safety study. Over 3,500 patients were exposed to plecanatide in the CIC clinical development program. The Prescription Drug User Fee Act (PDUFA) target action date is January 29, 2017.
- In May 2016, we presented additional plecanatide data, including one oral presentation and five posters, at Digestive Disease Week (DDW) 2016. Data presented at DDW showed that plecanatide met the primary and secondary endpoints in two phase 3 CIC clinical trials. In both trials, plecanatide significantly improved durable overall complete spontaneous bowel movement (CSBM) responder rates relative to placebo (primary endpoint). Plecanatide-treated patients also showed immediate and sustained improvements that were statistically significant in CSBM and SBM frequency and stool consistency scores compared to placebo. Furthermore, plecanatide showed statistically significant improvement in abdominal symptoms, such as straining and bloating, as well as constipation severity and treatment satisfaction scores compared to placebo. Most adverse events were mild to moderate in severity; the most common adverse event was diarrhea (<6.0% diarrhea rates in both trials). In addition to the plecanatide CIC clinical data, we presented new *in vitro* data showing that the pH-dependent activity of plecanatide replicates that of the body's naturally occurring GI peptide, uroguanylin.

Plecanatide IBS-C Development Update

- We have completed over 95% of planned patient enrollment in our two phase 3 irritable bowel syndrome with constipation (IBS-C) clinical trials with plecanatide and we expect top-line data in both trials in the fourth quarter of this year. The two double-blind placebo-controlled trials are designed to enroll a total of approximately 2,100 IBS-C patients. The primary endpoint being evaluated in these 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 previously met this endpoint in a phase 2b trial with 424 IBS-C patients that was completed in 2014.

Dolcanatide UC Development Update

- Earlier this year, we announced positive proof-of-concept in a phase 1b double-blind placebo-controlled four-week trial evaluating dolcanatide treatment in 28 patients with mild-to-moderate ulcerative colitis. We intend to announce next steps for the dolcanatide phase 2 clinical program in patients with mild-to-moderate ulcerative colitis following agreement on the development plans with regulators.

Commercial Planning & Launch Preparation

Our commercial, medical affairs and technical operations teams are continuing to execute on our key strategic imperatives to ensure launch readiness, including the following major initiatives:

Product Readiness

- Ensuring a robust supply chain process for launch and throughout plecanatide's life-cycle
- Building sufficient trade and sample stock for launch in early 2017
- Implementing our 3PL distribution network
- Developing and implementing strong Quality Management Systems

Market/Brand Readiness

- Driving and raising awareness of Synergy Pharmaceuticals, the unmet medical needs, and burden of disease
- Initiating KOL engagement & speakers bureau preparation plans
- Defining our pricing and reimbursement strategy, as well as initiating field payer activities
- Developing the plecanatide branding, positioning, messaging and creative launch campaign based on customer insights & segmentation

Organizational Readiness

- Hiring and onboarding key talent to support critical functions
- Onboarding and fielding our Market Access and Medical Liaison Teams
- Ensuring our IT and Compliance systems needs are defined and implemented
- Continuing to evaluate all potential sales force options, including a hybrid infrastructure supplemented by a contract sales organization and/or co-promotion partner

Financial Results

- As of June 30, 2016, we had approximately $141.2 million of cash and cash equivalents on hand as compared to approximately $111.8 million cash and cash equivalents and available for sale

securities as of December 31, 2015.

- Net cash used in operating activities was $60.1 million in the six months ended June 30, 2016, as compared to $49 million in the six months ended June 30, 2015.
- Research and development expenses in the second quarter of 2016 were approximately $26.6 million, as compared to $19.5 million in the second quarter of 2015. These increased expenses were primarily a result of higher spending on IBS-C studies, the filing of our CIC NDA in January 2016, and plecanatide API contract manufacturing costs for validation batches prepared for our anticipated commercial launch next year.
- Selling, general and administrative expenses were approximately $10.2 million in the second quarter of 2016, as compared to approximately $7.4 million in the second quarter of 2015. These increased expenses were primarily a result of higher spending in preparation for our anticipated commercial launch next year.
- On May 6, 2016, we closed on a registered direct offering of approximately 30 million shares of our common stock with gross proceeds of approximately $89.8 million.
- As of June 30, 2016, the principal balance of our 7.50% Convertible Senior Notes (“Notes”) due 2019 was $79.2 million as compared to $159.0 million at December 31, 2015.
- We had 179.8 million and 113.7 million common shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively, which reflects primarily an increase in the issuance of shares from the first quarter conversions of the Notes and the common stock offering noted above.
- Net loss in the second quarter of 2016 was $38.6 million, as compared to a net loss of $33.7 million incurred in the second quarter of 2015.

About Synergy Pharmaceuticals Inc.

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 on analogs of uroguanylin, a naturally occurring human GI peptide, for the treatment of functional GI disorders and inflammatory bowel disease. Synergy is developing and retains 100% worldwide rights to its proprietary uroguanylin analog technology platform that includes two lead product candidates - plecanatide and dolcanatide. Plecanatide is Synergy's first uroguanylin analog currently being evaluated for use as a once-daily tablet for the treatment of CIC and IBS-C. Dolcanatide is Synergy's second uroguanylin analog currently being explored for ulcerative colitis. 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 Annual Report on 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 Pharmaceutical Inc.
Condensed Consolidated Balance Sheets

($ in thousands)	**June 30, 2016 (unaudited)**	**December 31, 2015**
Assets		
Cash, cash equivalents and available for sale securities	$ 141,219	$ 111,750
Prepaid expenses and other current assets	4,266	3,305
Total Current assets	145,485	115,055
Other assets	1,067	874
Total assets	$ 146,552	$ 115,929
Liabilities and Stockholders' Equity/(Deficit)		
Total Current Liabilities	$ 23,127	$ 19,579
Senior Convertible Notes, net	75,818	151,241
Derivative financial instruments – warrants	85	322
Total Liabilities	99,030	171,142
Total Stockholders’ Equity/(Deficit)	47,522	(55,213)
Total Liabilities and Stockholders' Equity/(Deficit)	$ 146,552	$ 115,929

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

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Revenues	$ —	$ —	$ —	$ —
Costs and Expenses:				
Research and development	26,611	19,525	47,786	37,723
Selling, general and administrative	10,249	7,394	16,624	12,000
Loss from Operations	(36,860)	(26,919)	(64,410)	(49,723)
Other Loss:				
Interest and investment expense, net	(1,673)	(5,207)	(8,709)	(9,524)
Debt conversion expense	—	—	(25,615)	—
Change in fair value of financial instruments	(23)	(1,542)	237	(1,810)
Total Other Loss	(1,696)	(6,749)	(34,087)	(11,334)
Net Loss	$ (38,556)	$ (33,668)	$ (98,497)	$ (61,057)
Net Loss per Common Share, Basic and Diluted	$ (0.23)	$ (0.34)	$ (0.69)	$ (0.62)
Weighted Average Common Shares Outstanding	168,127,144	100,343,637	143,017,970	98,523,696

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