November 10, 2014

Synergy Pharmaceuticals Reports Third Quarter 2014 Financial Results

NEW YORK-- Synergy Pharmaceuticals Inc. (Nasdaq:SGYP), today reported its financial results and business update for the three and nine months ended September 30, 2014.

“With the recent closing of a $200 million private offering, Synergy is now fully funded to successfully drive both plecanatide chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) pivotal phase 3 clinical development programs through to NDA filing,” said Dr. Gary S. Jacob, Chairman and CEO of Synergy Pharmaceuticals Inc. “Over the next 12 months, we plan to announce top-line data results from our two ongoing pivotal phase 3 CIC trials and achieve our first NDA filing. Synergy is committed to plecanatide clinical execution and the very exciting year ahead.”

Third Quarter 2014 and Recent Highlights

Research & Development

- Synergy presented additional data results from the plecanatide phase 2b IBS-C study at the American College of Gastroenterology’s 2014 Annual Scientific Meeting. Data presented at ACG demonstrate that plecanatide, once-daily oral tablet, significantly improved complete spontaneous bowel movement (CSBM) frequency, bowel habits, patients’ global assessments and significantly reduced abdominal pain in patients with IBS-C throughout the 12 week treatment period. Notably, patients taking 3.0 and 9.0 mg plecanatide showed statistically significant improvement in the Overall Responder rate, a secondary analysis in this study and the endpoint required for FDA approval in IBS-C (41.9% and 40%, respectively, compared to 24.7% for placebo). The Company plans to assess both 3.0 and 6.0 mg plecanatide doses in the pivotal phase 3 IBS-C program that is scheduled to start in the fourth quarter of 2014.
- Synergy achieved the halfway mark for total enrollment in the second pivotal phase 3 trial of plecanatide in patients with chronic idiopathic constipation (CIC). This is the second of two ongoing phase 3 pivotal trials designed to confirm the efficacy and safety of plecanatide 3.0 and 6.0 mg in patients with CIC. The company reached the halfway mark for total enrollment in the first phase 3 CIC trial in July 2014. Synergy plans to release top-line data from the first phase 3 CIC trial in the second quarter of 2015 and top-line data from the second study in the third quarter of 2015.
- Synergy completed patient enrollment for the phase 2 dose-ranging study assessing safety and efficacy of SP-333 (1.0, 3.0 and 6.0 mg), a once-daily oral tablet, in adult patients with opioid-induced constipation (OIC). The Company expects top-line data results from this trial in the fourth quarter of 2014.

- Synergy initiated a phase 1b exploratory study of SP-333 treatment in patients with mild to moderate ulcerative colitis. The double-blind, placebo-controlled, four-week study is being conducted in the United States and will enroll approximately 24 patients.

Financial Results

- Net loss for the three months ended September 30, 2014 was $23.0 million or $0.24 per share, as compared to a net loss of $13.5 million, or $0.15 per share, for the quarter ended September 30, 2013. This increased loss was entirely attributable to higher clinical development costs associated with our lead drug candidate, plecanatide, now undergoing two pivotal phase 3 clinical trials in patients with chronic idiopathic constipation (CIC). During the three months ended September 30, 2014, non-cash expense items, principally a change in fair value of derivative instruments and stock based compensation expense, totaled approximately $0.5 million or $0.01 per share, whereas such non-cash expenses in the three months ended September 30, 2013 totaled $1.2 million, or $0.01 per share.
- Net loss for the nine months ended September 30, 2014 was $65.2 million or $0.70 per share, as compared to a net loss of $42.3 million or $0.51 per share for the quarter ended September 30, 2013. During the nine months ended September 30, 2014, non-cash expense items, principally a change in fair value of derivative instruments and stock based compensation expense, totaled approximately net loss $1.8 million or $0.02 per share, whereas such items in the nine months ended September 30, 2013 totaled net loss of approximately $2.6 million or $0.03 per share.
- Synergy's cash, cash equivalents and available-for-sale securities balance as of September 30, 2014 was $32.7 million as compared to $68.1 million on December 31, 2013. During the nine months ended September 30, 2014, net cash provided by financing activities was $24.9 million, as compared to $89.2 million during the nine months ended September 30, 2013. Net cash used in operating activities was $60.6 million during the nine months ended September 30, 2014, as compared to $38.7 million during the nine months ended September 30, 2013.
- On November 3, 2014, Synergy announced the closing of a private offering of $200 million aggregate principal amount of 7.50% Convertible Senior Notes due 2019 (including the full exercise of the over-allotment option granted to the initial purchasers to purchase an additional $25 million aggregate principal amount of 7.50% Convertible Senior Notes due 2019). The net proceeds from the offering were approximately $187.3 million after deducting the initial purchasers' discounts and estimated offering expenses. The Company intends to use the net proceeds from this offering primarily to fund the ongoing clinical development of plecanatide and any remaining proceeds will be used for working capital and other general corporate purposes.

About Synergy Pharmaceuticals Inc.

Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) is a biopharmaceutical company focused on the development of novel therapies to treat gastrointestinal (GI) diseases and

disorders. Synergy’s platform technology is based on the naturally occurring human GI hormone, uroguanylin, a key physiological regulator and natural agonist of the intestinal guanylate cyclase-C (GC-C) receptor. Synergy scientists have discovered and developed two unique uroguanylin analogs – plecanatide and SP-333 – designed to mimic uroguanylin’s natural activity on the GC-C receptor and target a variety of GI conditions. Plecanatide is currently in two pivotal phase 3 clinical trials for chronic idiopathic constipation and has successfully completed a phase 2b dose-ranging study in patients with irritable bowel syndrome with constipation. SP-333 is currently in phase 2 development for opioid-induced constipation and is also 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 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, 2013 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; and thus you should not unduly rely on these statements.

Condensed Consolidated Balance Sheets
($ in thousands)

	September 30, 2014 (unaudited)	December 31, 2013
Assets		
Cash, cash equivalents and short term available for sale securities	$ 32,768	$ 68,157
Prepaid expenses and other current assets	4,106	3,718
Total Current Assets	36,874	71,875
Property and equipment, net	607	589
Security deposits	163	94
Total Assets	$ 37,644	$ 72,558
Liabilities and Stockholders' Equity		
Accounts payable	$ 15,246	$ 13,542
Accrued expenses	3,355	2,134
Total Current Liabilities	18,601	15,676
Derivative financial instruments –warrants	130	1,534
Total Liabilities	18,731	17,210
Common stock	10	10
Additional paid-in capital	255,233	226,515
Accumulated deficit	(236,330)	(171,177)
Total Stockholders' Equity	18,913	55,348
Total Liabilities and Stockholders' Equity	$ 37,644	$ 72,558

Condensed Consolidated Statement of Operations

($ in thousands except share and per share data) **(unaudited)**	**Three Months ended September 30, 2014**	**Three Months ended September 30, 2013**	**Nine Months ended September 30, 2014**	**Nine Months ended September 30, 2013**
Revenues	$ --	$ --	$ --	$ --
Costs and Expenses:				
Research and development	20,946	10,782	58,724	34,181
General and administrative	2,506	2,692	7,963	8,773
Loss from Operations	(23,452)	(13,474)	(66,687)	(42,954)
Interest and investment income-net	19	14	47	48
State R&D tax credits	-	-	83	-
Change in fair value of derivative instruments - warrants	425	(77)	1,404	633
Total Other Income	444	(63)	1,534	681
Net Loss	$ (23,008)	$ (13,537)	$ (65,153)	$ (42,273)
Net Loss per common share, basic and diluted	$ (0.24)	$ (0.15)	$ (0.70)	$ (0.51)
Weighted Average Common Shares Outstanding	94,738,048	90,182,115	93,631,115	83,548,398

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