August 11, 2014

# Synergy Pharmaceuticals Reports Second Quarter and First Half 2014 Financial Results

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

**Key Development Highlights:**

- On April 28, 2014, we announced the start of our second pivotal phase 3 clinical trial to confirm the safety and efficacy of plecanatide, our lead uroguanylin analog and once-daily oral tablet, in adult patients with chronic idiopathic constipation (CIC). This study is running in parallel with the first pivotal phase 3 CIC trial that was initiated in November 2013 and achieved the halfway mark for total enrollment on July 14, 2014. The CIC registration program includes two randomized, double-blind clinical trials to compare a 12-week regimen of plecanatide (3.0 and 6.0 mg) versus placebo in adult patients with CIC. The primary endpoint for the two pivotal trials is the proportion of patients who are overall responders for the 12-week treatment period. An overall responder for CIC is defined as a weekly responder for at least 9 out of the 12 treatment weeks, including at least 3 of the last 4 weeks. A weekly responder is defined as a patient who has ≥ 3 CSBMs per week and an increase from baseline of ≥ 1 CSBM for that week. Top-line data for the first CIC pivotal trial is expected in the second quarter of 2015.

- On April 30, 2014, we announced positive top-line results from our phase 2b dose-ranging study assessing the efficacy and safety of plecanatide (0.3, 1.0, 3.0 and 9.0 mg) versus placebo in adult patients with irritable bowel syndrome with constipation (IBS-C). Plecanatide 1.0, 3.0 and 9.0 mg doses demonstrated statistically significant improvement in the study's primary endpoint – complete spontaneous bowel movement (CSBM) frequency- and was safe and well tolerated at all doses. Notably, patients taking the plecanatide 3.0 mg dose consistently experienced statistically significant improvement in key secondary endpoints, including change from baseline versus placebo in worst abdominal pain intensity, stool consistency (BSFS) and met the overall responder endpoint for the 12-week treatment. An overall responder for IBS-C fulfills both ≥30% reduction in worst abdominal pain and an increase of ≥1 CSBMs from baseline in the same week for at least 50% of the weeks (i.e., 6/12 weeks). The overall responder endpoint is the FDA endpoint required for U.S. approval in IBS-C. In addition, patients taking plecanatide 3.0 mg experienced a <10% diarrhea rate.

- On July 8, 2014, we announced a successful End-of-Phase 2 meeting with the FDA and that agreement was reached on the plecanatide pivotal phase 3 IBS-C clinical

development plan and primary endpoint for registration trials. The pivotal phase 3 IBS-C program is scheduled to begin in the fourth quarter of this year and will include two trials to evaluate the efficacy and safety of plecanatide 3.0 and 6.0 mg doses, consistent with the ongoing CIC registration trials. IBS-C patients successfully completing either of the 12-week placebo-controlled registration trials will be offered enrollment into a long-term safety trial in order to support the ongoing long-term safety database for the CIC indication.

- On July 17, 2014, we announced the successful completion of patient enrollment for our phase 2 trial of SP-333, our next-generation uroguanylin analog, in adult patients with opioid-induced constipation (OIC). This multi-center, randomized, double-blind clinical trial is designed to compare a 4-week, dose-ranging regimen of once-daily oral SP-333 (1.0, 3.0 and 6.0 mg) versus placebo in patients taking opioid analgesics for chronic, non-cancer pain for at least three months. The primary endpoint of the study is mean change from baseline in the number of SBMs during week 4 of the treatment period. Top-line data for this trial is expected in the fourth quarter of this year.
- On August 7, 2014, we learned that our request to the FDA for a waiver of the requirement to conduct a thorough QT study with plecanatide had been granted.

“We are pleased with the clinical milestones achieved over the last several months along with the positive interactions with the FDA,” said Dr. Gary S. Jacob, Chairman and CEO of Synergy. “We remain focused on the successful execution of our clinical programs as we enter the second half of this year and look to start our second registration program with plecanatide in IBS-C and continue to advance the ongoing pivotal phase 3 CIC trials toward our anticipated NDA filing next year.”

Synergy's cash, cash equivalents and available-for-sale securities balance as of June 30, 2014 was $51.2 million as compared to $68.1 million on December 31, 2013. During the six months ended June 30, 2014, net cash provided by financing activities was $22.2 million, as compared to $89.2 million during the six months ended June 30, 2013. Net cash used in operating activities was $39.5 million during the six months ended June 30, 2014, as compared to $28.6 million during the six months ended June 30, 2013.

Net loss for the three months ended June 30, 2014 was $25.9 million or $0.28 per share, as compared to a net loss of $10 million, or $0.11 per share, for the quarter ended June 30, 2013. During the three months ended June 30, 2014, non-cash expense items, principally a change in fair value of derivative instruments and stock based compensation expense, totaled approximately net loss of $0.2 million, whereas such items in the three months ended June 30, 2013 totaled a net gain of $0.9 million, or a net gain of $0.01 per share.

Net loss for the six months ended June 30, 2014 was $42.2 million or $0.45 per share, as compared to a net loss of $28.7 million, or $0.36 per share, for the six months ended June 30, 2013. During the six months ended June 30, 2014, non-cash expense items, principally a change in fair value of derivative instruments and stock based compensation expense, totaled approximately net loss $1.3 million or $0.01 per share, whereas such items in the six months ended June 30, 2013 totaled net loss of approximately $1.5

million, or $0.02 per share.

Synergy had approximately 94.1 million common shares issued and outstanding at June 30, 2014.

**About Synergy Pharmaceuticals Inc.**

Synergy Pharmaceuticals Inc. is a biotechnology company focused on the research and development of novel therapies based on the naturally occurring human hormone, uroguanylin, for the treatment of gastrointestinal (GI) diseases and disorders. Uroguanylin is a natural hormone produced by humans in the small intestine and plays a key role in regulating the normal functioning of the digestive tract through its activity on the guanylate cyclase-C (GC-C) receptor. The GC-C receptor is known to be a primary source for stimulating a variety of beneficial physiological responses. Synergy has created two unique analogs of uroguanylin – plecanatide and SP-333 – designed to mimic the natural hormone's activity on the GC-C receptor and target a variety of GI conditions. Plecanatide is in two pivotal phase 3 clinical trials for chronic idiopathic constipation and has successfully completed a phase 2b study for irritable bowel syndrome with constipation. SP-333 is 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 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, 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)**

| | June 30, 2014 (unaudited) | December 31, 2013 |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and short term available for sale securities | $ 51,199 | $ 68,157 |
| Prepaid expenses and other current assets | 4,798 | 3,718 |
| Total Current Assets | 55,997 | 71,875 |
| Property and equipment, net | 589 | 589 |
| Security deposits | 163 | 94 |
| **Total Assets** | $ 56,749 | $ 72,558 |
| **Liabilities and Stockholders' Equity** | | |
| Accounts payable | $ 12,223 | $ 13,542 |
| Accrued expenses | 5,713 | 2,134 |
| Total Current Liabilities | 17,936 | 15,676 |
| Derivative financial instruments –warrants | 555 | 1,534 |
| **Total Liabilities** | 18,491 | 17,210 |
| Common stock | 10 | 10 |
| Additional paid-in capital | 251,570 | 226,515 |
| Accumulated deficit | (213,322) | (171,177) |
| Total Stockholders' Equity | 38,258 | 55,348 |
| **Total Liabilities and Stockholders' Equity** | $ 56,749 | $ 72,558 |

**Condensed Consolidated Statement of Operations**

| **($ in thousands except share and per share data) (unaudited)** | **Three Months ended June 30, 2014** | **Three Months ended June 30, 2013** | **Six Months ended June 30, 2014** | **Six Months ended June 30, 2013** |
|---|---|---|---|---|
| **Revenues** | $ -- | $ -- | $ -- | $ -- |
| Costs and Expenses: | | | | |
| Research and development | 24,479 | 9,055 | 37,778 | 23,399 |
| General and administrative | 2,279 | 2,803 | 5,457 | 6,081 |
| Loss from Operations | (26,758) | (11,858) | (43,235) | (29,480) |
| Other income | | | | |
| Interest and investment income-net | (1) | 16 | 28 | 34 |
| State R&D tax credits | 83 | - | 83 | - |
| Change in fair value of derivative instruments - warrants | 756 | 1,803 | 979 | 710 |
| Total Other Income | 838 | 1,819 | 1,090 | 744 |
| **Net Loss** | $ (25,920) | $ (10,039) | $ (42,145) | $ (28,736) |
| Net Loss per common share, basic and diluted | $ (0.28) | $ (0.11) | $ (0.45) | $ (0.36) |
| Weighted Average Common Shares Outstanding | 94,069,703 | 87,482,939 | 93,068,476 | 80,176,564 |


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