

Biotechnology Raghuram Selvaraju, Ph.D. (646) 502-2464 rselvaraju@aegiscap.com

> Yi Chen, Ph.D. (646) 502-2463 ychen@aegiscap.com

> **Company Update**

#### December 28, 2012

#### **Key Metrics**

SGYP - NASDAQ	\$5.06
Pricing Date	Dec 28 2012
Price Target	\$25.00
52-Week Range	\$7.08 - \$2.98
Shares Outstanding (mm)	65.8
Market Capitalization (\$mm)	\$332.9
3-Mo Average Daily Volume	386,551
Institutional Ownership	NA
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$0.48
Price/Book	10.5x
Dividend Yield	NM
LTM EBITDA Margin	NM

#### EPS (\$) FY: December

		Prior Curr.		Prior	Curr.		
	2011A	2012E	2012E	2013E	2013E		
1Q-Mar	(0.04)		(0.13)A		(0.16)E		
2Q-Jun	(0.05)		(0.17)A		(0.16)E		
3Q-Sep	(0.01)		(0.15)A		(0.18)E		
4Q-Dec	(0.12)		(0.19)E		(0.19)E		
FY	(0.30)		(0.65)E		(0.69)E		
P/E	NM		NM		NM		



#### Company Description:

Synergy Pharmaceuticals, Inc., an emerging biopharmaceutical company, develops drugs to treat gastrointestinal (GI) disorders and diseases. It is developing plecanatide (SP-304), a guanylyl cyclase C (GC-C) receptor agonist, to treat GI disorders, primarily chronic constipation and IBS-C. The firm is headquartered in New York, New York; the company's website is www.synergypharma.com.

# Synergy Pharmaceuticals, Inc. Rating: Buy

# SP-333 Completes Initial Phase 1 Study

# **Investment Highlights:**

- Synergy Successfully Completes Phase 1 SP-333 Study. This morning, Synergy announced that it had successfully completed the first Phase 1 study of its second gastrointestinal (GI) tract disorders-focused pipeline candidate, SP-333. This agent is a novel analog of the endogenous human hormone uroguanylin, and has different pharmacokinetic and pharmacodynamics properties from Synergy's lead molecule, plecanatide. The Phase 1 data from this single ascending dose (SAD) study showed that SP-333 was safe and well-tolerated, with no unexpected side effects. Eight cohorts of healthy volunteers were given the drug, with dosing ranging from 0.1mg to 60mg. The pharmacokinetic profile of the drug demonstrated positive GI tract bioavailability that bodes well for its development in additional clinical studies. A multiple ascending dose (MAD) study is planned to begin early in 2013, with data expected in the first half of the year. Assuming positive results, Synergy plans to conduct a Phase 2 proof-of-concept clinical trial with SP-333 in ulcerative colitis, with data potentially available before the end of 2013. In the wake of the positive initial SAD data from the first Phase 1 trial of SP-333, and in anticipation of positive Phase 3 data with plecanatide in the chronic constipation study in the coming days, we reiterate our Buy rating and 12-month price target of \$25 per share for SGYP.
- Plecanatide Proof-Of-Concept Anticipated. Top-line data from the Phase 3 trial of plecanatide in chronic constipation are expected in early January 2013, within the next week or so. This double-blinded, placebo-controlled, randomized 12-week study enrolled 951 patients, above the original target of 880 subjects. We are encouraged by the progress that the company has made and expect positive data from this study from the perspective of both safety (where we anticipate superiority to the safety profile of linaclotide) and efficacy (where we expect comparable effectiveness to linaclotide in stimulating normalized bowel function). Furthermore, we remind investors that the plecanatide Phase 3 CIC study could firmly establish plecanatide as a best-in-class GI tract disorder drug.
- Significant Year Ahead. In our view, 2013 should be a transformative year for the company, with Phase 3 data for plecanatide in chronic constipation, Phase 2b data for plecanatide in IBS-C, and Phase 1 and Phase 2 data for SP-333 in ulcerative colitis. SP-333 has enhanced stability against proteolysis, which could enable it to become an effective chronic therapy for ulcerative colitis and other inflammatory bowel diseases. The drug's use in these disorders is expected to be protected beyond 2030. The firm's non-gastrointestinal disease-focused candidate, FV-100, could also re-enter late-stage clinical development later in 2013.

Synergy Pharmaceuticals, Inc.

December 28, 2012

Table 1: Synergy Pharmaceuticals, Inc. (SGYP) – Historical Income Statements, Financial Projections FY end December 31

\$ in thousands, except per share data

			2011A	2012E					2013E				
	2009A	2010A		1QA	2QA	3QA	4QE	2012E	1QE	2QE	3QE	4QE	2013E
Revenue													
Total revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Expenses													
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	4,257	9,559	13,419	5,338	7,626	8,246	10,000	31,210	9,000	10,000	11,000	12,000	42,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-	-	-
General and administrative	3,943	6,563	6,746	1,731	1,918	1,843	2,500	7,993	3,000	3,500	4,000	4,500	15,000
Total expenses	8,200	16,121	20,164	7,069	9,545	10,089	12,500	39,203	12,000	13,500	15,000	16,500	57,000
Gain (loss) from operations	(8,200)	(16,121)	(20,164)	(7,069)	(9,545)	(10,089)	(12,500)	(39,203)	(12,000)	(13,500)	(15,000)	(16,500)	(57,000)
Other income/expense													
Interest and investment income	-	-	90	39	48	63	45	195	75	60	50	45	230
Interest income/expense	75	109	(12)	-	-	-	-	-	-	-	-	-	-
Change in fair value of derivative instruments-warrants	-	297	5,257	8	(1,317)	140	-	(1,169)	-	-	-	-	-
Other income/expense	-	494	362	-	256	-	-	256	-	-	-	-	-
Total investment income and other	75	900	5,697	47	(1,014)	203	45	(719)	75	60	50	45	230
Loss before provision for income taxes	(8,125)	(15,221)	(14,467)	(7,023)	(10,558)	(9,885)	(12,455)	(39,921)	(11,925)	(13,440)	(14,950)	(16,455)	(56,770)
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss/income	(8,125)	(15,221)	(14,467)	(7,023)	(10,558)	(9,885)	(12,455)	(39,921)	(11,925)	(13,440)	(14,950)	(16,455)	(56,770)
Net loss per share (basic)	(0.11)	(0.17)	(0.30)	(0.13)	(0.17)	(0.15)	(0.19)	(0.65)	(0.16)	(0.16)	(0.18)	(0.19)	(0.69)
Net loss per share (diluted)	(0.11)	(0.17)	(0.30)	(0.13)	(0.17)	(0.15)	(0.19)	(0.65)	(0.16)	(0.16)	(0.18)	(0.19)	(0.69)
Weighted average number of shares outstanding (basic)	73,281	89,751	47,598	54,298	60,416	65,806	66,106	61,657	75,331	84,581	84,631	84,656	82,300
Weighted average number of shares outstanding (diluted)	73,281	89,751	47,598	54,298	60,416	65,806	66,106	61,657	75,331	84,581	84,631	84,656	82,300

Source: Company Reports and Aegis Capital Corp. estimates

## **Required Disclosures**

## **Price Target**

Our 12-month price target for SGYP is \$25 per share.

## Valuation Methodology

Given that Synergy is currently unprofitable, and considering our belief that this condition is likely to persist for the foreseeable future, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, we believe that the stock is worth \$25 per share, given our estimate of a \$2 billion risk-adjusted net present value (rNPV) for the firm's pipeline. This assumes that the shares trade in line with the comp group average enterprise value of roughly \$2 billion and that the firm has roughly 85 million shares outstanding in mid-2013.

## **Risk Factors**

Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Drugs in clinical development may not advance due to inadequate safety, efficacy, or tolerability. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all. The firm may require substantial funding to advance the clinical progress of its candidates, which could be dilutive to current shareholders. We expect competition for the company's drugs from several public and private companies developing pharmaceuticals. Sales of the firm's drugs could depend upon reimbursement from private, as well as public, reimbursement agencies.

## For important disclosures go to www.aegiscap.com.

We, Raghuram Selvaraju and Yi Chen, the authors of this research report, certify that the views expressed in this report accurately reflect our personal views about the subject securities and issuers, and no part of our compensation was, is, or will be directly or indirectly tied to the specific recommendations or views contained in this research report.

Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

Aegis Capital Corp. has performed investment banking services for and received fees from Synergy Pharmaceuticals, Inc. within the past 12 months.

Aegis Capital Corp. makes a market in Synergy Pharmaceuticals, Inc..

	Investment Banking					
	Services/Past 12 Mos.					
Rating	Percent	Percent				
BUY [BUY]	92.31	33.33				
HOLD [HOLD]	7.69	0.00				
SELL [SELL]	0.00	0.00				

#### Meaning of Ratings

- A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
- B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
- C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

#### **Other Disclosures**

The information contained herein is based upon sources believed to be reliable but is not guaranteed by us and is not considered to be all inclusive. It is not to be construed as an offer or the solicitation of an offer to sell or buy the securities mentioned herein. Again Capital

Corp., its affiliates, shareholders, officers, staff, and/or members of their families, may have a position in the securities mentioned herein, and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the Firm from time to time in the open market or otherwise. Opinions expressed are our present opinions only and are subject to change without notice. Aegis Capital is under no obligation to provide updates to the opinions or information provided herein. Additional information is available upon request.

## © Copyright 2012 by Aegis Capital

Aegis Capital Corp. (212) 813-1010 810 Seventh Avenue, 18th Floor New York, New York 10019