

Synergy Pharmaceuticals (SGYP) 3Q12 Update. Reiterate Buy.

November 15, 2012

SUMMARY

SGYP reported 3Q12 EPS of (\$0.15), roughly in line with our estimate. SGYP made great progress in 3Q12. It successfully completed the enrollment of 951 patients in the ongoing phase II/III trial of plecanatide in patients with chronic idiopathic constipation (CIC) at the end of August. The trial is on track to complete last patient visits by December 7th and release the top-line data during the first week of January 2013. Near term, we expect potentially positive topline data from the phase II/III CIC trial to provide significant upside. We reiterate our Buy rating and target price of \$9.

EVENT

SGYP reported 3Q12 EPS of (\$0.15), roughly in line with our estimate of (\$0.16). SGYP ended 3Q12 with cash and equivalents of ~\$37.4MM, which should be sufficient to fund the operation into 2H13, according to our projections. Management indicated top-line data from the phase II/III CIC trial should be released by SGYP in the first week of January 2013. It also expects to initiate the plecanatide phase II IBS-C trial in the near future.

INTERPRETATION

SGYP made great progress in 3Q12. It successfully completed the enrollment of 951 patients in the ongoing phase II/III trial of plecanatide in CIC by the end of August. The trial is on track to complete last patient visits by December 7th and release the top-line data during the first week of January 2013, after locking the database and analyzing the data. Management is very comfortable with the trial generating over 800 evaluable patients for data analysis. The detailed guidance on the timing of the data release is roughly in line with prior guidance of year-end 2012.

ACTION

We reiterate our Buy rating and target price of \$9. Near term, we expect potentially positive top-line data from the phase II/III CIC trial to provide significant upside.

SGYP

Rating: BUY

Price Target: \$9

Market Data

Price:	\$3.75
52-week high:	\$7.08
52-week low:	\$2.00
Shares out:	65.81MM
Shares short:	1.99M
Average volume (10-day):	397,438

Valuation Metrics

Market cap:	\$246.77M
Enterprise value:	\$210.53M
Book value/share:	\$0.63

Financial Highlights

Cash/equivalents:	\$37.4MM
Debt:	\$0.00

REV (\$MM)	2011A	2012E	2013E
Q1	0	0A	-
Q2	0	0A	-
Q3	0	0A	-
Q4	0	0E	-
FY	0	0E	0

EPS (\$)	2011A	2012E	2013E
Q1	(0.08)	(0.13)A	-
Q2	(0.10)	(0.17)A	-
Q3	(0.01)	(0.15)A	-
Q4	(0.12)	(0.15)E	-
FY	(0.30)	(0.61)E	(0.52)

One-Year History



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INVESTMENT THESIS

SGYP's lead compound, plecanatide, has great potential to become the second, but best-in-class, guanylate cyclase-C (GC-C) receptor agonist for treating chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). We expect potentially positive topline data from an ongoing phase II/III CIC trial, which is expected in early January 2013, to provide significant upside in the near term. Additionally, we expect potentially successful proof of concept of plecanatide in IBS-C (phase IIb trial planned in 4Q12) to significantly expand plecanatide's market opportunity. Assuming success, we expect plecanatide to potentially become a best-in-class oral treatment for both CIC and IBS-C, two large unmet medical needs that are not sufficiently served with available therapies. Although linaclotide, a first-in-class GC-C receptor agonist, is likely two to three years ahead of plecanatide, we believe the market is big enough to allow room for several players. Additionally, plecanatide's potential side effect advantage of causing less diarrhea might offer it a significant competitive advantage. While not our main thesis, we believe SGYP is an attractive acquisition target with plecanatide as a potential best-in-class compound targeting the large unmet medical needs of CIC and IBS-C.

VALUATION

We use a sum-of-the parts analysis to value SGYP shares. Our 12-month target price of \$9 is derived by summing up SGYP's development programs: the risk-adjusted NPV of plecanatide at ~\$477MM, SP-333 at \$35MM, and the company's technology and discovery engine at \$80MM (Figure 1).

Figure 1. Sum-of-the-Parts Analysis

Plecanatide	\$	476,984
SP-333	\$	35,000
Technology	\$	80,000
Fair value	\$	591,984
Fair value / share	\$	9.2

INVESTMENT RISKS

- Clinical risks associated with plecanatide: We assign a significant proportion of our projected value to plecanatide. Therefore, if the ongoing phase II/III trial in CIC or future clinical trials in CIC or IBS-C fail to deliver positive results, it would have a negative impact on our projections and target price.
- Regulatory risks associated with plecanatide: Plecanatide may not obtain regulatory approval even if it demonstrates positive clinical data. Our model factors in the risk-adjusted sales of plecanatide in CIC and IBS-C. If the drug does not obtain regulatory approval, it will negatively impact our target price.
- Liquidity and financing risk: We estimate SGYP's cash position should be sufficient to fund operations through 2013. There are risks associated with obtaining sufficient funding to sustain operations. The company may need to raise additional capital via equity financing, potentially causing dilution.
- Commercialization risk: The market potential of plecanatide in CIC and IBS-C may not be as large as we project.
- High stock price volatility: High stock price volatility is common among developmental companies in the biotechnology sector.

CATALYSTS/UPCOMING MILESTONES

- ✓ Complete patient enrollment in the pivotal phase II/III trial of plecanatide in CIC (3Q12)
- ✓ File an IND for SP-333 in patients with ulcerative colitis (3Q12)
- ✓ Potential for competitor linaclotide to obtain regulatory approval for CIC and IBS-C in the US (3Q12/September PDUFA date)
- ✓ Potential to initiate a phase I trial evaluating SP-333 in healthy volunteer (4Q12)
- Potential to initiate a randomized, placebo-controlled phase IIb trial evaluating plecanatide in patients with IBS-C (4Q12)
- Report topline results from a phase II/III trial of plecanatide in CIC (1Q13/first week of January)
- Potential to initiate a trial to evaluate multi-dose SP-333 in healthy volunteer (1Q13)
- Potential to report topline data from the phase IIb trial of plecanatide in patients with IBS-C (3Q13)

COMPANY DESCRIPTION

Synergy Pharmaceuticals, Inc., is a New York-based biopharmaceutical company focusing on the development of drugs to treat gastrointestinal disorders and diseases. Its leading compound, plecanatide, is being evaluated in a phase II/III trial (ongoing) in patients with chronic idiopathic constipation and in patients with constipation-predominant irritable bowel syndrome (phase IIb planned). The second compound, SP-333, a second-generation GC-C receptor analog, recently has an IND submitted for treating ulcerative colitis. SGYP also recently acquired FV-100, an orally available nucleoside analogue, for the treatment of shingles, from BMS.

PIPELINE

Figure 2. SGYP's Pipeline

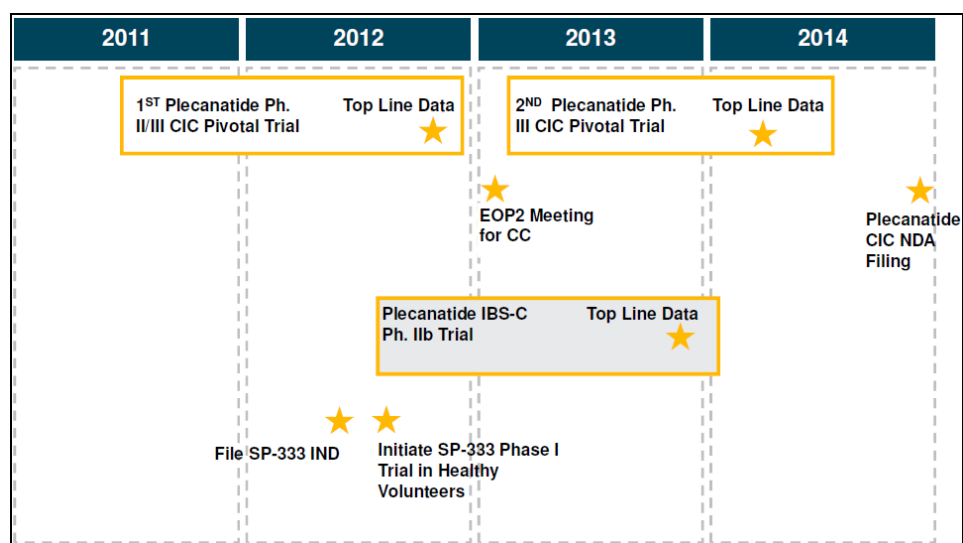


Figure 3. SGYP Income Statement

Synergy Pharmaceuticals, Inc.													
Income Statement													
Fiscal Year Ends December													
(in 000, except per share amounts)													
	2009A	2010A	1Q11A	2Q11A	3Q11A	4Q11A	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	2013E
Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Expenses:													
Cost of goods sold	-	-	-	-	-	-	-	-	-	-	-	-	-
Research and development	3,733	9,559	1,478	2,355	3,883	5,703	13,419	5,338	7,626	8,246	8,500	29,710	32,681
General and administrative	4,467	6,563	1,897	1,524	1,103	2,222	6,746	1,731	1,918	1,843	2,050	7,543	7,920
Total Operating Expenses	8,200	16,121	3,375	3,879	4,986	7,925	20,165	7,069	9,545	10,089	10,550	37,253	40,601
Loss from operations	(8,200)	(16,121)	(3,375)	(3,879)	(4,986)	(7,925)	(20,165)	(7,069)	(9,545)	(10,089)	(10,550)	(37,253)	(40,601)
Other income (expense):													
Interest and Investment Income	75	108	24	20	20	26	90	39	48	63	20	170	70
Interest expense			(12)				(12)						
Other income (expense):		494				362	363		256			256	
Change in fair value of derivative instruments - warrants		297	(339)	(698)	4,383	1,911	5,257	8	(1,317)	141		(1,168)	
Net loss before income taxes	(8,125)	(15,222)	(3,702)	(4,557)	(583)	(5,626)	(14,467)	(7,023)	(10,558)	(9,885)	(10,530)	(37,996)	(40,531)
Income tax benefit – principally from sale of New Jersey tax benefits in 2010 and 2008													
Net loss	(8,125)	(15,222)	(3,702)	(4,557)	(583)	(5,626)	(14,467)	(7,023)	(10,558)	(9,885)	(10,530)	(37,996)	(40,531)
Basic and diluted net loss per share	\$ (0.22)	\$ (0.34)	\$ (0.08)	\$ (0.10)	\$ (0.01)	\$ (0.12)	\$ (0.30)	\$ (0.13)	\$ (0.17)	\$ (0.15)	\$ (0.15)	\$ (0.61)	\$ (0.52)
Weighted average number of shares outstanding – basic and diluted	36,641	44,875	46,167	46,643	47,309	48,657	47,587	54,298	60,416	65,806	70,506	62,757	77,557

Disclosures and Disclaimers — Fourth Quarter 2012

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Investment Rating Distribution for the Period 7/1/12 through 9/30/12:

Rating	Count	Percentage
BUY	35	80%
NEUTRAL	8	18%
SELL	1	2%
Companies under coverage at 9/30/12	44	100%

We have assigned an investment rating for at least one year for the following subject companies mentioned in this report:

SGYP

Ratings History

Date	Rating	Share Price	Price Target
3/22/12	BUY	\$4.15	\$9.00

SGYP Investment Risks

- **Clinical:** If the ongoing phase II/III trial of plecanatide in CIC or future clinical trials in CIC or IBS-C fail to deliver positive results, it would have a negative impact on our projections and target price.
- **Regulatory:** Plecanatide may not obtain regulatory approval even if it demonstrates positive clinical data.
- **Commercialization:** The market potential of plecanatide in CIC and IBS-C may not be as large as we project.
- **High stock price volatility:** High stock price volatility is common among developmental companies in the biotechnology sector.

Valuation Method for Price Target: Sum of the parts

