

Synergy Pharmaceuticals (SGYP)

SGYP Licenses Ironwood's Method of Use Patent on Plecanatide. Reiterate Buy.

September 24, 2012

SUMMARY

SGYP recently enters into a definitive license agreement with Ironwood to obtain an exclusive worldwide license to IRWD's method of use patents on plecanatide for the treatment of chronic constipation. The licensing agreement with IRWD would allow SGYP to gain complete freedom of operation for plecanatide, which, in our view, is a positive for SGYP, especially for a potential partner or acquirer who is interested in plecanatide. We reiterate our Buy rating and our 12 month target price remains at \$9.

EVENT

SGYP recently issued an 8k, announcing it entered into a binding letter of intent (the "LOI") with Ironwood Pharmaceuticals, Inc. (IRWD, Not Rated) on under which the two companies agreed to enter into a definitive license agreement for SGYP to obtain an exclusive worldwide license to IRWD's method of use patents on plecanatide for the treatment of chronic constipation. The licensing agreement involves a low, single digit royalty on potential plecanatide net sales. The two companies agreed not to challenge each other's patents covering certain GC-C agonists, however, SGYP retains the right to challenge IRWD's method of use patents on plecanatide.

INTERPRETATION

SGYP gains full freedom to operate on plecanatide in exchange with low single digit royalties. IRWD has a broad method of use patent of GC-C agonists for the treatment of GI disorders granted by the US PTO, which also covers plecanatide (a GC-C agonist). Although IRWD's broad use patent on GC-C agonist could be overturned with potential patent challenge if SGYP chooses to do so, such patent dispute may take a long time to reach a resolution. The licensing agreement with IRWD would allow SGYP to gain complete freedom of operation for plecanatide, which, in our view, is a positive for SGYP, especially for a potential partner or acquirer who is interested in plecanatide. Of note, IRWD's method of use patent does not include SP-333, for which SGYP has full freedom to operate.

ACTION

We reiterate our Buy rating and target price of \$9. We view the licensing agreement with IRWD to exclusively license the method of use patent for plecanatide for chronic constipation in exchange with low single digit royalties (while still maintain the rights to challenge IRWD's method of use patent) a positive development for SGYP and it potentially removes overhang in case of potential partner or acquirer.

SGYP

Rating: BUY

Price Target: \$9

Market Data

Price:	\$4.70
52-week high:	\$7.08
52-week low:	\$1.86
Shares out:	65.81MM
Shares short:	1.93M
Average volume (10-day):	216,400

Valuation Metrics

Market cap:	\$309.29M
Enterprise value:	\$261.76M
Book value/share:	\$0.63

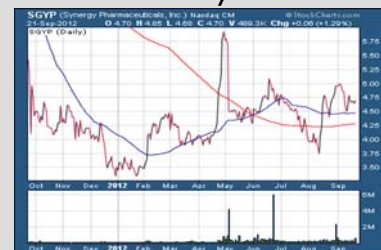
Financial Highlights

Cash/equivalents:	\$43.58MM
Debt:	\$0.00

REV (\$MM)	2010A	2011A	2012E
Q1	-	1.5	5.3
Q2	-	2.4	7.6
Q3	-	3.9	7.7
Q4	-	5.7	7.8
FY	9.6	13.4	28.5

EPS (\$)	2010A	2011A	2012E
Q1	-	(0.08)	(0.13)
Q2	-	(0.10)	(0.17)
Q3	-	(0.01)	(0.16)
Q4	-	(0.12)	(0.15)
FY	(0.34)	(0.30)	(0.60)

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 4Q12, 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 I).

Figure I. 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 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 (4Q12)
- 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 3. SGYP's Pipeline

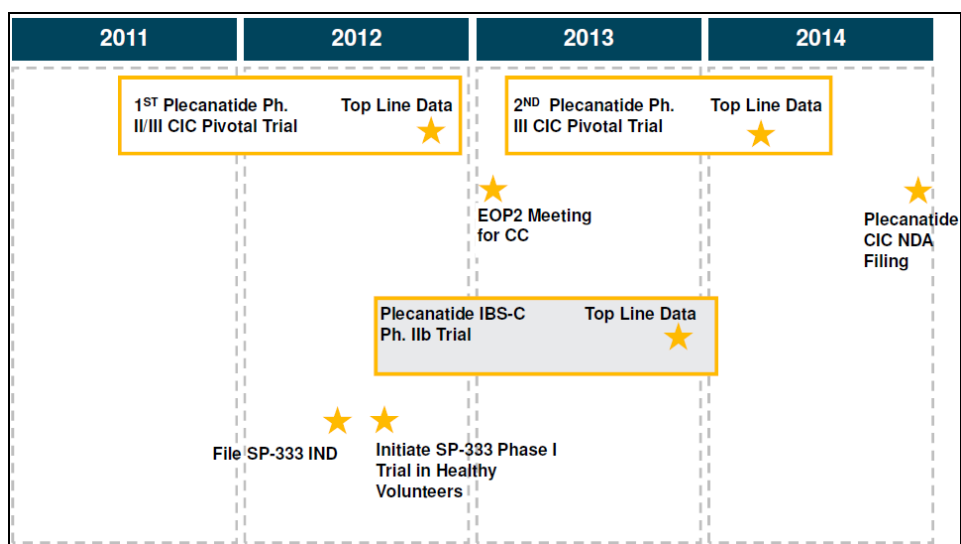


Figure 3. SGYP Income Statement

Synergy Pharmaceuticals, Inc.													
Income Statement													
Fiscal Year Ends December													
(In 000, except per share amounts)													
	2009A	2010A	1Q11A	2Q11A	3Q11A	4Q11A	2011A	1Q12A	2Q12A	3Q12E	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	7,700	7,800	28,464	31,311
General and administrative	4,467	6,563	1,897	1,524	1,103	2,222	6,746	1,731	1,918	2,000	2,100	7,750	8,137
Total Operating Expenses	8,200	16,121	3,375	3,879	4,986	7,925	20,165	7,069	9,545	9,700	9,900	36,214	39,448
Loss from operations	(8,200)	(16,121)	(3,375)	(3,879)	(4,986)	(7,925)	(20,165)	(7,069)	(9,545)	(9,700)	(9,900)	(36,214)	(39,448)
Other income (expense):													
Interest and Investment Income	75	108	24	20	20	26	90	39	48	20	20	127	70
Interest expense			(12)				(12)						
Other income (expense):		494				362	363		256				
Change in fair value of derivative instruments - warrants		297	(339)	(698)	4,383	1,911	5,257	8	(1,317)				
Net loss before income taxes	(8,125)	(15,222)	(3,702)	(4,557)	(583)	(5,626)	(14,467)	(7,023)	(10,558)	(9,680)	(9,880)	(36,087)	(39,378)
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)	(9,680)	(9,880)	(36,087)	(39,378)
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)	\$ (0.16)	\$ (0.15)	\$ (0.60)	\$ (0.55)
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	60,718	65,418	60,213	71,960

Disclosures and Disclaimers — Third Quarter 2012

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Investment Rating Distribution for the Period 4/1/12 through 6/30/12:

Rating	Count	Percentage
BUY	35	80%
NEUTRAL	8	18%
SELL	1	2%
Companies under coverage at 6/30/12	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

