

Equity Research

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Synergy Pharmaceuticals, Inc. (SGYP-\$3.13)

Rating: BUY

Target Price: \$7.00

Marching Towards Data Release in January; Maintain BUY and \$7.00 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2011A	0.0A	0.0A	0.0A	0.0A
2012E	0.0A	0.0A	0.0A	0.0E
2013E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2011A	(0.08)A	(0.10)A	(0.01)A	(0.12)A
2012E	(0.13)A	(0.17)A	(0.15)A	(0.16)E
<i>Prev</i>	—	—	(0.18)E	(0.17)E
2013E	—	—	—	—
<u>FY</u>	<u>2011A</u>	<u>2012E</u>	<u>2013E</u>	
REV	0.0A	0.0E	0.0E	
EV/REV	—	—	—	
P/S	—	—	—	
EPS	(0.30)A	(0.61)E	(0.72)E	
<i>Prev</i>	—	(0.65)E	(0.88)E	
P/E	(10.4)x	(5.1)x	(4.3)x	

- **Solid 3Q:12:** Synergy reported an operational loss of \$9.9M and EPS of (\$0.15) relative to consensus estimates of (\$0.16). 3Q:12 R&D expense included a \$1M base payment for FV-100, a shingles drug that the company acquired from Bristol-Myers. We have lowered 2013 R&D estimates slightly to accommodate what we believe are more realistic expectations of trial costs for the IBS-C and ulcerative colitis programs, as well as next steps in the chronic constipation indication. The company has approximately \$38.8M in cash on the balance sheet and is moving forward with its proposed merger with Callisto Pharma (closure is now estimated in January).
- **Plecanatide constipation data the critical catalyst for the company:** Data release from this Phase IIB trial has now been pushed out to the first week of January (from end of December). The company enrolled 951 patients (rather than the planned 880) to allow for analysis of more evaluable patients in case of a higher discontinuation rate (estimated in the 20% range). We expect this higher patient number to improve the power of the trial and give the company a stronger data set from which to identify an effective dose. In spite of the newly improved picture, we still remain somewhat cautious about the outcome of the study (we give it a 66% probability of success) given the inconsistent efficacy signal across doses from the Phase IIa trial. If data are positive, we believe that Synergy will become an attractive takeover candidate. On a recent earnings call, Salix management indicated that it continues to look for assets in the IBS-C/Chronic Constipation space, and we would expect interest from other companies as well.
- **Following in its predecessor's footsteps:** Synergy is actively leveraging plecanatide like Ironwood has done with linaclotide. The company plans to initiate a Phase IIB trial in IBS-C in 4Q:12 and is also investigating a next generation GC-C receptor analog for the treatment of ulcerative colitis (Phase I data expected in early 2013). Synergy also acquired an unrelated drug for the treatment of shingles, but we think that this product may be on the back burner while the company focuses its resources on plecanatide development. Unlike Ironwood, we appreciate how Synergy has 100% ownership of its drug, is maintaining a lower cost structure, and is open to a variety of exit opportunities.

Current Statistics

Market Cap (\$Mil)	\$206.9	Float Shares (Mil):	65.800
Avg. Daily Trading Volume (3 mo.):	272,351	Dividend Yield:	0.00%
Shares Out (Mil):	66.106		

Valuation

Our current valuation of the company is based upon weighted average of two scenarios:

- (1) We utilize discounted cash flow analysis (DCF) with a weighted average cost of capital of 14% (to account for the high clinical risk), and a conservative 0% terminal growth rate which generates a hypothetical \$11 price target. Under this scenario we assume positive data results in January and weight the probability of this outcome at 67%.
- (2) The ongoing Phase IIb CC trial fails to identify at least one plecanatide dose that is statistically different from placebo, and the company valuation falls to reflect its cash position (<\$1.00/share). We weight this negative outcome by a 33% probability.

We arrive at our \$7.00 price target by utilizing a probability-weighted average of these two outcomes.

We check our assumptions by evaluating a potential takeout scenario of the company. If we assume that Synergy is acquired at a 3x multiple of discounted and risk-adjusted 2022 sales of \$894 million then we derive a hypothetical price target of ~\$11, which supports our BUY rating.

Risks

- (1) Plecanatide may fail to demonstrate efficacy at any of the doses being tested in the ongoing Phase IIb trial for chronic constipation. If this is the case, we would expect the stock price to decline to reflect the cash position on the company's balance sheet with minimal additional value allocated for the pipeline assets.
- (2) Plecanatide may fail to show any tolerability differentiation from Ironwood's Linzess based on data from the ongoing Phase IIb trial in chronic constipation.
- (3) Management could fail to attract an acquirer for the company if data from the chronic constipation trial are not sufficiently robust.
- (4) Synergy may pursue additional dilutive financing to support its clinical development programs in plecanatide, SP-333 and FV-100.
- (5) Manufacturing issues could arise that delay or prevent FDA approval of plecanatide.
- (6) Synergy faces regulatory approval risk for plecanatide in chronic constipation.
- (7) Longer-term, plecanatide may fail to demonstrate efficacy in treating abdominal pain and may therefore fail to gain an IBS-C indication.
- (8) The commercial opportunity for plecanatide may be limited due to competition from Linzess and managed care restrictions.

Exhibit 1: Synergy Income Statement (dollars in millions)

	2009	2010	2011	1Q:12A	2Q:12A	3Q:12A	4Q:12E	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Net Sales	-	-	-	-	-	-	-	-	-	-	-	48.5	134.8	297.1	487.9	659.1	793.3	894.0	981.2
COGS	-	-	-	-	-	-	-	-	-	-	-	4.8	12.7	26.1	40.0	50.1	55.5	57.2	56.9
Gross Profit	-	-	-	-	-	-	-	-	-	-	-	43.6	122.1	271.0	447.9	609.0	737.7	836.8	924.3
SG&A	4.5	6.6	6.7	1.7	1.9	1.8	2.0	7.5	9.0	13.0	16.0	90.0	103.5	110.7	118.5	126.8	135.7	145.2	155.3
R&D	3.7	9.6	13.4	5.3	7.6	8.2	8.5	29.7	50.0	75.0	86.3	90.6	95.1	99.8	104.8	110.1	115.6	121.4	127.4
Operating Income (Loss)	(8.2)	(16.1)	(20.2)	(7.1)	(9.5)	(10.1)	(10.5)	(37.2)	(59.0)	(88.0)	(102.3)	(136.9)	(76.5)	60.4	224.6	372.2	486.5	570.3	641.5
Interest Income	0.1	0.1	0.1	0.0	0.0	0.1	0.1	0.2	0.1	0.2	0.2	0.2	0.1	0.3	1.0	2.3	4.0	6.0	8.2
Interest expense	-	-	(0.0)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other income	-	0.5	0.4	-	0.3	-	-	0.3	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of derivatives-warrants	-	0.3	5.3	0.0	(1.3)	0.1	0.1	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)
Pre-tax Income	(8.1)	(15.2)	(14.5)	(7.0)	(10.6)	(9.9)	(10.3)	(37.8)	(59.9)	(88.9)	(103.1)	(137.8)	(77.4)	59.6	224.5	373.4	489.4	575.2	648.7
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	38.0%	38.0%	38.0%	38.0%	38.0%	38.0%
Tax	-	-	-	-	-	-	-	-	-	-	-	-	-	22.6	85.3	141.9	186.0	218.6	246.5
Net income (Loss)	(8.1)	(15.2)	(14.5)	(7.0)	(10.6)	(9.9)	(10.3)	(37.8)	(59.9)	(88.9)	(103.1)	(137.8)	(77.4)	37.0	139.2	231.5	303.4	356.6	402.2
Diluted Shares	36.64	44.9	47.6	54.3	60.4	65.8	65.8	61.6	83.0	95.0	103.0	109.0	109.0	109.0	109.0	109.0	109.0	109.0	109.0
EPS	(\$0.22)	(\$0.34)	(\$0.30)	(\$0.13)	(\$0.17)	(\$0.15)	(\$0.16)	(\$0.61)	(\$0.72)	(\$0.94)	(\$1.00)	(\$1.26)	(\$0.71)	\$0.34	\$1.28	\$2.12	\$2.78	\$3.27	\$3.69
Consensus Revs				0.00				0.00	0.00	0.0	49.9	132.2							
Consensus EPS				(\$0.16)				(\$0.63)	(0.63)	(0.80)	(0.34)	0.12							
Margin Analysis	2009	2010	2011	1Q:12A	2Q:12A	3Q:12A	4Q:12E	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Gross Margin												NM	90.0%	90.6%	91.2%	91.8%	92.4%	93.0%	94.2%
COGS												NM	10.0%	9.4%	8.8%	8.2%	7.6%	7.0%	5.8%
SG&A												NM	185.7%	76.8%	37.3%	24.3%	19.2%	17.1%	15.8%
R&D												NM	186.8%	70.5%	33.6%	21.5%	16.7%	14.6%	13.0%
Operating Margin												NM	-282.5%	-56.7%	20.3%	46.0%	56.5%	61.3%	65.4%
Net Income Margin												NM	-284.3%	-57.4%	12.4%	28.5%	35.1%	38.3%	41.0%
Growth (Y/Y)	2009	2010	2011	1Q:12A	2Q:12A	3Q:12A	4Q:12E	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Net Sales													180%	122%	65%	36%	21%	13%	10%
COGS													161%	106%	53%	25%	11%	3%	-1%
Gross Profit													180%	122%	65%	36%	21%	13%	10%
SG&A		47%	3%	-9%	26%	67%	-10%	11%	20%	45%	23%	463%	15%	7%	7%	7%	7%	7%	7%
R&D		156%	40%	261%	224%	112%	49%	121%	68%	50%	15%	5%	5%	5%	5%	5%	5%	5%	5%
Operating Income (Loss)		97%	25%	109%	146%	102%	33%	84%	59%	49%	16%	34%	-44%	179%	272%	66%	31%	17%	12%
Interest Income		45%	-17%	61%	141%	129%	133%	133%	-57%	89%	18%	-13%	-51%	206%	127%	75%	50%	37%	37%
Pre-tax Income		87%	-5%	90%	132%	1596%	83%	161%	59%	48%	16%	34%	-44%	177%	277%	66%	31%	18%	13%
Tax															277%	66%	31%	18%	13%
Net income (Loss)		-87%	5%	-90%	-132%	-1596%	-83%	-161%	-259%	-248%	-216%	-234%	-156%	-52%	277%	66%	31%	18%	13%
EPS		-253%	-190%	-261%	-279%	-1319%	-235%	-301%	-18%	-30%	-7%	-26%	44%	148%	277%	66%	31%	18%	13%

Source: Company reports, Cantor Fitzgerald estimates, and Thomson Reuters Consensus

Company Description

Synergy Pharmaceuticals is a small developmental-stage pharmaceutical company focused on gastroenterology. Synergy is currently working to develop plecanatide (a GC-C agonist) for the treatment of chronic constipation and constipation-predominant irritable bowel syndrome. The company also has two early-stage assets for the treatment of ulcerative colitis and shingles.

Companies Mentioned:

Bristol-Myers Squibb Company (BMJ - NYSE): NC

Callisto Pharmaceuticals, Inc. (CLSP - OTC): NC

Ironwood Pharmaceuticals, Inc. (IRWD - NASDAQ): SELL

Salix Pharmaceuticals, Ltd. (SLXP - NASDAQ): BUY

Synergy Pharmaceuticals, Inc. (SGYP - NASDAQ): BUY

Disclosures Appendix

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HOLD - denotes stocks that we suggest will provide a total return or total negative return of up to 15% over 12-month period. A HOLD rated stock is expected to perform in-line with the total average return of the analyst's industry coverage universe on a risk adjusted basis.

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Rating and Price Target History for: Synergy Pharmaceuticals, Inc. (SGYP) as of 11-13-2012



B=Buy H=Hold S=Sell I=Initiated D=Dropped

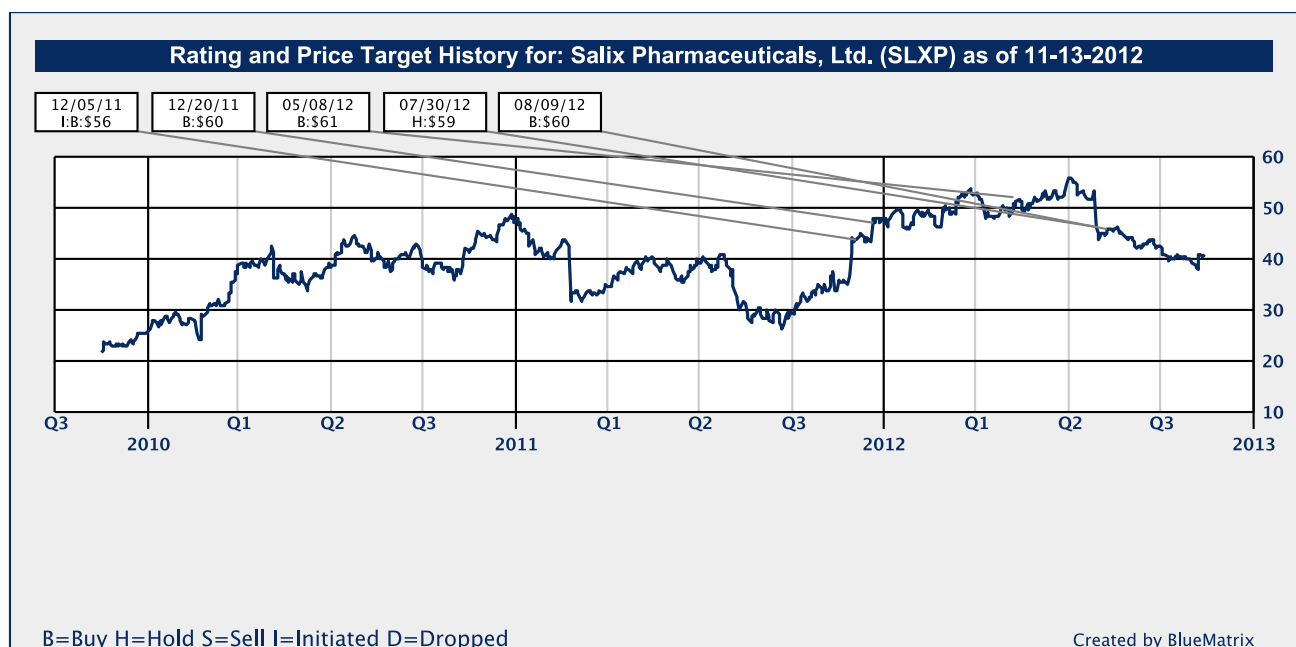
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Cantor

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	81	51.59	14	17.28
HOLD [H]	65	41.40	3	4.62
SELL [S]	11	7.01	0	0.00