

Expecting Positive Plecanatide Results In January – Reports 3Q12 Results

Buy
PT: \$13.00

Investment Summary

- Synergy finished recruiting participants for its Phase 2/3 trial of plecanatide, having enrolled 951 CIC patients by the end of August. We are encouraged to see enrollment that high, as it allows Synergy to comfortably have about 800 patients left once accounting for dropouts. We anticipate positive top-line results in January 2013 in at least the 1mg and 3mg dose groups versus placebo, and we believe that the full dataset can be presented as a late breaker at DDW in May 2013. We believe that positive Phase 2b/3 plecanatide data could rapidly garner the attention of an acquirer.
- Close peer drug Linzess already has established the utility of employing plecanatide's mechanism of action, hence, our Phase 2b/3 optimism when also considering the strong powering of Synergy's trial. We believe that the Linzess approval will continue to drive increased interest in plecanatide.
- Synergy is also in the process of initiating a Phase 2b trial of plecanatide for the indication of IBS-C in 4Q12. The company has already moved forward with SP-333, a drug related to plecanatide, indicated for the treatment of ulcerative colitis. Synergy recently initiated a Phase 1 single ascending dose trial in healthy volunteers, and will initiate a multiple ascending dose in healthy volunteers in 1Q13.
- Synergy ended 3Q12 with about \$37 million in cash and cash equivalents on hand, an increase from 2Q12 due mostly to the Callisto acquisition.

Discussion

Synergy finished recruiting participants for its Phase 2/3 trial of plecanatide, having enrolled 951 CIC patients by the end of August. We are encouraged to see enrollment that high, as it allows Synergy to comfortably have about 800 patients left once accounting for dropouts. The trial is a dose-ranging study that evaluates the efficacy and safety of 3 doses of plecanatide (0.3mg, 1.0mg, and 3.0mg) for 12 consecutive weeks in patients with CIC, and the trial's size should enable it to be used as one of the CIC registrational trials, in our view. The primary endpoint is a complete spontaneous bowel movement (CSBM) responder analysis, and it is 90% powered to detect at least a 10% difference in response rate between groups of plecanatide and placebo. We anticipate positive top-line results in January 2013 in at least the 1mg and 3mg dose groups versus placebo, and we believe that the full dataset can be presented as a late breaker at DDW in May 2013. We believe that positive Phase 2b/3 plecanatide data could rapidly garner the attention of an acquirer.

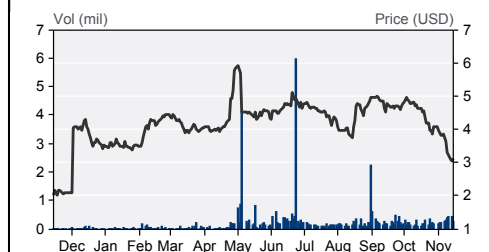
Close peer drug Linzess (Ironwood Pharmaceuticals) already has established the utility of employing plecanatide's mechanism of action, hence, our Phase 2b/3 optimism when also considering the strong powering of Synergy's trial. We believe that the Linzess approval will continue to drive increased interest in plecanatide. Given the 3Q12 approval of Linzess, we believe that the low-hanging fruit for Synergy out of the gate in 2015 will be patients motivated enough to seek treatment for CIC and IBS-C, but unable to tolerate Linzess. Ironwood estimates the Linzess market to be worth about \$6 billion annually, and to go after it, the launch will consist of greater than 1,200 sales representatives marketing Linzess to general practitioners, and more than 140 sales representatives marketing to GI specialists.

Synergy is also in the process of initiating a Phase 2b trial of plecanatide for the indication of IBS-C in 4Q12. The company has already moved forward with SP-333, a drug related to plecanatide, indicated for the treatment of ulcerative colitis. Synergy recently initiated a Phase 1 single ascending dose trial in healthy volunteers, and will initiate a multiple ascending dose in healthy volunteers in 1Q13. We look forward to the top-line results of plecanatide in CIC in January 2013, and to the Phase 2b initiation of plecanatide in IBS-C by YE12. The IBS-C trial should yield results no later than 1Q14.

3Q12 results. Synergy reported 3Q12 revenue of \$0 and EPS of \$(0.15), both of which were in line enough with consensus, as neither metric matters at this point in Synergy's development, in our view. Most importantly, Synergy ended 3Q12 with about \$37 million in cash and cash equivalents on hand, an increase from 2Q12 due mostly to the Callisto acquisition. R&D expense increased to \$8.2 million in 3Q12 from \$7.6 million in 2Q12 due to continued development of plecanatide and SP-333.

Price	\$3.13
52-Week High/Low	\$7.08-\$2.98
Shares Out (mm)	66.1
Market Cap (mm)	\$207
Avg. Daily Vol (000)	272,351
Short Interest	3.0%
Cash (mm)	NA
EV (mm)	159.3
Book Value / Share	NA

Revenue (\$M)	FY11A	FY12E	FY13E
Mar	\$0.0	\$0.0A	--
June	\$0.0	\$0.0A	--
Sept	\$0.0	\$0.0A	--
Dec	\$0.0	\$0.0	--
FY (Dec)	\$0.0	\$0.0	\$0.0
P/S (x)	--	--	--
EPS			
Mar	\$(0.08)	\$(0.13)A	--
June	\$(0.10)	\$(0.17)A	--
Sept	\$(0.01)	\$(0.15)A	--
Prior:	--	\$(0.16)	--
Dec	\$(0.11)	\$(0.16)	--
FY (Dec)	\$(0.30)	\$(0.61)	\$(0.68)
Prior:	--	\$(0.63)	\$(0.65)
P/E (x)	NM	NM	NM



Source: Bloomberg

Valuation / Target Price

We derive our target price of \$13 through a DCF analysis, assuming a 40% discount rate that is applied to all cash flows and the terminal value, which is based on a 5x multiple of the projected 2019 EBITDA.

Exhibit 1. Catalyst Calendar

Timing	Compound	Event	Indication
3Q12	plecanatide	Completed enrollment in Phase 2/3 trial	CIC
4Q12	SP-333	Initiated single dose Phase 1 trial	Ulcerative colitis
4Q12	plecanatide	Initiate Phase 2b trial	IBS-C
January 2013	plecanatide	Top-line results from Phase 2b/3 trial	CIC
1Q13	SP-333	Initiate multidose Phase 1 trial	Ulcerative colitis
1Q14	plecanatide	Top-line results from Phase 2b trial	IBS-C

Source: Company documents

Synergy Pharmaceuticals, Inc.
Income Statement

Fiscal Year ends December

(in 000, except per share items)

	2009A	2010A	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E
Plecanatide CIC revenue															84,591	192,296	361,243
Plecanatide IBS-C revenue															57,676	125,678	227,285
Total Revenue								-					-	-	142,268	317,974	588,528
COGS															7,904	22,126	48,967
R&D	3,733	9,559	13,419	5,338	7,626	8,246	8,658	29,869	9,091	10,000	11,000	11,550	41,642	52,053	59,861	65,847	69,139
SG&A	4,467	6,562	6,746	1,731	1,918	1,843	1,880	7,372	1,974	2,053	2,114	2,157	8,298	16,595	33,191	66,382	86,296
Total Operating Expenses	8,200	16,121	20,165	7,069	9,545	10,089	10,538	37,241	11,065	12,053	13,115	13,707	49,940	68,648	100,955	154,355	204,402
Operating Income	(8,200)	(16,121)	(20,165)	(7,069)	(9,545)	(10,089)	(10,538)	(37,241)	(11,065)	(12,053)	(13,115)	(13,707)	(49,940)	(68,648)	41,312	163,619	384,126
Interest income	75	108	90	39	48	63	66	216	69	69	66	63	268	276	284	292	301
Interest expense			(12)														
Other income (expense), net		494	363		256			256		250			250	238	226	214	204
Change in fair value of financial instrument		297	5,257	8	(1,317)	141	145	(1,023)					(1,054)	(1,085)	(1,118)	(1,152)	(1,186)
Pretax income	(8,125)	(15,222)	(14,467)	(7,023)	(10,558)	(9,885)	(10,327)	(37,793)	(10,996)	(11,734)	(13,049)	(13,644)	(50,476)	(69,221)	40,703	162,975	383,445
Provision for income tax (benefit)															4,889	95,861	
Net Income	(8,125)	(15,222)	(14,467)	(7,023)	(10,558)	(9,885)	(10,327)	(37,793)	(10,996)	(11,734)	(13,049)	(13,644)	(50,476)	(69,221)	40,703	158,085	287,584
EPS	(0.22)	(0.34)	(0.30)	(0.13)	(0.17)	(0.15)	(0.16)	(0.61)	(0.15)	(0.16)	(0.17)	(0.18)	(0.68)	(0.84)	0.47	1.78	3.20
EPS diluted, GAAP	(0.22)	(0.34)	(0.30)	(0.13)	(0.17)	(0.15)	(0.16)	(0.61)	(0.15)	(0.16)	(0.17)	(0.18)	(0.68)	(0.84)	0.44	1.67	2.99
Shares Outstanding Basic/Diluted	36,641	44,875	47,598	54,298	60,416	65,806	66,464	61,746	71,117	73,250	75,448	77,711	74,381	82,374	87,316	88,626	89,955
Diluted shares outstanding	36,641	44,875	47,598	54,298	60,416	65,806	66,464	61,746	71,117	73,250	75,448	77,711	74,381	82,374	93,316	94,716	96,137

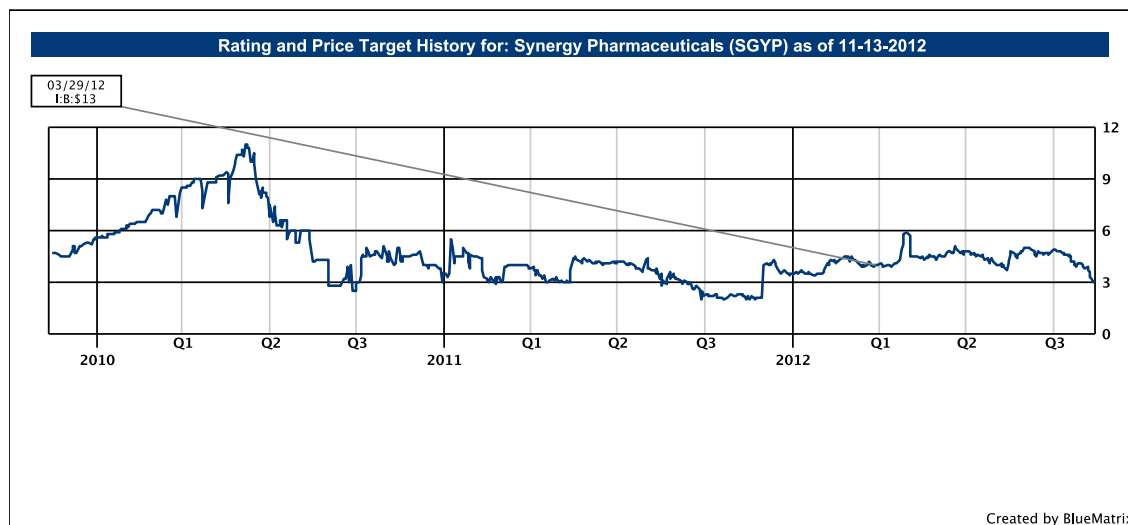
Source: Company reports, Brean Capital, LLC. estimates

Risks

Risks to the achievement of our target price include clinical, regulatory, financing, competitive risks, as well as stock price volatility.

Important Disclosures

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Buy - Expected to appreciate by at least 10% within the next 12 months.

Hold - Fully valued, not expected to appreciate or decline materially within the next 12 months.

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Rating Category	Count	Percent	IB Serv./ Past 12Mos.	
			Count	Percent
BUY	134	68.37%	70	52.24%
HOLD	59	30.10%	24	40.68%
SELL	3	1.53%	2	66.67%
NOT RATED				

Note: Stock price volatility may cause temporary non-alignment of some ratings with some target prices.

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