

Healthcare: Pharmaceuticals

Synergy Pharmaceuticals, Inc. | SGYP - \$4.62 - NASDAQ | Buy

Company Update

Stock Data

52-Week Low - High	\$3.17 - \$7.08
Shares Out. (mil)	65.81
Mkt. Cap.(mil)	\$304.0
3-Mo. Avg. Vol.	232,914
12-Mo.Price Target	\$12.00
Cash (mil)	\$47.6
Tot. Debt (mil)	\$0.0

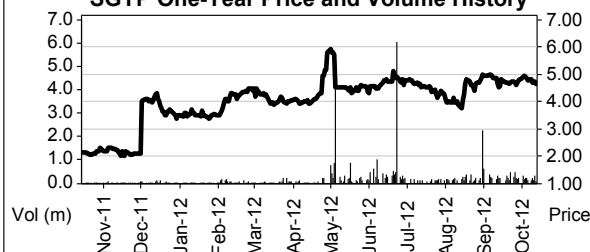
EPS \$

Yr Dec	—2011—	—2012E—	—2013E—
		Curr	Curr
1Q	(0.08)A	(0.13)A	-
2Q	(0.10)A	(0.17)A	-
3Q	(0.01)A	(0.15)E	-
4Q	(0.12)A	(0.14)E	-
YEAR	(0.30)A	(0.60)E	(0.50)E
P/E	NM	NM	NM

Revenue (\$ millions)

Yr Dec	—2011—	—2012E—	—2013E—
		Curr	Curr
1Q	0.0A	0.0A	-
2Q	0.0A	0.0A	-
3Q	0.0A	0.0E	-
4Q	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E

SGYP One-Year Price and Volume History



SGYP: Meetings with Management - Programs on Track

We recently met with management of Synergy Pharmaceuticals. All programs continue on track for important data readouts in late 4Q12/early 1Q13. We maintain our Buy rating. Key takeaways within the report.

- **Plecanatide CC update.** Chronic constipation (CC) enrollment looks to end at over 900 (common to over enroll by 10-20% in GI trials). Last patient could be out in early December, which drives data readout by late December/early January 2013. Company appears happy with the recent patent settlement with Ironwood, removing an overhang with only a low single digit royalty (my guess 2%). The company is looking to develop a room temperature version for future clinical trials.
- **Plecanatide IBS-C update.** IND to be filed soon. The trial should start in November. My cost estimates - P2b trial could cost ~\$10 million, P3 trials could cost ~\$20 million each. IBS-C patients are a sicker population than CC, have easier reimbursement, but slightly smaller # of patients. Speculative timeline - complete enrollment of IBS-C trial in August 2013, data end of 2013 (3 month treatment, 2 week follow-up).
- **Linacotide (Linzess) update.** The competitor launch is targeted for 1Q13. SGYP management continues to believe a positive launch for Linzess is good for Synergy. That said, management noted a couple areas that could enhance plecanatide marketing. Linzess surprisingly received a black box warning contraindicating in ages 6 and under. The insert also referenced that ~29% of patients taking Linzess are cutting dose or withdrawing in clinical trials.
- **SP-333 update.** SGYP filed an IND in September. P1 single-dosing trial should start soon, data by end of year. Another P1 trial (multi-dose) should start in 1Q13, data possibly by mid 2013.
- **FV-100 update.** Company is exploring the best strategy for future development. No current impact on burn rate from this program. Company could give more guidance on this program post the 10-Q filing in early November.
- **General.** Company continues to move programs forward. Exit strategy appears M&A (sale of the company), but still early. Cash through 2013

VALUATION

We value shares of Synergy Pharmaceuticals based on a sum-of-the-parts analysis. The main driver is plecanatide at \$9/share with lesser contribution from SP-333 (\$1.50/share), FV-100 (\$1/share), and future indications/technology value (\$0.50/share).

Impediments to our price target include, but are not limited to, unexpected adverse clinical outcomes, inability to attain a partnership, and inability to raise additional financial resources on reasonable terms.

RISKS

In addition to the risks inherent in drug development and marketing, key investment risks for Synergy Pharmaceuticals include:

- **Clinical risk** – We anticipate positive clinical data for the plecanatide program. Further, the phase 2/3 clinical data is longer in duration, which adds risk beyond the early stage trials. Failure of this data to match expectations could have a material adverse impact on company shares.
- **Partnership risk** – We expect that Synergy will outlicense, partner, or sell its clinical programs prior to product launch. Failure to monetize these assets on favorable terms could have a material adverse impact on company shares.

COMPANY DESCRIPTION

Synergy Pharmaceuticals, Inc., a development stage biopharmaceutical company, focuses on the development of drugs to treat gastrointestinal disorders and diseases. It is developing plecanatide that completed Phase 2a clinical trial and is undergoing a Phase II/III clinical trial for the treatment chronic idiopathic constipation and constipation-predominant irritable bowel syndrome; and SP-333, a second generation GC-C receptor analog, which is in pre-clinical stage for the treatment of gastrointestinal inflammatory diseases, such as ulcerative colitis. The company is headquartered in New York, New York.

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Within the last twelve months, ROTH has received compensation for investment banking services from Synergy Pharmaceuticals, Inc..

ROTH makes a market in shares of Synergy Pharmaceuticals, Inc. and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has managed or co-managed a public offering for Synergy Pharmaceuticals, Inc..

On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.

On May 26, 2011, ROTH changed its rating system in order to incorporate coverage that is Under Review.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years.

Distribution Ratings/IB Services shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 10/12/12	
			Count	Percent
Buy [B]	205	72.70	76	37.07
Neutral [N]	66	23.40	9	13.64
Sell [S]	1	0.35	0	0
Under Review [UR]	9	3.19	5	55.56

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Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH does not publish research or have an opinion about this security.

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