

Healthcare: Pharmaceuticals

Synergy Pharmaceuticals, Inc. | SGYP - \$3.13 - NASDAQ | Buy

Quarterly Update

Stock Data

52-Week Low - High	\$2.98 - \$7.08
Shares Out. (mil)	66.11
Mkt. Cap.(mil)	\$206.9
3-Mo. Avg. Vol.	272,351
12-Mo.Price Target	\$12.00
Cash (mil)	\$37.4
Tot. Debt (mil)	\$0.0

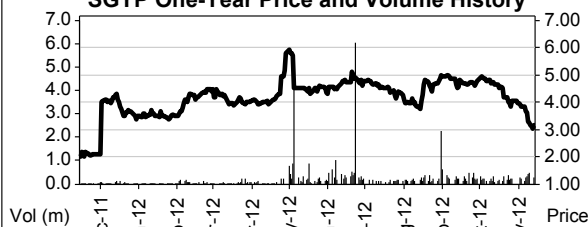
EPS \$

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)A	-
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	0.0A	-
4Q	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E

SGYP One-Year Price and Volume History



SGYP: 3Q12 Update - Plecanatide Data Coming 1st Week of January

SGYP reported an uneventful 3Q12. The main catalyst for shares is phase 2b/3 clinical data for plecanatide to treat constipation (targeted for release in first week of January 2013). We maintain our Buy rating as we expect this data to be positive.

- **3Q12 results (10-Q filed) - Uneventful.** SGYP reported no 3Q12 revenues as expected. The \$0.15 EPS loss matched our expectations as line items balanced out. We viewed the results as not particularly material.
- **Plecanatide update - Phase 2b/3 trial fully enrolled, data lock coming in December, readout in January.** The company announced that the phase 2b/3 plecanatide study for the treatment of chronic idiopathic constipation (CIC) completed enrollment at 951 patients. The last follow-up visit should occur by December 7, 2012. Post that event, the company will lock the data base, analyze the data and is expecting to release top-line data during the first week of January 2013. This is the key catalyst for shares, in our opinion. The final preparations have been made for the IBS-C phase 2b trial with commencement "shortly".
- **SP-333 (for ulcerative colitis) update.** A phase 1, healthy volunteer, oral dosing trial began in October 2012 (n=70). We expect data in 4Q12/1Q13. A multi-dose, dose-escalation trial is planned for early 2013. No changes to our targets.
- **FV-100 update.** No material updates as the company has yet to disclose a timeline for this asset. It may be contingent on financing. A \$1 million milestone for acquiring this asset was included in 3Q12 R&D expense.
- **Model changes.** Minimal changes from prior expectations.
- **Maintain Buy rating.** We continue to view plecanatide as an undervalued asset within the gastrointestinal arena. We believe that this compound could have similar efficacy to FRX/IRWD's linaclotide with potentially less diarrhea side effects. Although we view risk/reward favorable in front of January 2013 clinical data, investors should recognize that this is a binary event with significant downside risk.

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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.

QUARTERLY VARIANCE ANALYSIS

*(values in 000's**except per share data)***Revenues:**

	Actual 3Q12	Estimate 3Q12	Variance	Comments
Total revenue	-	-	-	
R&D	8,246	8,750	(504)	Slightly lower
SG&A	1,843	1,950	(107)	Slightly lower
Operating income (loss)	(10,089)	(10,700)	611	Benefitted from lower costs
Other income	63	275	(212)	Noise, offset lower costs
FV of fin instruments	140	-	140	Noise, offset lower costs
Pretax income	(9,885)	(10,425)	540	
Taxes	-	-	-	
Net income	(9,885)	(10,425)	540	
EPS	(\$0.15)	(\$0.15)	(\$0.00)	Netted as expected
FD Shares outstanding	65,806	69,700	(3,894)	

Source: ROTH Capital Partners and company reports

Synergy Pharmaceuticals																			
Earnings model (values in 000's)	FY 2010 A	1Q11A	2Q11A	3Q11A	4Q11A	FY 2011 A	1Q12A	2Q12A	3Q12A	4Q12E	FY 2012 E	FY 2013 E	FY 2014 E	FY 2015 E	FY 2016 E	FY 2017 E	FY 2018 E	FY 2019 E	FY 2020 E
Revenues:																			
Plecanatide US revenues														25,000	100,000	190,000	300,000	375,000	450,000
SP-333 end revenues																	47,299	99,384	156,620
FV-100 end revenues																	33,490	71,750	114,179
Plecanatide royalties														7,500	30,000	57,000	90,000	112,500	135,000
SP-333 royalties																	11,825	24,846	39,155
FV-100 royalties																	8,373	17,937	28,545
Total revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	7,500	30,000	57,000	110,197	155,283	202,700
R&D	9,559	1,478	2,354	3,883	5,703	13,419	5,338	7,626	8,246	8,000	29,210	34,000	42,500	40,500	26,500	23,250	23,000	22,000	22,000
G&A	6,562	1,898	1,524	1,103	2,222	6,746	1,731	1,918	1,843	2,150	7,643	7,750	8,000	8,250	8,750	9,500	12,500	13,250	14,000
Total expenses	16,121	3,376	3,879	4,986	7,925	20,165	7,069	9,545	10,089	10,150	36,853	41,750	50,500	48,750	35,250	32,750	35,500	35,250	36,000
Operating loss	(16,121)	(3,376)	(3,879)	(4,986)	(7,925)	(20,165)	(7,069)	(9,545)	(10,089)	(10,150)	(36,853)	(41,750)	(50,500)	(41,250)	(5,250)	24,250	74,697	120,033	166,700
Other income	494	24	20	20	362	363	-	256	-	-	256	300	325	350	375	400	425	450	475
Interest and inv income	108	(12)	-	-	26	90	39	48	63	75	225	200	100	-	-	-	-	-	-
Interest expense	-	-	-	-	-	(12)	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in FV of fin instruments	297	(339)	(698)	4,383	1,911	5,257	8	(1,317)	140	-	(1,169)	-	-	-	-	-	-	-	-
Pretax income																24,650	75,122	120,483	167,175
Taxes																1,233	9,015	16,265	42,630
Tax rate																5%	12%	14%	26%
Net loss	(15,222)	(3,702)	(4,557)	(583)	(5,626)	(14,467)	(7,023)	(10,558)	(9,885)	(10,075)	(37,541)	(41,250)	(50,075)	(40,900)	(4,875)	23,418	66,108	104,218	124,545
EPS	(0.34)	(0.08)	(0.10)	(0.01)	(0.12)	(0.30)	(0.13)	(0.17)	(0.15)	(0.14)	(0.60)	(0.50)	(0.60)	(0.45)	(0.05)	0.25	0.70	1.10	1.30
FD Shares outstanding	44,875	46,167	46,643	47,309	48,657	47,598	54,298	60,416	65,806	70,306	62,707	82,140	83,140	91,015	92,015	93,015	94,015	95,015	96,015

Source: ROTH Capital Partners and Company reports

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Synergy Pharmaceuticals Pipeline analysis

	2011A				2012E				2013E				2014E				2015E				2016E			
	1QA	2QA	3QA	4QA	1QA	2QA	3QA	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE
Plecanatide (SP-304)																								
For CIC																								
Phase 2/3 CIC Pivotal									DATA	Completed enrollment 8/13/2012 (n=951), data first week Jan 2013														
P3 CIC Pivotal									FDA				DATA											
NDA															PARTNER OR M&A	NDA								
Approval/Launch																					LAUNCH			
Scenario 2 (another trial)													DATA											
IBS-C, P2																								
SP-333																								
For ulcerative colitis																								
IND																								
Phase 1						n=70		DATA	Multi dose escalation trial planned for 2013															
Phase 1/2 program																								
Phase 2b																								
Phase 3 program																								
FV-100																								
For shingles pain																								
Phase 2b																								
Phase 3 program (2 trials)																								
NDA																								NDA

Source: ROTH Capital Partners Forecasts

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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 11/14/12	
			Count	Percent
Buy [B]	210	73.94	79	37.62
Neutral [N]	63	22.18	8	12.70
Sell [S]	1	0.35	0	0
Under Review [UR]	8	2.82	4	50.00

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH employs a rating system based on the following:

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

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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