ROTH Capital Partners

Scott R. Henry, CFA, (949) 720-7123
shenry@roth.com

Sales (800) 933-6830, **Trading** (800) 933-6820

Healthcare: Pharmaceuticals

Synergy Pharmaceuticals, Inc. | SGYP - $4.85 - NASDAQ | *Buy*

Company Update

Estimates Changed

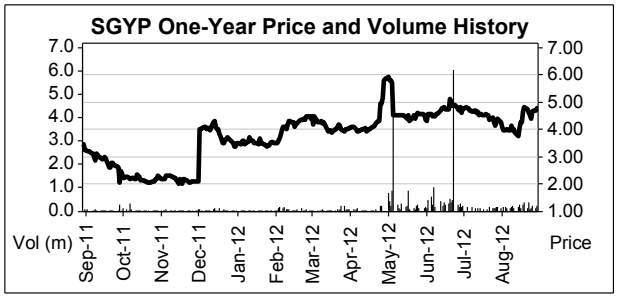
Stock Data	
52-Week Low - High	$3.17 - $7.10
Shares Out. (mil)	65.81
Mkt. Cap.(mil)	$319.2
3-Mo. Avg. Vol.	311,879
12-Mo.Price Target	$12.00
Cash (mil)	$47.6
Tot. Debt (mil)	$0.0

EPS $

Yr Dec	—2011—	—2012E—		—2013E—	
		Curr	Prev	Curr	Prev
1Q	(0.08)A	(0.13)A	(0.13)A	-	-
2Q	(0.10)A	(0.17)A	(0.17)A	-	-
3Q	(0.01)A	(0.15)E	(0.14)E	-	-
4Q	(0.12)A	(0.14)E	(0.14)E	-	-
YEAR	(0.30)A	(0.60)E	(0.58)E	(0.50)E	(0.45)E
P/E	NM	NM	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: FV-100 Primer - More Upside than Downside

SGYP recently acquired FV-100 from BMY. We view this compound with high reward ($500 million peak potential) and minimum risk (up front payment of $1 million). We maintain our Buy rating as we await the key catalyst from a different program, the phase 2b data release for the company's lead constipation drug plecanatide, in 4Q12.

- **SGYP acquires FV-100.** Synergy recently acquired the assets related to FV-100 from Bristol-Myers Squibb. FV-100 is an orally available nucleoside analogue being developed for the treatment of shingles. Notably, there is a history between FV-100 and Synergy as the compound originally came from Inhibitex (which has overlapping board members with Synergy). There should be no connection between this molecule and the recent safety issues for the BMY HCV candidate.
- **Terms of the deal.** Synergy paid a $1 million upfront payment with further milestone payments due upon marketing approval and aggregate net sales >= $125 million. Synergy will also pay single digit royalties based on net sales.
- **What we know about the compound.** The phase 2a trial enrolled ~350 patients dosed at FV-100 200mg (1X/day), FV-100 400mg (1X/day), and an active comparator (valacyclovir 1000mg 3X/day). Although the pain relief difference between FV-100 and valacyclovir was not statistically significant, positives from the trial included 1) numerical improvement in pain relief for FV-100 versus comparator, 2) a clear dose response for FV-100, and 3) the magnitude of effect appeared to improve over time. These three positives (along with better dosing - 1X/day versus 3X/day) make FV-100 a clinical candidate worth pursuing, in our opinion.
- **FV-100 revenue potential.** Our preliminary model suggests peak sales at ~$500 million. This assumes 10% penetration of the current valacyclovir market at a revenue/script of $250. (model attached)
- **Development timeline.** We target a phase 2b trial to start in 2013 and complete in mid 2014. Pending positive data, we target 2 phase 3 trials run concurrently through mid 2016 with an NDA filing in late 2016.
- **Risk/reward seems favorable.** SGYP should have a greater knowledge base of FV-100 than most (from Inhibitex overlap) and BMY appears a motivated seller. All of this should lend to a favorable risk/reward for SGYP shareholders. The modest upfront payment of $1 million supports this favorable thesis.

SUMMARY

- **Model changes - development costs.** We assume a $1 million upfront payment booked in 3Q12, with the following increases to R&D: 2013 +$5 million, 2014 +$10 million, 2015 +$15 million, and 2016 +$5 million (assume $10 million for phase 2b trial, $30 million combined for both phase 3 trials). We increased shares outstanding to reflect increased R&D demands, and we also added royalties for FV-100 in 2018+.

The Phase 2A Data

The trial enrolled ~350 patients with 3 arms including 1) FV-100 200 mg 1X/day (n=107), 2) FV-100 400 mg 1X/day (n=113), and 3) valacyclovir 1000 mg 3X/day (n=109). The primary endpoint was herpes zoster associated pain as measured by the Zoster Burden of Illness (BOI) at 30 days. Secondary endpoints included 90 day pain relief and incidence of post herpetic neuralgia (PHN).

Key takeaways include:

* Numerical benefit with FV-100 versus valacyclovir
* Clear dose response for FV-100
* Safety profile appeared similar to valacyclovir

Zoster BOI Day 30 (lower is better) - Source Inhibitex press release

FV-100 200mg - 114.49

FV-100 400mg - 110.31

valacyclovir 3000mg - 117.96

Zoster BOI Day 90

FV-100 200mg - 221.53

FV-100 400mg - 196.94

valacyclovir 3000mg - 229.59

Incidence of PHN

FV-100 200mg - 17.8%

FV-100 400mg - 12.4%

valacyclovir 3000mg - 20.2%

Treatment related AEs

FV-100 200mg - 20.5%

FV-100 400mg - 25.6%

valacyclovir 3000mg - 19.8%

Discontinuation of drug for AE

FV-100 200mg - 1.7%

FV-100 400mg - 1.7%

valacyclovir 3000mg - 1.7%

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

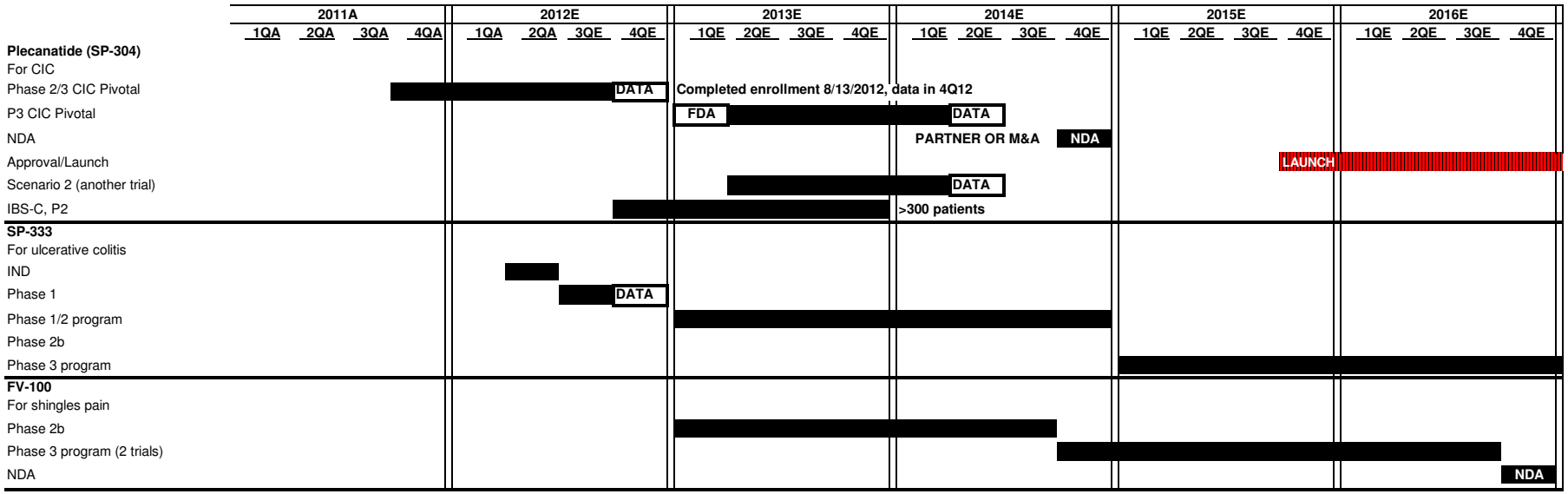
Synergy Pharmaceuticals, Inc., a development stage biopharmaceutical company, focuses on the development of drugs to treat gastrointestinal disorders and diseases. It is developing plecanatide that completed Phase 2a clinical trial and is undergoing a Phase II/III clinical trial for the treatment chronic 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.

Synergy Pharmaceuticals Earnings model (values in 000's)	FY 2010 A	FY 2011 A	1Q12A	2Q12A	3Q12E	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	13,419	5,338	7,626	8,750	8,000	29,714	34,000	42,500	40,500	26,500	23,250	23,000	22,000	22,000
G&A	6,562	6,746	1,731	1,918	1,950	2,250	7,850	7,750	8,000	8,250	8,750	9,500	12,500	13,500	14,000
Total expenses	**16,121**	**20,165**	**7,069**	**9,545**	**10,700**	**10,250**	**37,564**	**41,750**	**50,500**	**48,750**	**35,250**	**32,750**	**35,500**	**35,500**	**36,000**
Operating loss	(16,121)	(20,165)	(7,069)	(9,545)	(10,700)	(10,250)	(37,564)	(41,750)	(50,500)	(41,250)	(5,250)	24,250	74,697	119,783	166,700
Other income	494	363	-	256	75	75	406	400	425	450	475	500	525	550	575
Interest and inv income	108	90	39	48	200	175	462	400	100	-	-	-	-	-	-
Interest expense	-	(12)	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in FV of fin instruments	297	5,257	8	(1,317)	-	-	(1,309)	-	-	-	-	-	-	-	-
Pretax income												24,750	75,222	120,333	167,275
Taxes												1,238	9,027	16,245	42,655
Tax rate												5%	12%	14%	26%
Net loss	(15,222)	(14,467)	(7,023)	(10,558)	(10,425)	(10,000)	(38,006)	(40,950)	(49,975)	(40,800)	(4,775)	23,513	66,196	104,088	124,620
EPS	**(0.34)**	**(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	47,598	54,298	60,416	69,700	70,200	63,654	82,033	83,033	90,908	91,908	92,908	93,908	94,908	95,908

Source: ROTH Capital Partners and Company reports

Scott R Henry, CFA
shenry@roth.com
(949) 500-0863

Synergy Pharmaceuticals
Pipeline analysis



Source: ROTH Capital Partners Forecasts

Scott R Henry, CFA
shenry@roth.com
(949) 500-0863

FV-100 Revenue Model

	valacyclovir TRX	y-o-y	FV-100 share	Scripts	Rev/script	Revenues
2012	10,000,000		0.00%	-	-	-
2013	10,700,000	7%	0.00%	-	-	-
2014	11,342,000	6%	0.00%	-	-	-
2015	11,909,100	5%	0.00%	-	-	-
2016	12,385,464	4%	0.00%	-	-	-
2017	12,880,883	4%	0.00%	-	-	-
2018	13,396,118	4%	1.00%	133,961	250	33,490,295
2019	13,931,963	4%	2.00%	278,639	258	71,749,607
2020	14,349,921	3%	3.00%	430,498	265	114,178,738
2021	14,780,419	3%	4.00%	591,217	273	161,509,630
2022	15,223,832	3%	5.00%	761,192	281	214,181,958
2023	15,680,547	3%	7.00%	1,097,638	290	318,115,895
2024	16,150,963	3%	8.50%	1,372,832	299	409,808,258
2025	16,635,492	3%	10.00%	1,663,549	307	511,488,918

Source: Roth Capital Partners

SP-333 Revenue Model	5-ASA's TRX	y-o-y	SP-333 share	Scripts	Rev/script	Revenues
2012	5,250,000		0.00%	-	-	-
2013	5,355,000	2%	0.00%	-	-	-
2014	5,462,100	2%	0.00%	-	-	-
2015	5,571,342	2%	0.00%	-	-	-
2016	5,682,769	2%	0.00%	-	-	-
2017	5,796,424	2%	0.00%	-	-	-
2018	5,912,353	2%	2.00%	118,247	400	47,298,822
2019	6,030,600	2%	4.00%	241,224	412	99,384,284
2020	6,151,212	2%	6.00%	369,073	424	156,619,693
2021	6,274,236	2%	8.00%	501,939	437	219,392,866
2022	6,399,721	2%	10.00%	639,972	450	288,117,681
2023	6,527,715	2%	12.00%	783,326	464	363,235,723
2024	6,658,269	2%	14.00%	932,158	478	445,218,026
2025	6,791,435	2%	15.00%	1,018,715	492	501,156,491

Source: Roth Capital Partners

Plecanatide US Model	Bottoms-up Amitiza	Top-down SGYP	Average	RCP
2012	-	-	-	-
2013	-	-	-	-
2014	-	-	-	-
2015	-	73,055,470	36,527,735	25,000
2016	17,782,055	268,632,269	143,207,162	100,000
2017	110,939,699	403,178,659	257,059,179	190,000
2018	242,962,101	508,295,399	375,628,750	300,000
2019	332,509,383	623,017,671	477,763,527	375,000
2020	436,793,247	701,295,391	569,044,319	450,000
2021	557,763,926	785,899,667	671,831,796	540,000
2022	575,522,731	877,270,327	726,396,529	580,000
2023	629,750,514	975,875,512	802,813,013	640,000
2024	688,994,659	1,082,213,413	885,604,036	705,000
2025	753,712,640	1,196,814,118	975,263,379	775,000

Source: Roth Capital Partners

Synergy Pharmaceuticals

Net cash	47,587
Per share	0.79

Balance Sheets
December Year
values in $000's

	2010	2011	1Q12	2Q12
ASSETS				
Cash and equivalents	1,708	13,245	6,123	43,577
Prepaid and other	998	1,063	1,618	1,409
Total current assets	2,705	14,308	7,741	44,985
Property and equip, net	8	6	5	2
Avail for sale, LT				4,011
Security deposits	14	14	14	20
Due from controlling shareholder	1,674	1,541	1,820	1,937
TOTAL ASSETS	4,401	15,870	9,580	50,955
LIABILITIES AND SHAREHOLDERS EQUITY				
Accounts payable	2,961	1,416	2,084	1,154
Accrued expenses	2,051	1,331	965	3,765
Total current liabilities	5,012	2,747	3,050	4,920
Derivatives at FV	3,488	3,325	3,317	4,804
Total Liabilities	8,500	6,072	6,367	9,723
Shareholders equity				
Preferred stock	-	-	-	-
Common stock	5	5	5	7
APIC	51,038	79,401	79,839	128,415
Accumulated deficit	(55,142)	(69,609)	(76,632)	(87,190)
Total Shareholders equity	(4,099)	9,797	3,213	41,231
Total liabs and SE	4,401	15,870	9,580	50,955

Source: Company reports

Scott R Henry, CFA
shenry@roth.com
(949) 500-0863

Synergy Pharmaceuticals

Statement of cash flows
December year
values in $000's

	2010	2011	1Q12	2Q12
OPERATING ACTIVITIES				
Net loss	(15,221)	(14,467)	(7,023)	(17,581)
Adjustments:				
Deprec and amort	2	2	0	1
Stock comp	712	822	438	792
Loss (gain) on asset sales	-	-	-	2
Change in FV of derivatives	(297)	(5,257)	(8)	1,149
Changes in A and L:				
Accounts payable and accr exp	3,286	(2,265)	303	2,173
Prepaids and other CA	64	(66)	(554)	(351)
CASH FROM OPERATIONS	(11,454)	(21,231)	(6,843)	(13,815)
INVESTING ACTIVITIES				
Loans from related parties	(702)	133	(278)	(395)
Change in avail for sale				(20,000)
CASH FROM INVESTING	(702)	133	(278)	(20,395)
FINANCING ACTIVITIES				
Issuance of CS from priv placement	7,179	34,369	-	48,392
Warrants, other	(468)	(1,733)	-	-
CASH FROM FINANCING	6,711	32,636	-	48,392
Change in cash	(5,445)	11,537	(7,122)	14,182
Cash at beginning of year	7,153	1,708	13,245	13,245
Cash at end of the year	1,708	13,245	6,123	27,427

Obligations	
Less than 1 year	4,903
1-3 years	1,935
3-5 years	-
More than 5 yrs	-

Source: Company reports

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shenry@roth.com
(949) 500-0863

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Disclosures:

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

			IB Serv./Past 12 Mos. as of 08/29/12	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**205**	**71.18**	**75**	**36.59**
Neutral [N]	**71**	**24.65**	**8**	**11.27**
Sell [S]	**2**	**0.69**	**0**	**0**
Under Review [UR]	**9**	**3.12**	**3**	**33.33**

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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