

Gilead Sciences

Thoughts on the RSV Space; Sales Could Top \$2B

Although Gilead's hepatitis C franchise is by far the key focus for investors, the expanding pipeline has a number of major call options in hepatitis B, NASH, IPF, hematology/oncology and now respiratory syncytial virus (RSV). Indeed, at the ATS meeting this week, Gilead revealed phase 2a data for GS-5806 in RSV. In this report, we review the data, the therapeutic landscape and the opportunity in RSV including feedback we've received from several pulmonologists. From a timing perspective, Gilead expects to begin a phase 2/3 trial in RSV in mid 2014, with a potential for a regulatory filing in 2H16 in adults. Physicians we spoke to viewed the phase 2a data as "very promising," but were understandably cautious on extrapolating the results to children (the larger opportunity). Of note, no therapies are approved for active RSV; Synagis is approved as a prophylaxis in a narrow segment of infants and very few assets are in clinical development. GS-5806 is not included in JPM or Street models; confirmation is needed in patients with active infection, but we'd peg the WW opportunity at close to \$2B. When putting GS-5806 in the context of Gilead's growing pipeline, plus a stable base HIV business and aggressive growth expected in hep C, we'd argue that GILD shares still have meaningful upside. Reiterate Overweight.

- The basics of RSV:** RSV is a single-stranded RNA virus that infects the respiratory tract. The virus is fairly common and most healthy people recover within a few weeks, however, certain populations are at increased risk. These include children less than one year of age, those with certain pulmonary infections and immunocompromised adult patients where an RSV infection could lead to hospitalization and death. Of note, infections typically follow a seasonal pattern that differs based on geographically. In the US, the RSV season typically begins in November and ends in March.
- High unmet need:** There are currently no approved treatment options in infants or adults with RSV infection. Indeed, in children, RSV treatment guidelines issued by the American Academy of Pediatrics only recommends Synagis specifically for prophylaxis in an increasingly narrow segment of infants. Additionally, the guidelines caution that supportive therapy (inhaled bronchodilators and corticosteroids) and ribavirin should not be routinely used. Of note, physicians indicate that ribavirin is very difficult to administer in inhaled form and efficacy is "questionable".

Gilead Sciences, Inc. (GILD;GILD US)

FYE Dec	2013A	2014E	2015E	2016E
EPS Reported (\$)				
Q1 (Mar)	0.48	1.48A	-	-
Q2 (Jun)	0.50	1.32	-	-
Q3 (Sep)	0.52	1.18	-	-
Q4 (Dec)	0.55	1.63	-	-
FY	2.05	5.61	6.52	7.54
Bloomberg EPS FY (\$)	2.00	6.05	7.60	8.67

Source: Company data, Bloomberg, Morgan estimates.

Overweight

GILD, GILD US

Price: \$81.81

Price Target: \$100.00



US Biotechnology

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Price Performance



Company Data

Price (\$)	81.81
Date Of Price	21 May 14
52-week Range (\$)	84.88-46.70
Market Cap (\$ mn)	133,757.20
Fiscal Year End	Dec
Shares O/S (mn)	1,635
Price Target (\$)	100.00
Price Target End Date	31-Dec-14

See page 6 for analyst certification and important disclosures.

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- **Encouraging efficacy in phase 2a challenge study:** In a phase 2a challenge study in healthy adults, GS-5806 met the primary endpoint of viral load reductions and met the secondary endpoints that included improvement in total mucus weight and symptom diary score. Indeed, a significant 99.9% reduction in viral load was observed ($p < 0.001$). Additionally, GS-5806 resulted in a significant improvement in both mucus weight (6.9g vs. 15.1g placebo; $p = 0.028$) and symptom diary score (-20.2 vs. 204.9 placebo; $p = 0.005$).
- **Clean safety profile in phase 2a:** No SAEs were observed in the study and all AEs for GS-5806 were mild or moderate in severity. These included headache, diarrhea, nausea, upper respiratory tract infection and rash, with a Grade 1 decline in pulmonary function the only AE occurring in ≥ 2 patients.
- **Physicians perspective:** Physicians we spoke to characterized the phase 2a data as “very promising.” In particular, one physician was impressed with the study design that he indicated was “elegant” and “as good as it gets” referring to the double blind and placebo control. With respect to the primary endpoint, the 99.9% reduction in viral load was viewed as “unbelievable.” That said, in a phase 3 adult natural infection study, where patients are likely to have more comorbidities, a lower reduction in viral load would be expected, but even a 70% reduction would be impressive. Additionally, while physicians were encouraged they were cautious on read-through to pediatric patients (which are the larger market) given the difference in lung physiology compared to adults.
- **Phase 2/3 expected to begin mid 2014:** Gilead is currently finalizing the design of a phase 2/3 study expected to begin in mid 2014. While details have not been disclosed, further development will focus on both children and adult populations. That said, we anticipate an adult study will likely be first as it would provide for a faster path to market and help inform the design of a study in children. Based on feedback from physicians and prior studies in RSV, we anticipate a duration of 3-6 month implying data potential in 1H16. With respect to a primary endpoint, physicians were mixed (ranging from a mortality endpoint in children to length of stay in adults), but generally agreed it could be different in an adult and pediatric studies. Given the unmet need in RSV, we believe the phase 2/3 study could be used for registration.
- **Other therapies in development:** Despite the high unmet need for the treatment of RSV, there is a dearth of emerging treatments in the clinic. Alnylam and Cubist were collaborating on ALN-RSV, but further development has slowed since Cubist opted-out of the collaboration after a mixed result in a phase 2 study. Alios (private) has an oral nucleoside analog (AL-8176) currently in a proof-of-concept study in adults, which could have data in the near term.
- **Incidence of RSV.** RSV infections lead to complications most commonly in infants and immunocompromised adults. Of note, there are ~150K RSV-related hospitalizations in the US per year in children, weighted heavily towards infants (<6 mos), leading to death in ~5% of patients. Separately, there are another 25-30K hospitalizations in the adult immunocompromised segment, including (but not limited to) elderly patients, ~160K solid-organ transplant recipients, and ~20K recent hematopoietic stem-cell transplant recipients.

- **Potential Market Opportunity.** As noted above, we expect GS-5806 will be developed in two segments: infants and adults. Overall, we size the US opportunity at ~\$1.3B. In the pediatric segment, physician feedback indicates that ~50% of patients resolve with currently available treatments and a short period of hospitalization. Assuming 50% share in the remaining patients, and a conservative \$25K cost per treatment, we size the US pediatric opportunity at ~\$940M; using a 60% share in the adult population (25,000 patient addressable market), we size the US adult opportunity at ~\$375M. Assuming an US/OUS market split of 65/35 (relatively in-line with existing Synagis trends; \$975M WW with \$570M in the US), we forecast a WW opportunity at peak of ~\$2B.
- **Reiterate Overweight rating.**

Investment Thesis, Valuation and Risks

Gilead Sciences (*Overweight; Price Target: \$100.00*)

Investment Thesis

We rate GILD shares Overweight on the basis of solid fundamentals in HIV, very significant momentum in hep C, and an oncology pipeline coming into focus. We expect a continued robust launch of Solvadi in hep C given meaningful improvements relative to currently available therapies. We expect the fixed dose combination (FDC) of sofosbuvir + ledipasvir to raise the bar particularly high in GT1 with a once-a-day pill. We anticipate data from the ION studies will support approval in 4Q14. We conservatively estimate peak WW sales of \$12B+ for the hep C business. We also expect solid growth for the HIV franchise supported by the continued launch of Stribild and Complera, both once-daily, single-tablet regimens. Additionally, we expect oncology to begin to contribute to revenue growth with approval of idelalisib in mid 2014 in iNHL and CLL.

Valuation

Our December 2014 price target of \$100 is based on a P/E multiple of ~18x our 2014 non-GAAP EPS estimate of \$5.61. We believe growth and margin expansion from the HIV business (Stribild, in particular) are underappreciated in Street models. Gilead is also well on its way to repeating this story in hep C with the addition of Sovaldi. As such, we believe a P/E multiple inline to above that of the large-cap group is justified given the growth outlook and where GILD is currently trading (P/E of ~18x 2014E, in line with large-cap group at 19x). We believe our valuation multiple is warranted as Gilead's 2013-16E revenue and EPS CAGRs are 29% and 54%, respectively, well above the peer group average.

Risks to Rating and Price Target

Key downside risks include 1) commercial risk to the HIV franchise, 2) failure of Sovaldi to meet Street expectations, and 3) clinical and regulatory risk for the FDC or for idelalisib.

Gilead Sciences: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14A	2Q14E	3Q14E	4Q14E
Revenues	11,202	20,219	22,121	23,891	Revenues	4,999A	4,726	4,516	5,978
Cost of products sold	(2,708)	(3,319)	(3,327)	(3,335)	Cost of products sold	(611)A	(662)	(788)	(1,258)
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(1,557)	(2,173)	(2,632)	(2,604)	SG&A	(500)A	(525)	(551)	(598)
R&D	(1,948)	(2,302)	(2,478)	(2,437)	R&D	(558)A	(572)	(580)	(592)
Operating income	4,988	12,424	13,684	15,515	Operating income	3,330A	2,968	2,596	3,531
EBITDA	4,988	12,424	13,684	15,515	EBITDA	3,330A	2,968	2,596	3,531
Net interest (income) / expense	(318)	(183)	0	100	Net interest (income) / expense	(96)A	(43)	(28)	(16)
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Income taxes	(1,240)	(3,006)	(3,153)	(3,441)	Income taxes	(751)A	(732)	(643)	(880)
Net income - GAAP	3,449	9,255	10,554	12,200	Net income - GAAP	2,488A	2,197	1,930	2,640
Net income - recurring	3,449	9,255	10,554	12,200	Net income - recurring	2,488A	2,197	1,930	2,640
Diluted shares outstanding	1,685	1,649	1,619	1,619	Diluted shares outstanding	1,679A	1,659	1,639	1,619
EPS - excluding non-recurring	2.05	5.61	6.52	7.54	EPS - excluding non-recurring	1.48A	1.32	1.18	1.63
EPS - recurring	2.05	5.61	6.52	7.54	EPS - recurring	1.48A	1.32	1.18	1.63
Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	2,113	7,607	17,646	29,404	Sales growth	15.5%	80.5%	9.4%	8.0%
Accounts receivable	2,100	4,869	5,327	5,753	EBIT growth	8.9%	149.1%	10.1%	13.4%
Inventories	2,056	2,213	2,218	2,223	EPS growth - recurring	4.9%	174.3%	16.2%	15.6%
Other current assets	986	1,275	1,375	1,434	Gross margin	-	-	-	-
Current assets	7,274	15,983	26,585	38,833	EBIT margin	44.5%	61.4%	61.9%	64.9%
PP&E	1,166	1,139	1,106	1,073	EBITDA margin	44.5%	61.4%	61.9%	64.9%
Total assets	22,497	30,980	41,549	53,764	Tax rate	26.4%	24.5%	23.0%	22.0%
Total debt	6,876	5,720	5,220	4,720	Net margin	30.8%	45.8%	47.7%	51.1%
Total liabilities	10,688	9,448	8,954	8,460	Net Debt / EBITDA	95.5%	(15.2%)	(90.8%)	(159.1%)
Shareholders' equity	11,745	21,532	32,595	45,305	Net Debt / Capital (book)	28.9%	(9.6%)	(61.6%)	(119.7%)
Net income (including charges)	3,057	9,255	10,554	12,200	Return on assets (ROA)	15.8%	34.6%	29.1%	25.6%
D&A	345	345	345	345	Return on equity (ROE)	32.8%	55.6%	39.0%	31.3%
Change in working capital	(563)	(3,141)	(557)	(485)	Enterprise value / sales	9.1	4.7	3.8	3.0
Other	266	112	112	112	Enterprise value / EBITDA	20.4	7.7	6.2	4.7
Cash flow from operations	3,105	6,570	10,454	12,172	Free cash flow yield	2.3%	4.9%	7.8%	9.1%
Capex	(191)	(75)	(70)	(70)					
Free cash flow	3,148	6,633	10,384	12,024					
Cash flow from investing activities	(254)	(75)	(70)	(70)					
Cash flow from financing activities	(2,544)	(962)	(307)	(307)					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

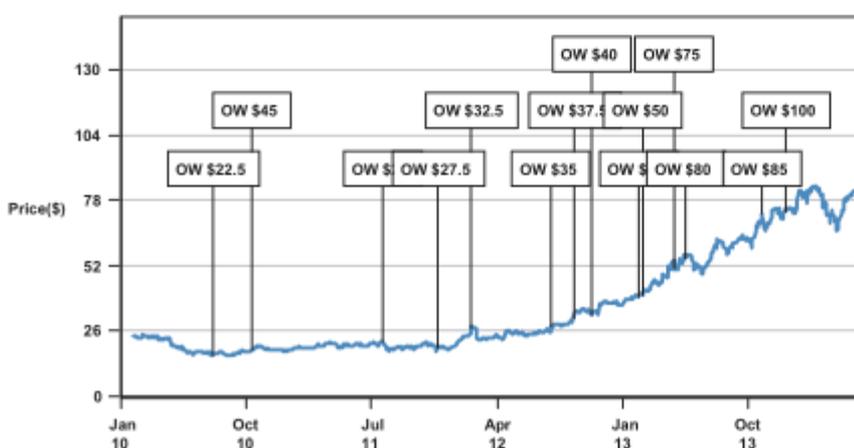
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Gilead Sciences (GILD, GILD US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
21-Jul-10	OW	16.46	22.50
13-Oct-10	OW	18.34	45.00
27-Jul-11	OW	21.48	25.00
22-Nov-11	OW	19.38	27.50
03-Feb-12	OW	27.35	32.50
27-Jul-12	OW	27.75	35.00
17-Sep-12	OW	31.01	37.50
24-Oct-12	OW	32.46	40.00
05-Feb-13	OW	39.59	45.00
12-Feb-13	OW	40.40	50.00
19-Apr-13	OW	50.86	75.00
17-May-13	OW	54.96	80.00
30-Oct-13	OW	72.67	85.00
18-Dec-13	OW	73.59	100.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends. Initiated coverage Jul 21, 2010.

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