

Gilead Sciences

Our Thoughts Post the 4Q Call

Gilead's strong 4Q results, newly announced dividend (1.6% yield) and \$15B share buyback were major positives from the call, but most investors will likely focus on hep C discounting (~46% gross/net adjustment). Clearly, the level of discounting (which has been a Street obsession) was a negative surprise but looking forward, 1) pricing is now stable with lower headline risk and 2) patient volumes are poised for a material acceleration from enhanced patient access. 2015 guidance looked conservative; we're still above it with \$28.9B in product sales (vs guidance of \$26-27B) with highly achievable patient numbers (196K US; 102K EU; 6K Japan). In sum, we're not concerned about AbbVie competitively, we don't think that pricing will see another leg down with Merck's launch in 2016e and we think the bar set by guidance gives a lot of room for P&L upside moving through 2015. Beyond hep C (yes, there are other franchises at Gilead), HIV demand trends look good going into 2015 and the pipeline is progressing in NASH, hep B, RSV, oncology, etc. So we're buyers on weakness today; we get it that hep C discounting may drive forecasts marginally lower but ultimately volumes can more than make up that difference in 2015 and beyond.

- Guidance: Gilead guided to 2015 product sales to \$26-27B (Barclays: \$28.9B), which implies hep C sales of ~\$13-14B (Barclays: \$15.6B). We forecast US/OUS hep C sales of \$10.0B/\$5.7B with a higher discount assumption which is likely to be lower in 1H15 (more commercial) but move higher in 2H (more public pay). OpEx guidance (R&D: \$3-3.3B; SG&A: \$3-3.3B) was marginally above estimates.
- Adjusting estimates: We've lowered our 2015-2017 hep C forecasts to \$15.6B, \$17.5B and \$18.2B from \$16.9B, \$19.9B and \$21.6B, but we're above 2015 guidance and consensus. We have fine-tuned operating expense, which together with lower revenue forecasts has lowered 2015-2017 non-GAAP EPS estimates to \$10.00, \$11.50 and \$12.25 from \$10.65, \$12.35 and \$13.30 previously. In year 1, Gilead's hep C revenue (\$12.4B) and cash flow (\$12.8B) eclipsed the price of the Pharmasset acquisition (\$11B); in our view the robust cash flow affords many options for value creation beyond the dividend and accelerated buyback.

GILD: Quarterly and Annual EPS (USD)

	2014		2015			2016		Chang	ge y/y
FY Dec	Actual	Old	New	Cons	Old	New	Cons	2015	2016
Q1	1.48A	2.57E	2.50E	2.38E	N/A	N/A	2.87E	69%	N/A
Q2	2.36A	2.61E	2.41E	2.47E	N/A	N/A	3.22E	2%	N/A
Q3	1.84A	2.64E	2.46E	2.50E	N/A	N/A	3.29E	34%	N/A
Q4	2.42A	2.83E	2.63E	2.54E	N/A	N/A	3.36E	9%	N/A
Year	8.08A	10.65E	10.00E	9.79E	N/A	11.50E	10.97E	24%	15%
P/E	13.3		10.7			9.3			

Source: Barclays Research.

Consensus numbers are from Thomson Reuters

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Equity Research

OVERWEIGHT

Healthcare | U.S. Biotechnology 4 February 2015

J	Unchanged
Industry View	POSITIVE
	Unchanged
Price Target	USD 125.00
	Unchanged
Price (03-Feb-2015)	USD 107.18
Potential Upside/Downside	+17%
Tickers	GILD
Market Cap (USD mn)	161699
Shares Outstanding (mn)	1508.66
Free Float (%)	99.43
52 Wk Avg Daily Volume (mn)	15.1
Dividend Yield (%)	N/A
Return on Equity TTM (%)	76.94
Current BVPS (USD)	8.96
Source: Thomson Reuters	

Stock Rating



Link to Barclays Live for interactive charting

U.S. Biotechnology

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U.S. Biotechnology Industry View: POSITIVE									
Gilead Sciences (GILD) Stock Rating: OVERWEIGHT									
Income statement (\$mn)	2014A	2015E	2016E	2017E	CAGR	Price (03-Feb-2015)	USD 107.18		
Revenue	24,883	29,319	32,016	33,188	10.1%	Price Target	USD 125.00		
EBITDA (adj)	N/A	N/A	N/A	N/A	N/A	Why Overweight? Gilead	is the market leader in hep		
EBIT (adj)	16,577	19,908	22,577	23,784	12.8%	C, and we expect this pos			
Pre-tax income (adj)	16,184	19,392	22,105	23,316	12.9%	strengthened with Harvo	ni, despite competition. We		
Net income (adj)	13,283	15,900	18,126	19,119	12.9%	•	e to inovate and raise the bar		
EPS (adj) (\$)	8.08	10.00	11.50	12.25	14.9%	in hep C with a pangenotypic regimen and a shorter			
Diluted shares (mn)	1,643.8	1,589.8	1,576.0	1,561.0	-1.7%		tionaly, we expect the core		
DPS (\$)	0.00	0.00	0.00	0.00	N/A	HIV business to remain s	trong.		
Margin and return data					Average	Upside case	USD 140.00		
Margin and return data	N1 / A	N1 / A	N1 / A	N1 / A	Average		inch of Harvoni in the US and		
EBITDA (adj) margin (%)	N/A 66.6	N/A 67.9	N/A	N/A 71.7	N/A	more rapid geographic ex			
EBIT (adj) margin (%)			70.5		69.2	business would drive ups	ide.		
Pre-tax (adj) margin (%)	65.0 53.4	66.1 54.2	69.0	70.3	67.6 55.5				
Net (adj) margin (%)		04.2 N/A	56.6 N/A	57.6 N/A	55.5 N/A	Downside case	USD 85.00		
ROIC (%)	N/A			N/A	N/A N/A	A greater-than-expected			
ROA (%) ROE (%)	N/A N/A	N/A N/A	N/A N/A	N/A	N/A N/A		ng pricing/reimbursement		
KOE (%)	IN/ A	IN/ A	IN/A	IN/ A	IN/ A	pressures would drive do	wnside.		
Balance sheet and cash flow (CAGR	Upside/Downside scena	rios		
Tangible fixed assets	N/A	N/A	N/A	N/A	N/A	Price History	Price Target		
Intangible fixed assets	N/A	N/A	N/A	N/A	N/A	Prior 12 months	Next 12 months		
Cash and equivalents	7,777	15,827	33,537	52,790	89.3%	High	Upside		
Total assets	32,842	41,988	60,264	79,448	34.2%	•	•		
Short and long-term debt	7,648	3,648	3,648	3,648	-21.9%		140.00		
Other long-term liabilities	6,843	7,090	7,240	7,305	2.2%		Target		
Total liabilities	14,491	10,738	10,888	10,953	-8.9%	116.83 Current	125.00		
Net debt/(funds)	N/A	N/A	N/A	N/A	N/A				
Shareholders' equity	21,047	33,947	52,073	71,192	50.1%	107.18			
Change in working capital	-4,565	-842	-408	142	N/A		85.00		
Cash flow from operations	8,960	15,300	17,960	19,503	29.6%		85.00		
Capital expenditure	-250	-250	-250	-250	N/A	63.50			
Free cash flow	N/A	N/A	N/A	N/A	N/A	Low	Downside		
Valuation and leverage metric					Average	-			
P/E (adj) (x)	13.3	10.7	9.3	8.8	10.5				
EV/EBITDA (adj) (x)	N/A	N/A	N/A	N/A	N/A				
Equity FCF yield (%)	N/A	N/A	N/A	N/A	N/A				
EV/sales (x)	6.8	5.4	4.4	3.6	5.1				
P/BV (x)	N/A	N/A	N/A	N/A	N/A				
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0				
Total debt/capital (%)	N/A	N/A	N/A	N/A	N/A				
Selected operating metrics					Average				
SG&A/sales (%)	11.1	10.4	10.0	9.5	10.3				
R&D/sales (%)	10.4	10.8	9.6	9.0	9.9				
R&D growth (%)	32.7	22.7	-3.1	-3.4	12.2				
SG&A growth (%)	77.0	10.9	4.7	-1.5	22.8				

Source: Company data, Barclays Research Note: FY End Dec

4 February 2015

Takeaways From the Quarter

- Hep C Reimbursement / Access. The key datapoint investors will focus on is the company's estimated 2015 Harvoni/Sovaldi gross-to-net adjustment (46% vs. 22% in 2014). Of note, this is a blended average reflecting a private/public mix 75/25 in 2014. Gilead emphasized that the increased rebates are designed to relax treatment restrictions and drive patient access. Based on this, we are lowering our U.S. price assumption to reflect a 28% discount for Sovaldi and a 40% for Harvoni in 2015. Capacity Gilead believes the US hep C market comprises 3-4M patients, of which 1.6M have been diagnosed, and that >250K could be treated in 2015. Our model assumes that ~220K treated US patients in 2015, with ~77% treated by Gilead products. Payor negotiations Noted that hep C negotiations have now concluded with payors addressing ~60% of covered lives in the U.S. (with 80% access to Harvoni). This is roughly in-line with our own estimates (~70% covered with 80% access for Harvoni; see our note from last week in conjunction with Barclays PBM analyst Eric Percher).
- **Hep C Commercial Performance**. Harvoni sales beat consensus by ~\$600M offset somewhat by a Sovaldi miss of ~\$270M. U.S. Harvoni sales were particularly strong at ~\$2B (given that WW consensus estimates were ~\$1.5B. U.S. Sovaldi sales were \$1.2B for the quarter. Gilead noted that Sovaldi still found use in ~30% of GT1 patients in the 4Q; the company expects use in GT1 patients to decrease dramatically as Harvoni launch continues. Overall, ~140K US patients have now been treated with sofosbuvir-based regimens since the Sovaldi launch in late 2013.
- EU Hep C Takeaways. We were encouraged by commentary on the sustainability of hep C patient volumes in Europe, with Gilead noting the EU market will likely have a longertail than the U.S. Specifically, the company characterized hep C revenues as sustainable for 10-15 years in Europe, perhaps longer in countries such as Italy. Pricing/Access Concluded price/volume negotiations in France, Italy, and Spain, while patients in Austria, Sweden, Finland, and Germany now have access to Harvoni. EU Volume Across Europe 32K (26K in EU Big 5, 4K with Harvoni) have started treatment with a sofosbuvir-based regimen; hep C EU patient volumes could exceed 100K in 2015.
- HIV Takeaways. 4Q HIV sales were strong (+6% q/q, +15% y/y), beating consensus estimates by ~\$240M, driven by Truvada, Atripla, and Stribild outperformance. Gilead noted switches from Atripla continue, as Stribild and Complera continue to gain share. We anticipate modest HIV franchise growth, with 2015 WW sales of \$11.1B (+8% y/y)
- Pipeline. <u>Simtuzumab</u> Failed to show clinical activity in myelofibrosis, pancreatic cancer, and colorectal cancer. Company cautioned from reading into ongoing studies in NASH and pulmonary fibrosis, given biologic differences in liver and pulmonary fibrosis relative to the previously evaluated settings. <u>GS-5745</u> Advancing the MMP-9 mAb into clinical development for ulcerative colitis / gastric cancer in 2015.
- 2015 Guidance. Net Product Sales \$26-27B (Barclays: \$2.89B). Assuming non-Hep C product sales of ~\$12.8B implies Hep C sales for the company of ~\$13.2-14.2B (Barclays: \$15.6B). Gross-margins: 87-90% (Barclays: 89%). R&D Expense \$3.0-3.3B (Barclays: \$3.2B). SG&A Expense \$3.0-3.3B (Barclays: \$3.1BB). Tax Rate: 18-20% (Barclays: 18%).
- Capital allocation strategy. <u>Dividend</u> Announced plans to start a quarterly dividend of \$0.43 (~1.6% yield) in 2Q, and to grow the dividend over time (though share repurchases remain the company's preferred mechanism). <u>Share repurchases</u> Disclosed plans to initiate a 5-year \$15B share repurchase plan, on top of an existing \$5B plan of which \$3B is remaining.

Changes to Our Model

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FIGURE 1
Changes to Our Model (\$ millions, except per share data)

	Barclays	Barclays	Barclays	Barclays	Barclays	Barclays
	2015E	2015E	2016E	2016E	2017E	2017E
	OLD	NEW	OLD	NEW	OLD	NEW
WW Truvada	3,205	3,265	3,122	3,202	3,038	3,078
WW Atripla	3,297	3,358	3,143	3,143	2,975	2,975
WW Complera / Eviplera	1,498	1,498	1,714	1,714	1,843	1,843
WW Stribild	1,812	1,948	2,471	2,576	2,982	3,070
WW TAF	52	89	424	462	919	919
WW Sovaldi	9,059	7,098	9,056	6,975	9,279	7,169
WW Harvoni	7,901	8,566	10,850	10,605	12,366	11,037
Zydelig	171	171	386	386	643	643
Letairis	606	691	666	760	700	798
Ranexa	553	561	597	606	621	630
Total Product sales	29,713	28,935	33,584	31,631	35,932	32,803
Total Revenue	30,106	29,319	33,976	32,016	36,325	33,188
COGS	3,268	3,183	3,358	3,163	3,593	3,280
R&D	2,881	3,171	3,058	3,073	3,269	2,970
SG&A	2,871	3,057	3,398	3,202	3,578	3,153
Total Op Ex	9,021	9,411	9,814	9,438	10,440	9,403
Net income	17,204	15,900	19,870	18,126	21,353	19,119
EPS	10.65	10.00	12.35	11.50	13.30	12.25
Fully diluted shares	1,615	1590	1,608	1576	1606	1561

Source: Barclays Research and Company reports

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Primary Stocks (Ticker, Date, Price)

Gilead Sciences (GILD, 03-Feb-2015, USD 107.18), Overweight/Positive, A/C/D/J/K/L/M

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U.S. Biotechnology

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Celgene Corp. (CELG)	Gilead Sciences (GILD)	Medivation Inc. (MDVN)
NPS Pharmaceuticals (NPSP)	Regeneron Pharmaceuticals (REGN)	United Therapeutics (UTHR)

Vertex Pharmaceuticals (VRTX)

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4 February 2015

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Gilead Sciences (GILD)

USD 107.18 (03-Feb-2015)

Stock Rating OVERWEIGHT

Industry View

WEIGHT	POSITIVI

150 -											
125 -											•
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Currency=USD								
Date	Closing Price	Rating	Adjusted Price Target					
05-Jan-2015	96.79	Overweight	125.00					
15-May-2014	80.10	Drop Coverage						
21-Feb-2014	82.59		95.00					
26-Nov-2013	74.37		90.00					
30-Oct-2013	72.67		74.00					
25-Jul-2013	60.86		68.00					
15-Apr-2013	50.68		65.00					
04-Feb-2013	39.59		42.00					
22-Jan-2013	38.96		42.00					
04-Dec-2012	37.08		38.00					
15-Oct-2012	33.66		36.50					
02-Aug-2012	28.65	Overweight	32.50					
21-Feb-2012	22.35	Equal Weight	26.50					
10-Feb-2012	26.88	Overweight	33.50					
Source: Thomson Reuters, Barclays Research								

Historical stock prices and price targets may have been adjusted for stock splits and dividends.

Source: IDC, Barclays Research

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Valuation Methodology: Our YE15 price target of \$125 is based on a P/E multiple. Gilead is currently trading at a P/E multiple of 9X 2015 EPS, yet has a 2014-2016E CAGR above peers (13% vs. 13% on revenue; 19% vs. 10% on EPS). As such, a multiple closer to the group in the 12X range (in-line with the EPS CAGR) is more reasonable; our PT of \$125/share based on 12X our 2015 EPS estimate of \$10.00.

Risks which May Impede the Achievement of the Barclays Research Price Target: 1) Commercial Risk: Gilead has successfully launched Sovaldi for hep C. However, Gilead could face challenges commercializing Harvoni in hep C with a combination of competitive and pricing pressures. Additionally, other competitors could enter the hep C market in the future further pressuring share gains with payors further influencing the market by preferences for specific products. This could limit growth and the peak potential of the hep C business, which would have a negative impact on share performance. 2) Regulatory Risk

Gilead has a broad pipeline that has produced positive late stage data including TAF-Stribild. However, positive data is no guarantee that the FDA or EMA will grant approval. Delays in timelines or an inability to gain approval could significantly impact Gilead's future sales. 3) Clinical Risk: Gilead is developing multiple drugs for a broad range of diseases. Gilead's sofosbuvir + GS-5816 could fail to demonstrate comparable benefits in phase 3 to that observed in phase 2. Additionally, other agents in early to mid stage development, such as simtuzuamab in phase 2 for NASH, could also fail to demonstrate any benefits. As such Gilead may be unable to sustain its revenue stream. 4) Patent Risk: Gilead relies on patents to protect its investment in drug development. Gilead is facing multiple patent challenges to its hep C business. While we believe Gilead will ultimately prevail and failure to successfully defend its hep C patents could significantly reduce future sales and pressure GILD shares.

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