

# Gilead Sciences, Inc.

# Strong Fourth-Quarter Operating Results; Expect an Active Pipeline Year in 2015

After the markets closed on Tuesday, February 3, Gilead reported fourth-quarter operating results that were highlighted by strong overall performance of key products. Notably, sales of HCV drugs **Sovaldi and Harvoni were \$3.8 billion**, just ahead of our expectations of \$3.5 billion. Exhibit 1 provides a variance analysis of the company's operating results compared with our estimates. Management also provided 2015 financial guidance, which takes into account the anticipated effects of shortened therapy duration and price discounts with the HCV franchise. We illustrate 2015 guidance in exhibit 2 along with our modified financial estimates.

#### **Key Conclusions Following Management's Call With Investors Include:**

- Overall key product performance was very strong in the quarter. As indicated in our variance analysis, we are encouraged by the overall performance of key products. In particular, the HIV franchise continues to provide a consistent revenue stream. We expect positive operating momentum to continue into 2015 and note from our experience that management historically gives conservative guidance on its year-end call.
- 2015 stands to be an active pipeline year highlighted by Phase III readouts with sofosbuvir in combination with GS-5816 in HCV genotypes 1-6. We expect 2015 to be a highly visible year for Gilead's HCV franchise, and we anticipate top-line data from four Phase III trials, which assess the combination of sofosbuvir plus GS-5816, a pan-genotypic NS5A inhibitor (formulated in a single-tablet regimen), for the treatment of all HCV genotypes. We believe that the company's pan-genotypic regimen could have the potential to address a broader patient population compared with Harvoni, eliminating the need to screen patients for the specific genotype. Consistent with past years, we believe Gilead will be extremely active at the two primary HCV conferences, the European Association for the Study of the Liver (EASL) in April and the American Association for the Study of Liver Diseases (AASLD) meeting in November, and we anticipate further clinical updates from the pipeline at these venues. Accordingly, exhibit 3 outlines the GS-5816 Phase III program, while exhibit 4 provides our expectation for upcoming clinical and regulatory catalysts.

In parallel, Gilead continues to push initiatives that have the potential to further shorten treatment duration. Phase II studies with sofosbuvir in combination with GS-5816 and GS-9857, which is a pan-genotypic protease inhibitor, are being explored as 4- to 6-week treatment regimens targeting patients who are treatment-naïve/treatment-experienced as well as with or without cirrhosis. We expect the Phase II top-line results will likely read out at EASL in April.

Gilead is a research-based biotechnology company focused on developing therapies for the treatment of life-threatening diseases. Gilead has been a leader in HIV/AIDS therapeutics and more recently in HCV, but also has a large product portfolio that includes therapeutics for liver, cardiovascular, metabolic, and respiratory diseases.

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#### February 03, 2015

Stock Rating: Outperform Company Profile: Core Growth

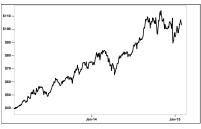
Symbol: GILD (NASDAQ)
Price: \$107.18 (52-Wk.: \$64-\$117)
Market Value (mil.): \$161,699
Fiscal Year End: December
Long-Term EPS Growth Rate: 17%
Dividend/Yield: None

	2014A	2015E	2016E
Estimates			
EPS Q1	\$1.48	\$2.26	\$2.55
Q2	\$2.36	\$2.37	\$2.61
Q3	\$1.84	\$2.43	\$2.66
Q4	\$2.43	\$2.49	\$2.73
FY	\$8.12	\$9.55	\$10.56
CY		\$9.55	\$10.56
Sales (mil.)	24,890	27,784	29,979
Valuation			
FY P/E	13.2x	11.2x	10.1x
CY P/E		11.2x	10.1x

Trading Data (FactSet)	
Shares Outstanding (mil.)	1,514
Float (mil.)	1,500
Average Daily Volume	16,462,976

# Financial Data (FactSet)Long-Term Debt/Total Capital (MRQ)0.0Book Value Per Share (MRQ)9.0Return on Equity (TTM)29.7

#### **Two-Year Price Performance Chart**



Sources: FactSet, William Blair & Company estimates

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- Capital allocation and balance sheet considerations: Gilead announces a \$0.43 quarterly dividend and a five-year, \$15 billion share-buyback program. Gilead generated operating cash flow of \$12.8 billion during 2014, and we highlight the \$2.0 billion share repurchase during the fourth quarter. We have received a considerable number of questions over the past year regarding Gilead's strategy for capital redeployment. While we continue to expect the company to pursue strategic acquisitions and licensing transactions, robust cash flows and a growing balance sheet enabled the company to offer shareholders a \$1.72 annual cash dividend program beginning in the second quarter of this year. In addition, we expect management to continue to repurchase shares as evidenced by the \$15 billion share repurchase authorization that will commence upon the completion of the existing May 2014 program (\$3 billion remaining). Cash and marketable securities at the end of the quarter were \$11.7 billion.
- Our thoughts on the stock remain unchanged, and we reiterate our Outperform rating on Gilead shares. With the launches of Sovaldi and Harvoni, we believe Gilead is in the early stages of contributing meaningfully to a major global public health problem. Combined with strong underlying core global infrastructure in HIV and cardiopulmonary disease and advancement into the oncology setting, we view the company as poised for a multiyear period of growth and cash flow generation significantly ahead of its peers. Share price weakness in the aftermarket was likely attributable to discussion surrounding price discounting, which we believe is 1) in line with expectations for a competitive market with shortening duration of therapy and 2) considered within the financial guidance framework provided by management. Based on our revised estimates, the company is trading at 11.2 times our projected EPS in 2015 and a PE/G ratio of 1.0; we reiterate our Outperform rating on GILD shares.

Exhibit 1
Gilead Sciences, Inc.
Fourth Quarter 2014 Variance Analysis
(dollars in millions except EPS)

GILD WB Variance Q/Q Growth Y/Y Growth Q4 2014A Q4 2014E \$925 -1% Atripla Sales \$830 11% 3% Truvada Sales \$897 \$827 3% 10% 8% Viread Sales \$311 \$238 31% 13% 16% \$348 \$330 Complera/Eviplera Sales 5% 5% 33% Stribild Sales \$385 \$370 4% 17% 89% Sovaldi/Harvoni Sales \$3,839 \$3,515 9% 36% 2662% AmBisome Sales \$104 \$90 16% 6% 11% Letairis Sales \$181 \$147 23% 24% 30% \$144 \$133 Ranexa Sales 8% 8% 11% \$7,222 **Total Product Sales** \$6,556 10% 21% 149% **Total Revenue** \$7,314 \$6,642 10% 21% 145% COGS \$847 \$850 0% 8% 13% 76% R&D \$899 \$650 38% 53% SG&A \$799 \$800 0% -10% 70% Net Income \$3,883 \$3,505 11% 29% 375% \$2.16 13% 32% 406%

Sources: Gilead reports and William Blair & Company, L.L.C. estimates.

### Exhibit 2 Gilead Sciences, Inc. Guidance and Estimates (dollars in millions except EPS)

	Guidance New 2015	WB Previous 2015E	WB Revised 2015E	WB Previous 2016E	WB Revised 2016E	WB Previous 2017E	WB Revised 2017E
Sovaldi/Harvoni Sales		\$15,095	\$15,170	\$16,695	\$16,695	\$17,880	\$17,880
Atripla Sales		\$3,210	\$3,210	\$3,070	\$3,070	\$2,990	\$2,990
Truvada Sales		\$3,097	\$3,097	\$3,056	\$3,056	\$2,904	\$2,904
Complera/Eviplera Sales		\$1,381	\$1,381	\$1,590	\$1,590	\$1,792	\$1,792
Stribild Sales		\$1,830	\$1,830	\$2,276	\$2,276	\$2,592	\$2,592
Viread Sales		\$800	\$800	\$740	\$740	\$694	\$694
Zydelig Sales		\$97	\$97	\$224	\$224	\$322	\$322
AmBisome Sales		\$324	\$324	\$302	\$302	\$302	\$302
Letairis Sales		\$588	\$588	\$584	\$584	\$580	\$580
Ranexa Sales		\$550	\$550	\$590	\$590	\$630	\$630
Total Product Sales	\$26,000-\$27,000	\$27,289	\$27,364	\$29,514	\$29,514	\$31,066	\$31,066
Total Revenue		\$27,709	\$27,784	\$29,979	\$29,979	\$31,531	\$31,531
COGS		\$3,339	\$3,082	\$3,584	\$3,228	\$3,728	\$3,352
R&D	\$3,000-\$3,300	\$2,650	\$3,170	\$2,730	\$3,250	\$2,730	\$3,330
SG&A	\$3,000-\$3,300	\$3,170	\$3,170	\$3,260	\$3,260	\$3,380	\$3,380
Net Income		\$15,271	\$15,001	\$16,766	\$16,430	\$17,769	\$17,433
EPS		\$9.47	\$9.55	\$10.49	\$10.56	\$11.19	\$11.24

Sources: Gilead reports and William Blair & Company, L.L.C estimates.

Exhibit 3
Gilead Sciences, Inc.
Phase III ASTRAL Trial Designs with Sofosbuvir Plus GS-5816 with or without Ribavirin in HCV Genotypes 1-6

	Phase III ASTRAL Trials in All HCV Genotypes								
Trial Name	ASTRAL-1		ASTRAL-2		ASTRAL-3		ASTRAL-4		
Disease	Genotypes 1, 2, 4, 5, and 6 Genotype 2 Genotype 3		Genotypes 1-6						
Patient Characteristics	Treatment-	nt-naïve experienced cirrhotics	Treatment-	ent-naïve experienced cirrhotics	Treatment-naïve Treatment-experienced Includes cirrhotics		Child-Pugh class B cirrhosis No liver transplant		
Treatment Arms	400 mg sofosbuvir 100 mg GS-5816	Placebo	400 mg sofosbuvir 100 mg GS-5816	400 mg sofosbuvir + ribavirin	400 mg sofosbuvir 100 mg GS-5816 400 mg sofosbuvir † ribavirin		400 mg sofosbuvir 100 mg GS-5816	400 mg sofosbuvir 100 mg GS-5816 + ribavirin	400 mg sofosbuvir 100 mg GS-5816
Enrollment	~500 patients	~100 patients	~120 patients	~120 patients	~250 patients ~250 patients		~75 patients	~75 patients	~75 patients
Treatment Duration	12 weeks	12 weeks	12 weeks	12 weeks	12 weeks 24 weeks		12 weeks	12 weeks	24 weeks

Note: GS-5816=NS5A inhibitor. Sofosbuvir=Nucleotide polymerase inhibitor. Sources: Company reports and www.clinicaltrials.gov.

#### Exhibit 4 Gilead Sciences, Inc. Timeline

Date	Product	Event
	GS-4774	Phase II trial top-line results in HBV (1H).
	GS-4997	Phase II study initiation in non-alcoholic steatohepatitis (2Q).
	GS-6615	Phase II/III study initiation in hypertrophic cardiomyopathy (Q1).
	GS-9620	Phase II trial top-line results in HBV (2H).
	GS-9883	Phase II study initiation in HIV (2H).
	Idelalisib	Phase II study initiation in first-line indolent non-Hodgkin lymphoma (Q1).
	Simtuzumab	Phase II trial top-line results in non-alcoholic steatohepatitis (4Q).
	Simtuzumab	Phase II trial top-line results in primary sclerosing cholangitis (4Q).
2015	Sofosbuvir	Regulatory decision in combination with ribavirin in HCV genotype 2 in Japan (1H).
	Sofosbuvir	Regulatory decision in combination with ledipasvir in HCV genotype 1 in Japan (2H).
	Sofosbuvir	Phase III trial results in combination with GS-5816 in HCV genotypes 1-6 (3Q).
	Sofosbuvir	Phase II trial top-line results in combination with GS-5816 and GS-9857 in HCV genotypes 1-6 (April 22).
	Tenofovir alafenamide	Regulatory decision in combination with elvitegravir, cobicistat, and emtricitabine in HIV in the United States (November 5).
	Tenofovir alafenamide	Regulatory decision in combination with elvitegravir, cobicistat, and emtricitabine in HIV in Europe (2H).
	Tenofovir alafenamide	Regulatory submission in combination with emtricitabine in HIV in the United States (Q2).
	Tenofovir alafenamide	Regulatory submission in combination with emtricitabine in HIV in Europe (Q2).
	Tenofovir alafenamide	Regulatory submission in combination with emtricitabine and rilpivirine in the United States (Q4).

Sources: Gilead reports.

#### **Valuation**

Gilead is trading at 11.2 times our updated adjusted EPS estimate for 2015 of \$9.55. We believe that Gilead has extensive expertise in drug discovery, development, and commercialization. The company has also been extremely active relative to its peers in strategic development. We see strong growth potential driven by greater confidence in HIV market growth, the potential of the HCV and oncology franchises, and accretive revenues from new products, such as Letairis, Ranexa, and other late-stage products. Based on our favorable outlook for the company, we believe Gilead will outperform the market in the near term.

#### Risks

In addition to the well-documented clinical, regulatory, and financial risks associated with owning the shares of a biotechnology company such as Gilead, we believe the company's dependence on its HIV franchise represents a fundamental risk for investors. Gilead's entrance into new markets, such as the cardiopulmonary space, where it is not a major player, poses a risk to the company. The HCV space is also very competitive, and even though we believe Gilead is the market leader, the competitive threat remains.

Our earnings model is shown on the following page.

#### Exhibit 5 Gilead Sciences, Inc. Income Statement

(dollars and shares in millions except EPS)

	2014A	Q1E	Q2E	Q3E	Q4E	2015E	2016E	2017E
Revenues	40.440	0.000	0.775	0.050	0.005	45 470	40.005	47.000
Sovaldi Franchise Sales	12,410	3,620	3,775	3,850	3,925	15,170	16,695	17,880
Atripla Sales	3,470	825 780	810 775	795 772	780 770	3,210 3,097	3,070 3,056	2,990 2,904
Truvada Sales Complera/Eviplera Sales	3,339 1,228	331	335	350	365	1,381	1,590	1,792
Stribild Sales	1,198	405	440	475	510	1,830	2,276	2,592
Viread Sales	1,058	205	202	198	195	800	740	694
Vitekta Sales	0	20	20	30	30	100	170	170
Other Antiviral Sales	70	17	16	16	16	65	63	56
Total Antiviral Products	22,791	6,203	6,373	6,486	6,591	25,653	27,660	29,078
7. della Calaa	00	40	0.4	00	0.5	07	004	200
Zydelig Sales	23 389	13 83	21 82	28	35 79	97	224 302	322 302
AmBisome Sales Letairis Sales	595	63 147	o∠ 147	80 147	79 147	324 588	584	580
Ranexa Sales	510	135	135	140	140	550	590	630
Other Product Sales	166	37	38	38	39	152	154	154
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Total Product Sales	24,474	6,618	6,796	6,919	7,031	27,364	29,514	31,066
Royalty, contract and other revenues	416	105	105	105	105	420	465	465
Tamiflu royalty	125	40	32	14	14	100	100	100
Contract and other revenues	291	65	73	91	91	320	365	365
E						*		****
Total revenues	\$24,890	\$6,723	\$6,901	\$7,024	\$7,136	\$27,784	\$29,979	\$31,531
Costs and Expenses								
Costs and Expenses Costs of Goods Sold (non-GAAP)	2,964	760	768	774	781	3,082	3,228	3,352
Product Gross Margin Reconciliation								
Product Gross Margin (non-GAAP)	87.9%	88.6%	88.8%	89.0%	89.1%	88.9%	89.4%	89.7%
Research and Development Expenses								
R&D (non-GAAP)	2,585	785	790	795	800	3,170	3,250	3,330
Salling Coneral and Administrative Evenence (SCSA)								
Selling, General and Administrative Expenses (SG&A) SG&A (non-GAAP)	2,757	790	790	795	795	3,170	3,260	3,380
SGAA (HOH-GAAF)	2,737	790	790	793	795	3,170	3,200	3,360
Operating Margin Reconciliation								
Operating Margin (non-GAAP)	66.6%	66.3%	67.1%	67.5%	68.0%	67.2%	69.0%	69.7%
Interest Expense Reconciliation								
Interest Expense (non-GAAP)	(412)	(115.0)	(110.0)	(110.0)	(105.0)	(440)	(490)	(390)
Net leaves Attaile table to Oilead Beauty Western								
Net Income Attributable to Gilead Reconciliation  Net income attributable to Gilead (non-GAAP)	10.014	2.500	2 722	2.042	2.067	15 001	16 420	17 100
Net income attributable to Glieau (non-GAAF)	13,314	3,589	3,733	3,812	3,867	15,001	16,430	17,433
Diluted Earnings Per Share Reconciliation								
Diluted earnings per share (non-GAAP)	\$8.12	\$2.26	\$2.37	\$2.43	\$2.49	\$9.55	\$10.56	\$11.24
Shares used in per share calculation (diluted) reconciliation Shares used in per share calculation (diluted) (non-GAAP)	1643.6	1586.0	1576.0	1566.0	1556.0	1571.0	1556.0	1551.0
Non-GAAP adjustment summary								
Total non-GAAP adjustments after tax	(1,214.71)	(263.5)	(258.5)	(268.5)	(273.5)	(1,064.09)	(1,064.09)	(1,064.09)
						L		

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Please consult the last page of this report for all disclosures.

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Sources: Gilead reports.

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William Blair is a market maker in the security of Gilead Sciences, Inc.

William Blair intends to seek investment banking compensation in the next three months from Gilead Sciences, Inc.

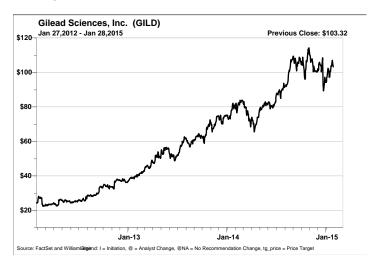
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DOW JONES: 17,666.40 S&P 500: 2,050.03 NASDAQ: 4,727.74



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