



# GILEAD

Advancing Therapeutics.  
Improving Lives.



## **Q2 2011 Earnings Results Conference Call and Webcast**

July 26, 2011

# Forward-looking Statements

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The projected financial results presented in the following slides represent management's estimates of Gilead's future financial results. Gilead cautions readers that forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include: Gilead's ability to achieve its anticipated full year 2011 financial results, including the possibility that its full year 2011 guidance may be revised at a later date; Gilead's ability to sustain growth in revenues for its antiviral, cardiovascular and respiratory franchises; unpredictable variability of Tamiflu royalties and the strong relationship between this royalty revenue and global pandemic planning and supply; the availability of funding for state ADAPs and their ability to purchase at levels to support the number of patients that rely on ADAPs; the levels of inventory held by wholesalers and retailers which may cause fluctuations in Gilead's earnings; Gilead's ability to submit new drug applications for new product candidates in the timelines currently anticipated; Gilead's ability to receive regulatory approvals in a timely manner or at all, for new and current products, including cobicistat and GS 7340; Gilead's ability to successfully commercialize its products; Gilead's ability to successfully develop its respiratory, cardiovascular and oncology franchises; safety and efficacy data from clinical studies may not warrant further development of Gilead's product candidates, including the clinical studies evaluating cobicistat and GS 7340; initiating and completing clinical trials may take longer or cost more than expected, including the clinical studies evaluating cobicistat and GS 7340; the potential for additional austerity measures in European countries that may increase the amount of discount required on Gilead's products; fluctuations in the foreign exchange rate of the U.S. dollar that may cause an unfavorable foreign currency exchange impact on Gilead's future revenues and pre-tax earnings; Gilead's ability to complete the current \$5.0 billion share repurchase program and commence purchases under the additional \$5.0 billion share repurchase program due to changes in its stock price, corporate or other market conditions; risks that the funding of the Gilead Sciences Research Center at the Institute of Organic Chemistry and Biochemistry will not lead to the discovery of any potential product candidates; risks that Gilead will not sign an agreement to develop the Emtriva, GS 7340, cobicistat and Tibotec Pharmaceutical's Prezista single tablet regimen and as a result, the parties will not develop the fixed-dose combination of cobicistat and Prezista; risks that the development and commercialization of cobicistat and Prezista will not be successful; risks that the collaboration with MicroDose Therapeutx will not lead to the commercialization of MDT-637; and other risks identified from time to time in Gilead's reports filed with the U.S. Securities and Exchange Commission.

Gilead directs readers to its Form 10-Q for the quarter ended March 31, 2011 and other subsequent disclosure documents filed with the SEC and press releases. Gilead claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements. This presentation includes GAAP and non-GAAP financial measures, a complete reconciliation between these two measures is available on the Company's website at [www.gilead.com](http://www.gilead.com) within the investor section. Management believes this non-GAAP information is useful for investors, taken in conjunction with Gilead's GAAP financial statements, because management uses such information internally for its operating, budgeting and financial planning purposes. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of Gilead's operating results as reported under U.S. GAAP.

# Q2 2011 Earnings Call Agenda

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## **Introduction**

Susan Hubbard, VP, Investor Relations

## **Opening Commentary**

John Martin, Chairman and CEO

Robin Washington, SVP and CFO

John Milligan, President and COO

## **Q&A with Management Team**

Including:

Norbert Bischofberger, EVP, R&D and CSO

Kevin Young, EVP, Commercial Operations



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**John C. Martin, Ph.D.**  
**Chairman and Chief Executive Officer**

July 26, 2011

# Q2 2011 Corporate Highlights

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- ◆ Entered into license agreement with Tibotec Pharmaceuticals for the development and commercialization of a new fixed-dose antiretroviral combination containing cobicistat and Tibotec's protease inhibitor darunavir
  - Also negotiating terms for development and commercialization of a future single-tablet regimen (STR) combining darunavir with Emtriva, GS 7340 and cobicistat
- ◆ Advanced multiple R&D pipeline programs
- ◆ Appointed Dr. Muzammil M. Mansuri as Senior Vice President, Research and Development Strategy and Corporate Development
- ◆ Repurchased \$724 million\* of Gilead stock resulting in the retirement of approximately 18 million shares

\* \$5.0 billion share repurchase program authorized May 10, 2010, with \$706.8 million remaining as of June 30, 2011.


# Tibotec Agreement: New Fixed-Dose Combination of Cobicistat and Prezista

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- ◆ Announced license agreement with Tibotec  
(June 28, 2011)
  - Develop and commercialize a new fixed-dose antiretroviral combination product containing Gilead's cobicistat and Tibotec's protease inhibitor darunavir
- ◆ Subject to regulatory approval:
  - Tibotec will be responsible for formulation, manufacturing, registration, distribution and commercialization of the cobicistat and darunavir fixed-dose combination worldwide
  - Gilead retains sole rights for the manufacture, development and commercialization of cobicistat as a stand-alone product and for use in combination with other agents
- ◆ Both companies also negotiating:
  - Terms for the development and commercialization of a future single-tablet regimen (STR) combining darunavir and Gilead's emtricitabine and its investigational agents GS 7340 and cobicistat
  - Gilead would be responsible for development and worldwide commercialization of the new STR
  - Agreement to develop the fixed-dose combination of cobicistat and darunavir is contingent upon executing the agreement to develop the Emtriva, GS 7340, cobicistat and Prezista STR

# HPTN Study 052: First Randomized Trial Showing that Initiation of ART Protects Uninfected Sexual Partners from HIV Infection

- ◆ Large multinational study started in April 2005; conducted by HIV Prevention Trials Network
  - Evaluated whether immediate vs. delayed use of ART by HIV-infected individuals would reduce transmission to their HIV-uninfected partners and potentially benefit the HIV-infected as well
  - N=1,763 HIV-serodiscordant couples; vast majority of which (97%) were heterosexual
  - Study conducted at 13 sites across Africa, Asia and the Americas
  - HIV-infected person required to have CD4 cell count between 350-500 cells/mm<sup>3</sup>
- ◆ DSMB review concluded that the initiation of ART resulted in a **96% reduction** in HIV transmission; study halted four years early (announced in May 2011)



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**FOR IMMEDIATE RELEASE:**  
Thursday, 12 May 2011, 11 am EST

**Initiation of Antiretroviral Treatment  
Protects Uninfected Sexual Partners from HIV Infection (HPTN Study 052)**

*96% reduction in HIV transmission, according to study conducted  
by HIV Prevention Trials Network*

**Washington, DC** - Men and women infected with HIV reduced the risk of transmitting the virus to their sexual partners through initiation of oral antiretroviral therapy (ART), according to findings from a large multinational clinical study conducted by the HIV Prevention Trials Network (HPTN), a global partnership dedicated to reducing the transmission of HIV through cutting-edge biomedical, behavioral, and structural interventions.

The study, known as HPTN 052, was designed to evaluate whether immediate versus delayed use of ART by HIV-infected individuals would reduce transmission of HIV to their HIV-uninfected partners and potentially benefit the HIV-infected individual as well. Findings from the study were reviewed by an independent Data and Safety Monitoring Board (DSMB). The DSMB recommended that the results be released as soon as possible and that the findings be shared with study participants and investigators. The DSMB concluded that initiation of ART by HIV-infected individuals substantially protected their HIV-uninfected sexual partners from acquiring HIV infection, with a 96 percent reduction in risk of HIV transmission. HPTN 052 is the first randomized clinical trial to show that treating an HIV-infected individual with ART can reduce the risk of sexual transmission of HIV to an uninfected partner.

"This is excellent news," said Dr. Myron Cohen, HPTN 052 Principal Investigator and Associate Vice Chancellor for Global Health and Director of the Institute of Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill. "The study was designed to evaluate the benefit to the sexual partner as well as the benefit to the HIV-infected person. This is the first randomized clinical trial to definitively indicate that an HIV-infected individual can reduce sexual transmission of HIV to an uninfected partner by beginning antiretroviral therapy sooner. HPTN recognizes the significant contribution that this study's participants have made to furthering the progress in HIV treatment and prevention. We are very grateful for their participation."



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**Robin Washington**  
**SVP and Chief Financial Officer**

July 26, 2011

# Financial Highlights: A Snapshot of Q2 2011

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- ◆ Total revenues of \$2.14 billion
- ◆ Product sales of \$2.04 billion
- ◆ Net income per diluted share of \$0.93;  
Non-GAAP net income per diluted share of \$1.00\*
- ◆ \$5.50 billion in cash, cash equivalents and marketable securities as of June 30, 2011
- ◆ Cash flow from operations of \$943.3 million

\* Excludes the after-tax impact of acquisition-related, restructuring and stock-based compensation expenses.

# Financial Highlights

(US\$ millions, except per share amounts)

	Q2 2011	Q2 2010	% Change
<b>Product sales</b>	<b>\$ 2,040</b>	<b>\$ 1,806</b>	13%
Antiviral products	1,764	1,592	11%
Atripla	822	716	15%
Truvada	711	642	11%
Viread	186	176	5%
Hepsera	39	51	-25%
AmBisome	89	78	13%
Letairis	74	60	22%
Ranexa	86	60	42%
Royalty, contract and other revenues	98	121	-19%
<b>Total revenues</b>	<b>\$ 2,137</b>	<b>\$ 1,927</b>	11%
<b>Non-GAAP costs and expenses*</b>	<b>\$ 1,053</b>	<b>\$ 867</b>	21%
COGS*	514	436	
R&D*	263	207	
SG&A*	276	224	
<b>Non-GAAP net income*</b>	<b>\$ 798</b>	<b>\$ 761</b>	4%
<b>Non-GAAP EPS*</b>	<b>\$ 1.00</b>	<b>\$ 0.85</b>	18%
<b>Cash, cash equivalents and marketable securities</b>	<b>\$ 5,499</b>		

\*Non-GAAP net income, EPS, costs and expenses exclude the impact of acquisition-related, restructuring and stock-based compensation expenses where applicable.

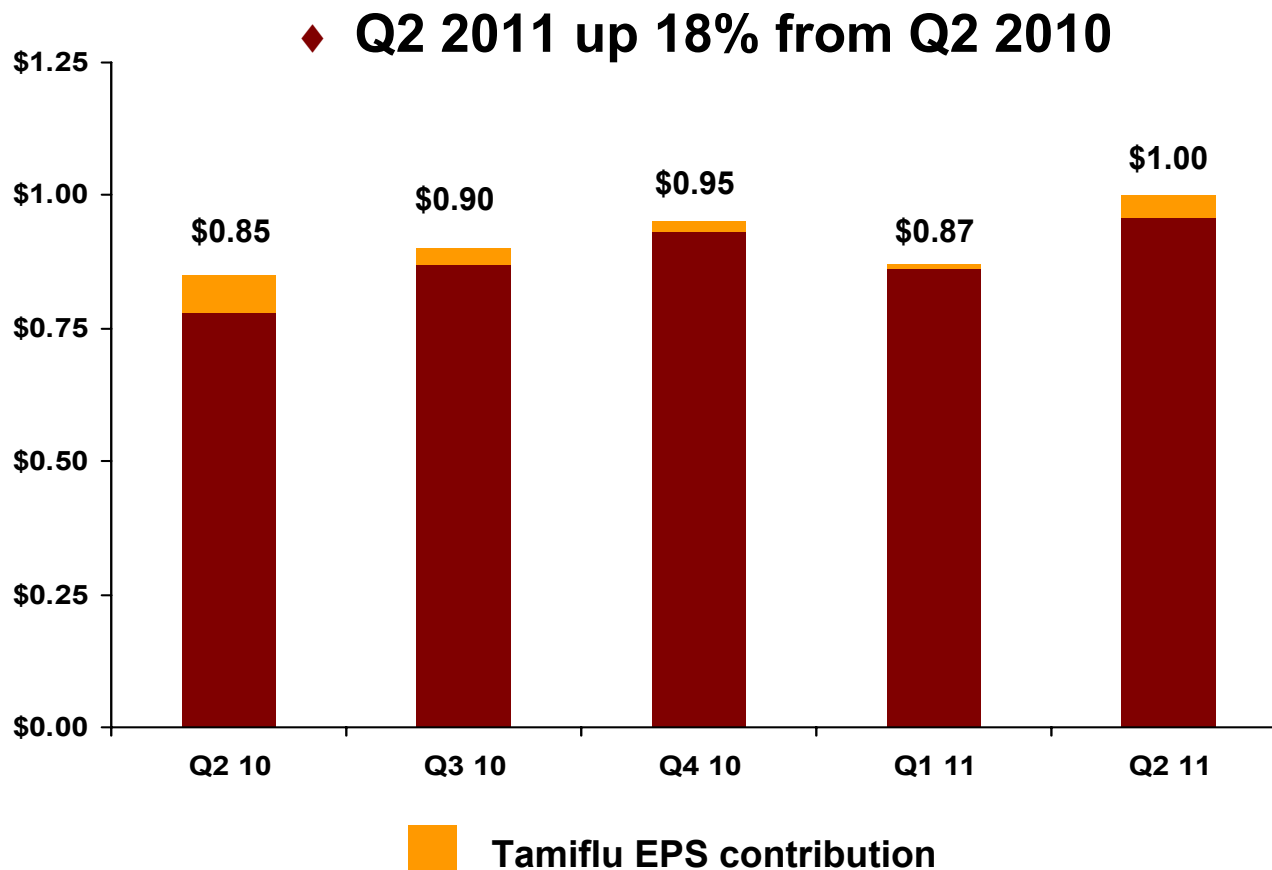


# 3 Year, \$5 Billion Share Repurchase Program Activity\*

	Type of Repurchase	Dollar Amount (In Millions)	Share Amount	Average Purchase Price
Q2 2010	Open Market	\$853.1	23,622,700	\$36.11
Q3 2010	Open Market	\$1,552.3	45,791,967	\$33.90
Q4 2010	Open Market	\$615.4	16,391,300	\$37.54
Q1 2011	Open Market	\$548.5	14,020,543	\$39.12
Q2 2011	Open Market	\$723.9	17,825,730	\$40.61
<b>Totals</b>		<b>\$4,293.2</b>	<b>117,652,240</b>	<b>\$36.49</b>

\* \$5.0 billion share repurchase program authorized May 10, 2010, with \$706.8 million remaining as of June 30, 2011.

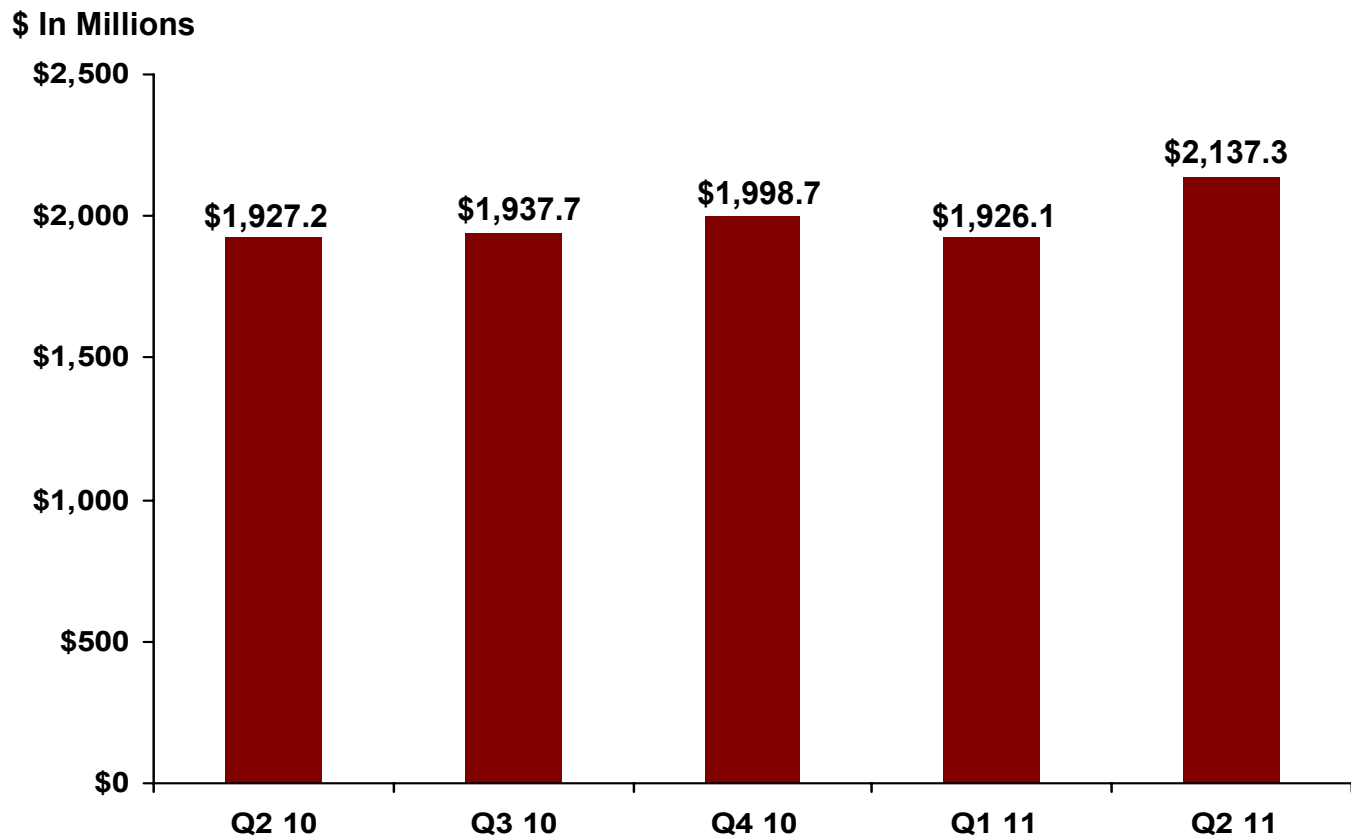
# Financial Highlights: Non-GAAP Diluted EPS



Note: For the 2010 and 2011 periods, non-GAAP diluted EPS excludes the after-tax impact of acquisition-related, restructuring and stock-based compensation expenses.

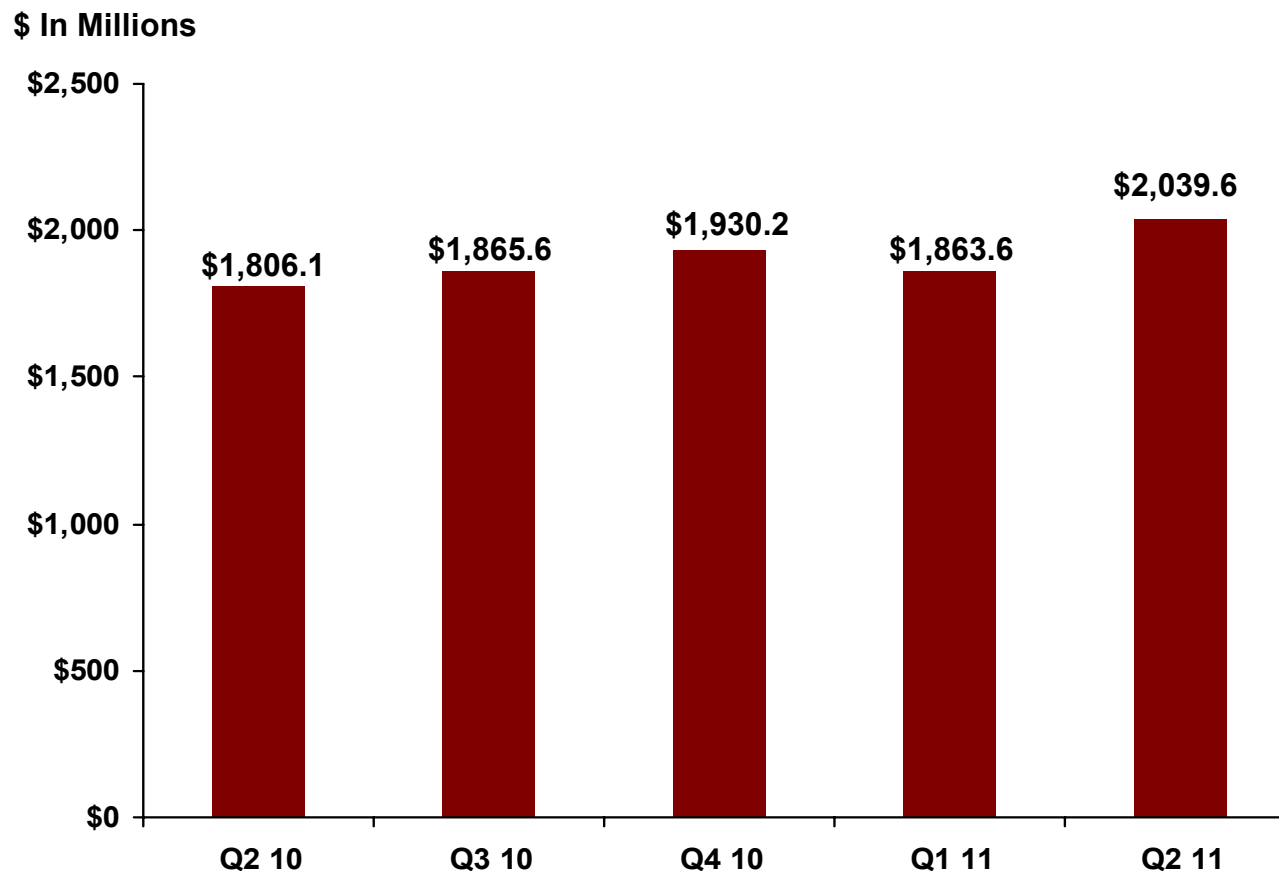
# Financial Highlights: Total Revenues

◆ Q2 2011 up 11% over Q2 2010



# Financial Highlights: Total Product Sales

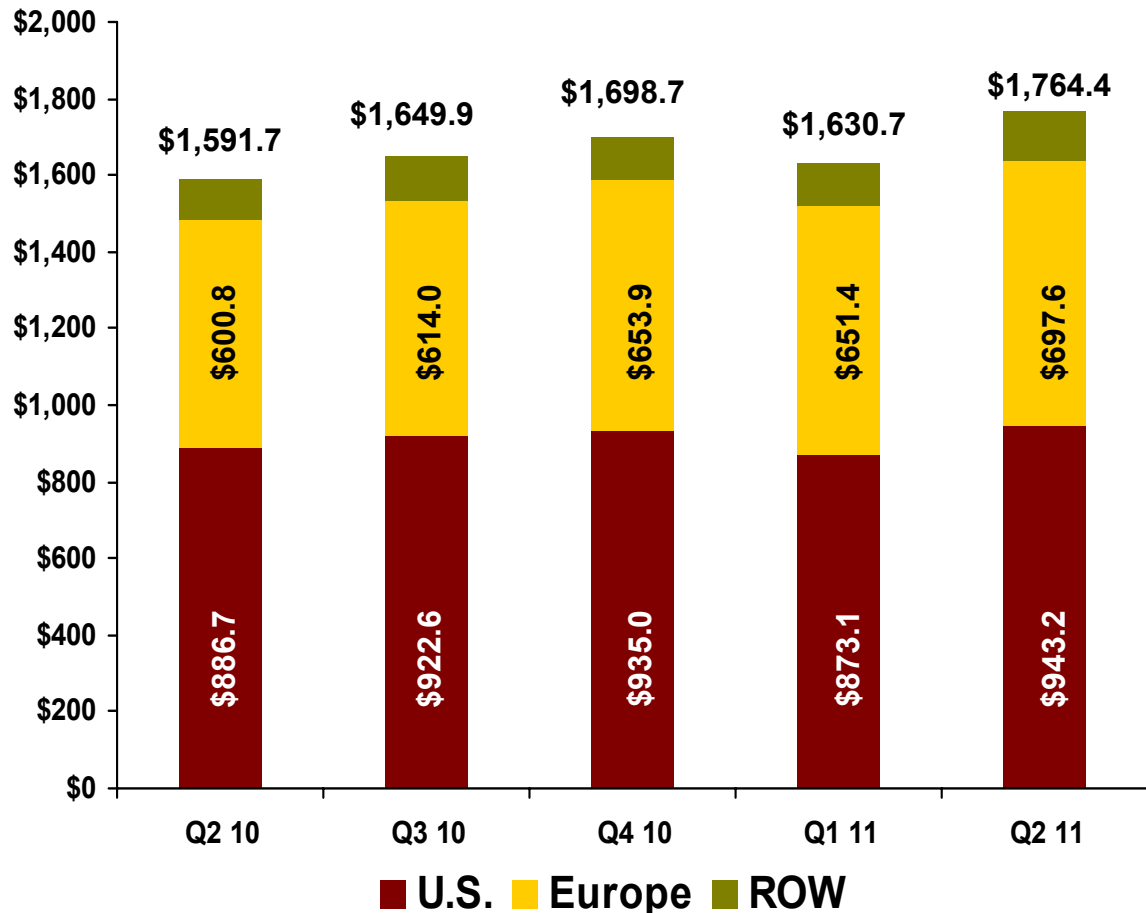
◆ Q2 2011 up 13% over Q2 2010



# Antiviral Franchise Q2 2011 Financial Performance and Key Metrics

◆ Q2 2011 up 11% from Q2 2010

\$ In Millions



## Key Metrics

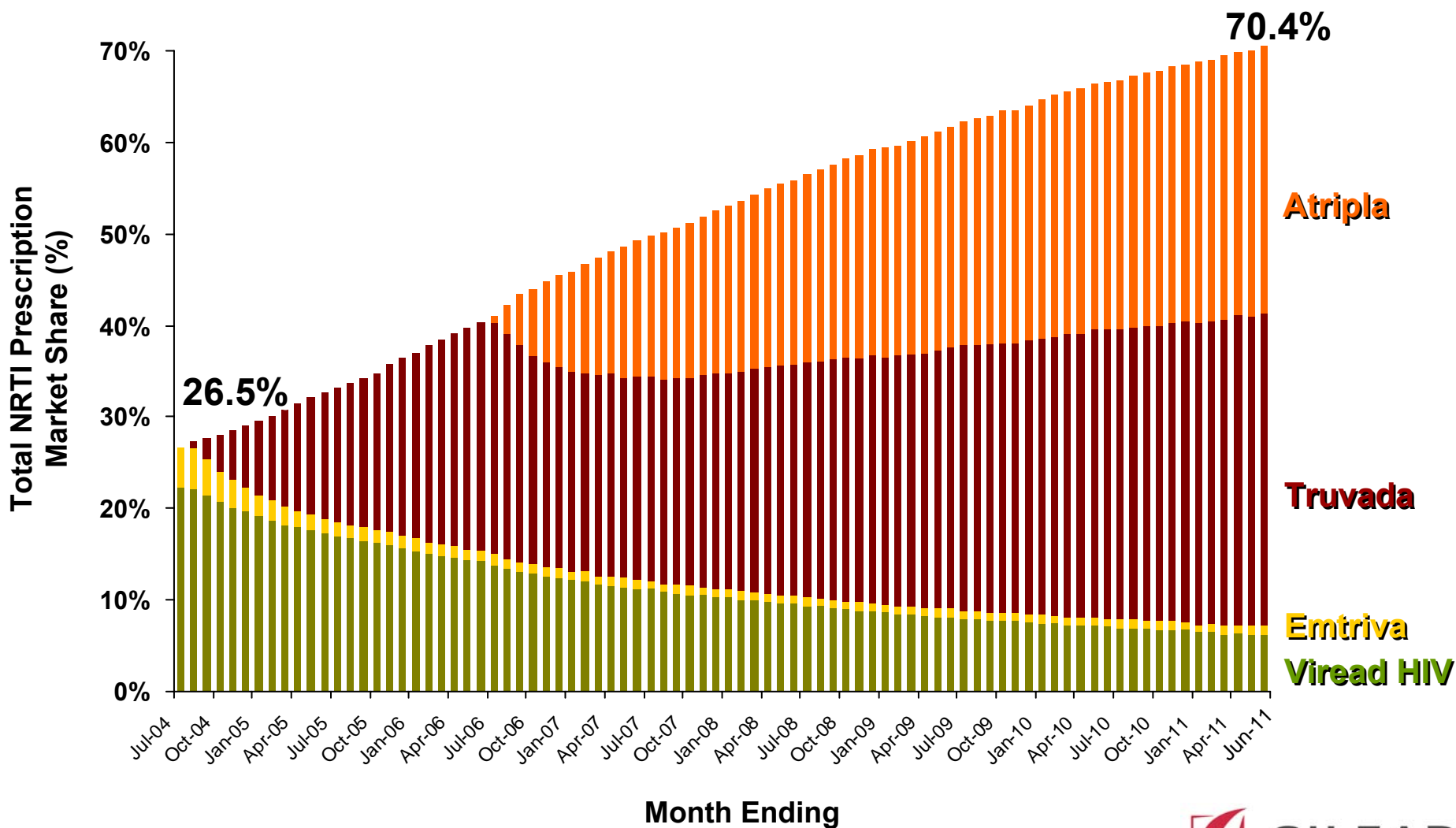
U.S.:

- ◆ Quarter-on-quarter inventory levels stable
- ◆ Quarter-on-quarter non-retail purchasing slightly below retail prescription growth
- ◆ Year-over-year revenue growth aided by April 1<sup>st</sup> Truvada price increase

EU:

- ◆ Quarter-on-quarter revenue growth driven by:
  - Increase in patient demand
  - Summer purchasing

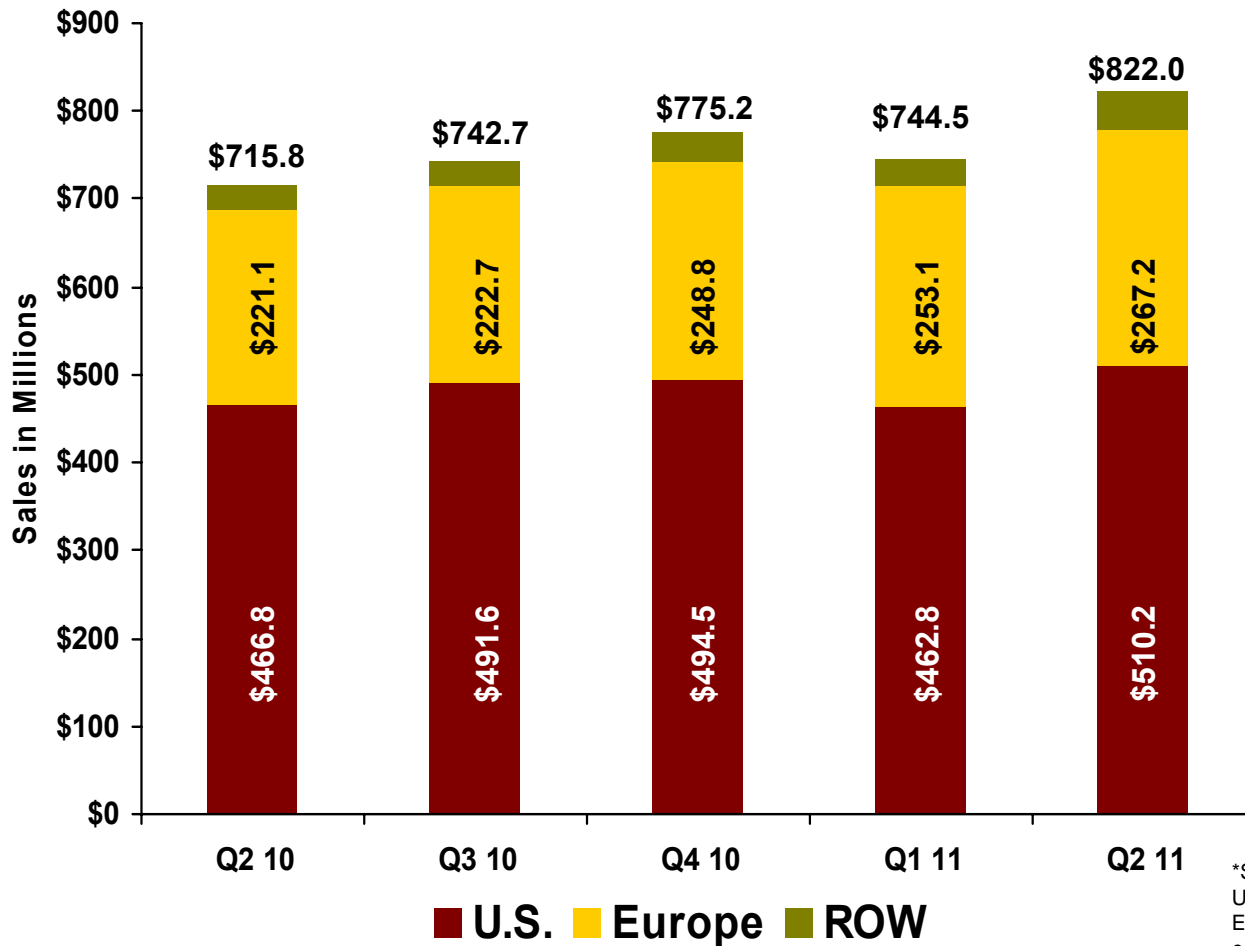
# Gilead's HIV Franchise Continues to Gain Share in the U.S.



Based on Source® monthly PHAST, Jul 04 to Jun 11, Wolters Kluwer Health

# Atripla Q2 2011 Financial Performance and Key Metrics

◆ Q2 2011 up 15% from Q2 2010



### Key Metrics\*

**U.S.:**

- ◆ Most prescribed regimen in HIV with 37% of all treated patients
- ◆ Captured 55% of naïve patient share

**EU:**

- ◆ Most prescribed regimen in HIV with 24% of all treated patients across the Big 5 markets
- ◆ Captured 24% of naïve patient share

Note: efavirenz (the active pharmaceutical component in Atripla purchased from BMS) accounted for approximately 37% of Atripla sales in Q2 2011 which represented \$298.4 million to be paid to BMS.

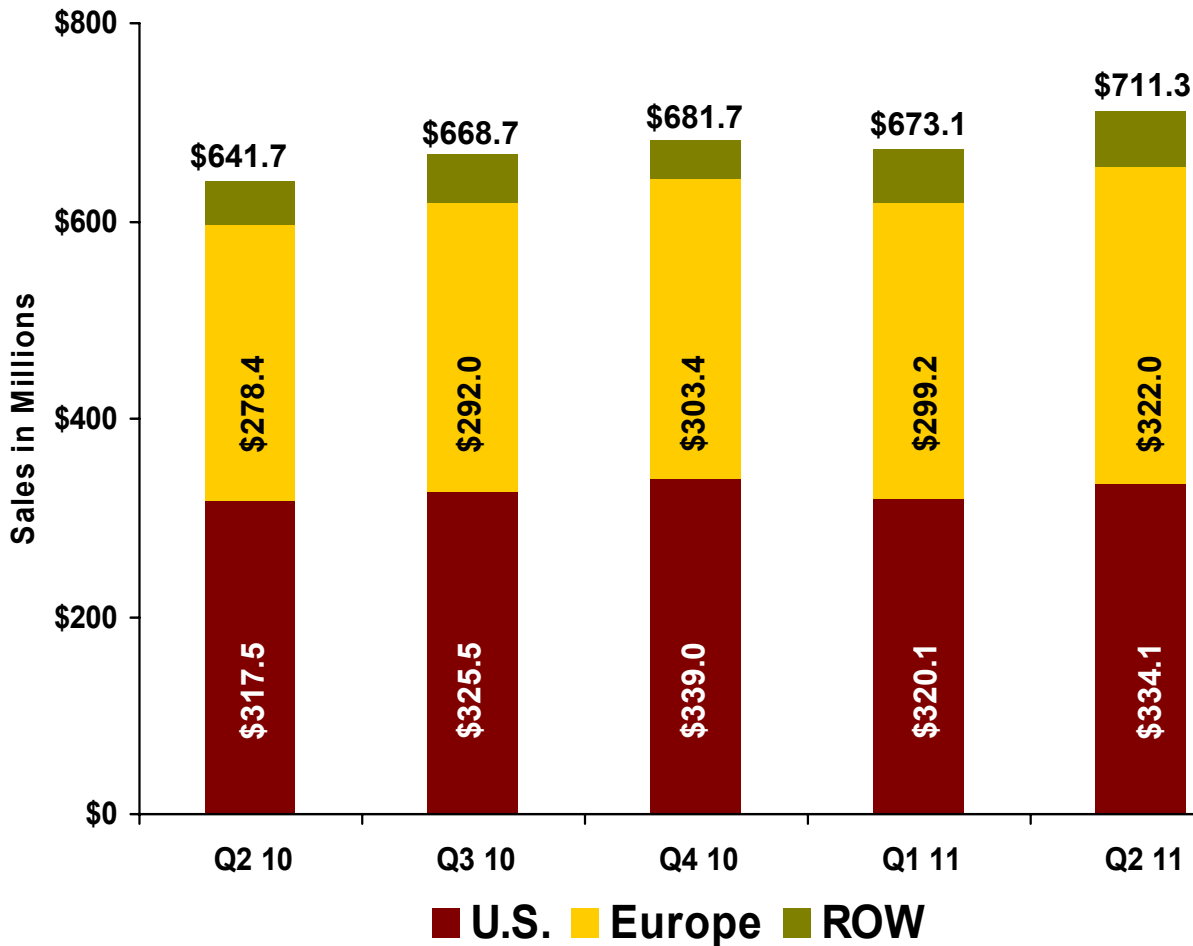
\*Sources:

U.S. data from Synovate Healthcare U.S. HIV Monitor Q1 2011. EU data from Synovate EU HIV Scope Q2 2011 and Gilead estimates.

Note: Atripla does not have a naïve indication in Europe and is not promoted to this group of patients.

# Truvada Q2 2011 Financial Performance and Key Metrics

◆ Q2 2011 up 11% from Q2 2010



## Key Metrics\*

U.S.:

- ◆ Most prescribed product in HIV with 38% of all treated patients
- ◆ Captured 36% of naïve patient share

EU:

- ◆ Most prescribed product in HIV with 44% of all treated patients
- ◆ Captured 53% of naïve patient share

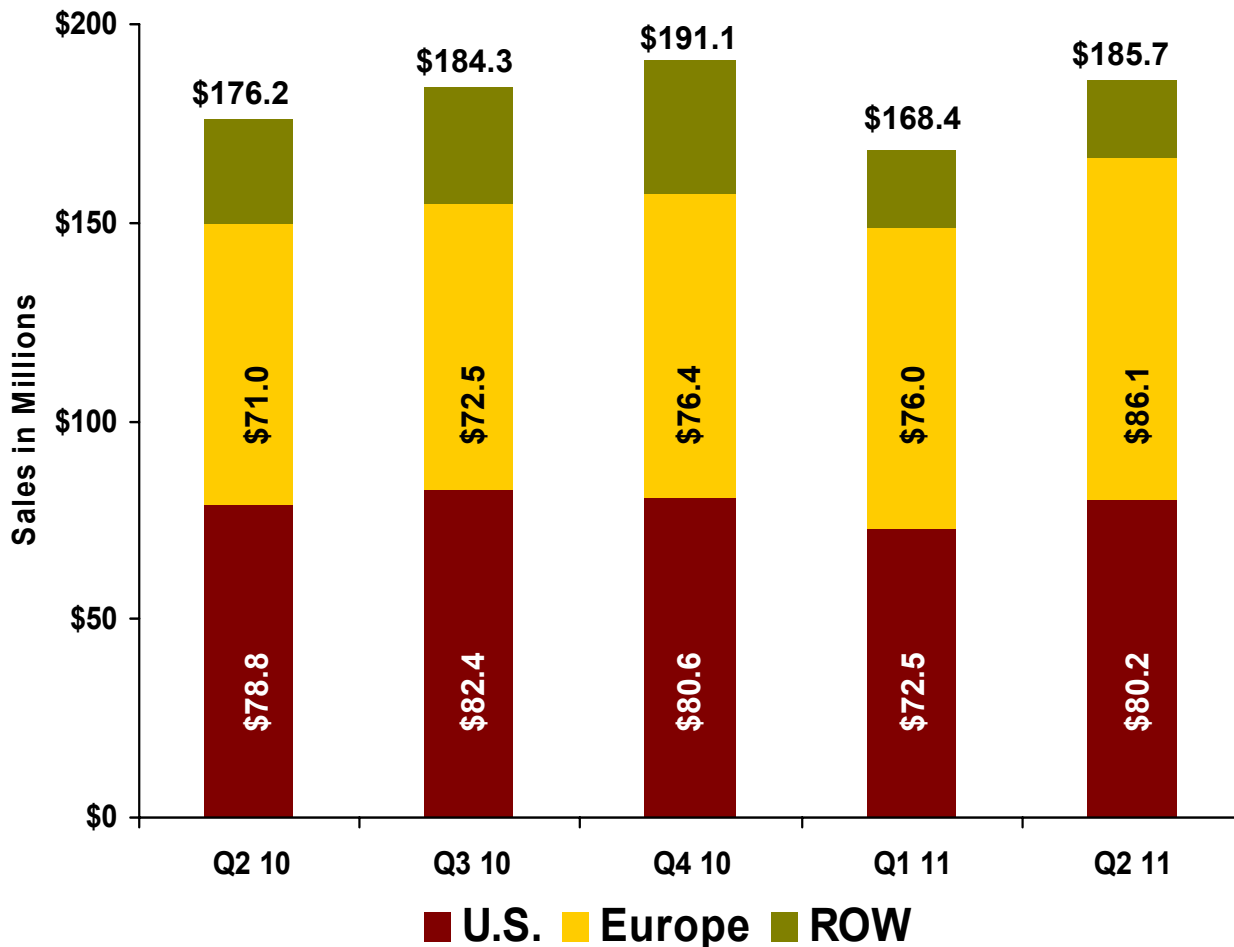
\*Sources:

U.S. data from Synovate Healthcare U.S. HIV Monitor Q1 2011.

EU data from Synovate Monitor Q1 2011 & SCOPE Q2 2011 and Gilead estimates.

# Viread Q2 2011 Financial Performance and Key Metrics

◆ Q2 2011 up 5% from Q2 2010



## Key Metrics\*

U.S.:

- ◆ #1 prescribed product for HBV; captured 46% total market share
- ◆ Captured 51% of HBV naïve patient share

EU:

- ◆ 33% total HBV market share across the Big 5
- ◆ Led entecavir in six of the top seven markets

ROW:

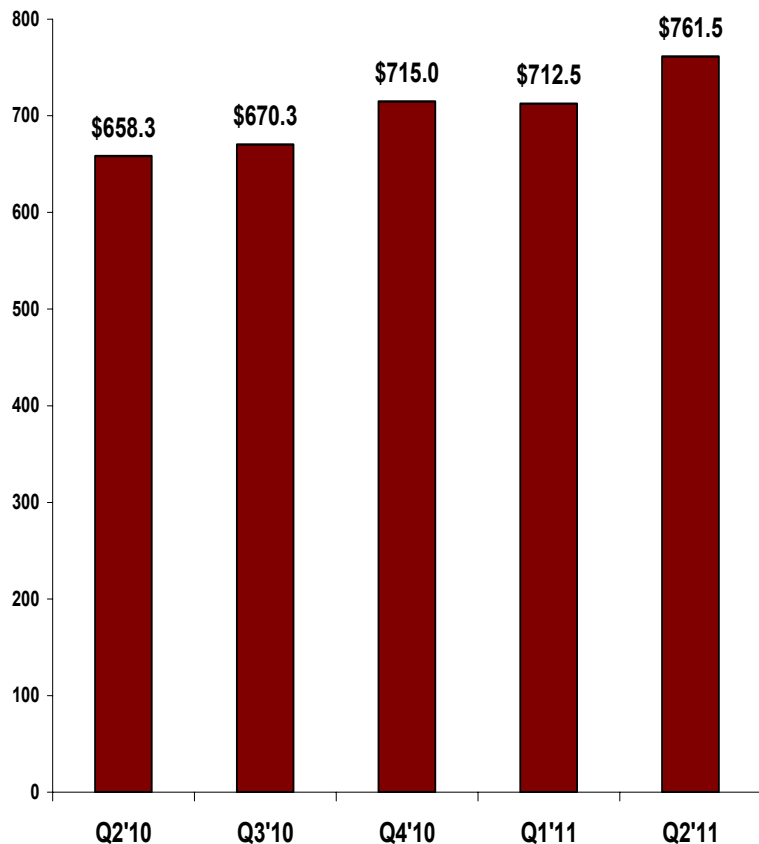
- ◆ Quarter-on-quarter revenue decrease driven by lower sales in Latin America

\* U.S. data from Synovate Healthcare U.S. Monitor Q1 2011.

EU data from IMS/GERS & Gilead proprietary method for Viread January 2011.

# European Total Product Sales Increased 13% Year-over-Year Excluding FX

\$ In Millions, Net Sales\*



- ◆ FX impact to international revenues was favorable \$9.3 million QoQ and \$27.3 million YoY
- ◆ FX impact to pre-tax income was unfavorable \$1.8 million QoQ and favorable \$9.7 million YoY
- ◆ YTD FX impact to international revenues was favorable \$23.2 million and \$1.6 million to pre-tax income

	Q2'11	Q2'10	YoY	Excl FX
Atripla	\$267	\$221	21%	18%
Truvada	\$322	\$278	16%	13%
Viread	\$86	\$71	21%	19%
Hepsera	\$21	\$29	(28%)	(\$29%)
AmBisome	\$59	\$55	9%	7%
Other	\$6	\$5	33%	30%
<b>Total</b>	<b>\$762</b>	<b>\$658</b>	<b>16%</b>	<b>13%</b>

\* Includes all regions of Europe included in the product sales breakdown in our earnings press release.

# Other Product Sales

Product (\$ in Millions)	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	%▲ From Q2 2010
<b>AmBisome</b>	\$78.2	\$75.1	\$75.5	\$78.5	\$88.6	+13%
<b>Letairis</b>	\$60.3	\$60.4	\$64.0	\$62.2	\$73.6	+22%
<b>Ranexa</b>	\$60.5	\$60.3	\$67.8	\$68.3	\$86.1*	+42%
<b>Hepsera</b>	\$51.3	\$47.5	\$43.6	\$38.1	\$38.7	-25%
<b>Cayston</b>	\$10.5	\$14.7	\$19.4	\$19.8	\$21.5	+106%

\* Includes a one-time \$8.3 million adjustment to sales return reserves.

# Letairis for Pulmonary Arterial Hypertension

- ◆ Q2 11 product sales of \$73.6 million
- ◆ FDA label update (3/4/2011)
  - Removal of Black Box Warning for potential liver injury
    - No requirement for monthly liver testing
    - No requirement for patient counseling related to effects on the liver
  - Monthly pregnancy testing will continue to be required for females of childbearing potential (~15% of patients)
- ◆ Immediate increase in Letairis uptake post label/REMS update
  - 18% revenue growth Q2 versus Q1
  - >350 speaker programs completed since label update
- ◆ Letairis Q2 11 patient makeup – 40% monotherapy/new, 29% monotherapy/Tracleer switch, 31% combination\*
- ◆ AMBITION trial ~ 20% enrolled



\* Add on therapy to PDE-5 and Prostanoids.

# Ranexa for Chronic Angina

- ◆ Q2 11 product sales of \$86.1\* million
- ◆ 155,000 patients on Ranexa in the U.S.
- ◆ 23% TRx growth Q2 11 versus Q2 10
- ◆ Movement to 1,000 mg dose (19% of TRx)
- ◆ New studies to be initiated in 2H 2011:
  - Phase IV program in coronary artery disease patients with type 2 diabetes mellitus
  - Phase III program in patients with type 2 diabetes mellitus
  - Phase III study in patients with a history of angina and incomplete revascularization post-PCI

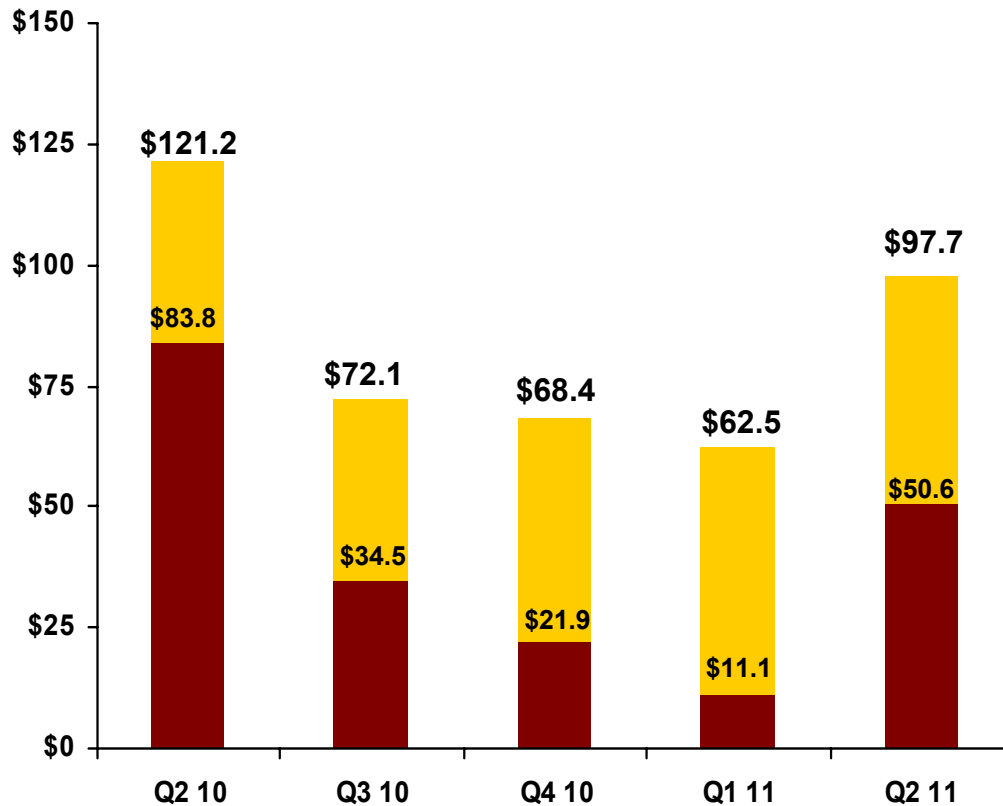


\* Includes a one-time returns reserve adjustment of \$8.3 million.

# Total Royalty, Contract and Other Revenues

◆ Q2 2011 down 19% from Q2 2010

\$ In Millions



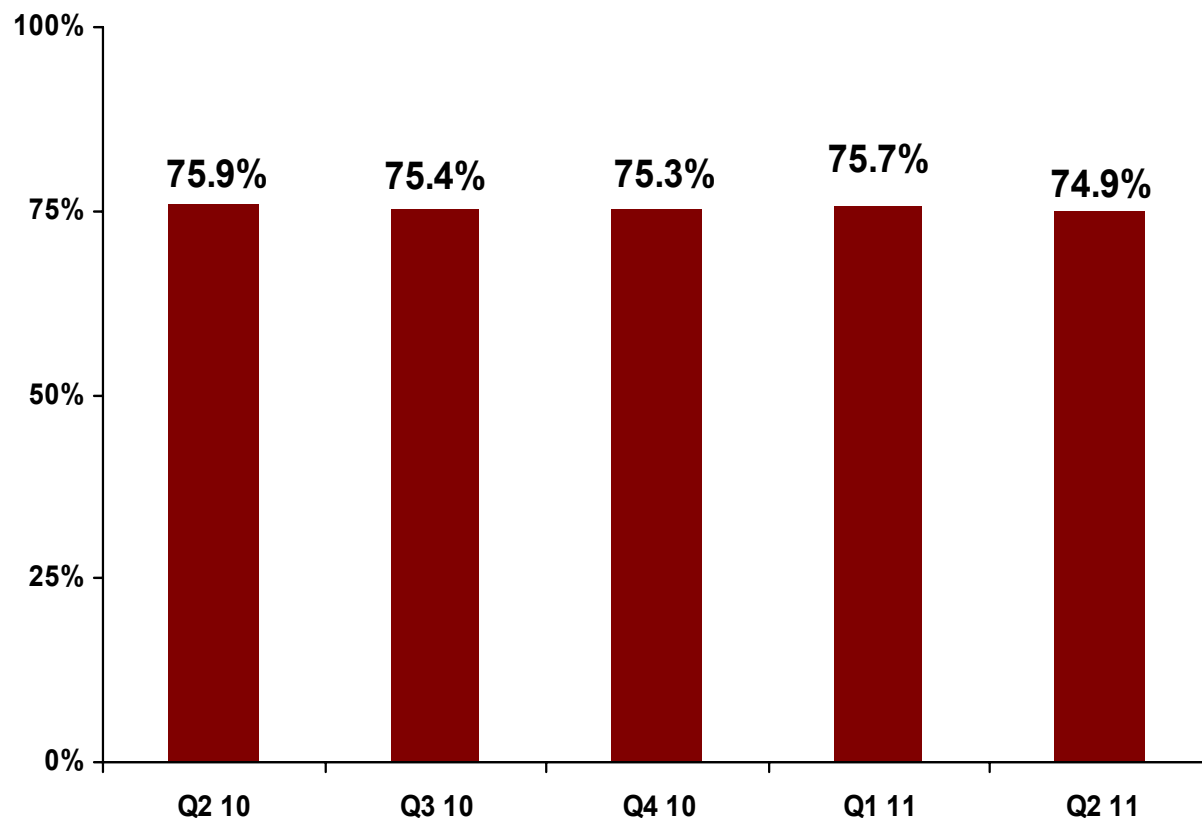
■ Tamiflu ■ Other

## Key Metrics

- ◆ Q2 2011 decrease from Q2 2010 due to:
  - Lower Q2 2011 Tamiflu royalties from Roche of \$50.6 million, down 40% from \$83.8 million in Q2 2010 as pandemic planning initiatives worldwide have declined

# Non-GAAP Product Gross Margins

◆ Q2 2011 down 1% from Q2 2010



## Key Metrics

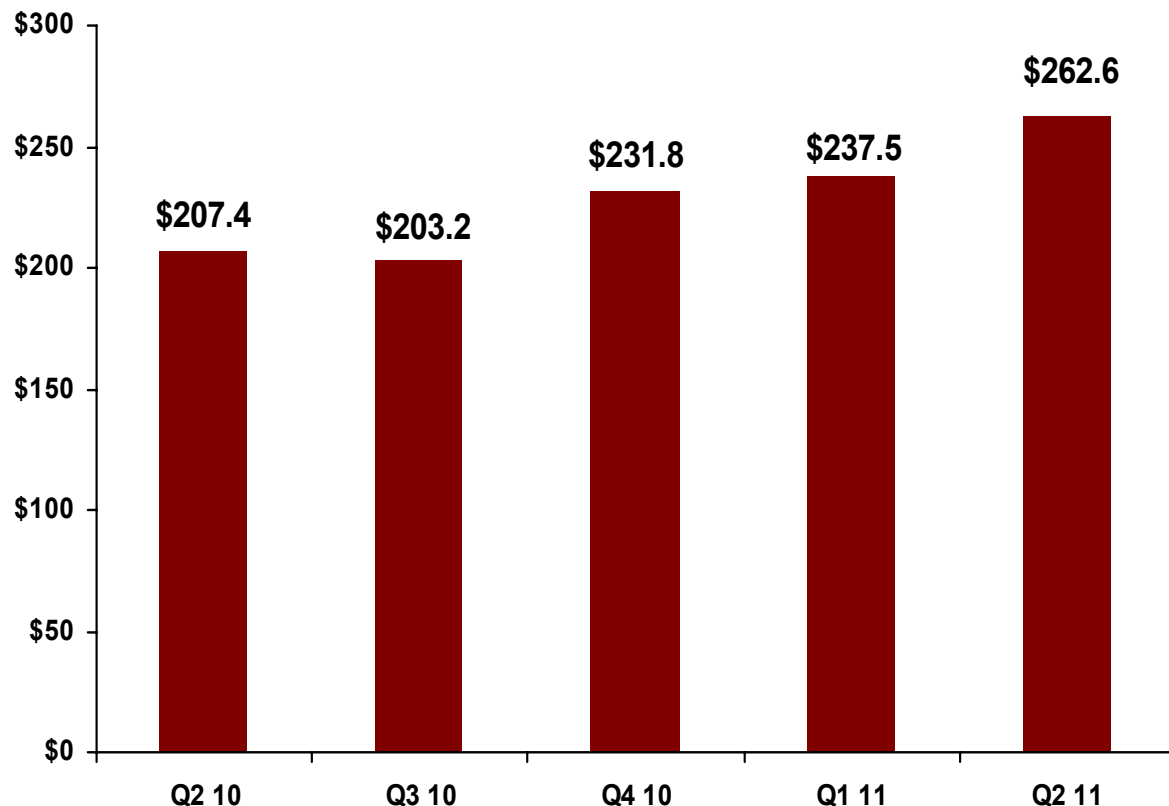
- ◆ Q2 2011 lower from Q2 2010 driven primarily by:
  - Impact from U.S. healthcare reform and pricing pressures in Europe

Note: For the 2010 and 2011 periods, non-GAAP product gross margins exclude acquisition-related and stock-based compensation expenses.

# Non-GAAP R&D Expenses

◆ Q2 2011 up 27% from Q2 2010

\$ In Millions



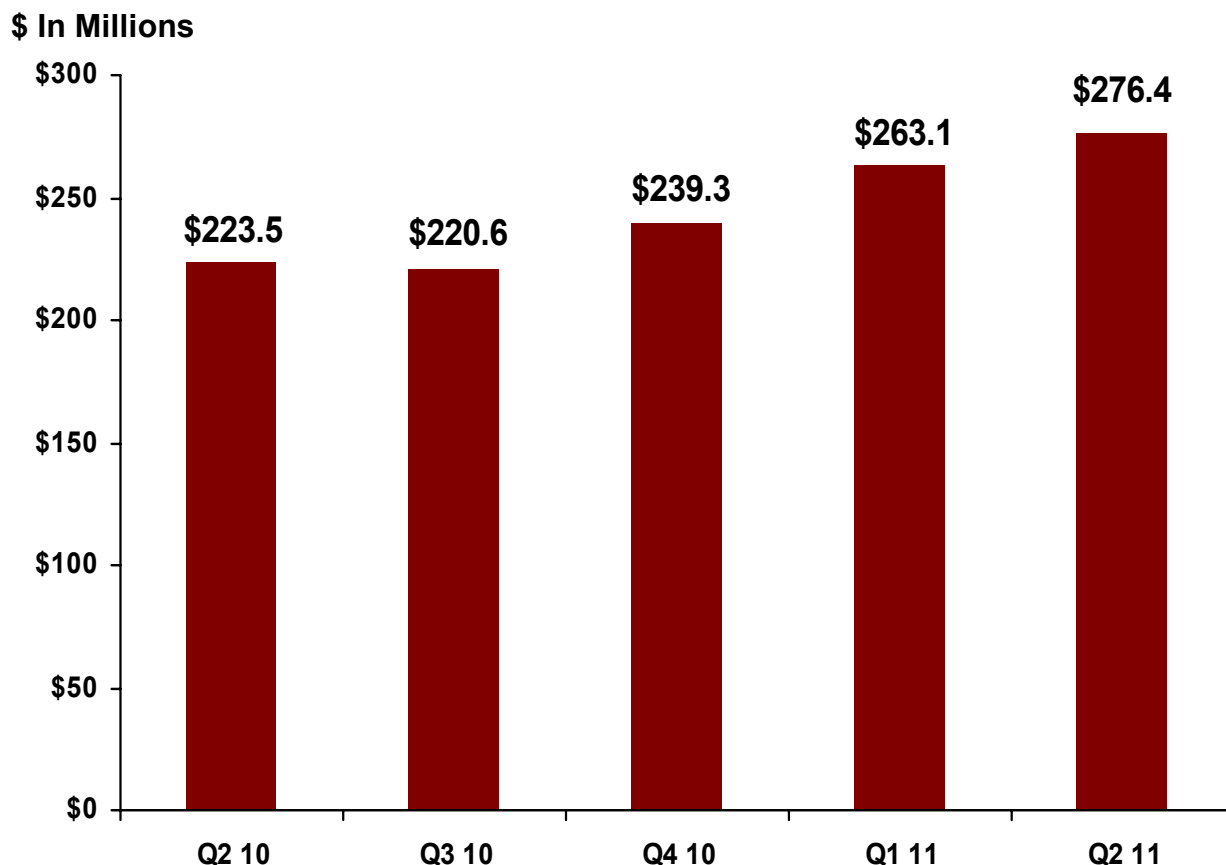
## Key Metrics

- ◆ Higher R&D expenses in Q2 2011 over Q2 2010 due primarily to:
  - Increased clinical activities and expenses associated with acquisitions, collaborations and the ongoing growth of Gilead's business

Note: For the 2010 and 2011 periods, non-GAAP R&D expenses exclude acquisition-related, restructuring and stock-based compensation expenses.

# Non-GAAP SG&A Expenses

◆ Q2 2011 up 24% from Q2 2010



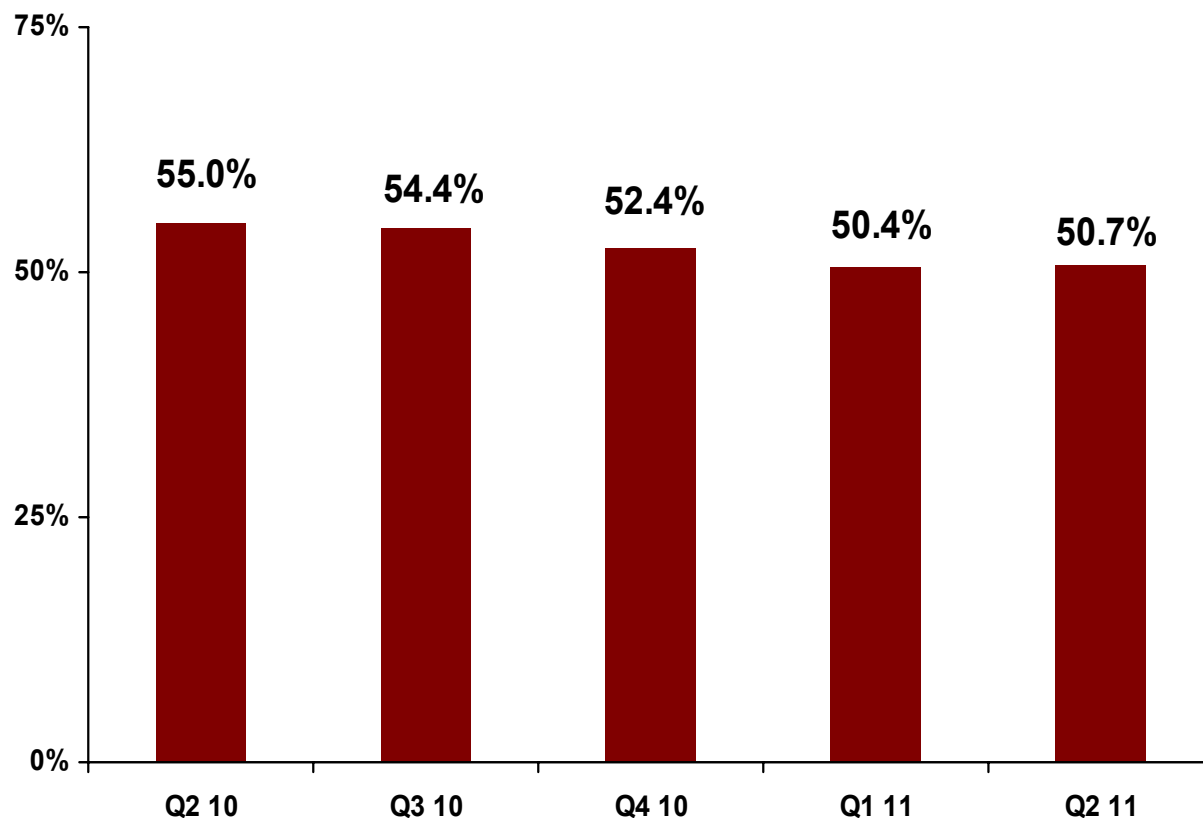
Note: For the 2010 and 2011 periods, non-GAAP SG&A expenses exclude acquisition-related, restructuring and stock-based compensation expenses.

## Key Metrics

- ◆ Higher SG&A expenses in Q2 2011 over Q2 2010 driven primarily by:
  - Increased expenses associated with the ongoing growth of Gilead's business
  - Pharmaceutical excise tax of ~ \$12 million in Q2 2011
    - estimated at ~\$50 million for FY 2011

# Non-GAAP Operating Margins

◆ Q2 2011 down 8% from Q2 2010



## Key Metrics

- ◆ Q2 2011 decrease from Q2 2010 driven primarily by:
  - Increased investments in R&D
  - Increased SG&A driven predominantly by the pharmaceutical excise tax
  - Tamiflu royalties of \$50.6 million, which were down 40 percent as pandemic planning initiatives worldwide have declined

Note: For the 2010 and 2011 periods, non-GAAP operating margins exclude acquisition-related, restructuring and stock-based compensation expenses.

# Effective Tax Rate

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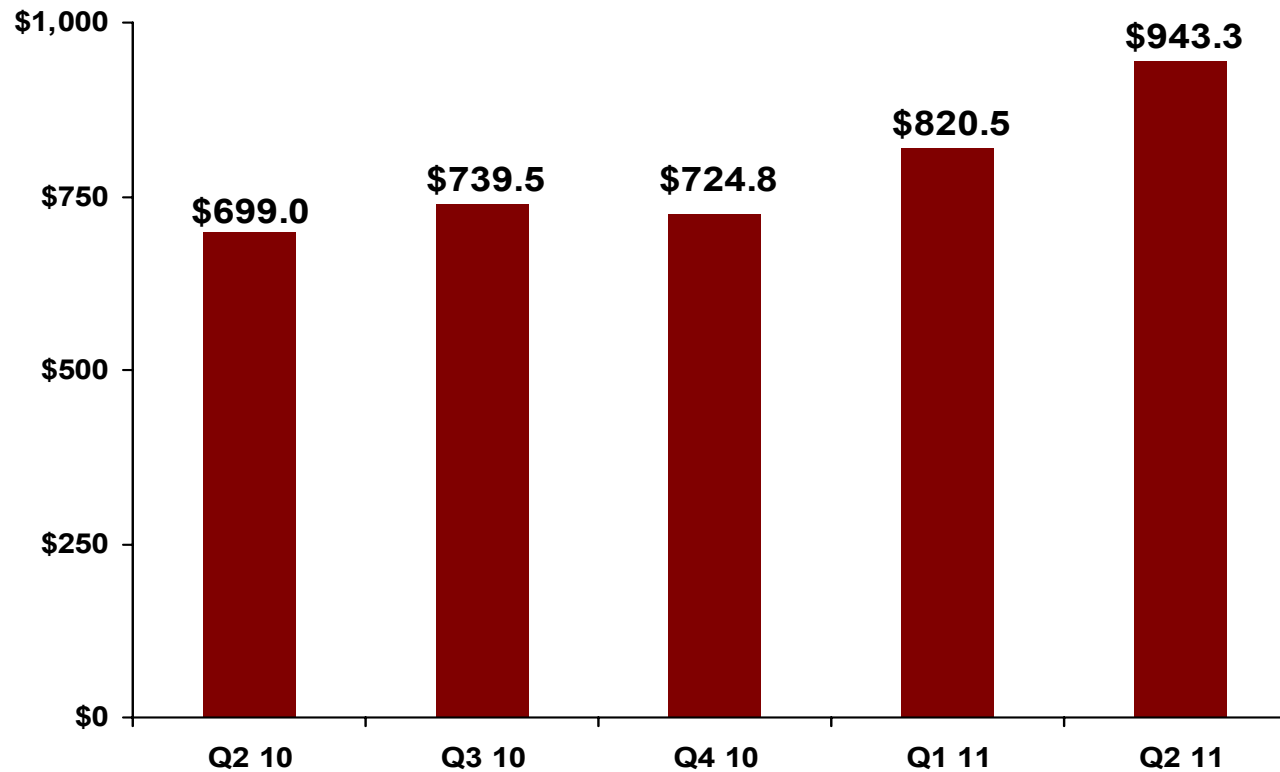
	Q2 2010	Q1 2011	Q2 2011	YTD 2011
<b>Effective Tax Rate</b>	28.6%	26.0%	24.4%	25.2%

- ◆ Effective tax rate decreased year-over-year driven primarily by:
  - Research and development tax credit and lower state taxes

# Financial Highlights: Operating Cash Flows

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\$ In Millions



# Other Selected Financial Information

	Mar. 31, 2011	Jun. 30, 2011
<b>Cash, Cash Equivalents &amp; Marketable Securities</b> (\$ in Millions)	\$6,356.3	\$5,499.3
<b>Interest Income/(Expense) and Other Income, net</b> (\$ in millions)	(\$27.4)	(\$34.1)
<b>Inventories</b> (\$ in Millions)	\$1,304.5	\$1,321.6
<b>Days Sales Outstanding</b> (Accounts Receivable)	73	71
<b>Common Shares Repurchased During the Quarter*</b> (\$ in Millions)	\$548.5	\$723.9
<b>Diluted Shares Used in Per Share Calculation for the Quarter (Non-GAAP)</b> (In thousands)	809,827	798,790
<b>Diluted Shares Used in Per Share Calculation for the Quarter (GAAP)</b> (In thousands)	811,857	800,800
<b>Common Shares Outstanding</b> (In thousands)	791,470	776,405

\* As of June 30, 2011 Gilead had \$706.8 million remaining in its \$5.0 billion share repurchase program authorized by its Board on May 10, 2010.

# Full Year 2011 Guidance

*(\$ in millions, except percentages and per share amounts)*

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First provided on 1/25/11,  
reiterated on 4/20/11 and 7/26/11

<b>Net Product Sales</b>	<b>\$ 7,900 – \$ 8,100</b>
<b>Non-GAAP Product Gross Margin*</b>	<b>74% – 76%</b>
<b>Non-GAAP Expenses</b>	
<b>R &amp; D*</b>	<b>\$ 950 – \$ 1,000</b>
<b>SG &amp; A*</b>	<b>\$ 1,000 – \$ 1,050</b>
<b>Effective Tax Rate</b>	<b>25% – 27%</b>
<b>Diluted EPS Impact of Acquisition-Related and Stock-Based Compensation Expenses</b>	<b>\$ 0.25 – \$ 0.28</b>

\* Non-GAAP product gross margin and expenses exclude the impact of acquisition-related, and stock-based compensation expenses where applicable.

# Full Year 2011 Guidance

(\$ in millions, except percentages and per share amounts)

<b>Projected product gross margin GAAP to non-GAAP reconciliation:</b>	<b>7/26/11</b>
GAAP projected product gross margin	73% - 75%
Acquisition-related amortization of purchased intangibles	1% - 1%
Non-GAAP projected product gross margin*	74% - 76%
 <b>Projected research and development expenses GAAP to non-GAAP reconciliation:</b>	
GAAP projected research and development expenses	\$1,036 - \$1,096
Stock-based compensation expenses	(\$86 - \$96)
Non-GAAP projected research and development expenses	\$950 - \$1,000
 <b>Projected selling, general and administrative expenses GAAP to non-GAAP reconciliation:</b>	
GAAP projected selling, general and administrative expenses	\$1,101 - \$1,162
Stock-based compensation expenses	(\$101 - \$112)
Non-GAAP projected selling, general and administrative expenses	\$1,000 - \$1,050
 <b>Projected diluted EPS impact of acquisition-related and stock-based compensation expenses:</b>	
Acquisition-related expenses	\$0.06 - \$0.06
Stock-based compensation expenses	\$0.19 - \$0.22
Projected diluted EPS impact of acquisition-related and stock-based compensation expenses	\$0.25 - \$0.28

\* Stock-based compensation expenses have a less than one percent impact on non-GAAP projected product gross margin



# GILEAD

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Improving Lives.



**John F. Milligan, Ph.D.**  
**President and Chief Operating Officer**

July 26, 2011

# Truvada / Edurant Single-Tablet Regimen (STR)

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- ◆ Phase III studies of Edurant (ECHO / THRIVE) demonstrated non-inferiority to efavirenz
- ◆ STR registration status:
  - US: Resubmitted NDA with PDUFA date of August 10, 2011
  - EU: Submitted on September 3, 2010; anticipate Q4 11 approval
- ◆ Three key supportive studies underway
  - Switch from Atripla and PI-containing regimens
  - Head-to-head versus Atripla
- ◆ Improved economics versus Atripla

# Phase III Programs for Elvitegravir, Cobicistat and Quad Nearing Completion

## Elvitegravir

**Study 145**  
Elvitegravir vs  
Raltegravir  
N = 717 (1:1),  
Treatment-experienced  
Patients  
(Background regimen  
requires a PI + RTV)

**Primary Endpoint of  
Non-inferiority Achieved**

## Cobicistat

**Study 114**  
ATV + Cobicistat +  
Truvada  
vs ATV+RTV + Truvada  
N = 693 (1:1),  
Treatment-naïve  
Patients

**Data in  
Q4 11**

## Quad (EVG/TVD/Cobicistat)

**Study 102**  
QUAD vs Atripla  
N = 701 (1:1),  
Treatment-naïve  
Patients

**Study 103**  
QUAD vs ATV + RTV +  
Truvada  
N = 707 (1:1),  
Treatment-naïve  
Patients

**Data in  
Q3 11**

*Four Cross-referenced Studies to  
Support Regulatory Filings*

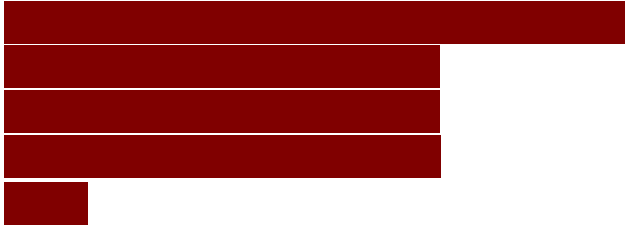
PI = protease inhibitor  
RTV = ritonavir  
ATV = atazanavir

# Pipeline Product Candidates

Phase			Filed for Marketing Approval
I	II	III	

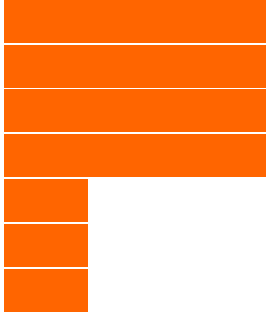
### HIV/AIDS

- Truvada/Rilpivirine STR
- Elvitegravir (integrase inhibitor)
- Integrase STR "Quad" (elvitegravir/FTC/TDF/cobicistat)
- Cobicistat (PK enhancer)
- GS 7340 (nucleotide reverse transcriptase inhibitor)



### Liver Disease

- GS 9190 (non-nuc NS5B site 1 polymerase inhibitor) - HCV
- GS 9256 (NS3 protease inhibitor) - HCV
- GS 9451 (NS3 protease inhibitor) - HCV
- GS 5885 (NS5A inhibitor) - HCV
- GS 6620 (nucleotide NS5B polymerase inhibitor) - HCV
- GS 9620 (TLR-7 agonist) - HCV/HBV
- GS 9669 (non-nuc NS5B polymerase site 2 inhibitor) - HCV



# Pipeline Product Candidates (cont'd)

	Phase			Filed for Marketing Approval
	I	II	III	
<b>Respiratory</b>				
Aztreonam for Inhalation Solution - <i>Bronchiectasis</i>		█		
GS 6624 (monoclonal antibody) - <i>IPF</i>	█			
<b>Cardiovascular/Metabolic</b>				
Cicletanine (antihypertensive) - <i>PAH</i>		█		
Ranolazine (late sodium current inhibitor) - <i>CAD in Type 2 Diabetes Mellitus</i>		█		
<b>Inflammation/Oncology</b>				
GS 1101 (PI3K delta inhibitor) - <i>iNHL</i>		█		
GS 1101 (PI3K delta inhibitor) - <i>CLL</i>		█		
GS 6624 (monoclonal antibody) - <i>Myelofibrosis</i>		█		
GS 6624 (monoclonal antibody) - <i>Solid Tumors</i>	█			

# Anticipated Key Pipeline Milestones in 2011

## HIV/AIDS

Truvada / Rilpivirine STR	Q3	<input type="checkbox"/> U.S. marketing approval and launch (PDUFA date 8/10/11)
	Q4	<input type="checkbox"/> EU marketing approval and initial launches
Quad	Q3	<input type="checkbox"/> Unblinding of both Phase III studies
Cobicistat	Q4	<input type="checkbox"/> Unblinding of Phase III study
GS 7340	Q4	<input type="checkbox"/> Initiate Ph II study

## Liver Disease

GS 9190	Q4	<input type="checkbox"/> Commence second, four drug, all oral antiviral Ph II study in treatment-experienced HCV patients
GS 9451 GS 5885	Q4	<input type="checkbox"/> Commence third, four drug, all oral antiviral Ph II study in PEG ineligible/intolerant HCV patients

## Cardiovascular

		<input type="checkbox"/> Initiate Phase IV program in coronary artery disease patients with type 2 diabetes mellitus
Ranolazine	Q4	<input type="checkbox"/> Initiate Phase III program in patients with type 2 diabetes mellitus
		<input type="checkbox"/> Initiate Phase III study in patients with a history of angina and incomplete revascularization post-PCI

## Inflammation/Oncology

	Q3	<input checked="" type="checkbox"/> Initiate Ph II in myelofibrosis
GS 6624	Q4	<input type="checkbox"/> Initiate Ph II in pancreatic cancer
	Q4	<input type="checkbox"/> Initiate Ph II in colon cancer

# Focused on Three Strategic Fronts in 2011

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## ◆ Drive commercial growth

- HIV testing and earlier treatment
- Viread HBV market leadership
- Letairis and Ranexa growth
- Cayston launch

## ◆ Execute on R&D pipeline

- Truvada / Edurant STR and Quad
- Seven HCV molecules currently in clinical studies

## ◆ Effective use of strong cash flow

- Continued investment in growing pipeline
- Selective licensing and M&A
- Utilize share repurchases to return value to shareholders



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Improving Lives.



## Q&A

July 26, 2011



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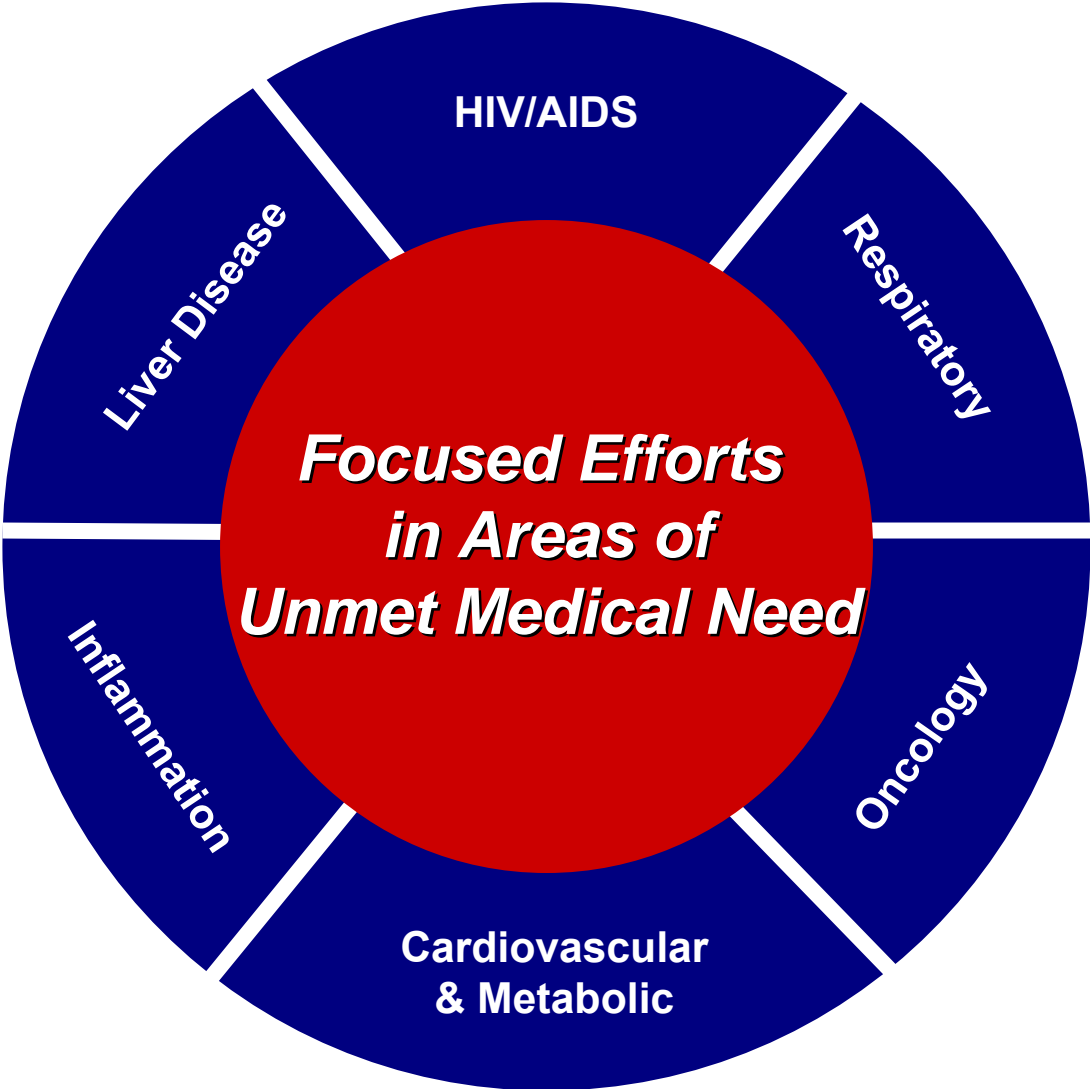


## Backup Slides

July 26, 2011

# Expanded Research and Development Focus

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# Gilead's Current Commercial Portfolio Consists of 13 Products Generating Revenue Through Direct Sales or Partner Promotion

**ATRIPLA**

**HIV/AIDS**

Bristol-Myers Squibb (US, EU)  
Merck (Developing Countries)

**Truvada**

**HIV/AIDS**

Japan Tobacco (Japan)

**viread**

**HIV/AIDS**

Japan Tobacco (Japan)

**Emtriva**

**HIV/AIDS**

Japan Tobacco (Japan)

**Vistide**

**CMV Retinitis/AIDS**

**viread**

**Chronic Hepatitis B**

GSK (Asia)

**Hepsera**  
adefovir dipivoxil

**Chronic Hepatitis B**

GSK (Asia, Latin America)

**Ranexa**  
RANOLAZINE EXTENDED-RELEASE TABLETS

**Chronic Angina**

500 mg - 1000 mg

Menarini (EU)

**Letairis**

**Pulmonary Arterial Hypertension**

GSK (EU)

**Lexiscan**  
(regadenoson) injection

**Myocardial Perfusion Imaging**

Astellas (US and Canada)

Rapidscan (Europe & select other markets)

**Cayston**

**Cystic Fibrosis**

**Tamiflu**

**Influenza A & B**

Roche (Worldwide)

**AmBisome**

liposomal amphotericin B

**Severe Fungal Infections**

Astellas (US and Canada)

Sumitomo (Japan)

**MACUGEN**

**Age-related Macular Degeneration**

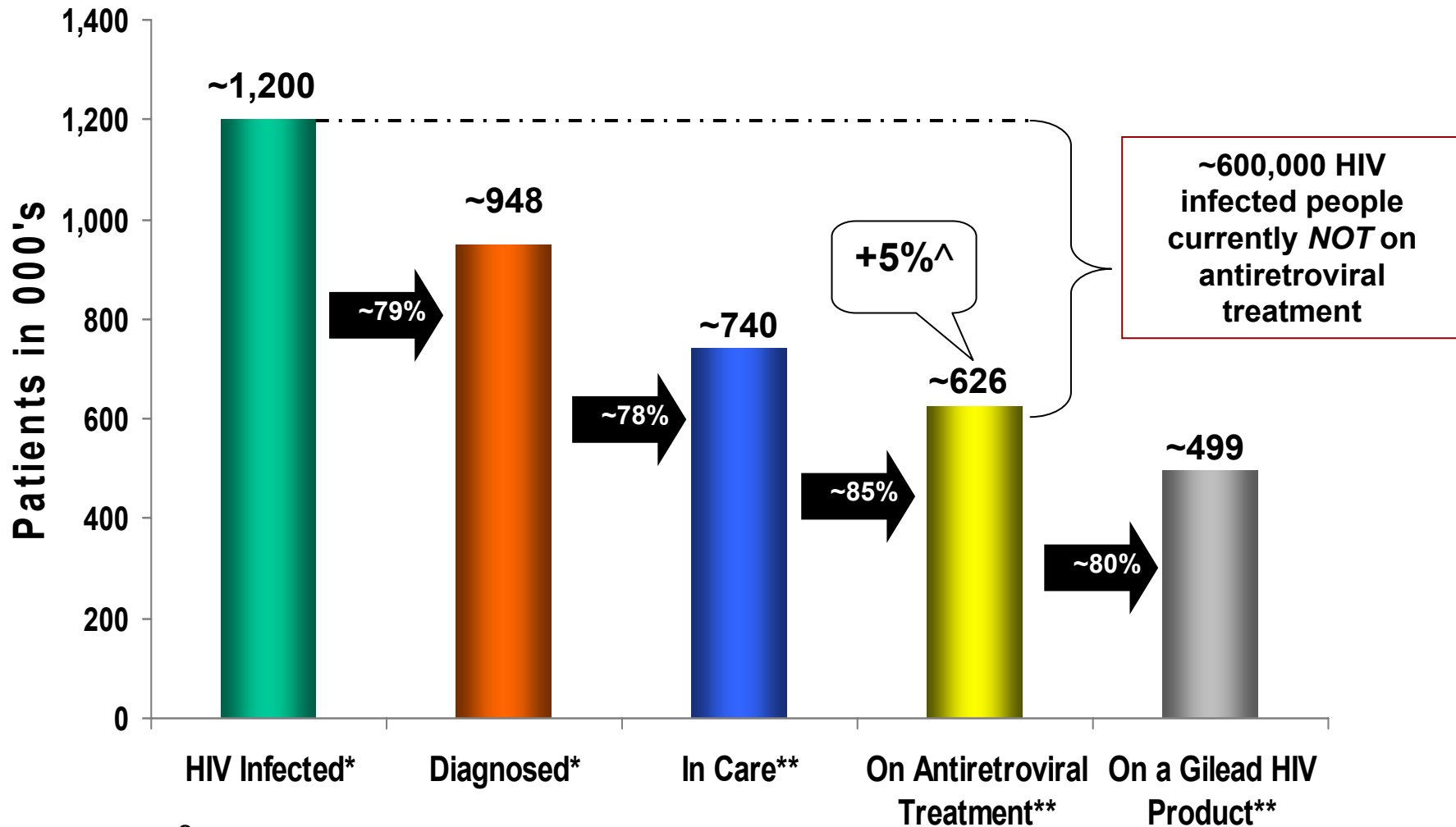
Eyetech (US) / Pfizer (OUS)

# GAAP to Non-GAAP Earnings Per Share Reconciliation

	Three Months Ended Mar. 31, 2011	Three Months Ended Jun. 30, 2011
<b>GAAP EPS</b>	\$0.80	\$0.93
<b>Stock-Based Compensation Expenses</b>	\$0.05	\$0.05
<b>Acquisition-Related Expenses</b>	\$0.02	\$0.02
<b>Non-GAAP EPS</b>	\$0.87	\$1.00

Note: Amounts may not sum due to rounding.

# U.S. HIV Market Dynamics



Sources:

\* October 2008 CDC estimates as of the end of 2006.

\*\* Synovate Healthcare U.S. HIV Monitor Q1 2011.

^ Growth rate calculated on a moving annual total basis.

# Federal ADAP Drug Budget for 2011\*

	<b>Initial Grant</b>		<b>Additional Funding</b>	<b>Total</b>
<b>2011</b>	<b>\$835 M</b>		<b>\$50 M</b>	<b>\$885 M</b>
<b>Timing and Allocation</b>	<b>April ~50%</b>	<b>July/Aug ~50%</b>	<b>September State by state needs-based distribution</b>	

\* Department of Defense and Full-Year Continuing Appropriations Act, 2011.

# AIDS 2011, 25:000-000: Clinical Implications of Fixed-Dose Coformulations of Antiretrovirals on the Outcome of HIV-1 Therapy

- ◆ Outlines the benefits of fixed dose antiretroviral coformulations and the differentiation of FTC vs. 3TC.
- ◆ Fixed-dosed drugs:
  - Reduce the risk of treatment error
  - Are associated with a lower risk of hospitalization
  - Can lessen the possibility of covert monotherapy in situations of selective non-compliance
- ◆ FDACs can reduce the risk of selection of HIV-1 resistances, which not only adversely affect the treatment options of the individual patient but also constitute a public health concern

OPINION

## Clinical implications of fixed-dose coformulations of antiretrovirals on the outcome of HIV-1 therapy

Josep M. Llibre<sup>a</sup>, José R. Arribas<sup>b</sup>, Pere Domingo<sup>c</sup>, Josep M. Gatell<sup>d</sup>, Fernando Lozano<sup>e</sup>, José R. Santos<sup>a</sup>, Antonio Rivero<sup>f</sup>, Santiago Moreno<sup>g</sup>, and Bonaventura Clotet<sup>h</sup> the Spanish Group for FDAC Evaluation

The substitution by generic equivalents of some of the drugs included in fixed-dose antiretroviral coformulations (FDACs) poses the potential risk of disrupting these combinations and administering the components separately in order to incorporate the new generic drug, which offers a more competitive sales price. This may represent a step backwards in the advance achieved in simplicity and adherence to therapy, posing an increased risk of selective non-compliance of some of the separately administered drug substances. Available antiretroviral drugs must be administered for life in the affected individuals – both children and adults.

The FDACs represent a significant advance in the simplification of antiretroviral therapy, facilitating adherence to complex and chronic treatments, and contributing to a quantifiable improvement in patient quality of life. These drug coformulations reduce the risk of treatment error, are associated with a lower risk of hospitalization, and can lessen the possibility of covert monotherapy in situations of selective non-compliance. Thus, FDACs can reduce the risk of selection of HIV-1 resistances, which not only adversely affect the treatment options of the individual patient but also constitute a public health problem, and further increase the cost and complexity of therapy. With the exception of those cases requiring dose adjustments, the preferential use of FDACs should be recommended for the treatment of HIV-1 infection in those situations where the agents included in the coformulation are drugs of choice.

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AIDS 2011, 25:000–000

Keywords: AIDS, antiretroviral treatment, combined treatment, fixed-dose combinations, human immunodeficiency virus infection, recommendation

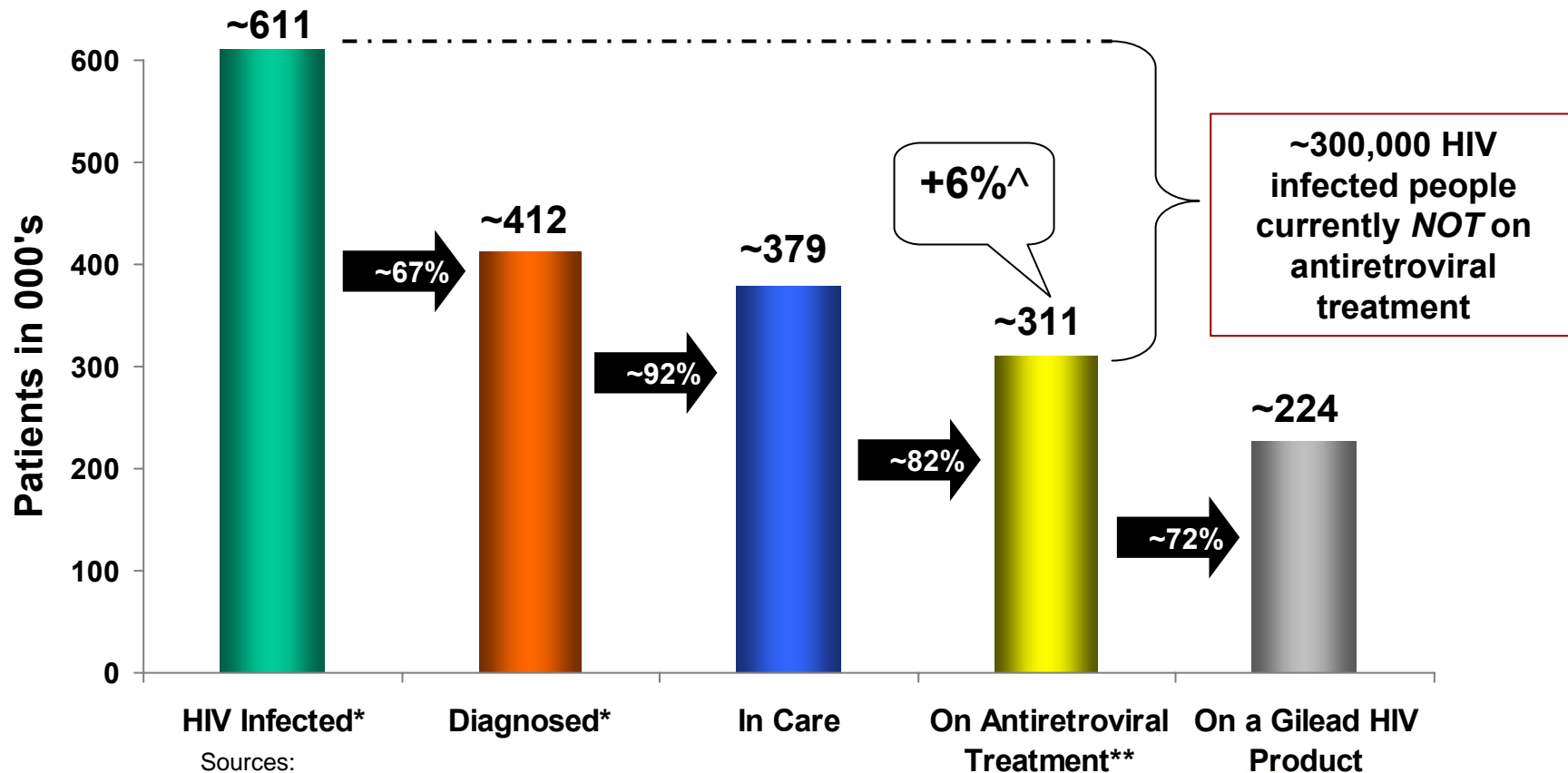
### Introduction

HIV-1 infection causes gradual destruction of host cellular immunity and persistent activation of the entire immune system and associated nonspecific inflammatory mechanisms. It is a world pandemic, one of the main public health problems worldwide since the late twentieth century, and also probably the most significant success

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Received: 2 February 2011; revised: 12 May 2011; accepted: 7 June 2011.  
DOI: 10.1097/QAD.0b013e318203499e09

# EU Big 5 HIV Market Dynamics

*Similar Growth Opportunity Exists in Europe by Increasing Diagnosis and Treatment*



Sources:

\* National Surveillance Units per country & ECDC estimates at end Q1 11.

\*\* IMS/GERS & Synovate Q1 2011.

<sup>^</sup> Growth rate calculated using moving annual total.

# Fixed-Dose Regimens Now Becoming Highlighted in Major Treatment Guidelines

	U.S. (DHHS)	International AIDS Society (IAS - USA)	EUROPE (EACS)
<b>Preferred First-line</b>	<b>Atripla</b>	<b>Atripla</b>	<b>Truvada or ABC/3TC</b> + <b>One of the following: EFV, NVP, ATV/r, DRV/r, LPV/r, SQV/r, RAL</b>
	<b>Truvada + ATV/r</b>	<b>Truvada + ATV/r</b>	
	<b>Truvada + DRV/r (once daily)</b>	<b>Truvada + DRV/r (once daily)</b>	
	<b>Truvada + RAL</b>	<b>Truvada + RAL</b>	
		Fixed-dose formulations and once-daily regimens are generally preferred for initial therapy.	Generic HIV drugs are becoming more available and can be used as long as they replace the same drug but do not break recommended fixed dose combinations.

1 U.S. Department of Health and Human Services guidelines, updated January 2011.

2 International AIDS Society (IAS) guidelines, updated July 2010.

3 European AIDS Clinical Society guidelines, updated March 2011.

# GS 7340 for HIV: Novel Nucleotide Prodrug Advancing in the Clinic

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- ◆ Novel prodrug of tenofovir that specifically targets the lymphatic system, the primary site of HIV replication
- ◆ Phase I/II study results (CROI, March 2011)
  - 14 day monotherapy in treatment naïve patients, 50 and 150 mg of GS 7340 versus 300 mg of Viread
  - Plasma tenofovir levels were 88% and 56% lower compared to Viread
  - Intracellular PBMC levels of tenofovir were 4.0x and 33x higher
  - Viral load reductions at day 14 were -1.6 and -1.7 logs versus -0.95 logs for Viread
  - Safe and well tolerated
- ◆ GS 7340 is a potential improvement over Viread
  - Safety and efficacy
  - Smaller size allows for fixed-dose formulations currently not possible with Viread