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# Eli Lilly and Company First Quarter Financial Review

April 18<sup>th</sup>, 2011

The Eli Lilly logo, featuring the word "Lilly" in a red, cursive script font.

Answers That Matter.

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# Agenda

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## Key Recent Events, Financial Results and Pipeline Update

- Phil Johnson, Vice President, Investor Relations
- Ronika Pletcher, Director, Investor Relations

## Key Future Events, Financial Guidance and Summary

- Derica Rice, Executive Vice President, Global Services and Chief Financial Officer

## Question and Answer Session

# Safe Harbor Provision

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This presentation contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. The company's results may be affected by such factors as the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform. For additional information about the factors that affect the company's business, please see the company's latest Forms 10-K and 10-Q filed with the Securities and Exchange Commission.

The company undertakes no duty to update forward-looking statements.

# Beyond the Quarterly Financial Results

## Key events since the last earnings call

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### Business Development:

- Announced an unconditional offer to acquire the animal health business of Janssen Pharmaceutica NV, a Johnson & Johnson company

### Commercial/Regulatory:

- Began active promotion of Cymbalta for chronic musculoskeletal pain
- Launched Axiron, the first and only testosterone replacement therapy applied to the underarm
- Submitted response to FDA's Complete Response Letter (CRL) for Erbitux in first-line head and neck cancer
- Received a CRL from the FDA for florbetapir, a PET imaging agent under investigation for the detection of beta-amyloid plaque in the brains of living patients
- Received a CRL from the FDA for liprotamase, a pancreatic enzyme replacement therapy
- In Europe, submitted Alimta induction followed by Alimta maintenance in advanced nonsquamous, non-small cell lung cancer
- Received CHMP recommendation for approval of Bydureon for the treatment of type 2 diabetes; EC approval expected in late-June

### Clinical:

- Announced positive top-line results of Phase 2 trial of exenatide once-monthly formulation
- Announced top-line results from DURATION-6 Phase 3 trial comparing Bydureon to highest approved dose of Victoza; study failed to meet primary endpoint of non-inferiority on reduction in HbA1c
- Initiated Phase 3 clinical program for mGlu2/3 prodrug in schizophrenia

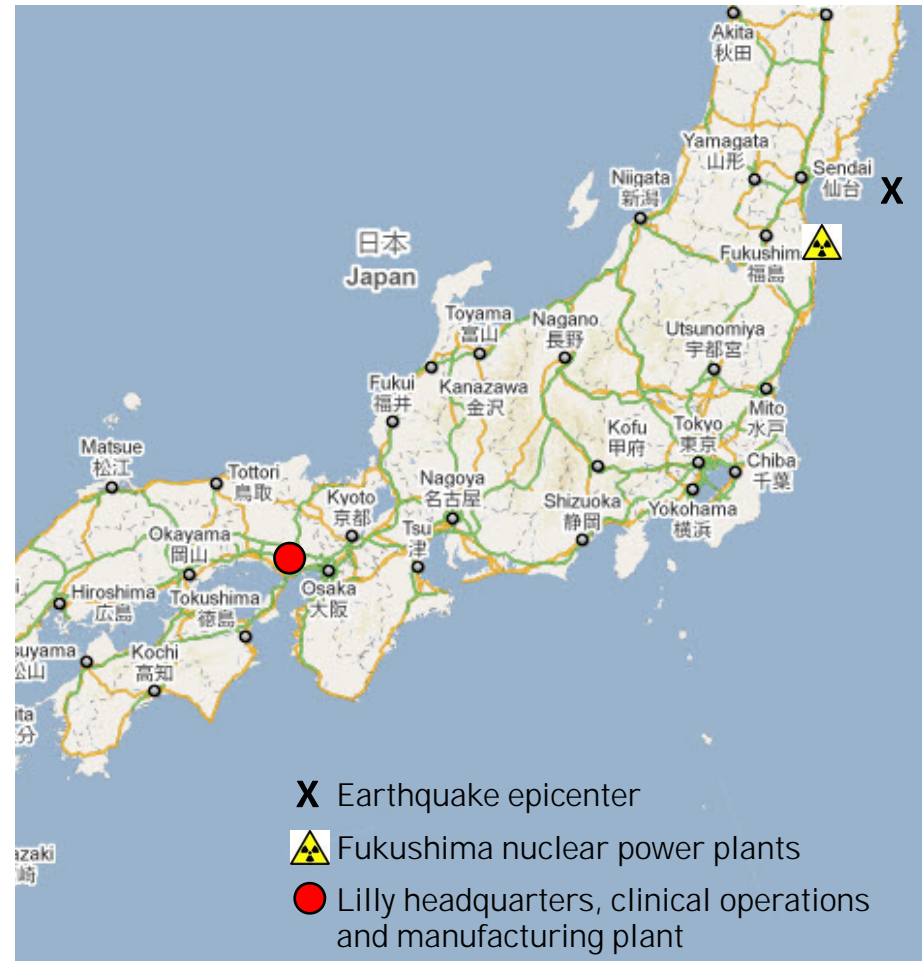
### Legal:

- Received favorable ruling in the Cymbalta patent litigation; meeting in late April to determine next steps in this litigation

# Japan Update

## March 11 earthquake and aftermath:

- All Lilly employees safely accounted for within hours of the earthquake
- Company and employees have provided monetary and product donations
- Affiliate headquarters, clinical operations and manufacturing plant unaffected
- No issues getting products into – or out of – the country
- No issues with supply from Japanese companies
- \$30-\$35 million in precautionary orders from customers in Q1



# Comparison Measures

Results shown two ways to aid analysis

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## “Reported” results

- Include all financial results as reported in accordance with GAAP

## “Non-GAAP” results

- Start with “Reported” results
- Include adjustments for items such as:
  - Restructuring charges, asset impairments and special charges
  - In-process R&D charges from business development activities

# 2011 Income Statement (Non-GAAP)

Millions; except per share data

	<u>Q1 2011</u>	<u>Q1 2010</u>	<u>Growth</u>
Total Revenue	5,839	5,486	6%
Gross Margin	79.8%	79.5%	0.3pp
Total Operating Expense	2,910	2,653	10%
Operating Income	1,749	1,709	2%
Other Income / (Deductions)	(11)	75	NM
<i>Effective Tax Rate</i>	<i>20.9%</i>	<i>27.3%</i>	<i>(6.4)pp</i>
Net Income	<u>\$1,375</u>	<u>\$1,298</u>	6%
Diluted EPS	\$1.24	\$1.18	5%

\* Includes Research and Development expense and Selling, Marketing and Administrative expense.

# 2011 Income Statement (Reported)

Millions; except per share data

	<u>Q1 2011</u>	<u>Q1 2010</u>	<u>Growth</u>
Total Revenue	5,839	5,486	6%
Gross Margin	79.8%	79.5%	0.3pp
Total Operating Expense*	3,374	2,730	24%
Operating Income	1,285	1,633	(21)%
Other Income / (Deductions)	(11)	75	NM
<i>Effective Tax Rate</i>	<i>17.1%</i>	<i>26.9%</i>	<i>(9.8)pp</i>
Net Income	<u>\$1,056</u>	<u>\$1,248</u>	(15)%
Diluted EPS	\$0.95	\$1.13	(16)%

\* Includes Research and Development expense, Selling, Marketing and Administrative expense and other charges.

**Notes:** Q1 2011 includes a restructuring charge of \$76.3 million (pretax), or \$0.06 (after-tax). This charge is primarily related to severance costs from previously announced strategic actions to reduce the company's cost structure and global workforce. In addition, Q1 2011 includes a charge of \$388.0 million (pretax), or \$0.23 per share (after-tax), for acquired in-process research and development associated with the collaboration with Boehringer Ingelheim.

Q1 2010 includes a restructuring charge of \$26.2 million (pretax), or \$0.02 (after-tax). This charge is primarily related to severance costs from previously announced strategic actions to reduce the company's cost structure and global workforce. In addition, Q1 2010 includes a charge of \$50.0 million (pretax), or \$0.03 per share (after-tax), for acquired in-process research and development associated with the in-licensing agreement with Acrux Ltd.



# EPS Reconciliation

	<u>Q1 2011</u>	<u>Q1 2010</u>	<u>Growth</u>
EPS (reported)	\$0.95	\$1.13	(16%)
Asset impairments and restructuring charges	0.06	0.02	
In-process research and development charges associated with Boehringer Ingelheim (2011) and Acrux (2010) agreements	0.23	0.03	
EPS (non-GAAP)	<u>\$1.24</u>	<u>\$1.18</u>	5%

Note: Numbers may not add due to rounding.

# Effect of Price/Rate/Volume on Revenue

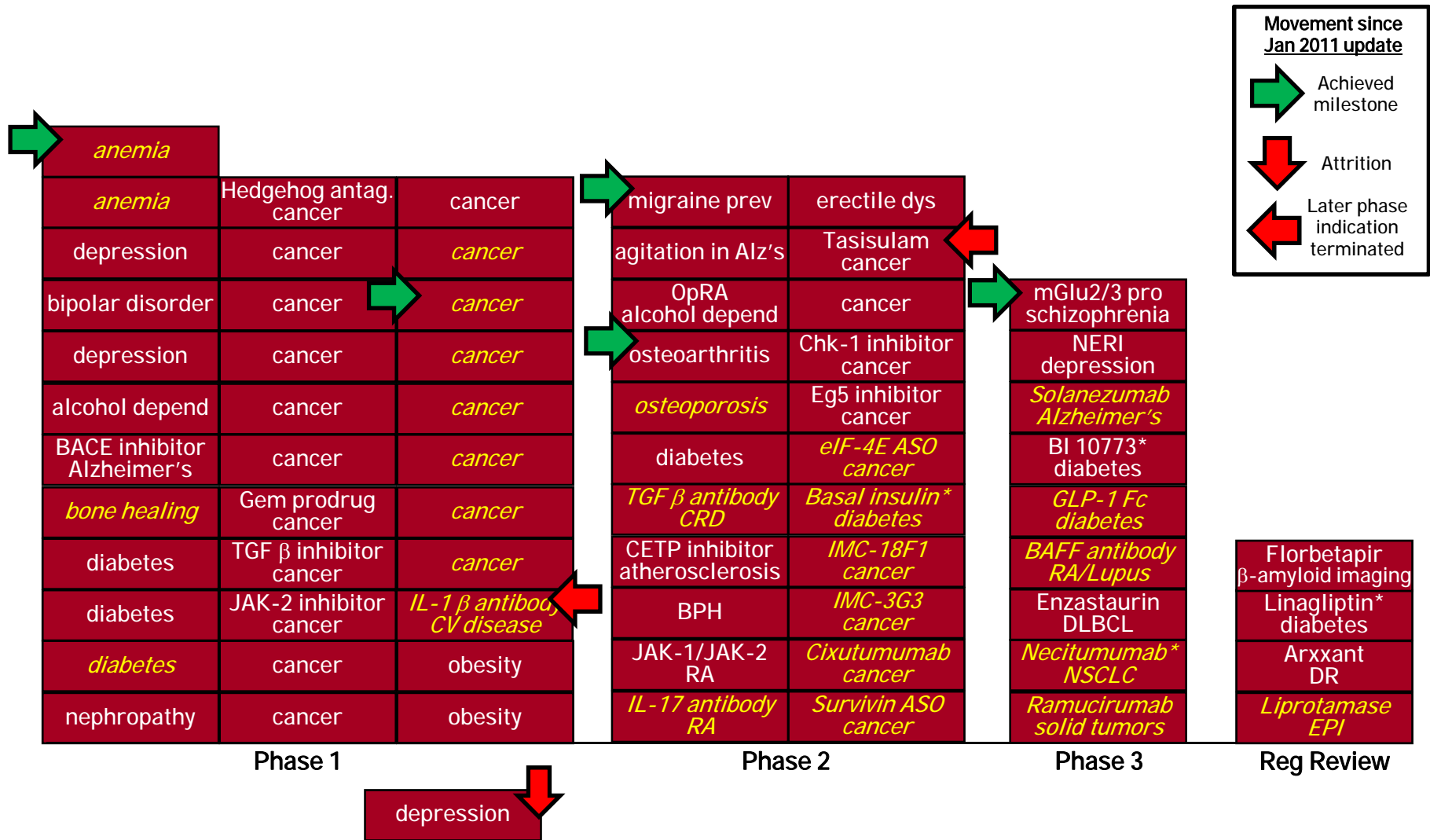
	Q1 2011 Amount	Q1 2011 vs. Q1 2010			
		Price	FX Rate	Volume	Total
Pharmaceuticals					
U.S.	\$2,757.4	2%	-	(2)%	0%
Europe	1,259.9	(3)%	(1)%	6%	2%
Japan	464.2	(4)%	12%	34%	41%
ROW	838.4	(1)%	3%	14%	16%
Total Pharma	5,320.1	0%	1%	5%	5%
Animal Health	369.8	1%	1%	25%	28%
Net Product Sales	5,689.9	0%	1%	6%	7%
Collab/Other Revenue	149.3	(0)%	0%	(2)%	(2)%
<b>Total Revenue</b>	<b>\$5,839.2</b>	<b>0%</b>	<b>1%</b>	<b>5%</b>	<b>6%</b>

Note: Numbers may not add due to rounding.

# Lilly NME Pipeline

April 11, 2011

New Chemical Entity (NCE)
<i>New Biotech Entity (NBE)</i>



\* commercial collaborations; see note on Pipeline Disclaimer page on Lilly.com

# Key Future Pipeline Events in 2011

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## Potential regulatory approvals:

- Linagliptin in the U.S., Europe and Japan
- In the U.S.:
  - Cialis for BPH
  - Byetta in combination with basal insulin
  - Erbitux for 1<sup>st</sup>-line head and neck cancer

## Expected regulatory submissions:

- Response to FDA complete response letter for Bydureon
- sBLAs for Erbitux in first-line mCRC and first-line NSCLC
- Byetta in combination with basal insulin (EU)
- Response to FDA complete response letter for Amyvid

## Clinical trial data disclosures:

- Initial results from Alimta followed by Alimta in nonsquamous NSCLC at ASCO
- Results from two Phase 2 trials of our BAFF antibody in RA at EULAR
- Cialis BPH safety study at AUA

## Initiation of Phase 3 trials:

- Novel basal insulin analog
- New insulin glargine product
- anti-IL-17 antibody for RA

# 2011 Guidance

Millions, except per share amounts

Total Revenue	Low-single digits
Gross Margin % of Revenue	Declining
Mktg, Selling & Admin.	Low- to mid-single digit increase
Research & Development	Essentially flat
Other Income/(Expense)	\$(50) - \$(150)
Tax Rate (reported)	Approximately 20%
Tax Rate (non-GAAP)	Approximately 21%
EPS (reported)	\$3.86 - \$4.01
Reconciling Items (estimated) <i>(excludes any potential future items)</i>	\$0.29
EPS (non-GAAP)	\$4.15 - \$4.30
Capital Expenditures	\$800-\$900

For complete reconciliation to reported guidance, please see slide 14 of this presentation and our earnings press release dated April 18, 2011.

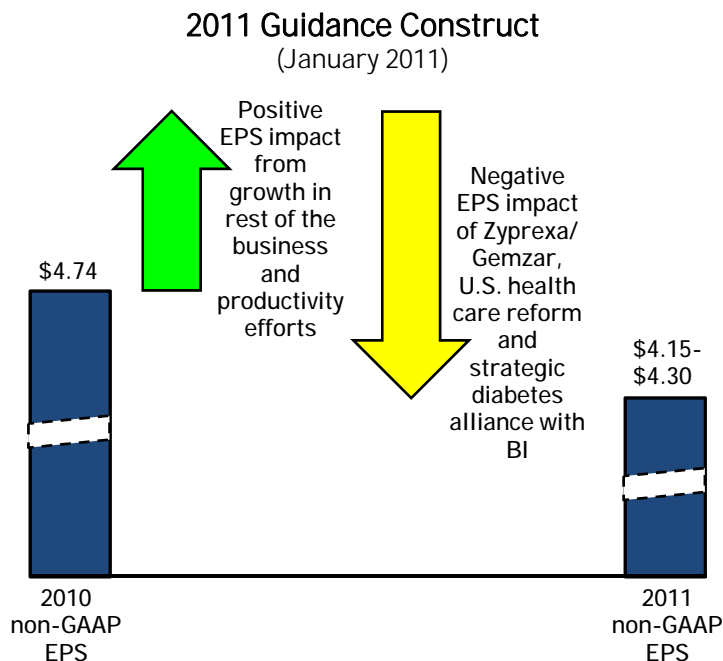
# Earnings per Share Expectations

	<u>2011</u>	<u>2010</u>	<u>Growth</u>
Earnings per share (reported)	\$3.86-\$4.01	\$4.58	(12)%-(16)%
Asset impairments and restructuring charges	0.06	0.13	
In-process research and development charges associated with the Boehringer Ingelheim (2011) and Acrux (2010) agreements	0.23	0.03	
EPS (non-GAAP)	<u><u>\$4.15-\$4.30</u></u>	<u><u>\$4.74</u></u>	(9)%-(12)%

Note: Numbers may not add due to rounding.

# Q1 2011 Summary

- Advancing the pipeline:
  - Nine molecules currently in Phase 3 development
  - On track to achieve goal of 10 molecules in Phase 3 by the end of 2011
- Tracking to achieve 2011 headcount and expense containment goals
- Solid non-GAAP financial results:
  - Revenue, OPEX and net income growth of 6%, 10% and 5%, respectively
  - Excluding Gemzar outside of Japan, U.S. health care reform and investments for the BI alliance, the rest of the business generated:
    - Revenue growth of 10%
    - OPEX growth of 7% (21% on a reported basis)
    - Low double-digit EPS growth (high-single digit decline on a reported basis)



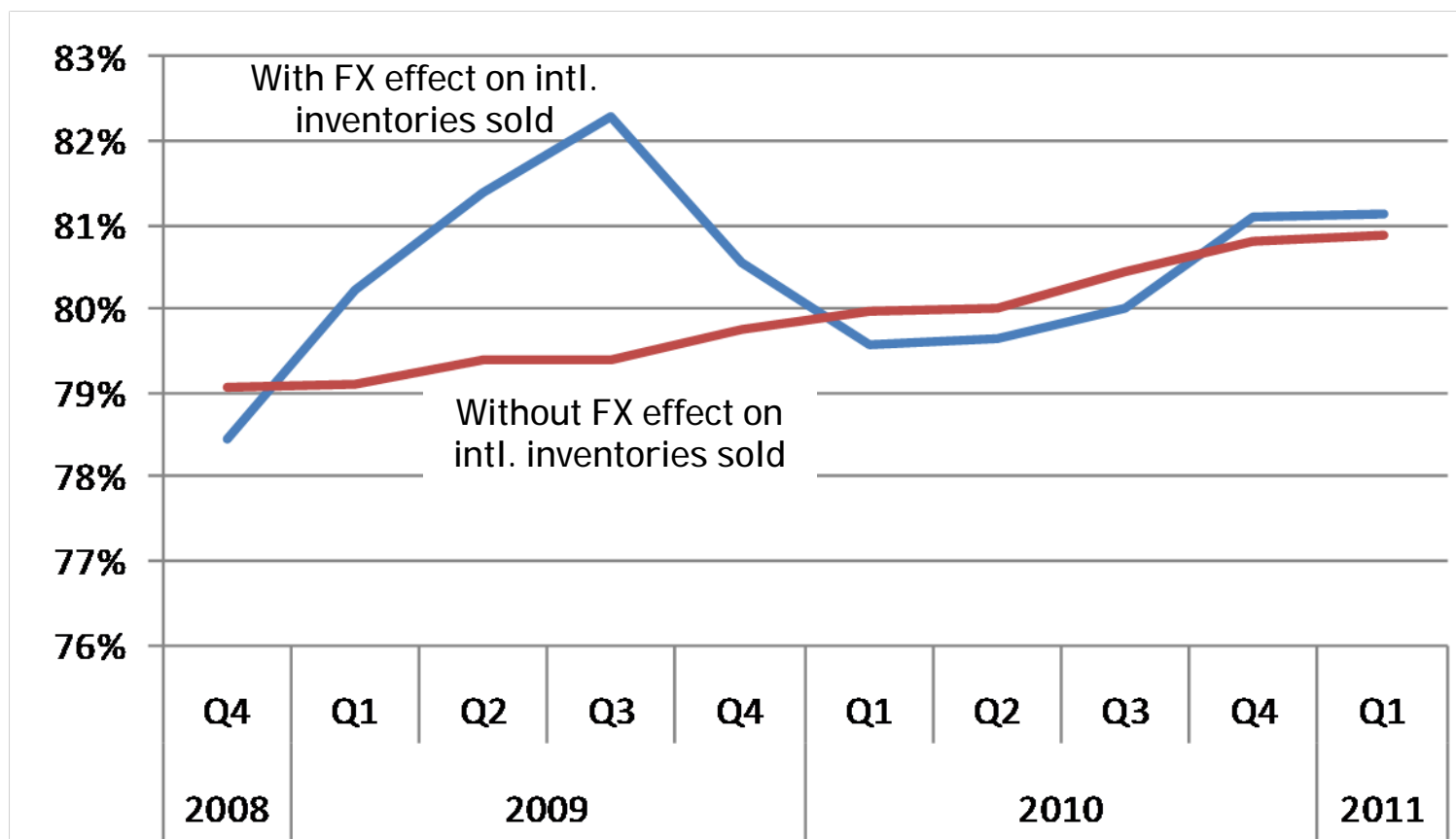
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# Supplementary Slides



# Gross Margin % - Moving Annual Total

Pro-forma non-GAAP



Individual quarter GM% of Revenue:

with FX effect on intl inv sold	82.3%	83.8%	82.1%	81.1%	75.9%	79.5%	82.2%	82.5%	80.1%	79.8%
w/o FX effect on intl inv sold	77.7%	79.4%	81.7%	78.8%	79.2%	80.4%	81.7%	80.6%	80.6%	80.7%

Note: The lines in the graph are moving annual totals (i.e. trailing 4 quarters) while the two rows of numbers are from specific quarters.

# Effect of Foreign Exchange on 2011 Results

(Non-GAAP)

## Year-on-Year Growth

	Q1 2011	
	With FX	w/o FX
Total Revenue	6%	6%
Cost of Sales	5%	5%
Gross Margin	7%	6%
Operating Expense <i>(R&amp;D and SG&amp;A)</i>	10%	9%
Operating Income	2%	1%
EPS	5%	3%

# Effect of Foreign Exchange on 2011 Results

(Reported)

## Year-on-Year Growth

	Q1 2011	
	With FX	w/o FX
Total Revenue	6%	6%
Cost of Sales	5%	5%
Gross Margin	7%	6%
Operating Expense <i>(R&amp;D, SG&amp;A and sign. items)</i>	24%	23%
Operating Income	(21)%	(23)%
EPS	(16)%	(18)%

# Comparative EPS Summary 2010/2011

	1Q10	2Q10	3Q10	4Q10	2010	1Q11	2Q11	3Q11	4Q11	2011
Non-GAAP	1.18	1.24	1.21	1.11	4.74	1.24				
Reported	1.13	1.22	1.18	1.05	4.58	0.95				

Note: Numbers may not add due to rounding.

For complete reconciliation to reported earnings, please see slide 9 of this presentation and our earnings press release dated April 18, 2011.

# Q1 Other Income/(Deductions)

Millions

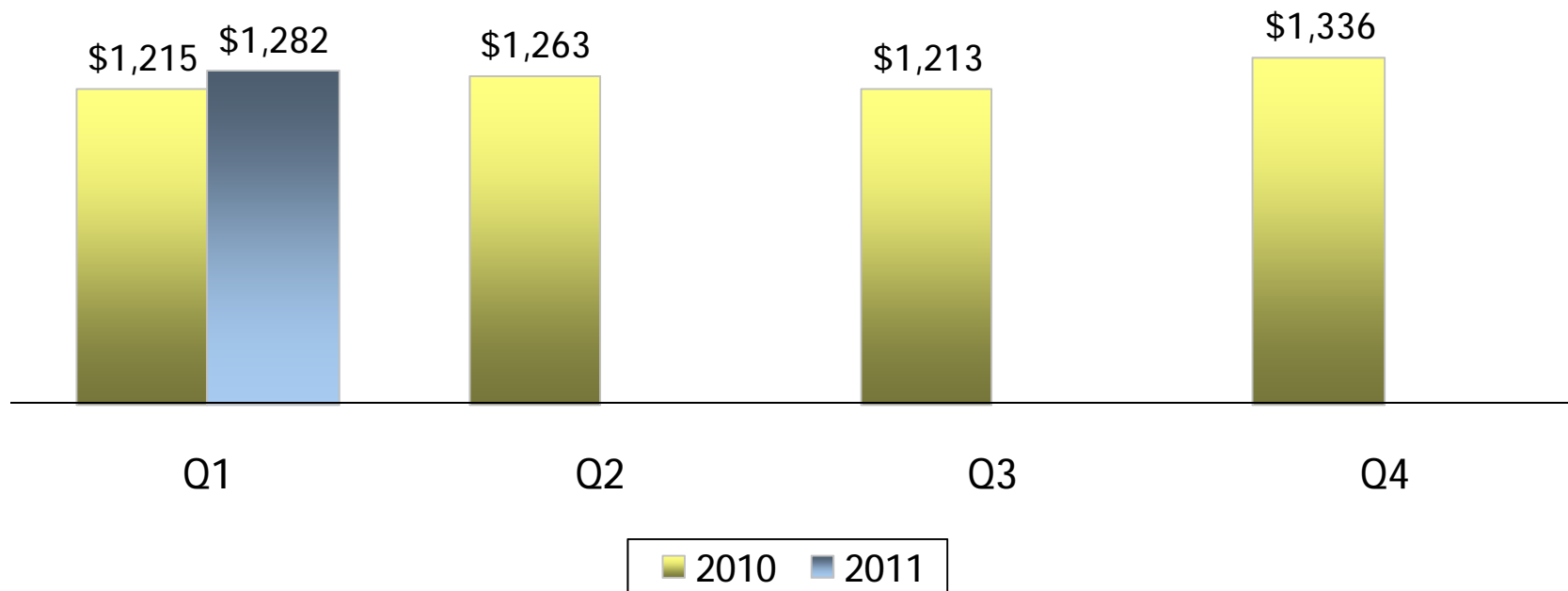
	<u>Q1 11</u>	<u>Q1 10</u>
- Interest Expense	(\$45.8)	(\$47.6)
- Interest Income	15.5	10.6
<b>Interest, net</b>	<b>(30.3)</b>	<b>(37.0)</b>
- FX Gains / (Losses)	(10.4)	(14.3)
- Gains / (Losses) on Equity Investments	35.4	54.9
- Miscellaneous Income / (Loss)	(5.9)	70.9
<b>Other Income, net</b>	<b>19.1</b>	<b>111.5</b>
<b>Net Other Income (Loss)</b>	<b><u>\$(11.2)</u></b>	<b><u>\$74.5</u></b>

Note: Numbers may not add due to rounding.

# Q1 Zyprexa<sup>®</sup> Sales Increased 6%

Millions

U.S. sales increased 2%  
International sales increased 8%

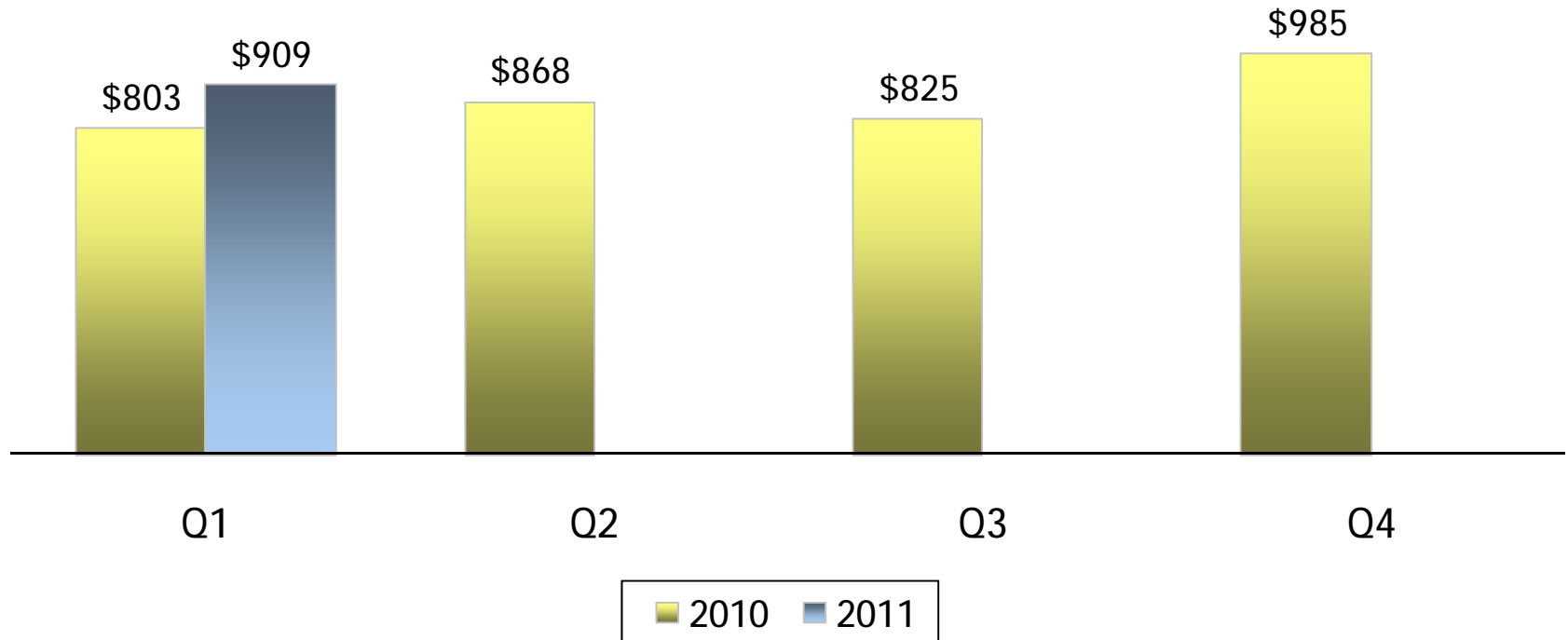


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Cymbalta<sup>®</sup> Revenue Increased 13%

Millions

U.S. sales increased 6%  
International revenue increased 43%

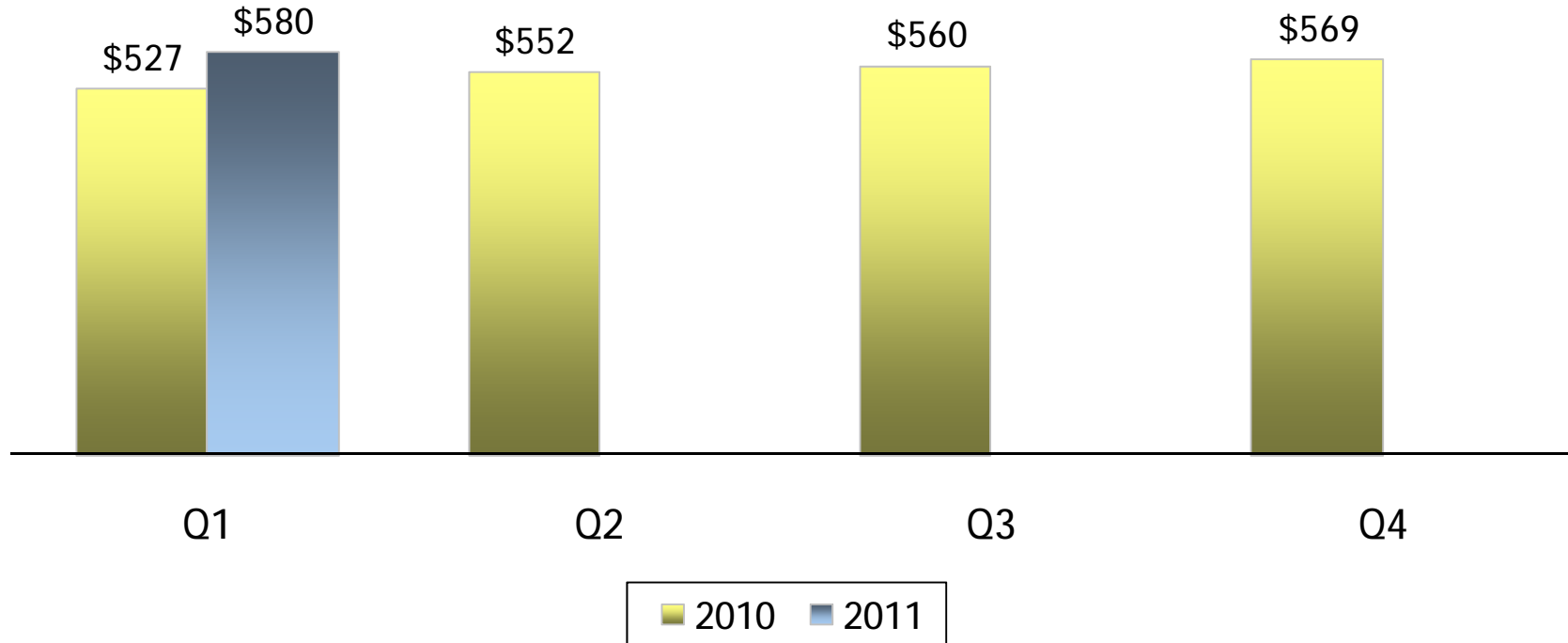


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Alimta<sup>®</sup> Sales Increased 10%

Millions

U.S. sales increased 5%  
International sales increased 14%



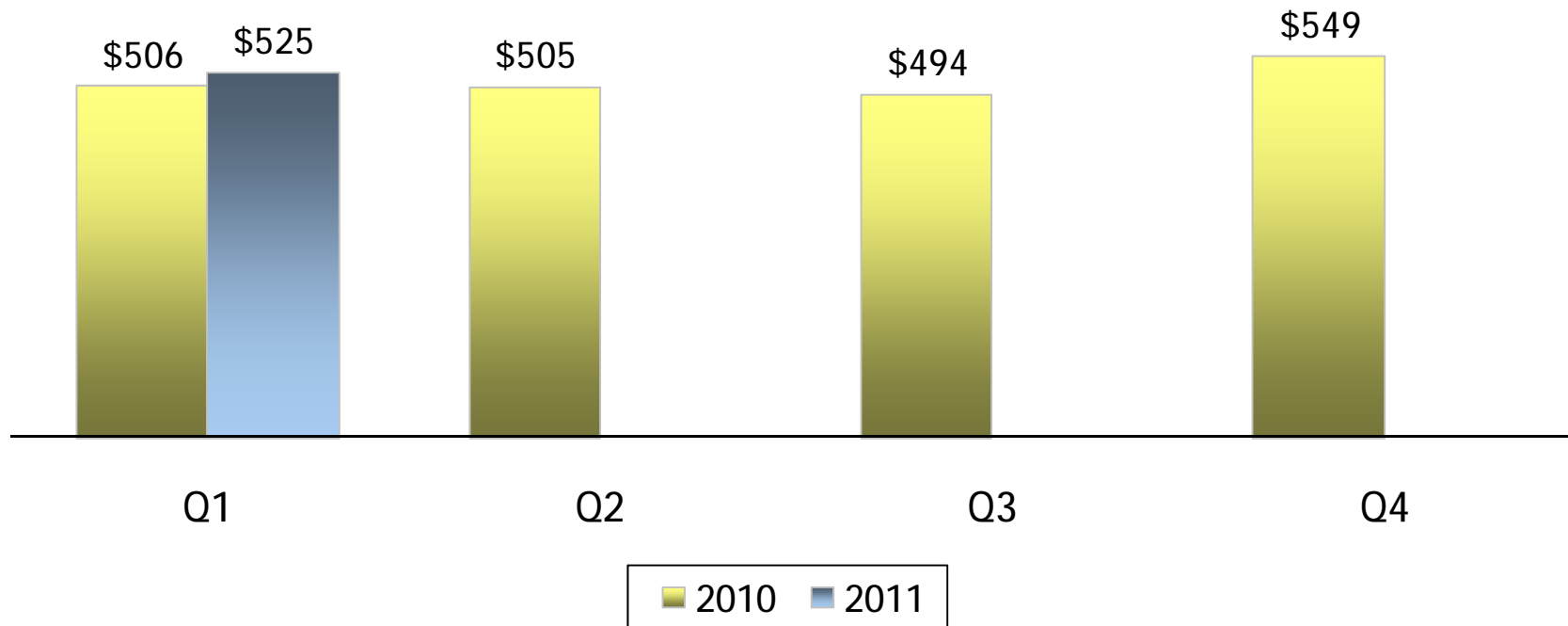
Note: Quarterly numbers may not add to year-to-date totals due to rounding.



# Q1 Humalog<sup>®</sup> Sales Increased 4%

Millions

U.S. sales decreased 2%  
International sales increased 13%

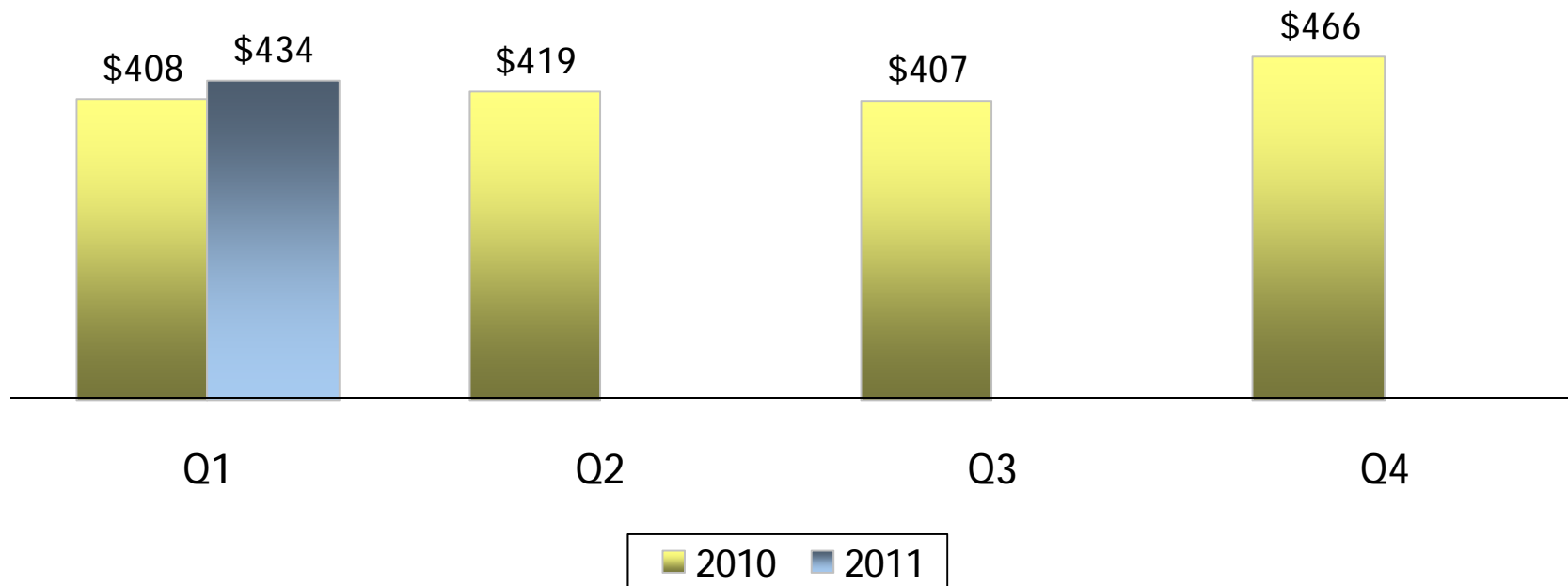


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Cialis<sup>®</sup> Sales Increased 6%

Millions

U.S. sales increased 5%  
International sales increased 7%

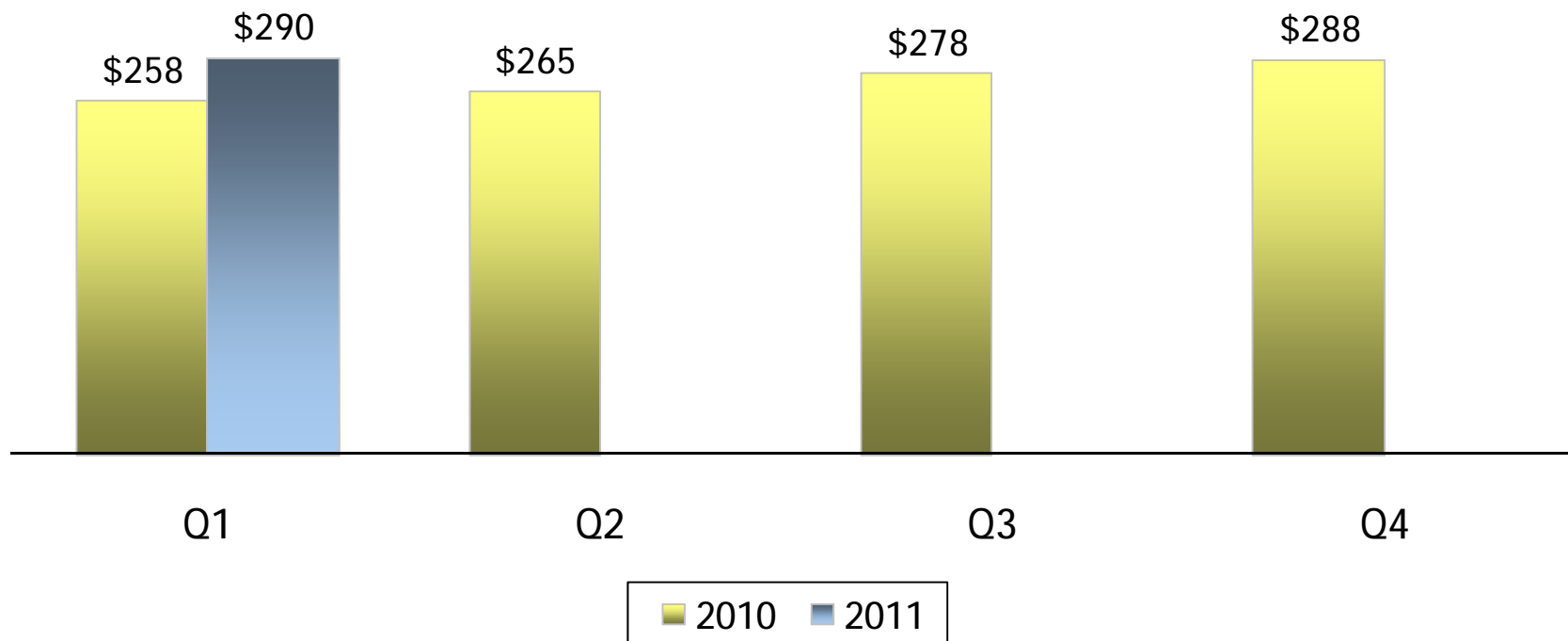


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Humulin<sup>®</sup> Sales Increased 12%

Millions

U.S. sales increased 13%  
International sales increased 12%

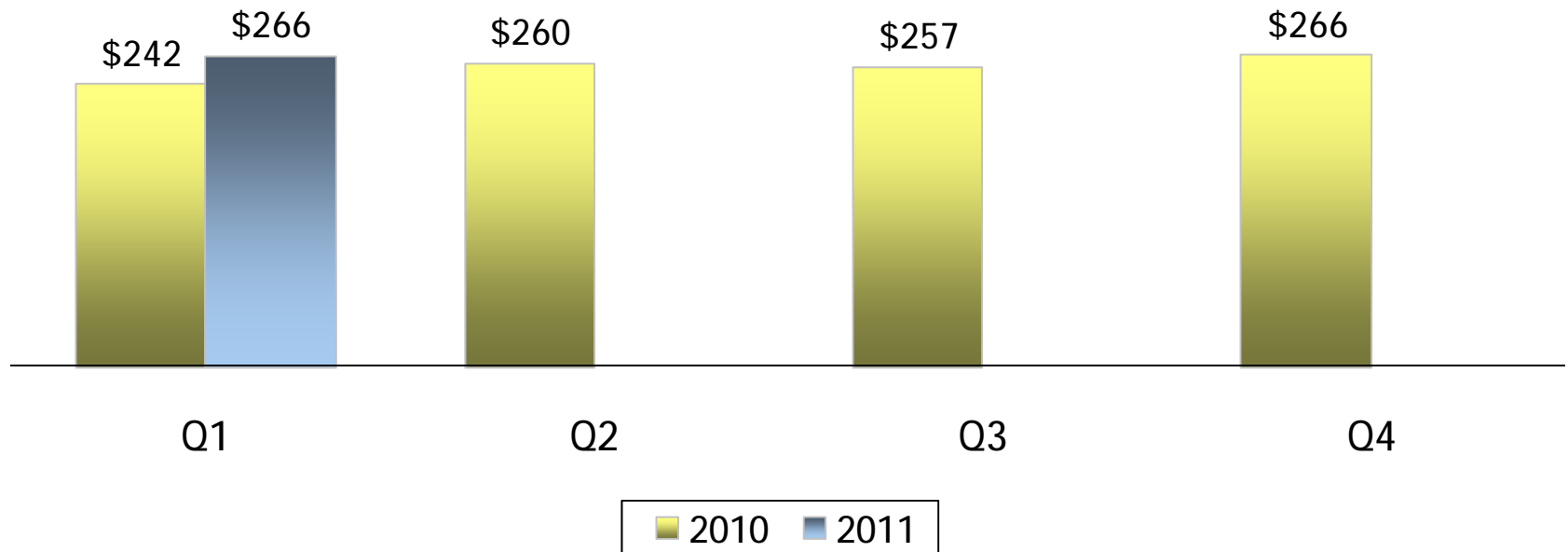


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Evista<sup>®</sup> Sales Increased 10%

Millions

U.S. sales increased 10%  
International sales increased 10%

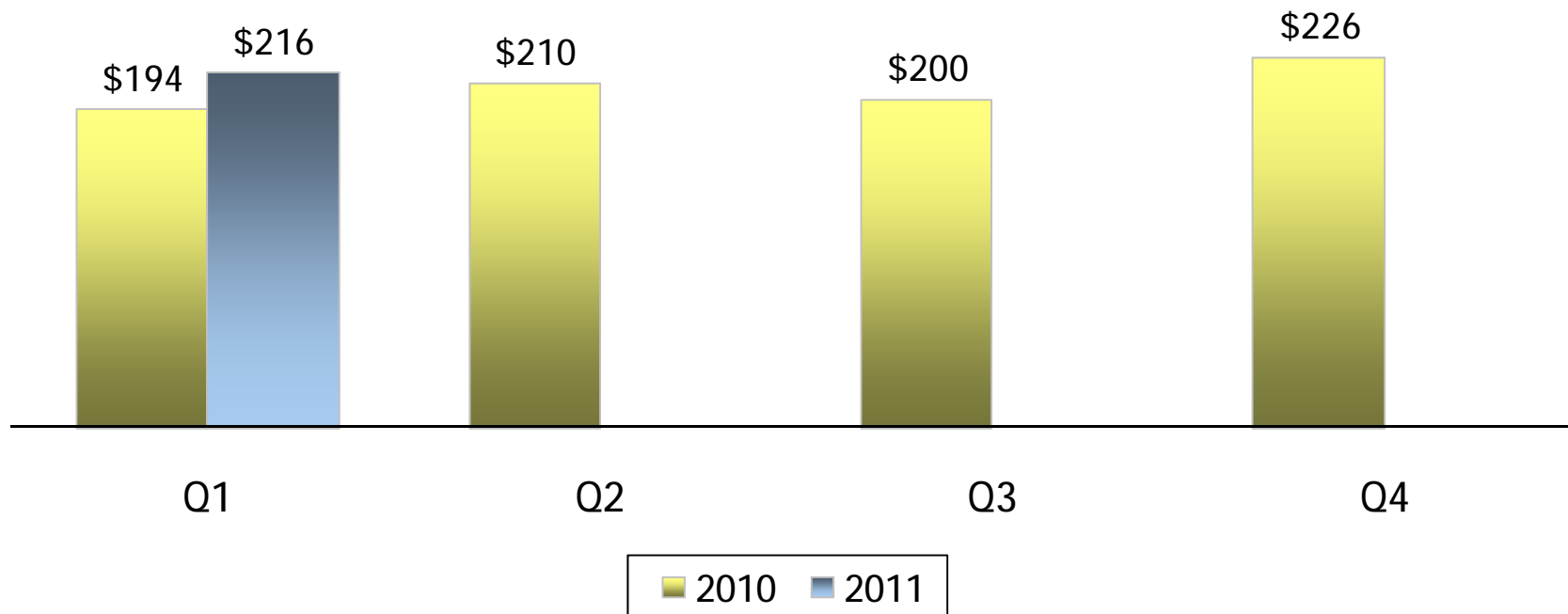


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Forteo<sup>®</sup> Sales Increased 11%

Millions

U.S. sales decreased 4%  
International sales increased 34%

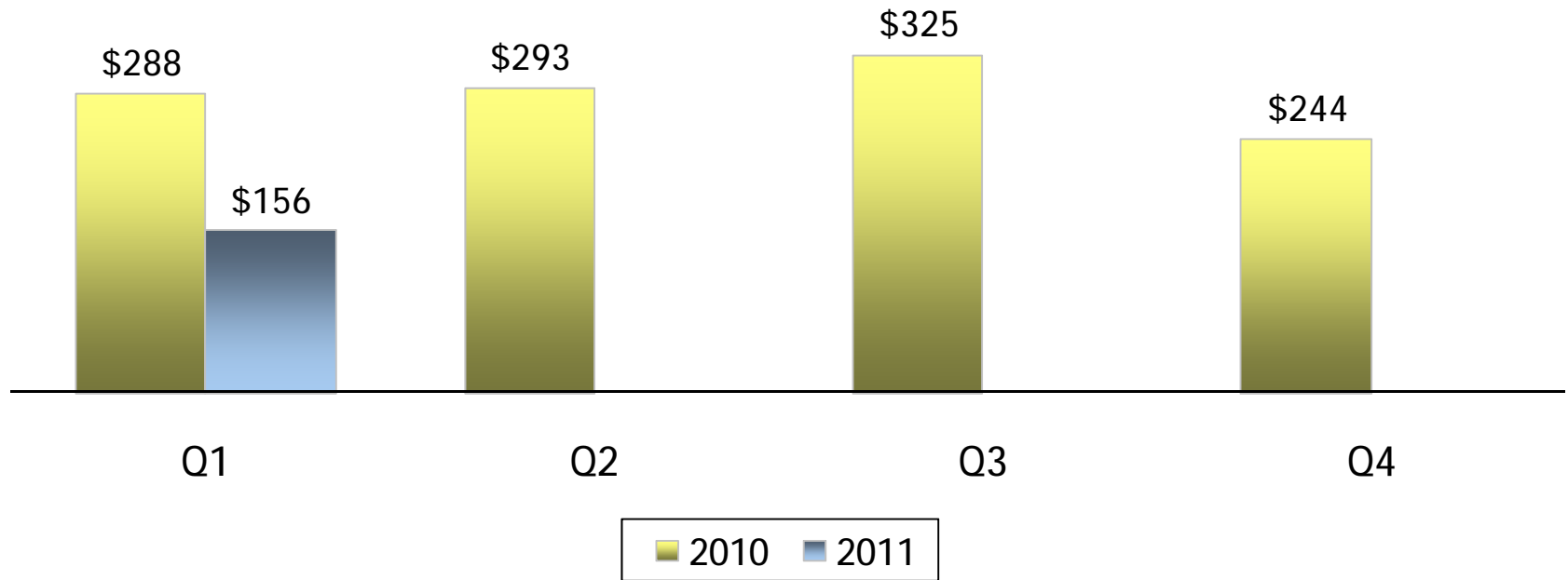


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Gemzar<sup>®</sup> Sales Decreased 46%

Millions

U.S. sales decreased 66%  
International sales decreased 15%

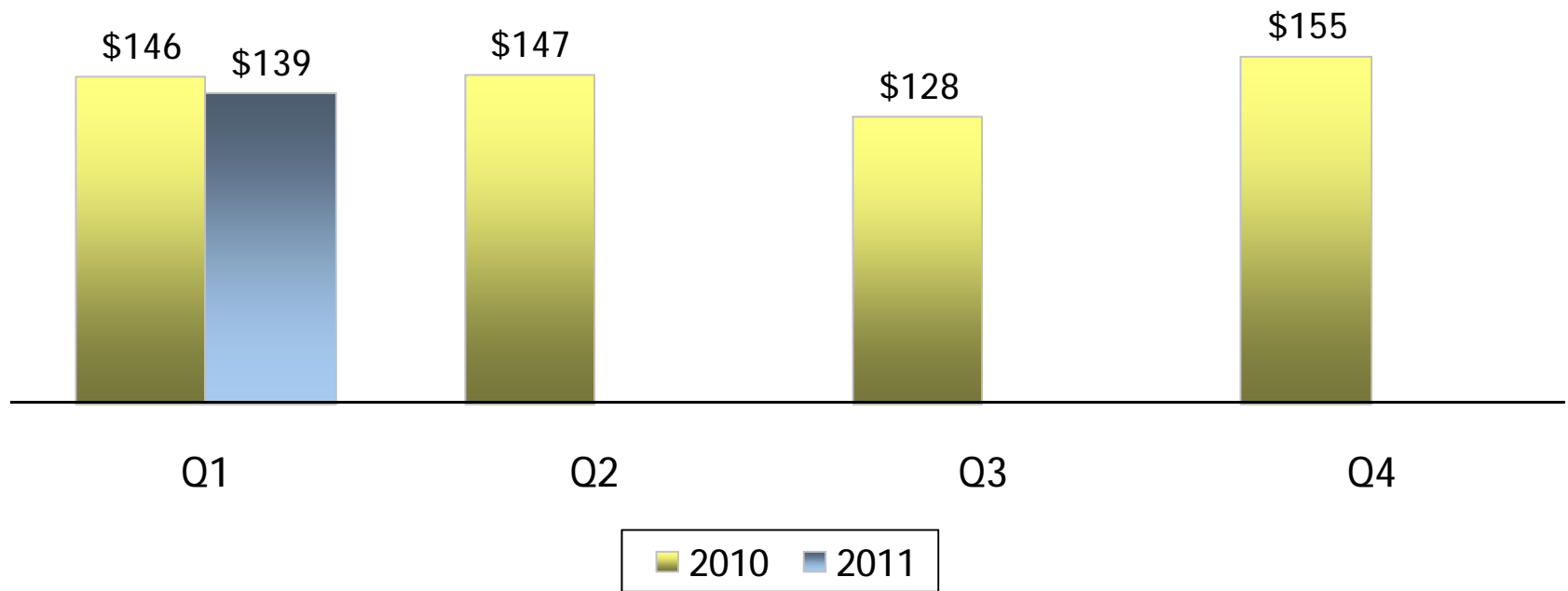


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Strattera<sup>®</sup> Sales Decreased 5%

Millions

U.S. sales decreased 16%  
International sales increased 20%

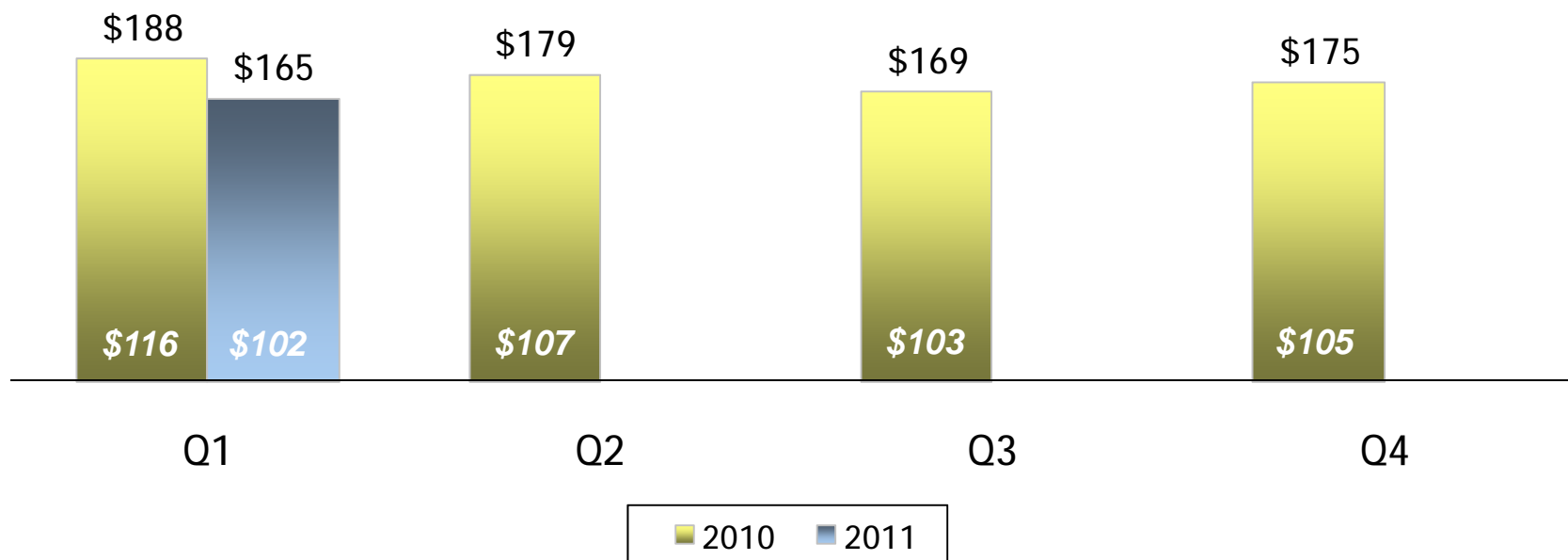


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q1 Byetta<sup>®</sup> Worldwide Sales \$165.4 Million

Millions

Worldwide sales decreased 12%  
Lilly revenue decreased 12%



Note: Quarterly numbers may not add to year-to-date totals due to rounding.