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# Eli Lilly and Company

## Third Quarter Financial Review

October 21<sup>st</sup>, 2010

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The Lilly logo is written in a red, cursive script font.

Answers That Matter.

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# Agenda

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## Opening Remarks and Q3 Highlights

- Phil Johnson, Vice President, Investor Relations

## Financial Review and Guidance Update

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

## Pipeline, U.S. Patent Challenge and Japan Updates

- Nick Lemen, Director, Investor Relations

## Question and Answer Session

## Closing Remarks

- John Lechleiter, Chairman, President and Chief Executive Officer

# 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.

# Q3 2010 Financial Highlights

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- Robust Q3 EPS of \$1.18 reported and \$1.21 non-GAAP
- Excluding FX, productivity efforts allowed us to leverage 3% revenue growth into 7% operating income growth
- Strong human pharmaceutical revenue growth in international markets and in Animal Health globally
- U.S. human pharmaceutical revenue growth negatively affected by wholesaler buying patterns
- Impact of FX on revenue negative for the first time in 2010
- Raising 2010 EPS guidance

# Beyond the Quarterly Financial Results

## Key events since the last earnings call

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### Legal:

- CAFC upheld District Court ruling that Gemzar's method-of-use patent is invalid
- District Court ruled that Strattera's method-of-use patent is invalid; CAFC appeal will be heard on December 9<sup>th</sup>
- CAFC upheld District Court ruling that Evista's method-of-use patents are valid
- Court of Appeals for the Second Circuit ruled that a class should not have been certified in a pending Zyprexa third-party payor suit and that the plaintiffs' overpricing claims should not go forward

### Clinical and Regulatory:

- FDA issued a Complete Response Letter for Bydureon; goal is to reply the end of 2011
- Teplizumab did not meet primary efficacy endpoint in Phase 3 PROTÉGÉ study; dosing to be suspended in on-going clinical trials; evaluating next steps
- Development of semagacestat, a gamma secretase inhibitor being studied as a potential treatment for Alzheimer's disease, was halted
- FDA advisory committee voted 8-6 in favor of expanding the pain indications for Cymbalta to a broader population that will be further defined by the FDA, if approved

# 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

# 2010 Income Statement (Non-GAAP)

Millions; except per share data

	<u>Q3 2010</u>	<u>Q3 2009</u>	<u>Growth</u>
Total Revenue	5,655	5,562	2%
Gross Margin	82.5%	81.1%	1.4pp
Total Operating Expense*	2,915	2,824	3%
Operating Income	1,753	1,686	4%
Other Income / (Deductions)	(22)	(67)	(68)%
<i>Effective Tax Rate</i>	<i>22.5%</i>	<i>19.0%</i>	<i>3.5pp</i>
Net Income	<u>\$1,341</u>	<u>\$1,312</u>	2%
Diluted EPS	\$1.21	\$1.20	1%

For notes to the 2010 non-GAAP income statement, please see slide 8.

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

# 2010 Income Statement (Reported)

Millions; except per share data

	<u>Q3 2010</u>	<u>Q3 2009</u>	<u>Growth</u>
Total Revenue	5,655	5,562	2%
Gross Margin	82.5%	81.1%	1.4pp
Total Operating Expense*	2,974	3,374	(12)%
Operating Income	1,693	1,136	49%
Other Income / (Deductions)	(22)	(67)	(68)%
<i>Effective Tax Rate</i>	<i>22.0%</i>	<i>11.9%</i>	<i>10.1pp</i>
Net Income	<u>\$1,303</u>	<u>\$942</u>	38%
Diluted EPS	\$1.18	\$0.86	37%

## Notes:

The third quarter 2010 results include charges of \$59.5 million (pretax), or \$0.03 per share (after-tax). These charges are primarily related to severance and other related costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. The third quarter 2009 results include a special pretax charge of \$424.8 million, or \$0.26 per share (after-tax), primarily related to the sale of the company's Tippecanoe manufacturing site and a special pretax charge of \$125.0 million, or \$0.07 per share (after-tax), in connection with several states' litigation claims involving Zyprexa.

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



# EPS Reconciliation

	<u>Q3 2010</u>	<u>Q3 2009</u>	<u>Growth</u>
EPS (reported)	\$1.18	\$0.86	37%
Charge related to Zyprexa litigation		0.07	
Asset impairments and restructuring charges	0.03	0.26	
EPS (non-GAAP)	<u>\$1.21</u>	<u>\$1.20</u>	1%

Note: Numbers may not add due to rounding.

# Effect of Price/Rate/Volume on Revenue

	Q3 2010 Amount	Q3 2010 vs. Q3 2009			
		Price	FX Rate	Volume	Total
Pharmaceuticals					
U.S.	\$2,837.3	7%	-	(6)%	1%
Europe	1,126.7	(4)%	(10)%	3%	(11)%
Japan	397.2	(1)%	10%	18%	27%
ROW	772.4	1%	3%	10%	14%
Total Pharma	5,133.5	3%	(1)%	(0)%	1%
Animal Health	353.2	(1)%	(0)%	13%	12%
Net Product Sales	5,486.8	3%	(1)%	0%	2%
Collab/Other Revenue	168.0	11%	-	(16)%	(5)%
<b>Total Revenue</b>	<b>\$5,654.8</b>	<b>3%</b>	<b>(1)%</b>	<b>(0)%</b>	<b>2%</b>

Note: Numbers may not add due to rounding.

# Effect of Foreign Exchange on 2010 Results

(Non-GAAP)

Year-on-Year Growth

	Q3 2010		YTD 2010	
	With FX	w/o FX	With FX	w/o FX
Total Revenue	2%	3%	6%	5%
Cost of Sales	(6)%	(7)%	11%	0%
Gross Margin	3%	5%	5%	6%
Operating Expense <i>(R&amp;D plus SG&amp;A)</i>	3%	4%	6%	5%
Operating Income	4%	7%	4%	8%
EPS	1%	5%	3%	8%

Strong underlying financial performance,  
excluding the effect of foreign exchange

# Effect of Foreign Exchange on 2010 Results

(Reported)

## Year-on-Year Growth

	Q3 2010		YTD 2010	
	With FX	w/o FX	With FX	w/o FX
Total Revenue	2%	3%	6%	5%
Cost of Sales	(6)%	(7)%	11%	0%
Gross Margin	3%	5%	5%	6%
Operating Expense <i>(R&amp;D, SG&amp;A and other items)</i>	(12)%	(11)%	(0)%	(1)%
Operating Income	49%	54%	16%	21%
EPS	37%	42%	14%	18%

# 2010 Guidance

Millions, except per share amounts

 Changes

Total Revenue	Mid-single digits
Gross Margin % of Revenue	Flat to increasing
Mktg, Selling & Admin.	Low-single digits
Research & Development	Low-double digits
Other Income/(Expense)	\$0 - \$(50)
Tax Rate	Approximately 23%
EPS (non-GAAP)	\$4.65 - \$4.75
Reconciling Items <i>(excludes any potential future items)</i>	\$0.10
EPS (reported)	\$4.55 - \$4.65
Capital Expenditures	Approx. \$700

For complete reconciliation to reported guidance, please see slide 14 of this presentation and our earnings press release dated Oct 21, 2010.

# Earnings per Share Expectations

	<u>2010</u>	<u>2009</u>	<u>Growth</u>
Earnings per share (reported)	\$4.55-\$4.65	\$3.94	15%-18%
Charges related to Zyprexa litigation	-	0.13	
Asset impairments and restructuring charges	0.07	0.29	
In-process research and development charges associated with the Acrux (2010) and Incyte (2009) licensing agreements	0.03	0.05	
EPS (non-GAAP)	<u><u>\$4.65-\$4.75</u></u>	<u><u>\$4.42</u></u>	5%-7%

Note: Numbers may not add due to rounding.



# U.S. Patent Challenge Update

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## Next Steps for Recent Patent Events:

- Gemzar: requested reconsideration by the CAFC of the ruling that the method-of-use patent is invalid; waiting to hear if that request will be granted
  - In the event the rehearing is denied or unsuccessful, we could lose U.S. exclusivity as early as November 15, 2010 when the compound patent and extensions expire
- Strattera: CAFC hearing scheduled on December 9, 2010 for the method-of-use patent
  - Patent was set to expire in May 2017; CAFC granted an injunction that prevents the launch of generic versions of atomoxetine until an appeal ruling is rendered
- Evista: CAFC's decision on the method-of-use patents can be considered final as the period for requesting a rehearing has passed; appeal to the Supreme Court possible
  - Patents provide protection for Evista in the U.S. through March 2014

## Upcoming Patent Cases:

- Alimta: compound patent trial starts on November 8, 2010 at the U.S. District Court for the District of Delaware
  - Patent provides exclusivity through July 2016
- Cymbalta: compound patent trial scheduled to start on June 6, 2011 at the U.S. District Court for the Southern District of Indiana
  - Patent provides exclusivity through June 2013, or December 2013 with pediatric extension



# Japan Update

## Overview

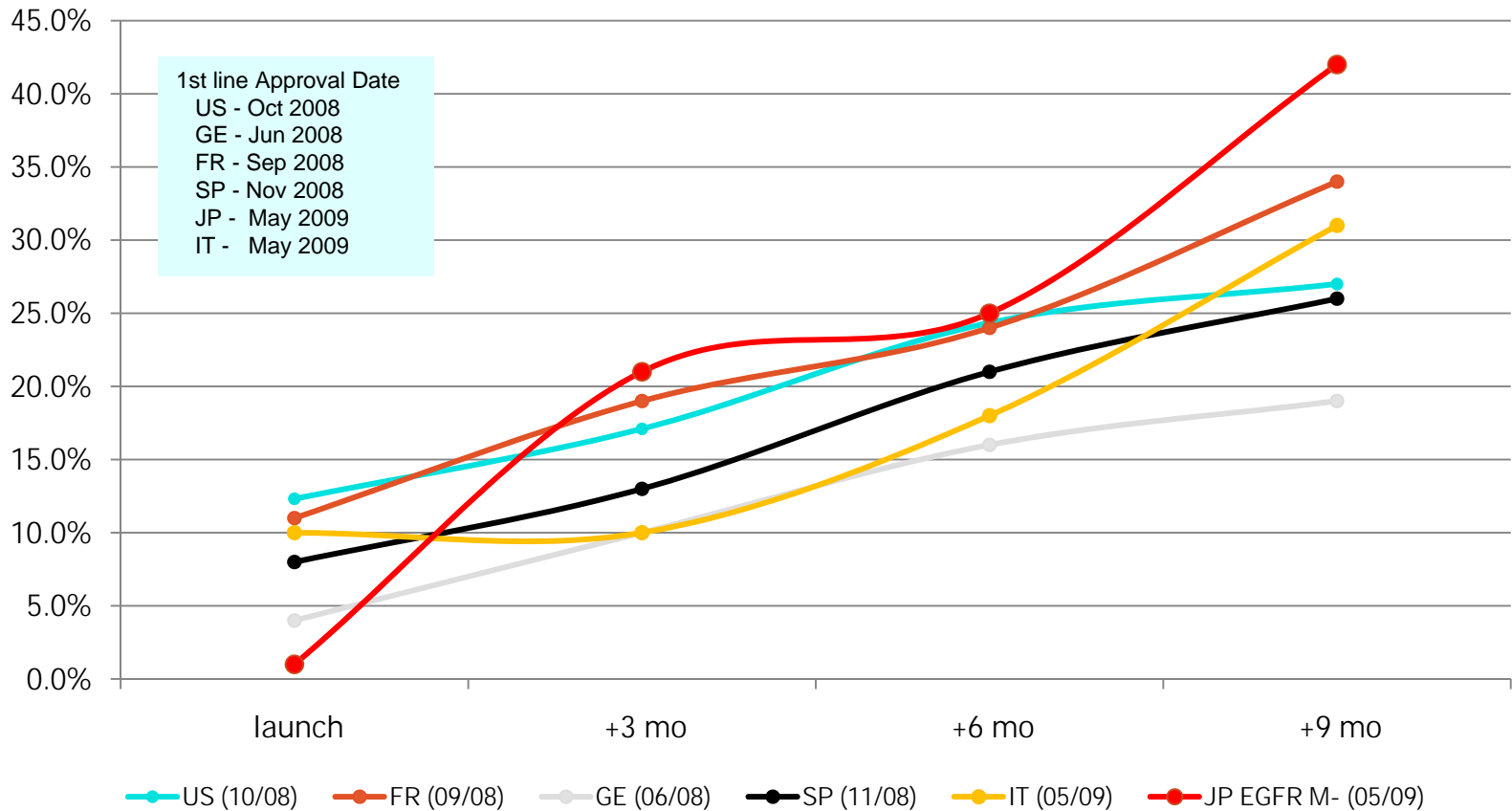
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- Along with Emerging Markets and Animal Health, Japan expected to provide substantial countercyclical growth as we experience patent expirations in the U.S. and Europe
- Lilly Japan by the numbers
  - 2009 pharmaceutical sales of nearly \$1.2 billion
  - Second largest market for Lilly behind the United States
  - September YTD 2010 sales performance growth of 26%
  - According to IMS data, fastest growing major pharma company in Japan August YTD, with 29% growth vs. market growth of 1%
  - Now among top 20 pharmaceutical companies
- Zyprexa is our biggest seller in the Japanese market
  - Over \$300 million in sales and 8% performance growth year-to-date
  - Hope to receive approval for an indication in bipolar mania soon
  - Expect to submit an application for bipolar depression by year-end
  - Expect to maintain exclusivity in Japan until December 2015

# Japan Update

## Alimta Share of Market Uptake

### Quarterly SOM in 1st Line for NSQ NSCLC

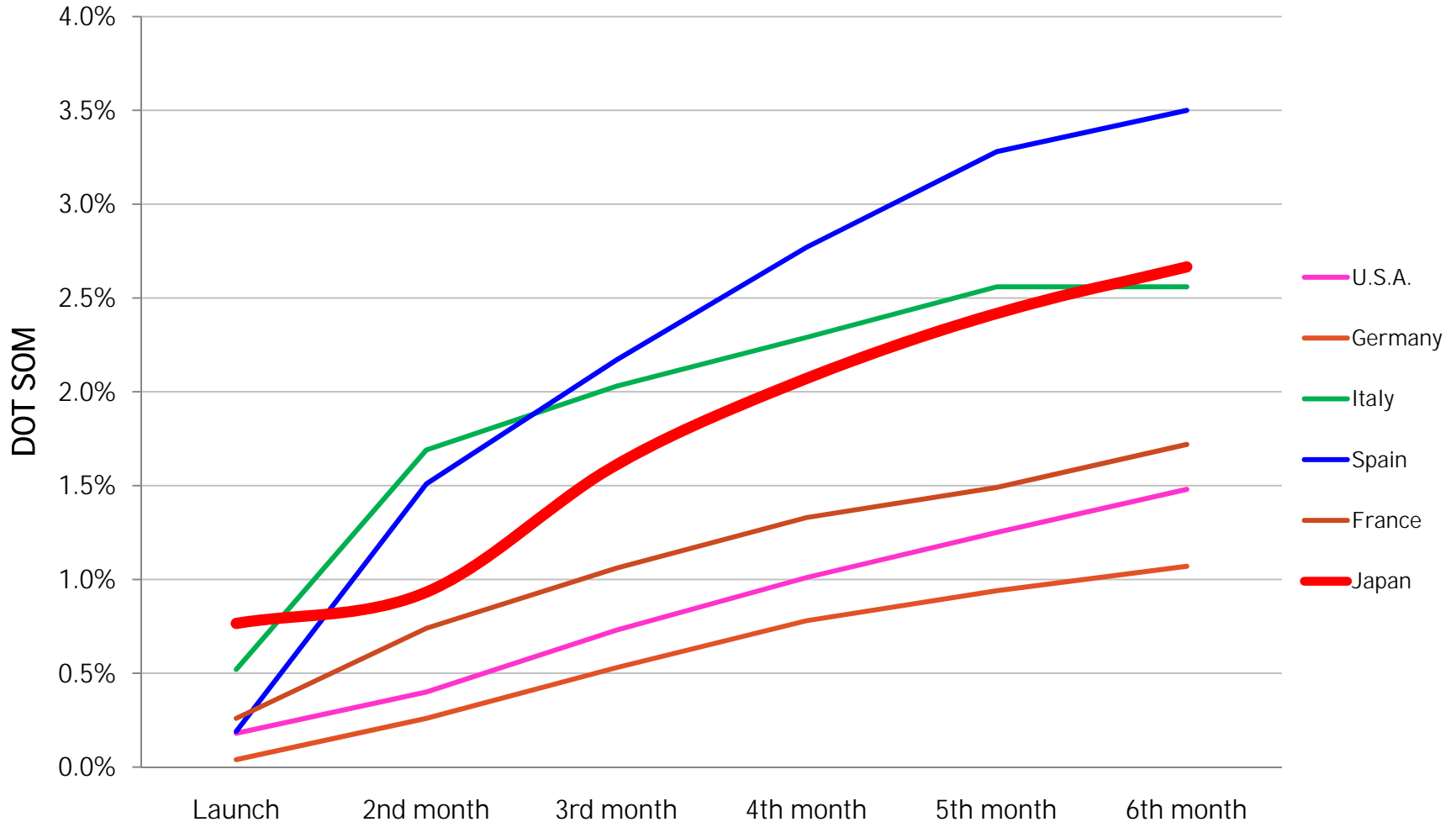


Source: U.S. data from IntrinsiQ, EU data from GfK Tracking, Japan data from Synovate

# Japan Update

## Cymbalta Share of Market Uptake

### Monthly DOT SOM Uptake

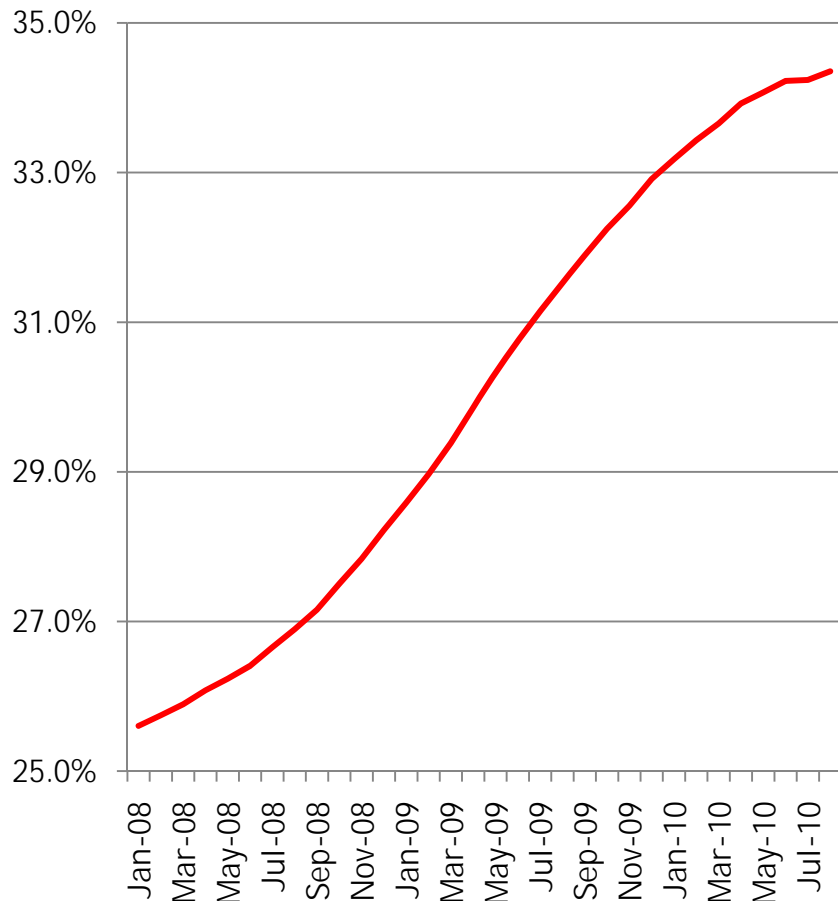


Source: IMS MIDAS

# Japan Update

## Humalog SOM Trend and Recent/Anticipated Approvals

Humalog Mix 12 Month Moving Average SOM%



Source: IMS MIDAS

### Recent and Potential Approvals:

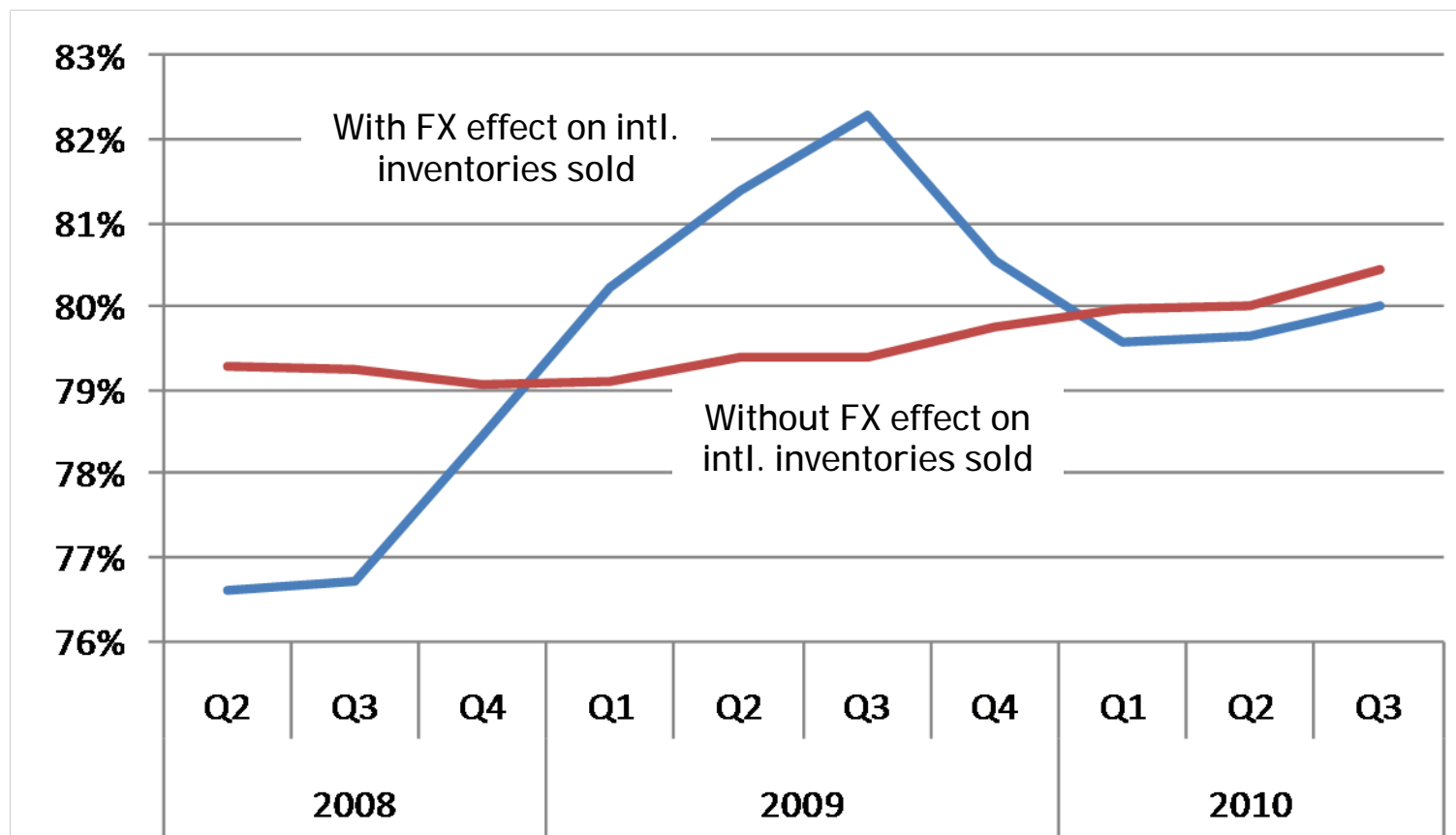
- Strattera for ADHD for children in 2009
- Forteo for osteoporosis in Q3 2010
  - Launched on October 1 after receiving a first-time exemption from the 14-day prescription rule in Japan
- Hope to receive approval for Byetta for type 2 diabetes soon

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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	77.5%	77.4%	82.3%	83.8%	82.1%	81.1%	75.9%	79.5%	82.2%	82.5%
w/o FX effect on intl inv sold	80.6%	78.8%	77.7%	79.4%	81.7%	78.8%	79.2%	80.4%	81.7%	80.6%

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.

# Comparative EPS Summary 2009/2010

	1Q09	2Q09	3Q09	4Q09	2009	1Q10	2Q10	3Q10	4Q10	2010
Non-GAAP	1.20	1.12	1.20	.91	4.42	1.18	1.24	1.21		
Reported	1.20	1.06	.86	.83	3.94	1.13	1.22	1.18		

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 Oct 21, 2010.

# Q3 Other Income/(Deductions)

Millions

	<u>Q3 10</u>	<u>Q3 09</u>
- Interest Expense	(\$47.2)	(\$59.2)
- Interest Income	16.3	15.2
<b>Interest, net</b>	<b>(30.9)</b>	<b>(44.0)</b>
- Outlicense of Marketed Products	-	1.2
- Outlicense of Development Stage Products	3.5	6.0
- Miscellaneous Income / (Loss)	5.7	(30.1)
<b>Other Income, net</b>	<b>9.2</b>	<b>(22.9)</b>
<b>Net Other Income (Loss)</b>	<b><u>\$(21.7)</u></b>	<b><u>(\$66.9)</u></b>

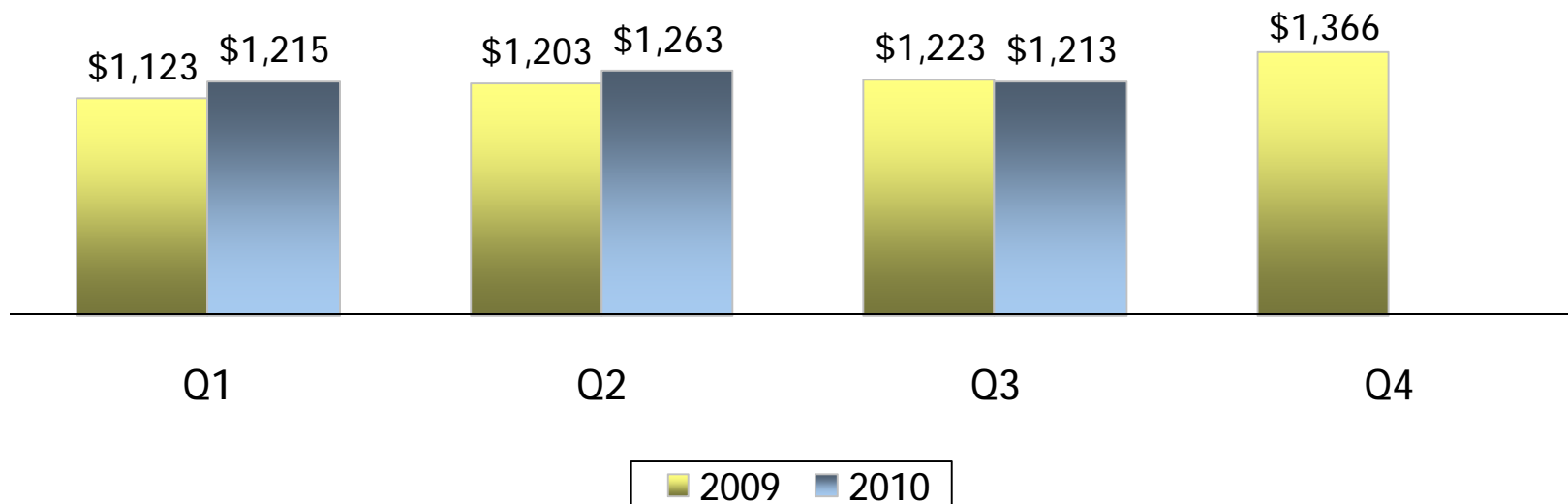
Note: Numbers may not add due to rounding.



# Q3 Zyprexa<sup>®</sup> Sales Decreased 1%

Millions

U.S. sales increased 6%  
International sales decreased 7%

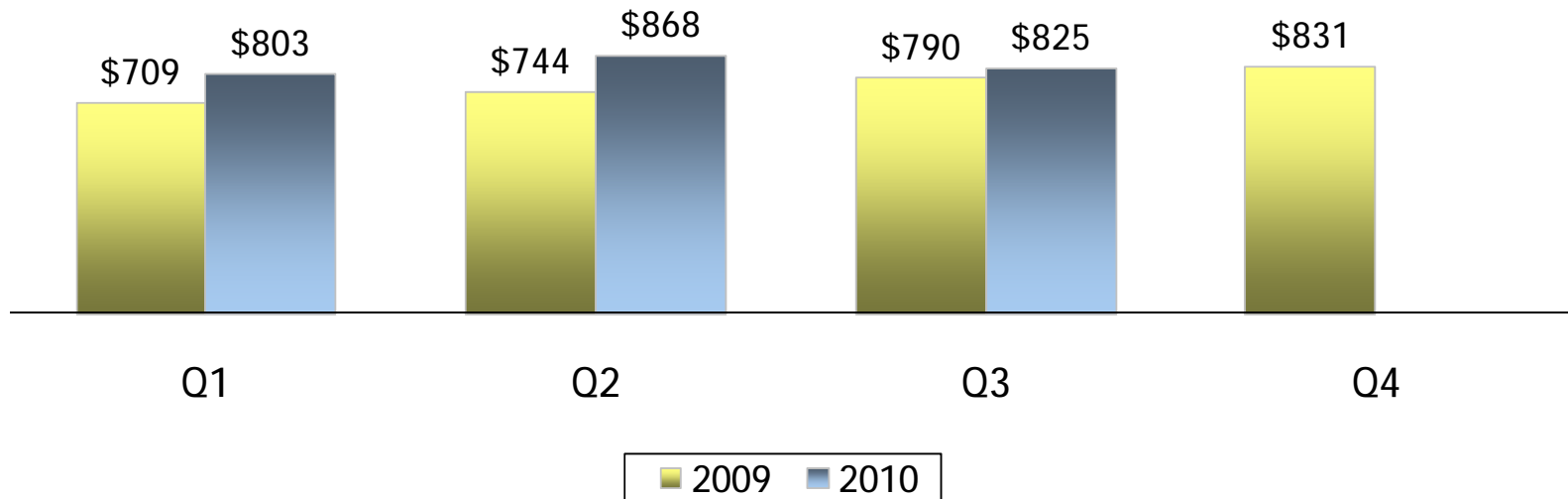


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Cymbalta<sup>®</sup> Revenue Increased 4%

Millions

U.S. sales decreased 1%  
International sales increased 32%

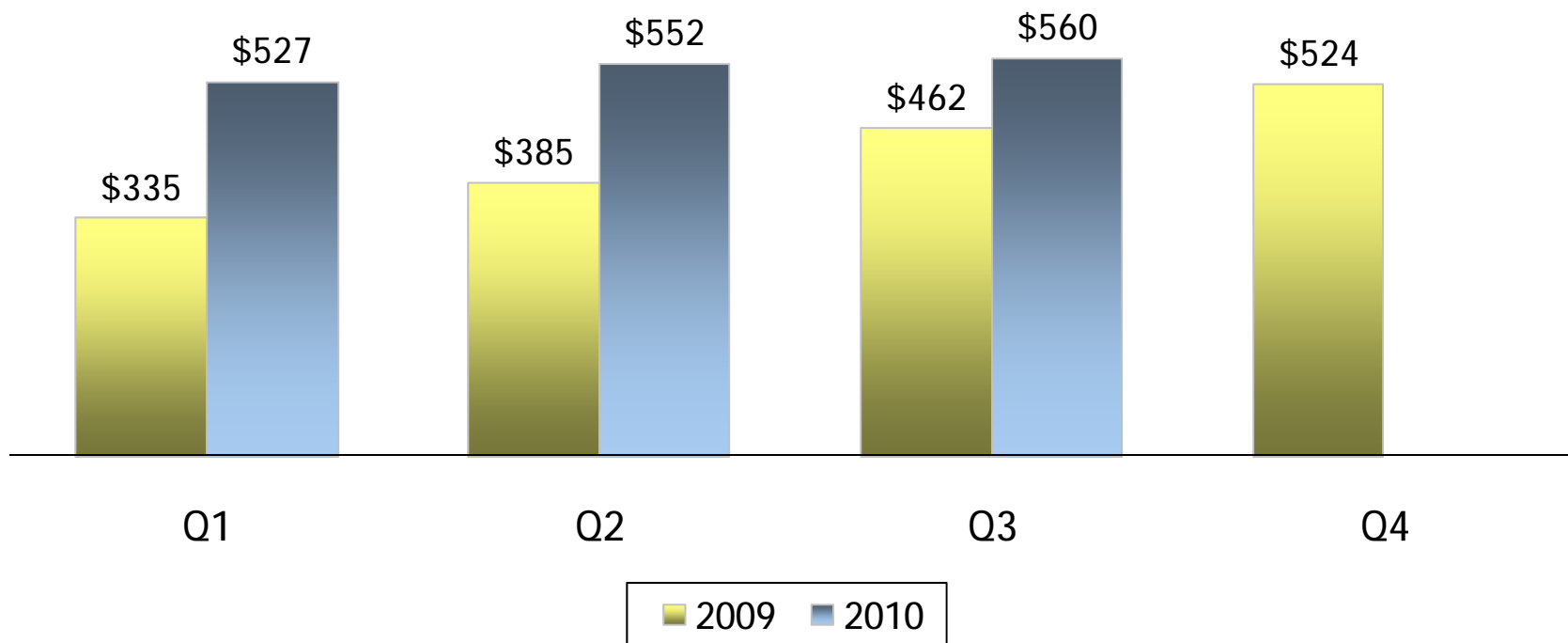


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Alimta<sup>®</sup> Sales Increased 21%

Millions

U.S. sales increased 14%  
International sales increased 28%

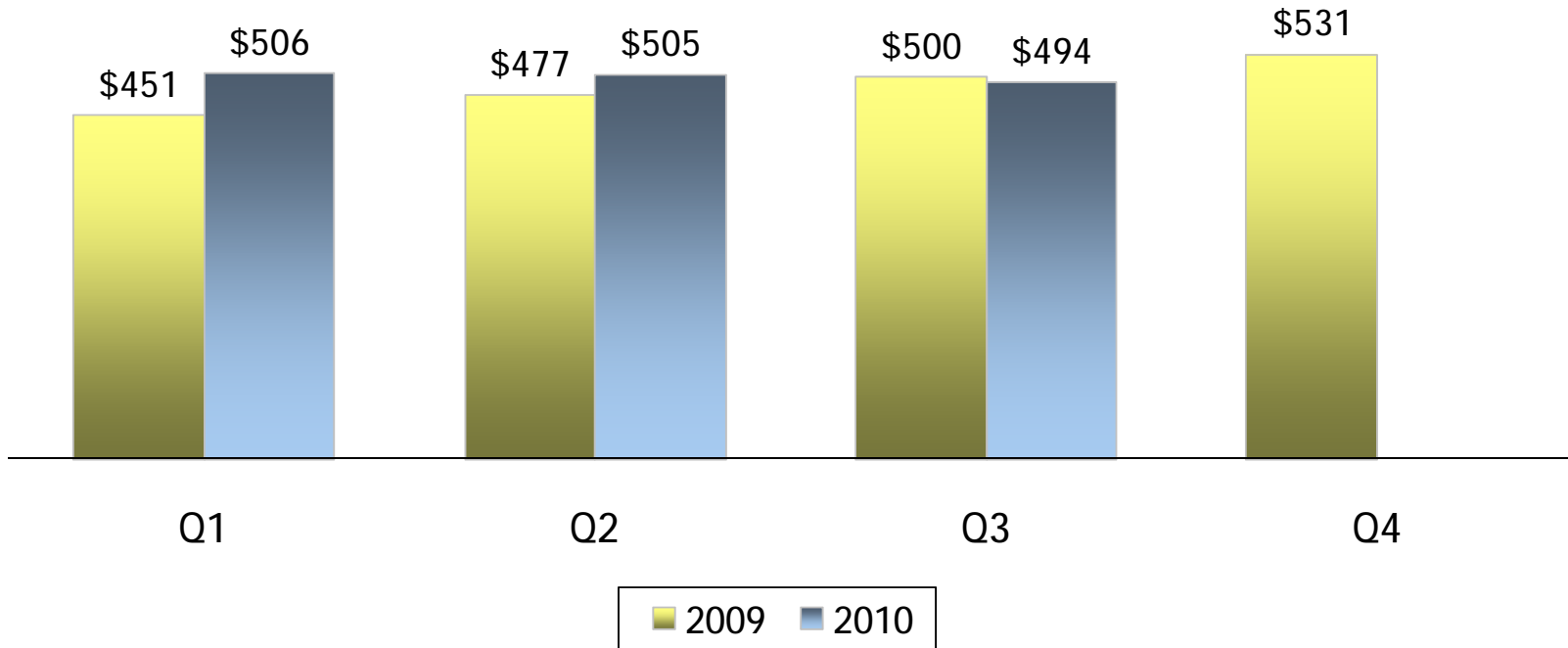


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Humalog<sup>®</sup> Sales Decreased 1%

Millions

U.S. sales decreased 7%  
International sales increased 8%

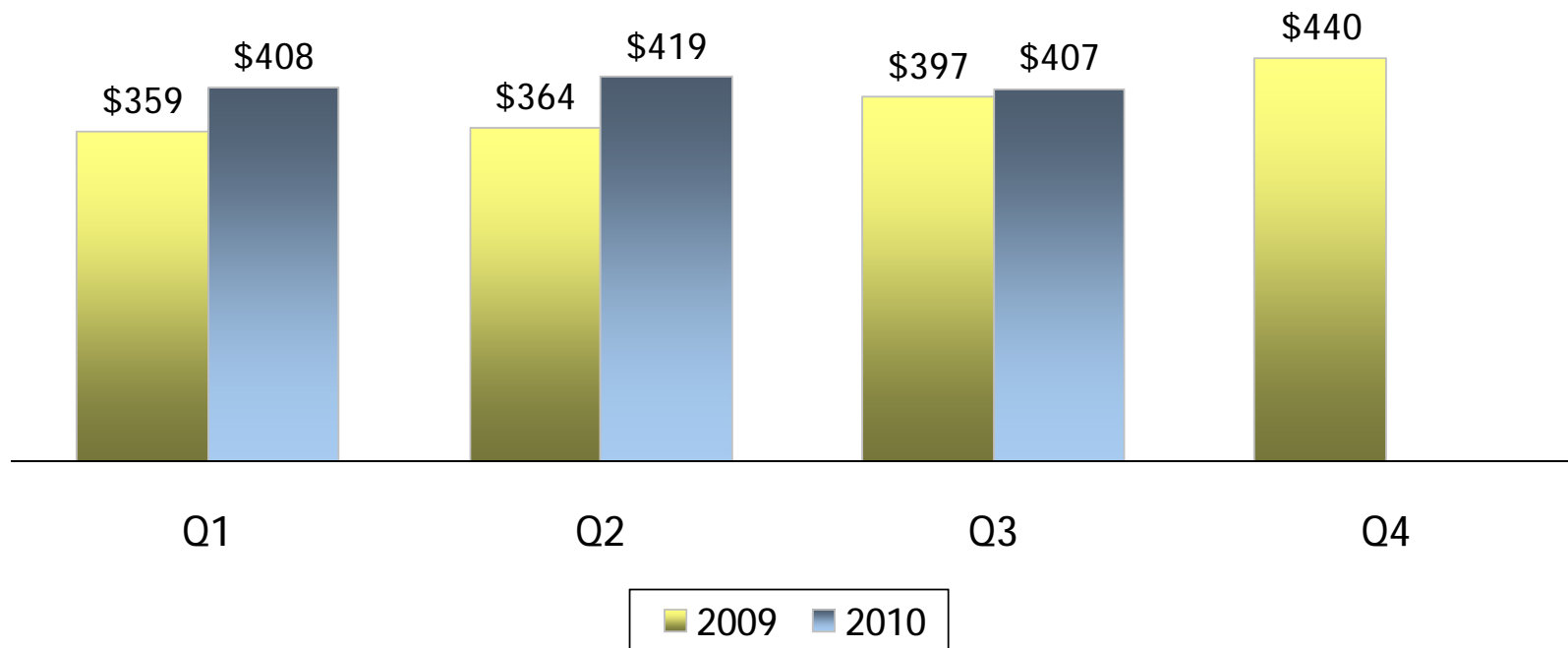


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Cialis<sup>®</sup> Sales Increased 2%

Millions

U.S. sales decreased 3%  
International sales increased 6%

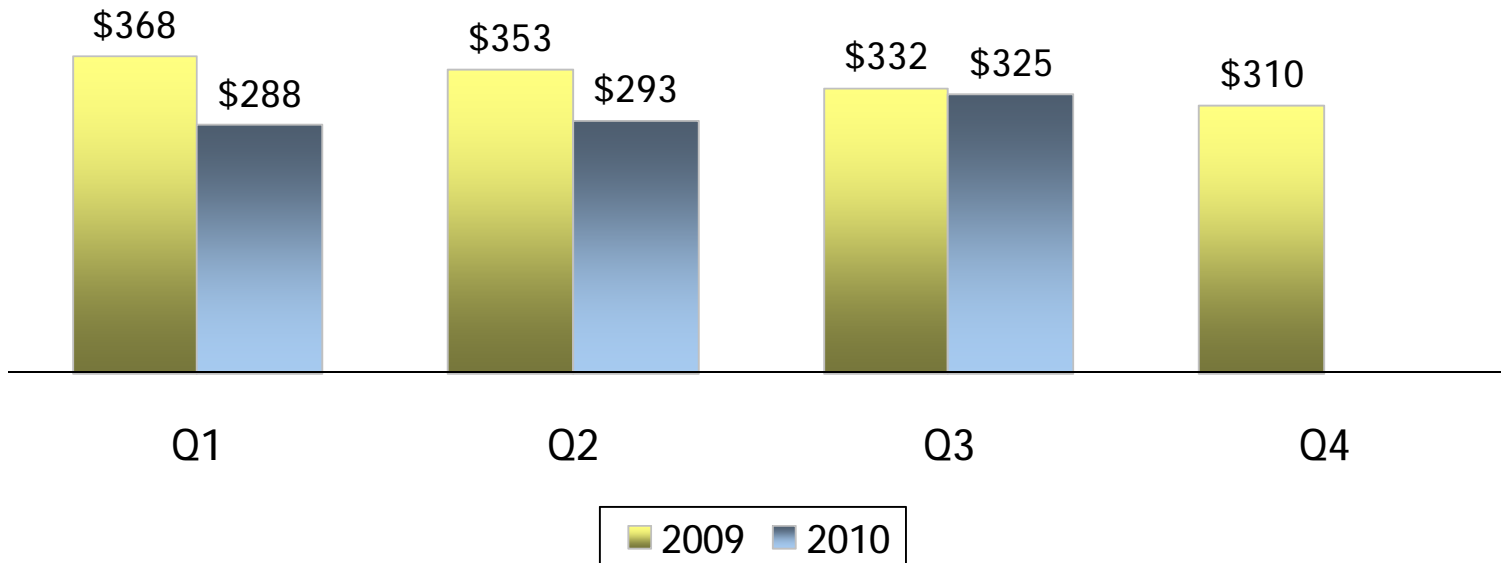


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Gemzar<sup>®</sup> Sales Decreased 2%

Millions

U.S. sales increased 15%  
International sales decreased 25%

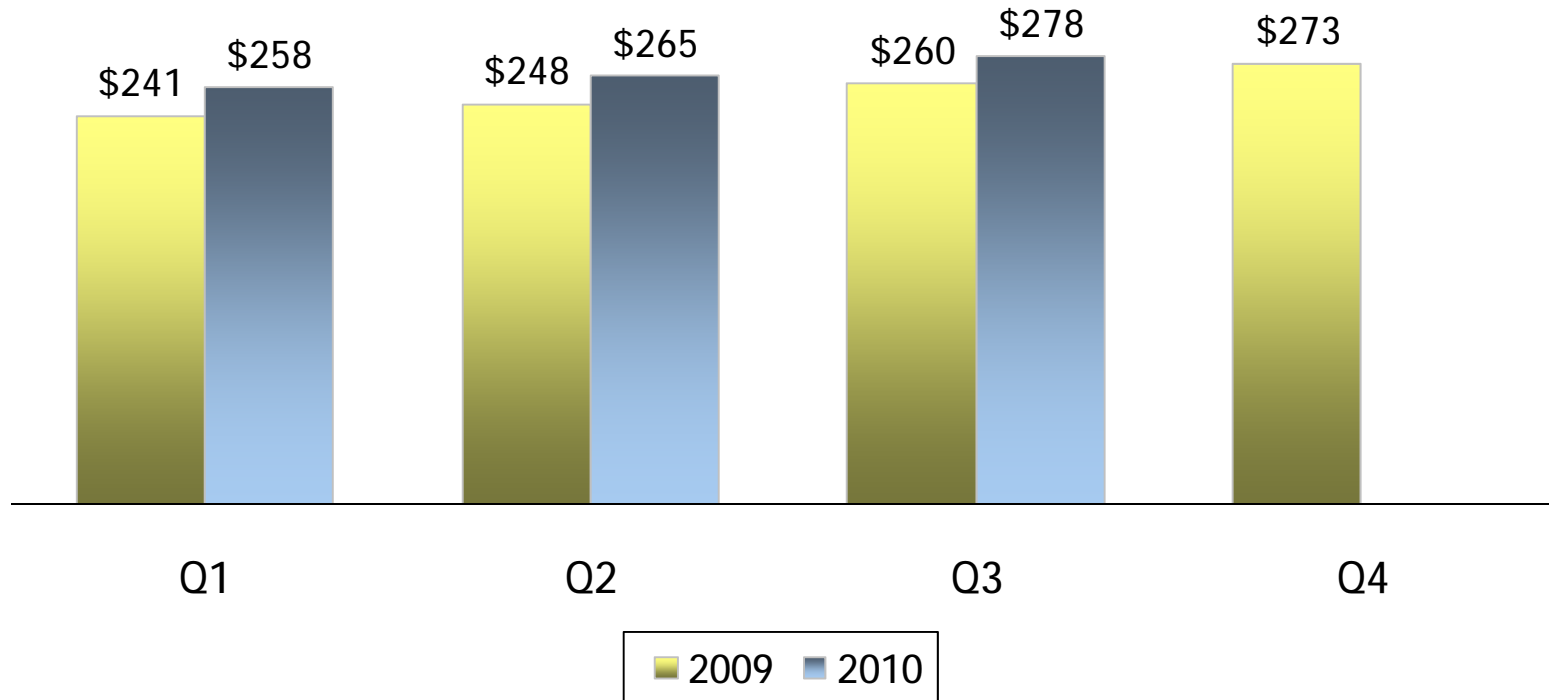


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Humulin<sup>®</sup> Sales Increased 7%

Millions

U.S. sales increased 14%  
International sales increased 2%

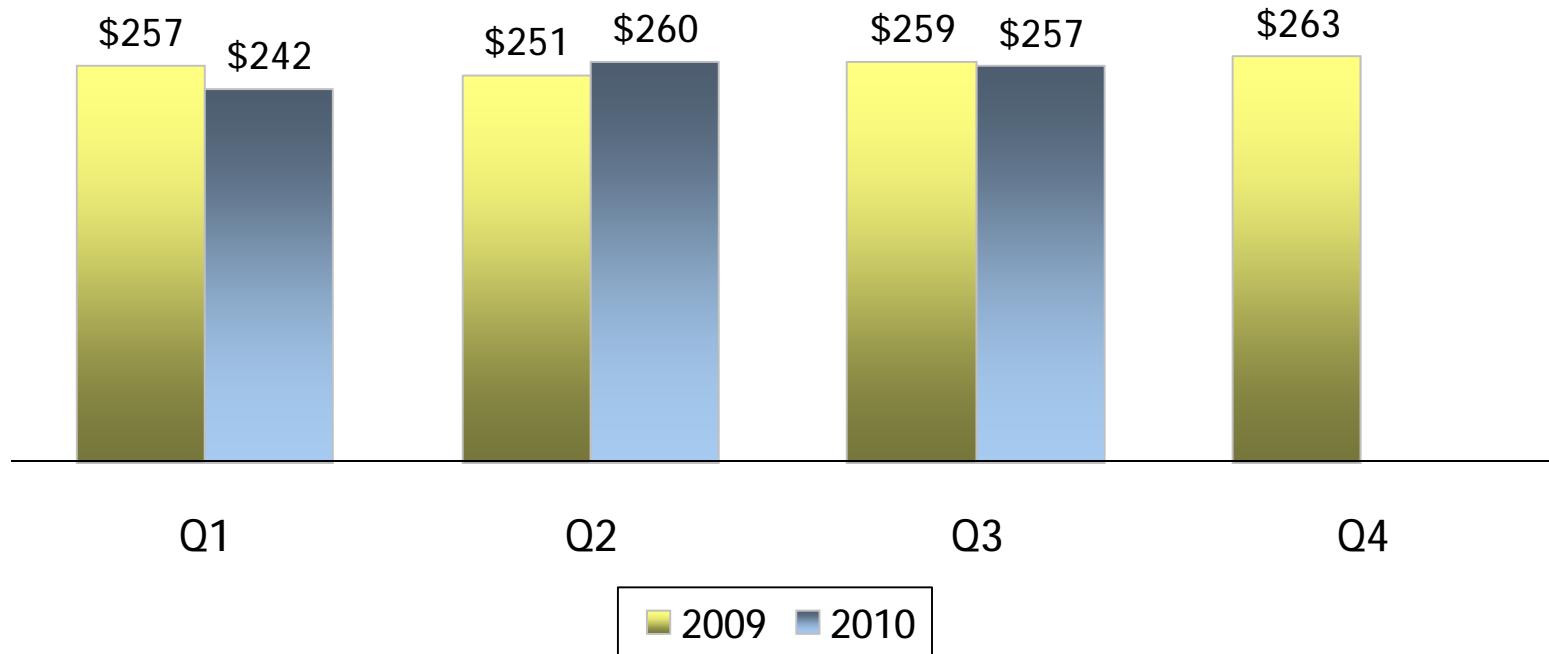


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Evista<sup>®</sup> Sales Decreased 1%

Millions

U.S. sales decreased 5%  
International sales increased 6%



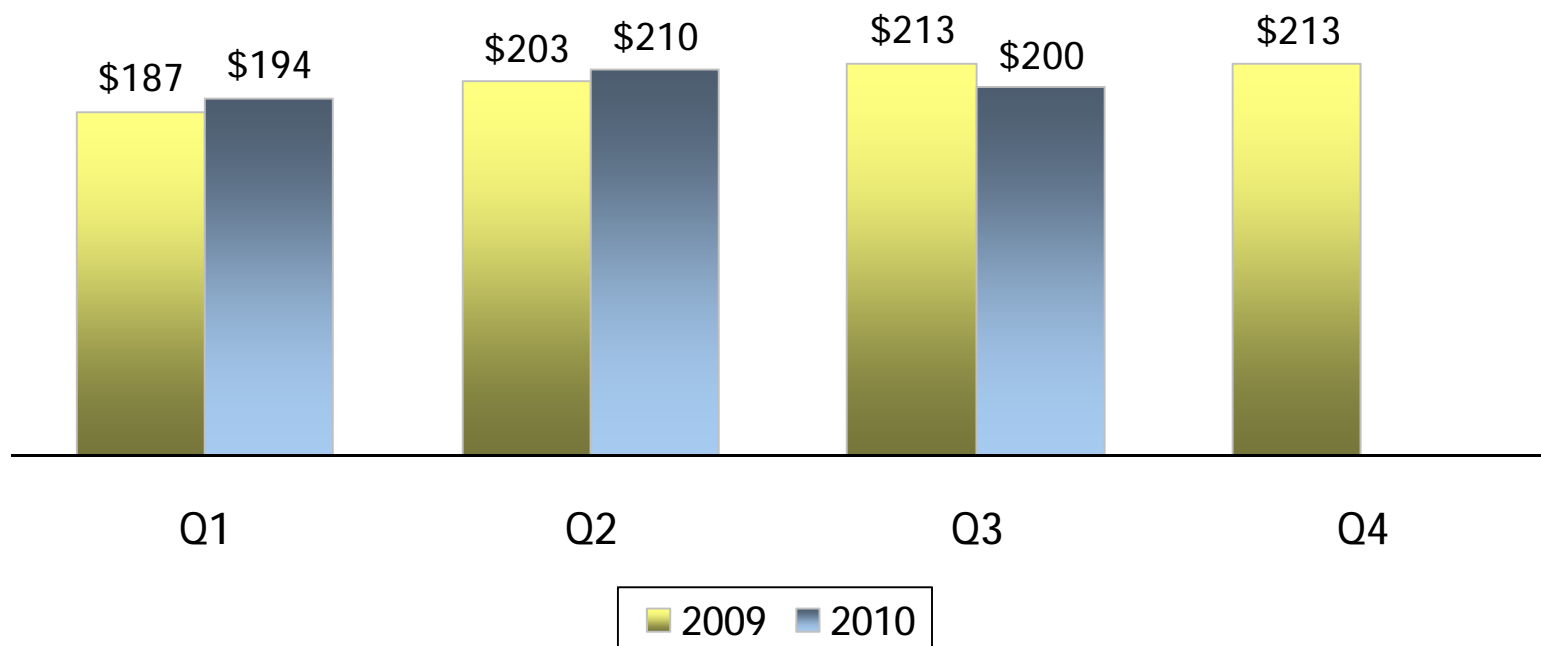
Note: Quarterly numbers may not add to year-to-date totals due to rounding.



# Q3 Forteo<sup>®</sup> Sales Decreased 6%

Millions

U.S. sales decreased 12%  
International sales increased 4%

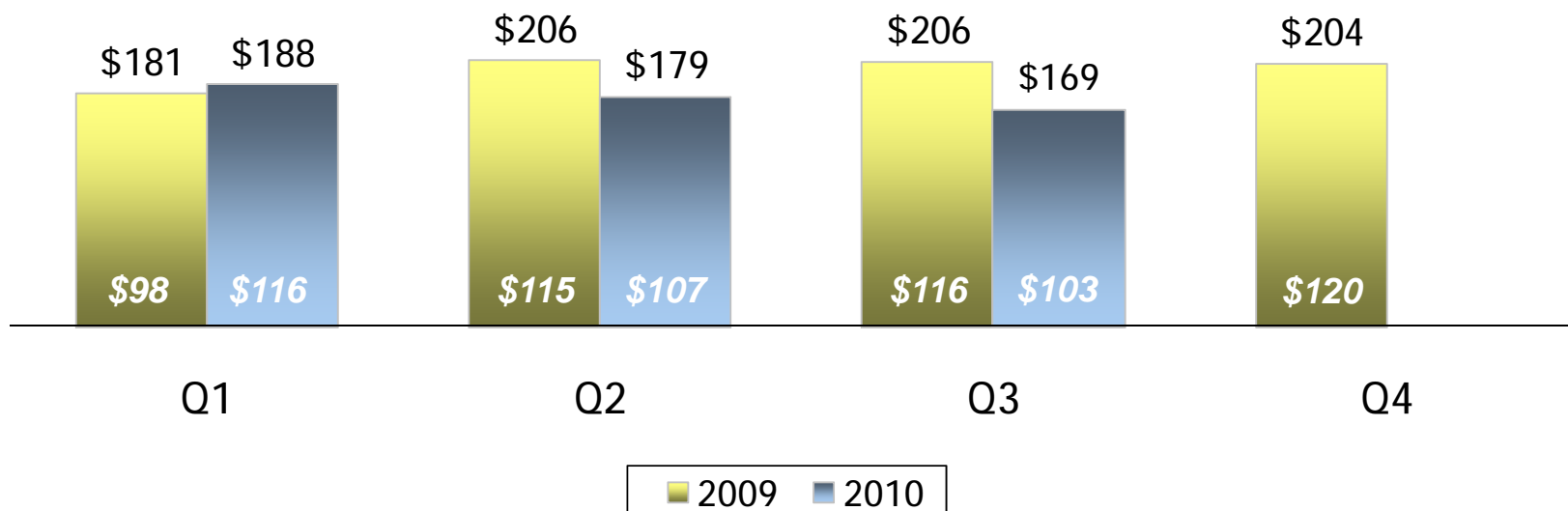


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Byetta<sup>®</sup> Worldwide Sales \$168.8 Million

Millions

Worldwide sales decreased 18%  
Lilly revenue decreased 11%



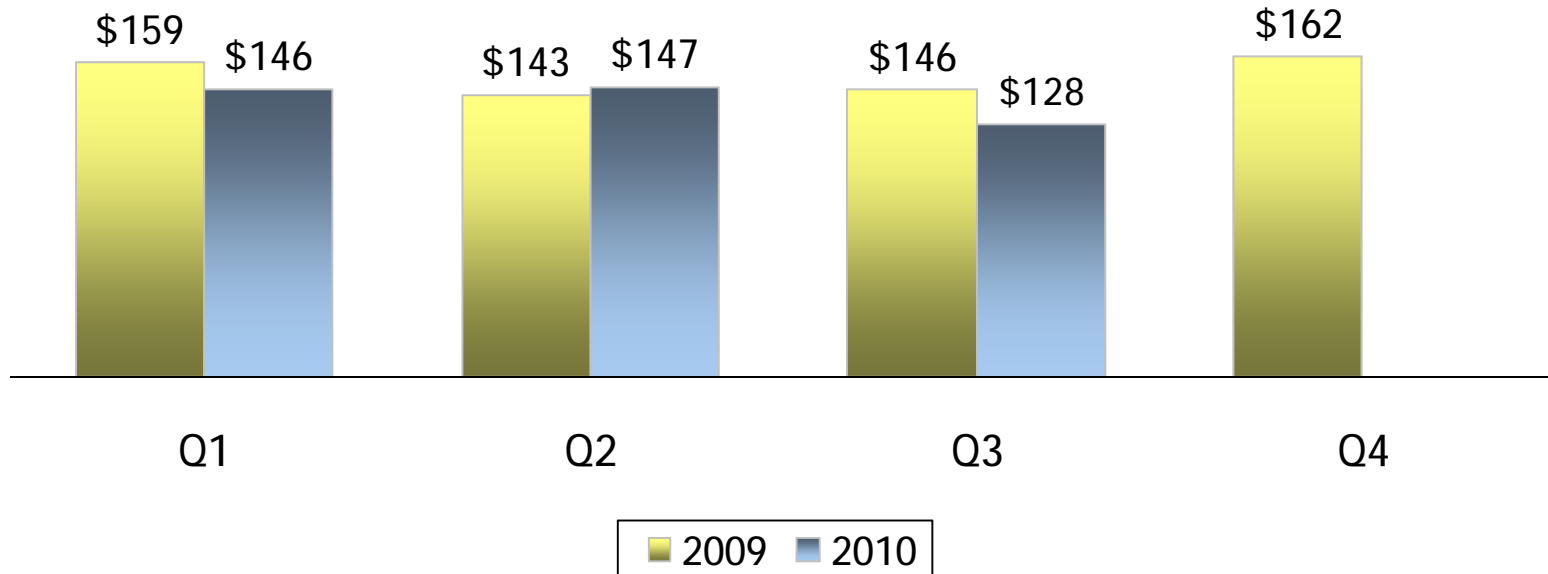
Note:

- Quarterly numbers may not add to year-to-date totals due to rounding.
- Bar height represents total molecule sales; values shown inside bars represent amount recorded in Lilly revenue line.

# Q3 Strattera<sup>®</sup> Sales Decreased 12%

Millions

U.S. sales decreased 20%  
International sales increased 11%



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