# Eli Lilly and Company Fourth Quarter Financial Review January 27<sup>th</sup>, 2011



## Agenda

#### 2010 Summary, Financial Results and Pipeline Update

• Phil Johnson, Vice President, Investor Relations

#### Key 2011 Events and 2011 Financial Guidance

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

#### **Question and Answer Session**

#### Closing Remarks

John Lechleiter, Chairman, President and Chief Executive Officer

### Safe Harbor Provision

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.

## 2010 Summary

- Strong financial performance with 6% revenue growth leveraged into 8% non-GAAP net income growth
- Substantial progress made toward headcount reduction and cost containment goals
- Nearly \$7 billion of operating cash flow easily covered capital expenditures of ~\$700 million and the dividend of ~\$2.2 billion
- Pipeline disappointments with semagacestat, teplizumab and tasisulam; focus on pipeline led to advancement of 16 new molecules into Phase 1, nine into Phase 2 and two into Phase 3
- Concluded multiple business development deals focused on current or potential near-term revenues

## Beyond the Quarterly Financial Results

#### Key events since the last earnings call

#### Clinical:

- Initiated Phase 3 clinical programs for our anti-BAFF antibody in both RA and lupus
- Decided to advance mGlu2/3 into Phase 3 for schizophrenia; Phase 3 trials to start in 2011
- Disclosed Phase 2a data in RA for the JAK-1/JAK-2 inhibitor, in-licensed from Incyte

#### Regulatory:

- FDA approved Cymbalta for the management of chronic musculoskeletal pain
- FDA approved Axiron for replacement therapy in males for certain conditions associated with a deficiency in testosterone; launch to occur mid-2011
- Health Canada approved Byetta to improve glycemic control in patient with type 2 diabetes
- Submitted sNDAs to the FDA for Byetta as add-on therapy to basal insulin and for Cialis for BPH

#### Legal:

- U.S. District Court ruled that judgment would be entered in Lilly's favor confirming the validity of Alimta's compound patent through January 2017
- U.S. CAFC heard Strattera appeal on December 9<sup>th</sup> awaiting court's decision

#### **Business Development:**

- Announced and completed Avid Radiopharmaceuticals acquisition and the FDA assigned priority review designation to florbetapir, a beta-amyloid imaging agent
- Announced a global agreement to co-develop and co-commercialize two oral diabetes compounds from Boehringer Ingelheim and two basal analog insulins from Lilly

## Comparison Measures

#### Results shown two ways to aid analysis

#### "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

	Q4 2010	Growth	Year	Growth
Total Revenue	\$6,187	4%	\$23,076	6%
Gross Margin	80.1%	4.2pp	81.1%	0.5pp
Total Operating Expense*	3,427	8%	11,938	6%
Operating Income	1,528	15%	6,772	6%
Other Income / (Deductions)	(39)	(42)%	(5)	(98)%
Effective Tax Rate	17.0%	(4.0)pp	22.6%	1.6pp
Net Income	\$1,235	24%	\$5,241	8%
Diluted EPS	\$1.11	22%	\$4.74	7%

For notes to the 2010 non-GAAP income statement, please see slide 22.

<sup>\*</sup> Includes Research and Development expense and Selling, Marketing and Administrative expense.

## 2010 Income Statement (Reported)

Millions; except per share data

	Q4 2010	Growth	<u>Year</u>	Growth
Total Revenue	\$6,187	4%	\$23,076	6%
Gross Margin	80.1%	4.2pp	81.1%	0.5pp
Total Operating Expense*	3,506	6%	12,180	1%
Operating Income	1,449	20%	6,530	17%
Other Income / (Deductions)	(39)	(42)%	(5)	(98)%
Effective Tax Rate	17.0%	(2.5)pp	22.3%	3.1pp
Net Income	\$1,170	28%	\$5,070	17%
Diluted EPS	\$1.05	27%	\$4.58	16%

<sup>\*</sup> Includes Research and Development expense, Selling, Marketing and Administrative expense and other charges.

## **EPS Reconciliation**

	Q4 2010	Growth	Year	Growth
EPS (reported)	\$1.05	27%	\$4.58	16%
Asset impairments and restructuring charges (included in asset impairments, restructuring and other				
special charges)	0.06		0.13	
In-process research and development charge			0.00	
associated with the Acrux in-licensing agreement	-		0.03	
EPS (non-GAAP)	\$1.11	22%	\$4.74	7%

Note: Numbers may not add due to rounding.

## Effect of Price/Rate/Volume on Revenue

			Q4 2010		
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$3,064.4	4%		(0)%	4%
Europe	1,287.6	(2)%	(7)%	4%	(5)%
Japan	463.2	0%	8%	21%	30%
ROW	794.1	1%	3%	1%	4%
Total Pharma	5,609.3	2%	(1)%	2%	3%
Animal Health	424.3	(0)%	0%	20%	20%
Net Product Sales	6,033.7	2%	(1)%	4%	4%
Collab/Other Revenue	153.3	2%	-	(2)%	0%
Total Revenue	\$6,187.0	2%	(1)%	3%	4%
			Full Year 20	10	
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$11,607.2	6%		(1)%	5%
Europe	4,837.5	(3)%	(4)%	3%_	(3)%
Japan .	1,565.1	(1)%	7%	26%	32%
ROW	3,041.1	(1)%	6%	6%	12%
Total Pharma	21,050.9	2%	0%	3%	5%
Animal Health	1,391.4	(0)%	1%	14%	15%
Net Product Sales	22,442.3	2%	0%	4%	6%
Collab/Other Revenue	633.7	3%	-	(8)%	(5)%
Total Revenue	\$23,076.0	2%	0%	3%	6%
Note: Numbers may not add due	to rounding.				

# Effect of Foreign Exchange on 2010 Results (Non-GAAP)

Year-on-Year Growth

	Q4 2	2010	20	10
	With FX w/o FX		With FX	w/o FX
Total Revenue	4%	5%	6%	5%
Cost of Sales	(14)%	(2)%	3%	(0)%
Gross Margin	10%	7%	6%	7%
Operating Expense (R&D plus SG&A)	8%	9%	6%	6%
Operating Income	15%	3%	6%	7%
EPS	22%	10%	7%	8%

# Effect of Foreign Exchange on 2010 Results (Reported)

Year-on-Year Growth

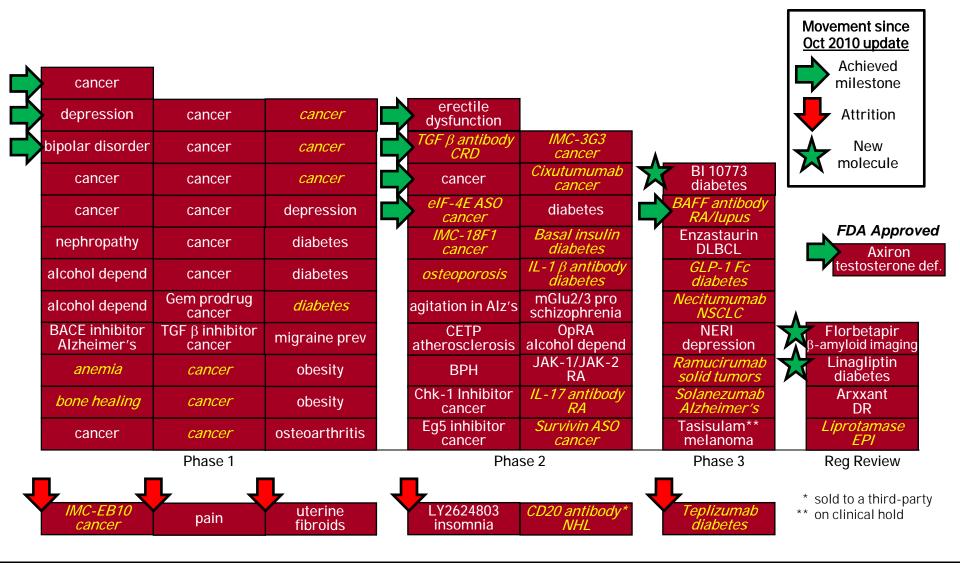
	Q4 2	2010	20	10
	With FX	w/o FX	With FX	w/o FX
Total Revenue	4%	5%	6%	5%
Cost of Sales	(14)%	(2)%	3%	(0)%
Gross Margin	10%	7%	6%	7%
Operating Expense (R&D, SG&A and other	6% items)	7%	1%	1%
Operating Income	20%	8%	17%	18%
EPS	27%	13%	16%	17%

## Lilly NME Pipeline

January 24, 2011

New Chemical Entity (NCE)

New Biotech Entity (NBE)



## Key Events in 2011

#### Launches:

- Cymbalta for management of chronic musculoskeletal pain in early Q1
- Axiron for testosterone deficiency in mid-2011

# Potential regulatory actions/approvals:

- Bydureon in the EU
- In the U.S.:
  - Linagliptin for type 2 diabetes
  - Liprotamase, recombinant pancreatic enzyme replacement therapy
  - Florbetapir, a radiopharmaceutical for imaging beta-amyloid in the brain
  - Cialis for BPH
  - Byetta in combination with basal insulin

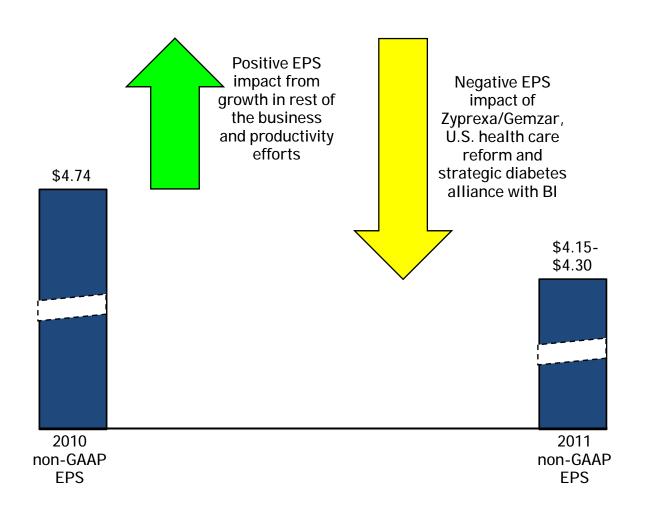
# Expected regulatory submissions:

- Response to FDA complete response letter for Bydureon
- sBLAs for Erbitux in 1<sup>st</sup>-line mCRC, head and neck cancer and NSCLC

#### Phase 3 trials:

- Completion of DURATION-6 trial comparing Bydureon to Victoza
- Initial results of Alimta induction followed by Alimta maintenance
- Initiation of trials for:
  - mGlu2/3 for schizophrenia
  - Our novel basal insulin analog
  - Our new insulin glargine product
  - anti-IL-17 antibody for RA

#### 2011 Guidance Framework

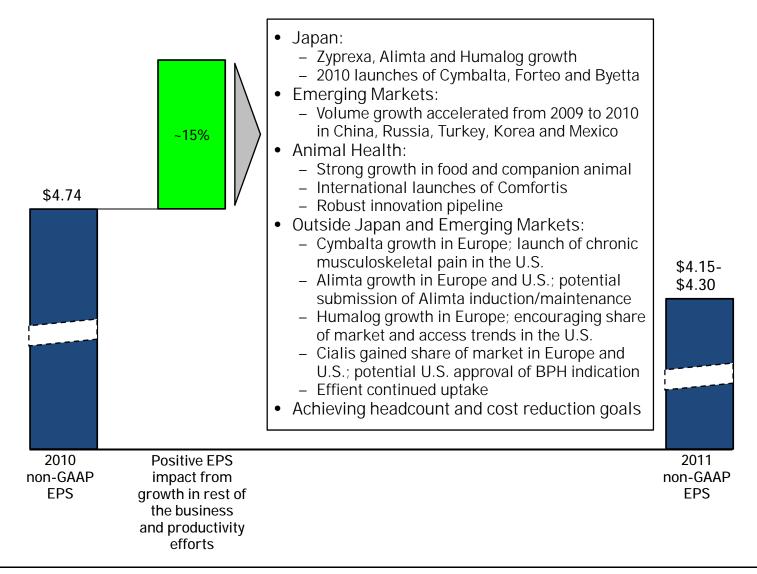


#### **QUESTION:**

How big are the positive and negative factors driving the projected 9%-12% decline in 2011 non-GAAP EPS?

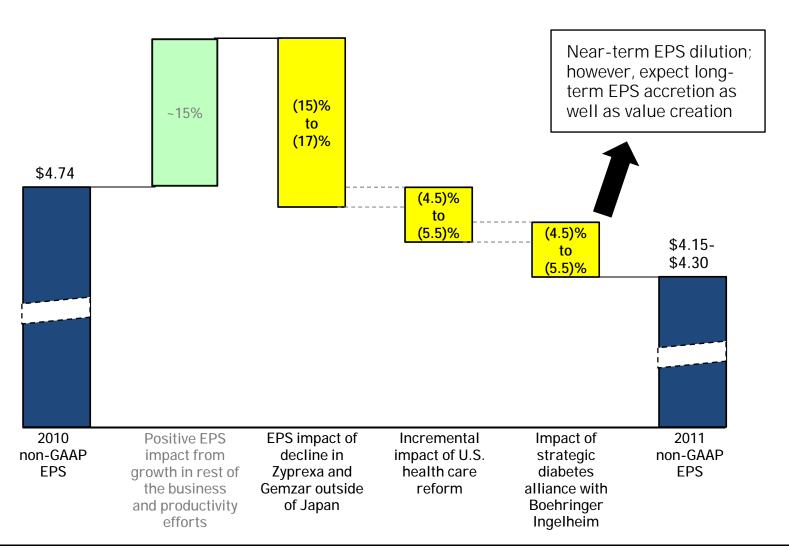
#### 2011 Guidance

#### Factors driving EPS to increase



#### 2011 Guidance

#### Factors driving EPS to decrease



### 2011 Guidance

Millions, except per share amounts

Total Revenue Flat to slightly increasing

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 Approximately 21.5%

EPS (reported) \$3.92 - \$4.07

Reconciling Items (estimated) \$0.23 (excludes any potential future items)

EPS (non-GAAP) \$4.15 - \$4.30

Capital Expenditures \$800-\$900

For complete reconciliation to reported guidance, please see slide 19 of this presentation and our earnings press release dated Jan 27, 2011.

# Earnings per Share Expectations

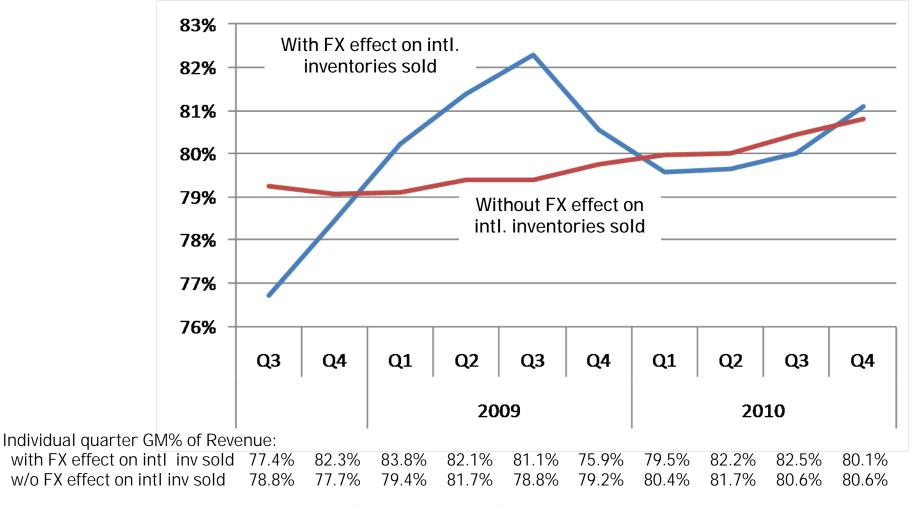
	2011	2010	Growth
Earnings per share (reported)	\$3.92-\$4.07	\$4.58	(11)%-(14)%
Asset impairments and restructuring charges	-	0.13	
In-process research and development charges associated with the BI (2011) and Acrux (2010) licensing agreements	0.23	0.03	
EPS (non-GAAP)	\$4.15-\$4.30	\$4.74	(9)%-(12)%

Note: Numbers may not add due to rounding.

# Supplementary Slides

# Gross Margin % - Moving Annual Total

Pro-forma non-GAAP



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.

#### 2010 Non-GAAP Income Statement Notes

#### Notes:

- The fourth-quarter and full-year 2010 financial statements have been adjusted to eliminate a restructuring charge of \$79.0 million (pretax), or \$0.06 (after-tax), related to severance costs from previously announced strategic actions.
- The year-to-date 2010 financial statements have also been adjusted to eliminate an additional restructuring charge of \$113.0 million (pretax), or \$0.07 (after-tax). This charge is primarily related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. In addition, the year-to-date 2010 financial statements have been adjusted to eliminate 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.
- The fourth- quarter and full-year 2009 financial statements have been adjusted to eliminate an asset impairment and restructuring charge of \$37.9 million (pretax), or \$0.02 (after-tax),. This charge is primarily related to severance costs from previously announced strategic actions. In addition, the fourth quarter and full-year 2009 financial statements have been adjusted to eliminate a charge of \$90.0 million (pretax), of \$0.05 per share (after-tax) for acquired in-process research and development associated with the licensing agreement with Incyte.
- The year-to-date 2009 financial statements have been adjusted to eliminate an additional special pretax charge of \$230.0 million, or \$0.13 per share (after-tax), related with several states' litigation claims involving Zyprexa. In addition, the full-year 2009 financial statements have also been adjusted to eliminate an asset impairment and restructuring charge of \$424.8 million (pretax), or \$0.26 (after-tax) primarily related to severance costs from previously announced strategic actions.

## Comparative EPS Summary 2009/2010

	1009	2009	3Q09	4009	2009	1Q10	2Q10	3Q10	4Q10	2010
Non-GAAP	1.20	1.12	1.20	.91	4.42	1.18	1.24	1.21	1.11	4.74
Reported	1.20	1.06	.86	.83	3.94	1.13	1.22	1.18	1.05	4.58

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 Jan 27, 2011.

## Q4 Other Income/(Deductions)

#### Millions

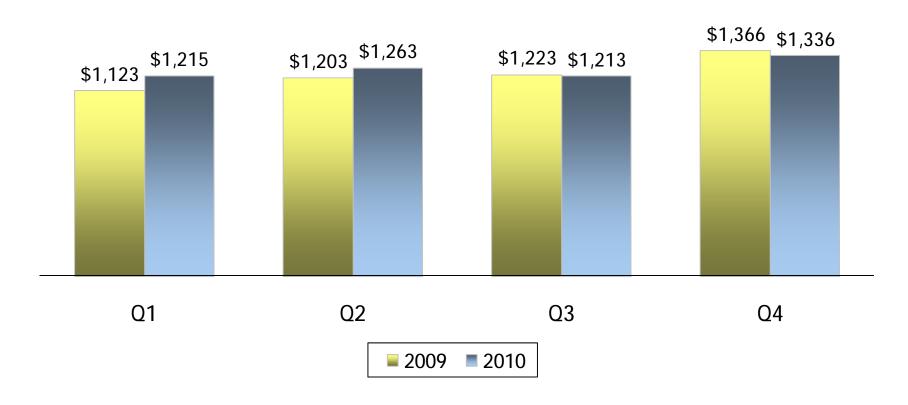
	Q4 10	Q4 09
- Interest Expense	(\$43.2)	(\$50.2)
- Interest Income	14.0	13.8
Interest, net	(29.2)	(36.4)
<ul><li>Outlicense of Development Stage Products</li><li>Miscellaneous Income / (Loss)</li><li>Other Income, net</li></ul>	1.2 (11.4) (10.2)	(31.4) (31.4)
Net Other Income (Loss)	\$(39.4)	<u>(\$67.8)</u>

Note: Numbers may not add due to rounding.

# Q4 Zyprexa® Sales Decreased 2%

Millions

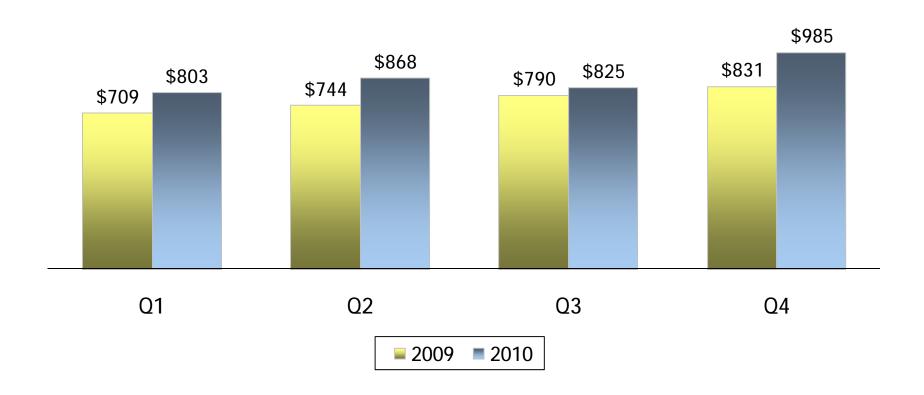
U.S. sales increased 4% International sales decreased 8%



# Q4 Cymbalta® Revenue Increased 19%

Millions

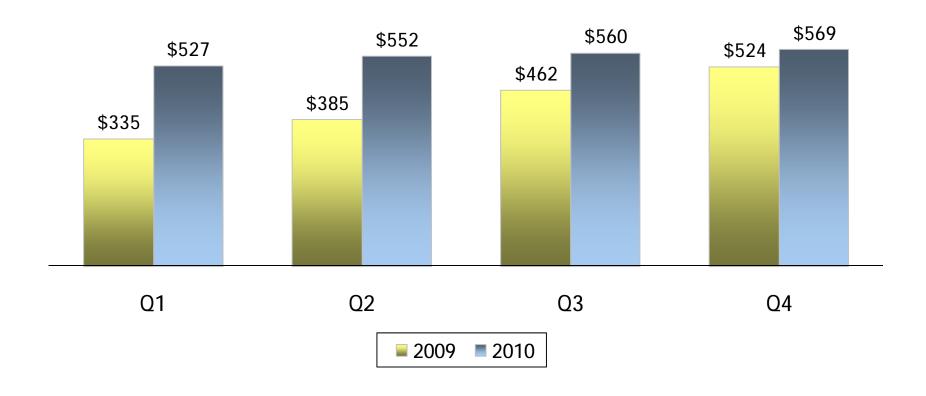
U.S. sales increased 13% International revenue increased 43%



## Q4 Alimta® Sales Increased 9%

Millions

U.S. sales increased 3% International sales increased 13%



# Q4 Humalog® Sales Increased 3%

Millions

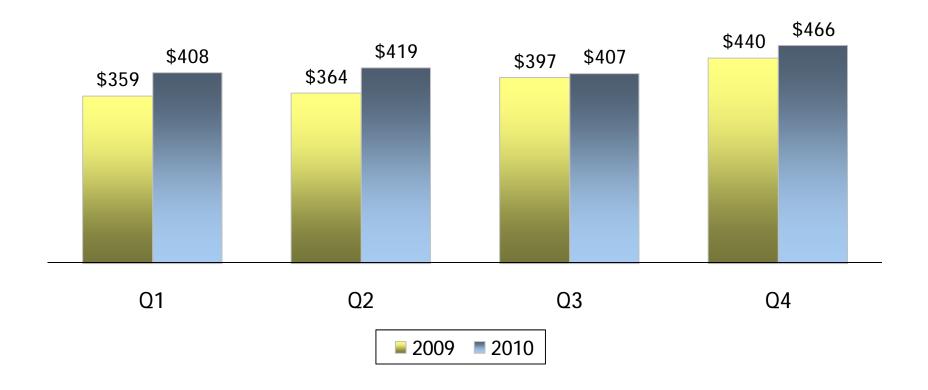
U.S. sales increased 1% International sales increased 7%



## Q4 Cialis® Sales Increased 6%

Millions

U.S. sales increased 14% International sales increased 1%



### Q4 Gemzar® Sales Decreased 22%

Millions

U.S. sales decreased 27% International sales decreased 13%



## Q4 Humulin® Sales Increased 5%

Millions

U.S. sales increased 17% International sales decreased 2%



### Q4 Evista® Sales Increased 1%

Millions

U.S. sales increased 3% International sales decreased 2%



## Q4 Forteo® Sales Increased 6%

Millions

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



# Q4 Byetta® Worldwide Sales \$174.6 Million

Millions

Worldwide sales decreased 14% Lilly revenue decreased 13%



## Q4 Strattera® Sales Decreased 4%

Millions

U.S. sales decreased 14% International sales increased 21%

