# Eli Lilly and Company Second Quarter Financial Review July 22<sup>nd</sup>, 2010



# Agenda

### Opening Remarks, Recent Events and European Update

Phil Johnson, Vice President, Investor Relations

#### Financial Overview and Guidance

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

#### Pipeline Update

Ronika Pletcher, Director, Investor Relations

**Question and Answer Session** 

Closing Remarks

### 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 Form 10-K filed February 2010 and 10-Q filed May 2010.

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

# Beyond the Quarterly Financial Results

### Key events since the last earnings call

#### **Business Development:**

- Acquired Alnara Pharmaceuticals; liprotamase under FDA review for treatment of exocrine pancreatic insufficiency
- Entered into a development and exclusive license agreement for Marcadia Biotech's short-acting glucagon program

#### Regulatory:

- The FDA notified Lilly that an Advisory Committee will be held to discuss the Cymbalta sNDA submission for the management of chronic pain on August 19, 2010
- Submitted response to the Bydureon Complete Response Letter; new PDUFA goal date of October 22, 2010
- Received a positive final appraisal from UK's NICE for use of Alimta as a maintenance therapy for patients with nonsquamous NSCLC

#### Commercial:

- Launched Livalo in the United States
- Announced an agreement with Walmart to make Humulin® available across the U.S. under the dual-branded name Humulin® ReliOn®
- Various European governments announced measures to reduce pharmaceutical expenditures

## **European Pricing Update**

#### Germany

- Temporary measures effective August 1st through the end of 2013:
  - Increase in rebate from 6% to 16%
  - Additional rebate to restore prices to August 1<sup>st</sup>, 2009 level

#### Spain

 7.5% rebate on public sector purchases from June 1<sup>st</sup>; only 4% on orphan drugs but 25% for generics

#### Greece

- Temporary price reduction up to 27% from May 1<sup>st</sup> through August 31<sup>st</sup>
- Expected to be replaced with reference pricing by August 31st

#### Romania

10% rebate retroactive to January 1<sup>st</sup>

#### Italy

No price cuts on patented products; 12.5% reduction for generics

Despite increased pricing pressures, European business still fundamentally sound

## **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

	Q2 2010	Q2 2009	Growth
Total Revenue	5,749	5,293	9%
Gross Margin	82.2%	82.1%	0.1pp
Total Operating Expense*	2,943	2,749	7%
Operating Income	1,782	1,597	12%
Other Income / (Deductions)	(18)	(24)	(24)%
Effective Tax Rate	22.5%	22.0%	0.5pp
Net Income	\$1,367	\$1,227	11%
Diluted EPS	\$1.24	\$1.12	11%

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

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

### 2010 Income Statement (Reported)

Millions; except per share data

	Q2 2010	Q2 2009	Growth
Total Revenue	5,749	5,293	9%
Gross Margin	82.2%	82.1%	0.1pp
Total Operating Expense*	2,970	2,854	4%
Operating Income	1,755	1,492	18%
Other Income / (Deductions)	(18)	(24)	(24)%
Effective Tax Rate	22.3%	21.1%	1.2pp
Net Income	\$1,349	\$1,159	16%
Diluted EPS	\$1.22	\$1.06	15%

#### Notes:

The second-quarter 2010 results include restructuring charges of \$27.3 million (pretax), or \$0.02 per share (after-tax). These charges are primarily related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. The second quarter 2009 results include a special pretax charge of \$105.0 million, or \$0.06 per share (after-tax), in connection with several states' litigation claims involving Zyprexa.

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

### **EPS Reconciliation**

	Q2 2010	Q2 2009	Growth
EPS (reported)	\$1.22	\$1.06	15%
Charge related to Zyprexa litigation		0.06	
Restructuring charges	0.02		
EPS (non-GAAP)	\$1.24	\$1.12	11%

Note: Numbers may not add due to rounding.

### Effect of Price/Rate/Volume on Revenue

	Q2 2010	Q2 2010 vs. Q2 2009					
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total		
U.S.	\$2,956.8	6%	-	3%	9%		
Europe	1,182.0	(3)%	(2)%	4%	(1)%		
Japan	376.2	(1)%	6%	33%	38%		
ROW	750.1	(2)%	9%	7%	14%		
Total Pharma	5,265.1	2%	1%	5%	9%		
Animal Health	324.2	(2)%	2%	18%	18%		
Net Product Sales	5,589.3	2%	1%	6%	9%		
Collab/Other Revenue	159.4	-	-	(11)%	(11)%		
Total Revenue	\$5,748.7	2%	1%	5%	9%		

Note: Numbers may not add due to rounding.

# Effect of Foreign Exchange on 2010 Results

(Non-GAAP)

Year-on-Year Growth

	Q2 2	2010	YTD	2010
	With FX	w/o FX	With FX	w/o FX
Total Revenue	9%	7%	9%	7%
Cost of Sales	8%	8%	22%	4%
Gross Margin	9%	7%	6%	7%
Operating Expense (R&D plus SG&A)	7%	6%	7%	6%
Operating Income	12%	9%	4%	9%
EPS	11%	8%	4%	9%

Strong underlying financial performance, excluding the effect of foreign exchange

# Effect of Foreign Exchange on 2010 Results (Reported)

Year-on-Year Growth

	Q2 2	2010	YTD	2010	
	With FX w/o FX		With FX	w/o FX	
Total Revenue	9%	7%	9%	7%	
Cost of Sales	8%	8%	22%	4%	
Gross Margin	9%	7%	6%	7%	
Operating Expense (R&D, SG&A and other	4% items)	3%	7%	6%	
Operating Income	18%	15%	4%	9%	
EPS	15%	13%	4%	9%	

### 2010 Guidance

Millions, except per share amounts

Changes

**Total Revenue** 

Gross Margin % of Revenue

Mktg, Selling & Admin.

Research & Development

Other Income/(Expense)

Tax Rate

EPS (non-GAAP)

Reconciling Items (excludes any potential future items)

EPS (reported)

Capital Expenditures

Mid-single digits

Flat to increasing

Low-single digits

Low-double digits

\$(50) - \$(100)

Approximately 23%

\$4.50 - \$4.65 \$0.06

\$4.44 - \$4.59

Less than \$900

For complete reconciliation to reported guidance, please see slide 14 of this presentation and our earnings press release dated July 22, 2010.

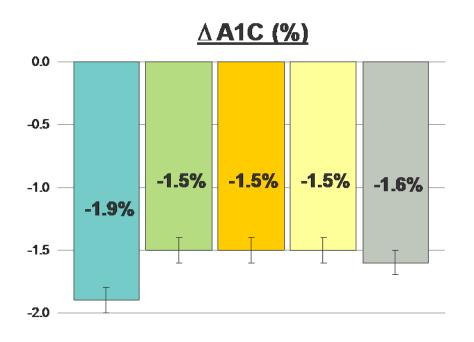
# Earnings per Share Expectations

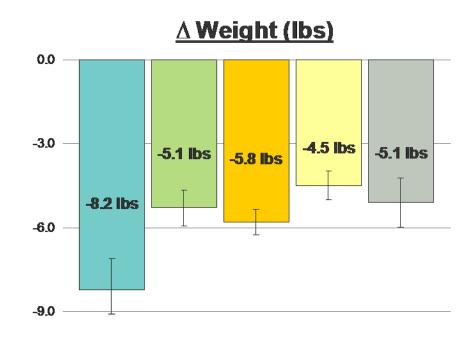
	2010	2009	Growth
Earnings per share (reported)	\$4.44-\$4.59	\$3.94	13%-16%
Charges related to Zyprexa litigation	-	0.13	
Asset impairments and restructuring charges	0.03	0.29	
In-process research and development charges associated with the Acrux (2010) and Incyte (2009) licensing agreements	0.03	0.05	
EPS (non-GAAP)	\$4.50-\$4.65	\$4.42	2%-5%

Note: Numbers may not add due to rounding.

# Bydureon Results from DURATION Studies

Consistently demonstrated reductions in HbA1c and weight







All Data from ITT Analyses

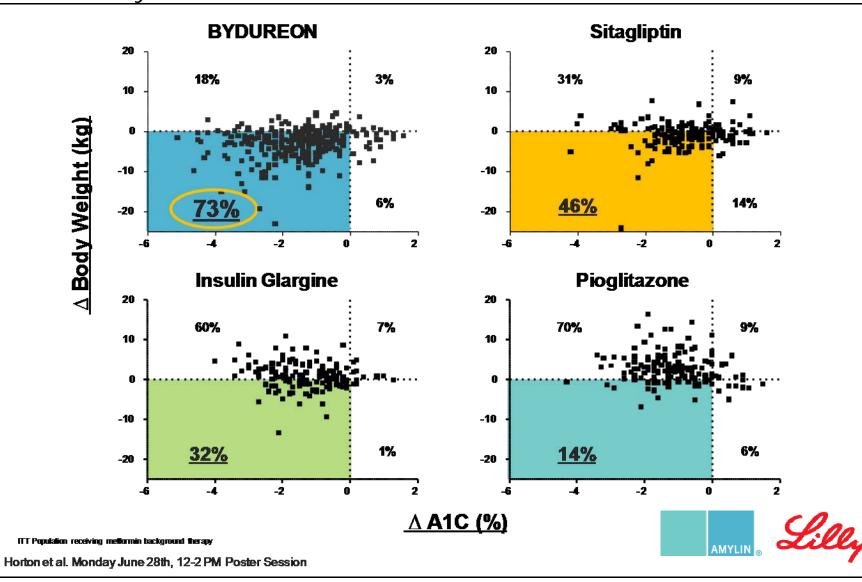
Common treatment-emergent adverse events with Bydureon have included injection-site pruritis, nausea, vomiting, diarrhea and constipation.





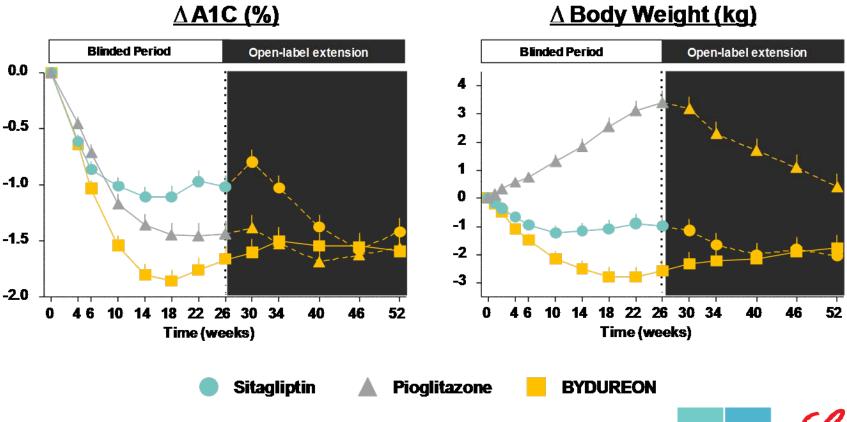
# Changes in HbA1c and Weight

Pooled analysis from DURATION-1, -2 and -3 studies



### DURATION-2 52-week Extension Data

> Extension of 26-week double-blind, double dummy study of BYDUREON compared to sitagliptin and pioglitazone (N=364)



Wysham et al. Monday June 28th, 12-2 PM Poster Session



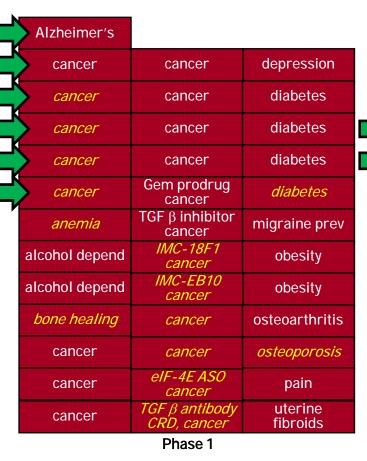


# Lilly NME Pipeline

July 20, 2010

New Chemical Entity (NCE)

New Biotech Entity (NBE)



atherosclerosis

agitation in Alz's LY2599506 atherosclerosis diabetes iGluR5 antag **BPH** pain LY2624803 cancer insomnia Eq5 inhibitor mGlu2/3 pro II schizophrenia cancer IMC-3G3 **NFRI** cancer depression Cixutumumab **A**RqO alcohol depend cancer CD20 antibody JAK-1/JAK-2 NHL RA IL-17 antibody diabetes Basal insulin BAFF antibody diabetes IL -1 β antibody Survivin ASO diabetes cancer Phase 2

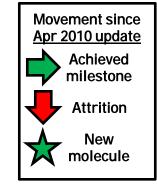
GLP-1 PEG

diabetes

obesity

IL-23 antibody

psoriasis



Enzastaurin DLBCL GLP-1 Fc diabetes Necitumumab **NSCLC** Ramucirumab breast /gastric Semagacestat Alzheimer's Solanezumab Alzheimer's Tasisulam melanoma Teplizumab diabetes

Livalo **lipidemia** 

Liprotamas: **EPI** Arxxant DR Axiron testosterone def

Phase 3

Rea Review

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pain

# Advancing the Pipeline

#### JAK-1/JAK-2:

- Disclosed top-line, 3-month Phase 2a data in early May
- Plan to present detailed 3-month data and 6-month data at ACR in November
- Plan to initiate Phase 2b study later this year

#### **BAFF Antibody:**

- Completed two Phase 2 trials for rheumatoid arthritis; plan to present at ACR
- Expect to start Phase 3 trials by early 2011

#### Additional Phase 2 Trial Completions:

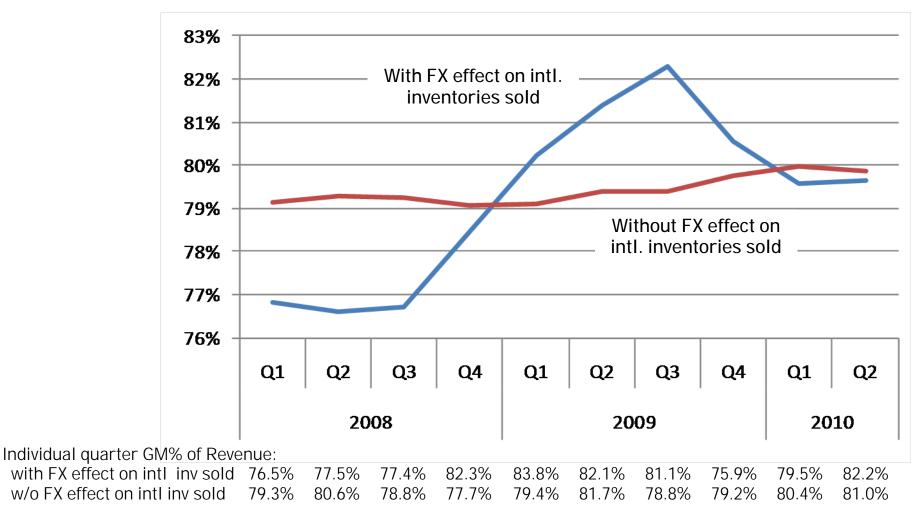
- NERI for depression
- OpRA for alcohol dependence
- LY2624803 for insomnia

On track to have 10 molecules in Phase 3 by late 2011 and launch two novel molecules per year beginning in 2013

# 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.

# 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			
Reported	1.20	1.06	.86	.83	3.94	1.13	1.22			

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 July 22, 2010.

# Q2 Other Income/(Deductions)

#### Millions

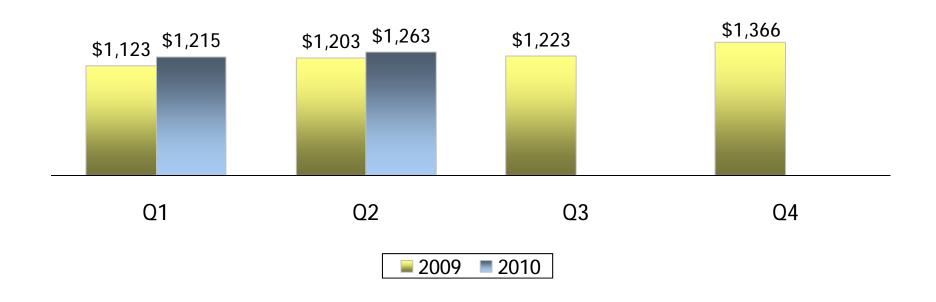
	Q2 10	Q2 09
- Interest Expense	(\$47.5)	(\$64.3)
- Interest Income	11.0_	18.8
Interest, net	(36.5)	(45.5)
- Outlicense of Marketed Products	-	4.8
- Outlicense of Development Stage Products	1.6	-
- Miscellaneous Income / (Loss)	16.5	16.6
Other Income, net	18.1	21.4
Net Other Income (Loss)	<u>\$(18.4)</u>	<u>(\$24.1)</u>

Note: Numbers may not add due to rounding.

# Q2 Zyprexa® Sales Increased 5%

Millions

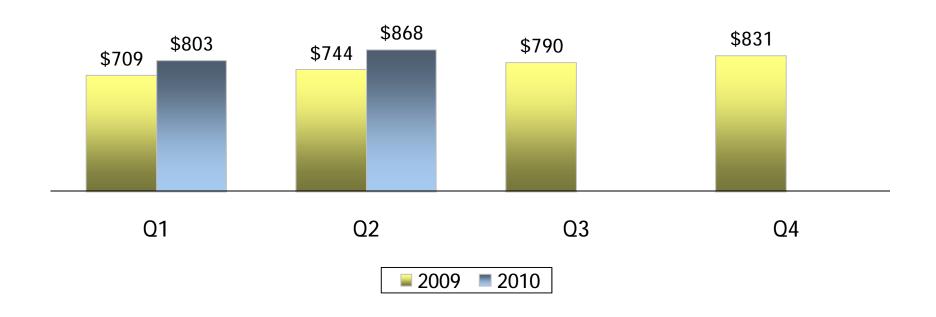
U.S. sales increased 10% International sales increased 1%



# Q2 Cymbalta® Sales Increased 17%

Millions

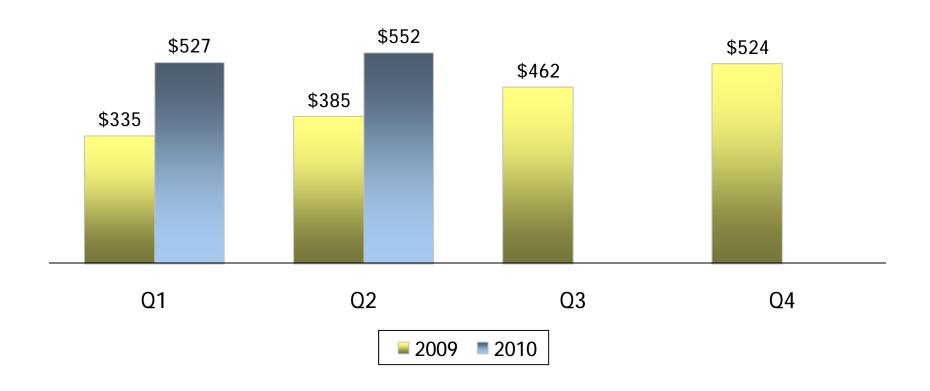
U.S. sales increased 14% International sales increased 30%



### Q2 Alimta® Sales Increased 43%

Millions

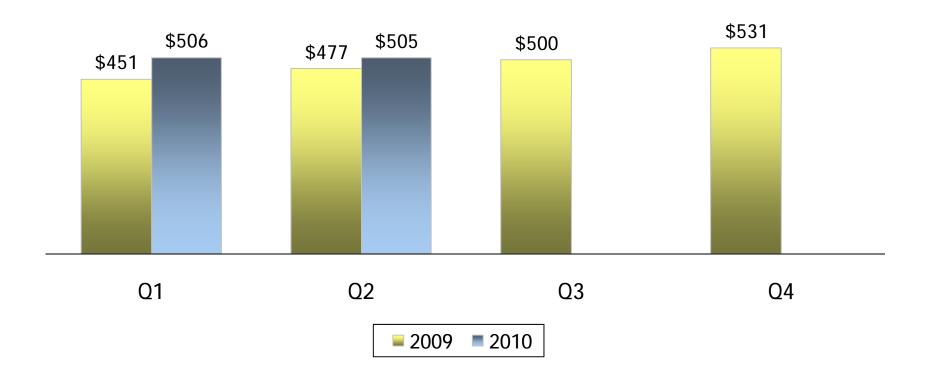
U.S. sales increased 28% International sales increased 60%



# Q2 Humalog® Sales Increased 6%

Millions

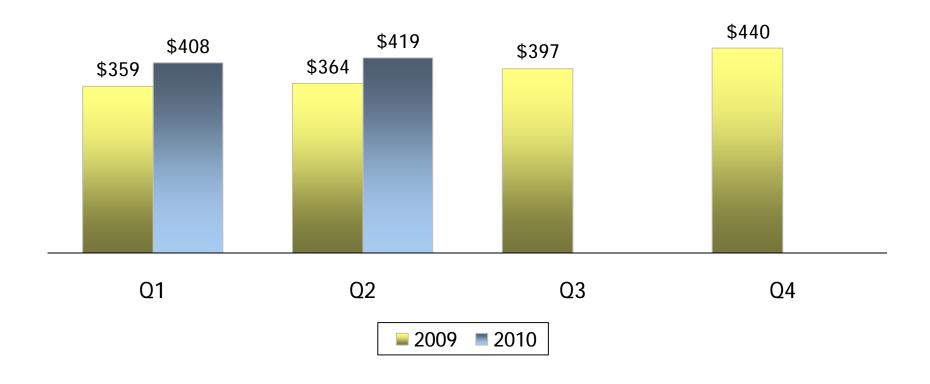
U.S. sales increased 3% International sales increased 10%



### Q2 Cialis® Sales Increased 15%

Millions

U.S. sales increased 11% International sales increased 18%



### Q2 Gemzar® Sales Decreased 17%

Millions

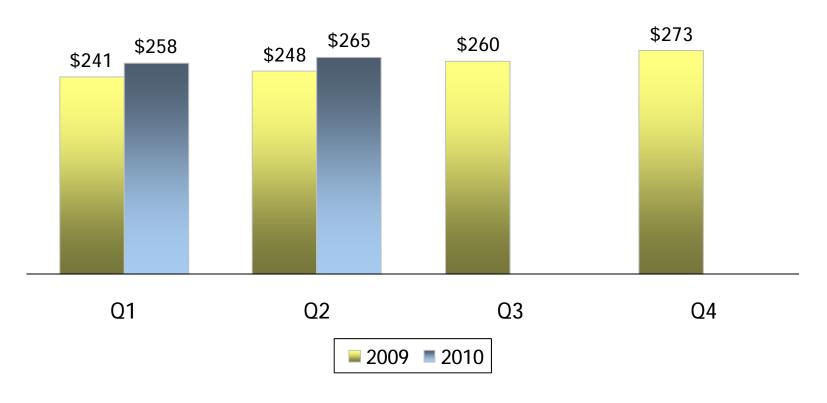
U.S. sales decreased 3% International sales decreased 34%



### Q2 Humulin® Sales Increased 7%

Millions

U.S. sales increased 21% International sales decreased 2%



### Q2 Evista® Sales Increased 3%

Millions

U.S. sales increased 4% International sales increased 1%



### Q2 Forteo® Sales Increased 3%

Millions

U.S. sales flat International sales increased 10%



# Q2 Byetta® Worldwide Sales \$178.8 Million

Millions

Worldwide sales decreased 13% Lilly revenue decreased 7%



#### 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.

### Q2 Strattera® Sales Increased 3%

Millions

U.S. sales decreased 5% International sales increased 26%

