### Eli Lilly and Company Fourth Quarter Financial Review January 28<sup>th</sup>, 2010



### Agenda

#### **Opening Remarks**

- Phil Johnson, Vice President, Investor Relations
- Key Events
  - John Lechleiter, Chairman, President and Chief Executive Officer

#### Financial Overview and Guidance

• Derica Rice, Senior Vice President and Chief Financial Officer

**Business Development and Pipeline Update** 

• Nick Lemen and Ronika Pletcher, Directors, Investor Relations

**Question and Answer Session** 

**Closing Remarks** 

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-Q filed October 2009 and Form 10-K filed February 2009.

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

### Q4 2009 Summary

Continued strong financial results, with:

- Volume-driven revenue growth
- Excluding the impact of foreign exchange:
  - Increasing gross margin as a percent of revenue
  - Leverage between revenue and operating income growth
  - Robust EPS growth
- Strong operating cash flow

Current financial performance provides resources to:

- Build a robust pipeline to drive future growth
- Invest in our transformation
- Deal with patent expirations in the next decade
- Respond to a challenging health care environment

## Beyond the Quarterly Financial Results

Significant events since the last earnings call

#### Strengthen operations:

- Lilly signed a co-promotion agreement with Kowa Pharmaceuticals America to commercialize Livalo in the U.S.; entered into a licensing agreement with Kowa Company, Limited to market Livalo in Latin America
- On January 1, 2010, the company completed the sale of its Tippecanoe manufacturing facility in Lafayette, Indiana to Evonik Industries
- Lilly and Bristol Myers Squibb restructured our agreement to allow for the co-development and co-commercialization of necitumumab, or IMC-11F8

#### Pipeline enhancements:

• Announced the exclusive worldwide license and collaboration agreement with Incyte Corporation for the development and commercialization of Incyte's oral JAK1/JAK2 inhibitor, INCB28050, for inflammatory and autoimmune diseases

### **Beyond the Quarterly Financial Results**

Significant events since the last earnings call

#### Regulatory:

- The FDA approved Zyprexa Relprevv for the treatment of schizophrenia in adults
- The FDA approved Byetta as monotherapy along with diet and exercise in adults with type 2 diabetes
- The FDA approved Zyprexa as an option for the treatment of schizophrenia and manic or mixed episodes associated with bipolar I disorder in adolescents
- The European Commission approved Adcirca as a once-daily treatment option to improve exercise capacity for patients with IPAH and PAH. Adcirca was also approved in Canada and Japan
- Shionogi received approval from Japanese regulatory authorities of Cymbalta for treatment of depression

### **Comparison Measures**

Results shown two ways to aid analysis

#### "Reported" results

- Include all financial results as reported in accordance with GAAP
- Consequently, they reflect the results of ImClone as of the acquisition date of November 24<sup>th</sup>, 2008

#### "Pro forma 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
- Adjust results as if Lilly owned ImClone as of January 1<sup>st</sup>, 2008

### 2009 Income Statement (Pro forma non-GAAP)

Millions; except per share data

	Q4 2009	Growth	Year	Growth
Total Revenue	\$5,934	13%	\$21,836	5%
Gross Margin	75.9%	(6.4)pp	80.6%	2.2pp
Total Operating Expense	3,170	12%	11,219	5%
Operating Income	1,333	(10)%	6,370	15%
Other Income / (Deductions)	(68)	(38)%	(230)	(14)%
Effective Tax Rate	21.0%	1.9рр	21.0%	0.4рр
Net Income	\$999	(10)%	\$4,851	16%
Diluted EPS	\$0.91	(11)%	\$4.42	16%

For notes to the 2009 pro forma income statement, please see slide 24.

### 2009 Income Statement (Reported)

Millions; except per share data

	Q4 2009	Growth	Year	Growth
Total Revenue	\$5,934	14%	\$21,836	7%
Gross Margin	75.9%	(6.6)pp	80.6%	2.1pp
Total Operating Expense	3,298	(56)%	12,002	(31)%
Operating Income	1,205	NM	5,587	NM
Other Income / (Deductions)	(68)	(17)%	(230)	NM
Effective Tax Rate	19.5%	NM	19.2%	NM
Net Income	\$915	NM	\$4,329	<u>NM</u>
Diluted EPS	\$0.83	NM	\$3.94	NM

### Significant Items Affecting EPS

	Q4 2009	Growth	Year	Growth
EPS (as reported)	\$0.83	NM	\$3.94	NM
Charges related to Zyprexa litigation	-		0.13	
Asset impairments and restructuring charges (included in asset impairments, restructuring and other				
special charges)	0.02		0.29	
In-process research and development charge associated with the Incyte in-licensing agreement	0.05		0.05	
EPS (pro forma non-GAAP)	\$0.91	-11%	\$4.42	16%

# Effect of Price/Rate/Volume on Revenue

#### (Pro forma non-GAAP)

			Q4 2009		
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$2,949.6	7%		4%	11%
Europe	1,357.7	(2)%	8%	7%	13%
Japan	357.2	(5)%	14%	24%	34%
ROW	763.3	2%	5%	11%	18%
Total Pharma	5,427.8	3%	3%	7%	14%
Animal Health	353.1	5%	2%	1%	8%
Net Product Sales	5,780.9	3%	3%	6%	13%
Collab/Other Revenue	153.3	-	-	(4)%	(4)%
Total Revenue	\$5,934.2	3%	3%	6%	13%
			Full Year 20	09	
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$11,066.6	7%	_	3%	10%
Europe	4,992.0	(2)%	(9)%	7%	(3)%
Japan	1,186.6	(2)%	14%	17%	28%
ROW	2,719.2	0%	(10)%	7%	(2)%
Total Pharma	19,964.3	3%	(3)%	6%	6%
Animal Health	1,207.2	3%	(2)%	9%	10%
Net Product Sales	21,171.5	3%	(3)%	6%	6%
Collab/Other Revenue	664.5	-	-	(8)%	(8)%
Total Revenue	\$21,836.0	3%	(3)%	5%	5%

# Effect of Price/Rate/Volume on Revenue (Reported)

			Q4 2009		
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$2,949.6	7%		4%	12%
Europe	1,357.7	(2)%	8%	7%	13%
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Net Product Sales	5,780.9	3%	3%	7%	14%
Collab/Other Revenue	153.3	-	-	34%	34%
Total Revenue	\$5,934.2	3%	3%	<b>7</b> %	14%
			Full Year 20	09	
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Japan	1,186.6	(2)%	14%	17%	28%
ROW	2,719.2	0%	(10)%	8%	(2)%
Total Pharma	19,964.3	3%	(3)%	6%	6%
Animal Health	1,207.2	3%	(2)%	9%	10%
Net Product Sales	21,171.5	3%	(3)%	6%	6%
Collab/Other Revenue	664.5	-	-	49%	49%
Total Revenue	\$21,836.0	3%	(3)%	<b>7</b> %	7%

#### Effect of Foreign Exchange on 2009 Results (Pro forma non-GAAP)

Year-on-Year Growth

	Q4 2	009	2009		
	With FX	w/o FX	With FX	w/o FX	
Total Revenue	13%	10%	5%	8%	
Cost of Sales	54%	3%	(5)%	6%	
Gross Margin	4%	11%	8%	9%	
Operating Expense (R&D plus SG&A)	12%	9%	5%	6%	
Operating Income	(10)%	15%	15%	14%	
EPS	(11)%	16%	16%	14%	

# Strong underlying financial performance, excluding the effect of foreign exchange

# Effect of Foreign Exchange on 2009 Results (Reported)

Year-on-Year Growth

	Q4 2	2009	2009		
	With FX	w/o FX	With FX	w/o FX	
Total Revenue	14%	11%	7%	10%	
Cost of Sales	57%	5%	(3)%	8%	
Gross Margin	5%	12%	10%	11%	
Operating Expense (R&D, SG&A and sign. I	(56)% items/	(57)%	(31)%	(29)%	
Operating Income	NM	NM	NM	NM	
EPS	NM	NM	NM	NM	

# Strong underlying financial performance, excluding the effect of foreign exchange

### 2010 Guidance

Millions, except per share amounts

EPS (reported and non-GAAP)	\$4.65 - \$4.85
Total Revenue	High-single digits
Gross Margin % of Revenue	Flat to declining
Mktg, Selling & Admin.	Low- to mid-single digits
Research & Development	Low-double digits
Other Income/(Expense)	\$(150) - \$(200)
Tax Rate	Approximately 22%
Capital Expenditures	Approximately \$1,000

For complete reconciliation to reported guidance, please see slide 16 of this presentation and our earnings press release dated Jan. 28, 2010.

### Earnings per Share Expectations

	2010	2009	Growth
Earnings (Loss) per share (reported)	\$4.65-\$4.85	\$3.94	18%-23%
Charges related to Zyprexa litigation	-	0.13	
Asset impairments and restructuring charges (included in asset impairments, restructuring and other special charges)	-	0.29	
In-process research and development charge associated with the Incyte in-licensing agreement	-	0.05	
EPS (pro forma non-GAAP)	\$4.65-\$4.85	\$4.42	5%-10%

### Business Development - Livalo

- Livalo is a HMG-CoA reductase inhibitor
  - Approved by the FDA in August of 2009
  - Available in Japan since 2003
- Deal positions Lilly to
  - More effectively utilize current sales force and;
  - Expand our product offerings in the cardiovascular therapeutic area
- Once launched, Livalo will offer a new treatment option
  - LDL lowering consistent with common doses of prominent statins; option for patients not responding to current treatment and in need of managing risk of drug-drug interactions
- U.S. launch planned for mid-2010, where Lilly and Kowa share the costs of commercialization and development equally
  - Kowa pays Lilly an escalating co-promotion fee based on level of annual net sales
  - Kowa manufactures, and Lilly distributes, product
- In Latin America, Lilly plans to submit Livalo to regulatory agencies during the 2nd half of 2010, with launch planned by mid-2011

### Business Development - Incyte

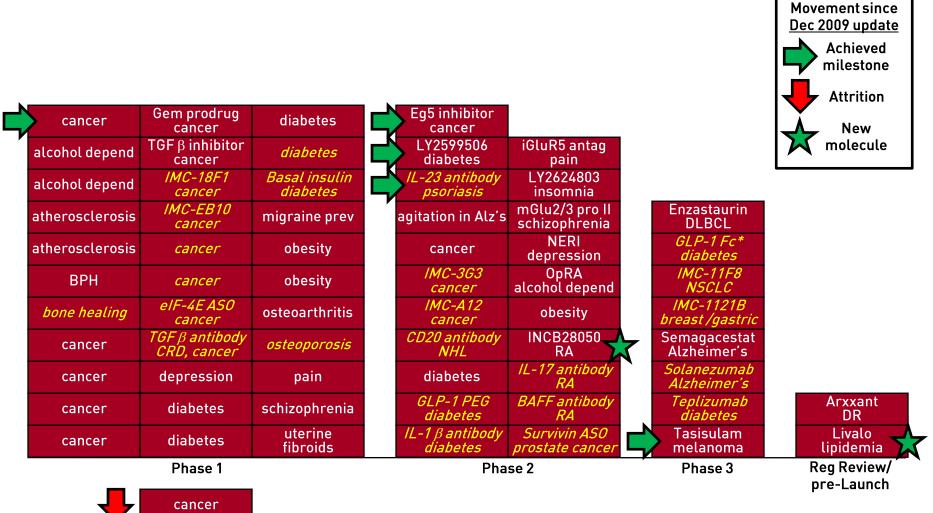
- INCB28050 is an oral JAK1/JAK2 inhibitor for inflammatory and autoimmune diseases
- INCB28050 is currently in an on-going, placebo controlled, Phase 2 trial in patients with rheumatoid arthritis (RA)
- Next steps running a larger Phase 2b trial to generate the data necessary to inform dose selection for Phase 3
- Current data disclosure plan includes sharing Phase 2:
  - Top-line, three-month results in the first half of this year
  - 6-month results at ACR in October of this year
  - Lilly is very excited about this opportunity given RA and other autoimmune diseases are chronic, debilitating diseases that still present an unmet medical need
  - INCB28050 fits nicely into our current internal portfolio of biologics

### Business Development - Necitumumab

- Lilly and Bristol Myers Squibb restructured our agreement to allow for the co-development and co-commercialization of necitumumab, or IMC-11F8
- Necitumumab is currently in Phase 3 trials for non-small cell lung cancer
- Necitumumab is a fully humanized version of Erbitux
- Lilly and BMS will share the cost of developing and, potentially, commercializing necitumumab in the U.S., Canada and Japan

#### Lilly NME Pipeline January 21, 2010

New Biotech Entity (NBE)



\* in an ongoing phase 2/3 trial

### H1 2010 Milestones

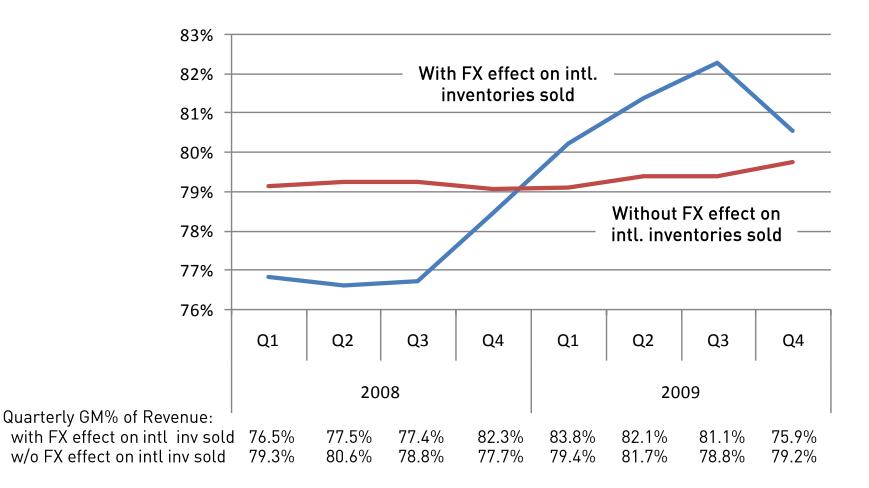
- Exenatide once weekly:
  - Potential action by the FDA on our exenatide once weekly NDA
  - Submission of exenatide once weekly to the European Medicines Agency
  - Results from the DURATION-4 monotherapy trial
  - Initiation of our cardiovascular outcomes study, EXSCEL, designed to show an improvement in cardiovascular outcomes
  - And initiation of DURATION-6, an open-label study of exenatide once weekly versus liraglutide
- Potential FDA action on the Cymbalta chronic pain sNDA; and
- Initiation of the GLP-1 Fc Phase 3 AWARD program

# Supplementary Slides

### **Manufacturing Productivity Gains**

Increasing gross margin as a percent of revenue; Pro forma non-GAAP

Trailing 4 quarters



### 2009 Pro-forma Income Statement Notes

#### Notes:

- 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), or \$0.05 per share (after-tax), for acquired in-process research and development associated with the licensing agreement with Incyte.
- The 2009 full-year financial statement has also 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 statement has 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.
- The 2008 fourth-quarter and full-year financial statements have been adjusted to eliminate a charge of \$4.730 billion (pre-tax), or \$4.46 per share (after tax), for acquired in-process research and development as well as ImClone operating results subsequent to the acquisition, including \$35.6 million of Erbitux sales, incremental interest costs and amortization of the intangible asset associated with Erbitux; a charge of \$80.0 million (pre-tax), or \$0.05 per share (after tax), for asset impairments, restructuring and other special charges primarily related to severance costs from previously announced strategic actions; and a tax benefit of \$136.9 million, or \$0.13 per share, based upon a determination that a portion of the EDPA settlement is tax deductible.

The 2008 fourth quarter financial statement has been adjusted to reflect the acquisition of ImClone as if it was completed by Lilly effective January 1, 2008. This pro forma adjustment reduced earnings per share by \$.05.

• The full-year 2008 financial statement has also been adjusted to eliminate charges totaling \$1.477 billion (pre-tax), or \$1.33 per share (after tax), related to Zyprexa investigations; \$150.0 million (pre-tax), or \$0.10 per share (after tax), for acquired in-process research and development associated with the SGX acquisition and the in-licensing of compounds from BioMS, and TransPharma; a charge of \$474.1 million (pre-tax), or \$0.29 per share (after tax), for asset impairments, restructuring, and other special charges; and a discrete income tax benefit of \$210.3 million, or \$(0.19) per share, related to the resolution of a substantial portion of an IRS audit.

The full-year 2008 financial statement has been adjusted to reflect the acquisition of ImClone as if it was completed by Lilly effective January 1, 2008. This pro forma adjustment reduced earnings per share by \$.20.

### **Comparative EPS Summary 2008/2009**

	1Q08	2Q08	3Q08	4Q08	2008	1Q09	2Q09	3Q09	4Q09	2009
Pro forma non-GAAP	.88	.94	.98	1.02	3.82	1.20	1.12	1.20	.91	4.42
Reported	.97	.88	(.43)	(3.31)	(1.89)	1.20	1.06	.86	.83	3.94

Note: Numbers may not add due to rounding.

For complete reconciliation to reported earnings, please see slide 10 of this presentation and our earnings press release dated Jan. 28, 2010.

#### **Q4 Other Income/(Deductions)** (Pro forma non-GAAP)

Millions

	Q4 09	Q4 08
- Interest Expense	(\$50.2)	(\$61.1)
- Interest Income	13.8	1.8
Interest, net	(36.4)	(59.3)
- Outlicense of Marketed Products	-	33.8
<ul> <li>Outlicense of Development Stage Products</li> </ul>	-	2.0
- Partnered Products	-	-
- Miscellaneous Income / (Loss)	(31.4)	(85.8)
Other Income, net	(31.4)	(50.0)
Net Other Income (Loss)	(\$67.8)	( <u>\$109.3)</u>

### Q4 Other Income/(Deductions) (Reported)

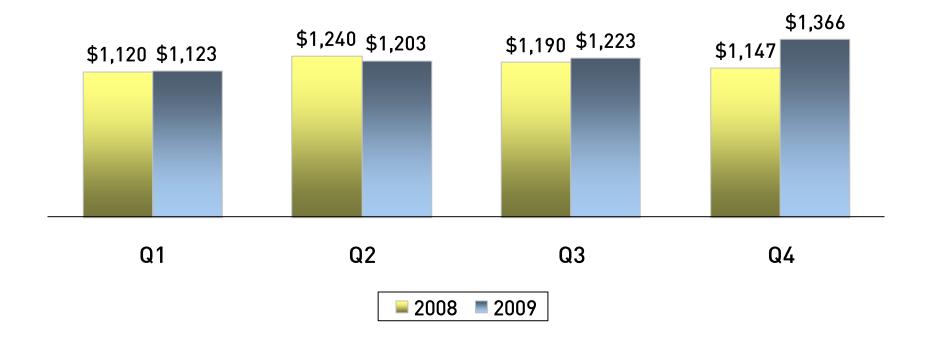
Millions

	Q4 09	Q4 08
- Interest Expense	(\$50.2)	(\$81.9)
- Interest Income	13.8	53.9
Interest, net	(36.4)	(28.0)
<ul> <li>Outlicense of Marketed Products</li> </ul>	-	33.8
<ul> <li>Outlicense of Development Stage Products</li> </ul>	-	2.0
- Partnered Products	-	-
- Miscellaneous Income / (Loss)	(31.4)	(89.0)
Other Income, net	(31.4)	(53.2)
Net Other Income (Loss)	(\$67.8)	<u>\$(81.2)</u>

### Q4 Zyprexa<sup>®</sup> Sales Increased 19%

#### Millions

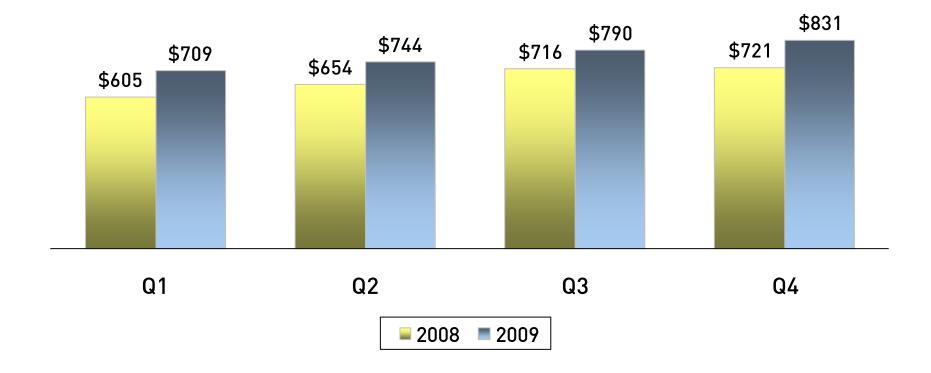
#### U.S. sales increased 10% International sales increased 28%



### Q4 Cymbalta<sup>®</sup> Sales Increased 15%

#### Millions

#### U.S. sales increased 13% International sales increased 27%



### Q4 Humalog<sup>®</sup> Sales Increased 16%

#### Millions

#### U.S. sales increased 16% International sales increased 16%



### Q4 Alimta<sup>®</sup> Sales Increased 64%

#### Millions

#### U.S. sales increased 42% International sales increased 87%



### Q4 Cialis<sup>®</sup> Sales Increased 19%

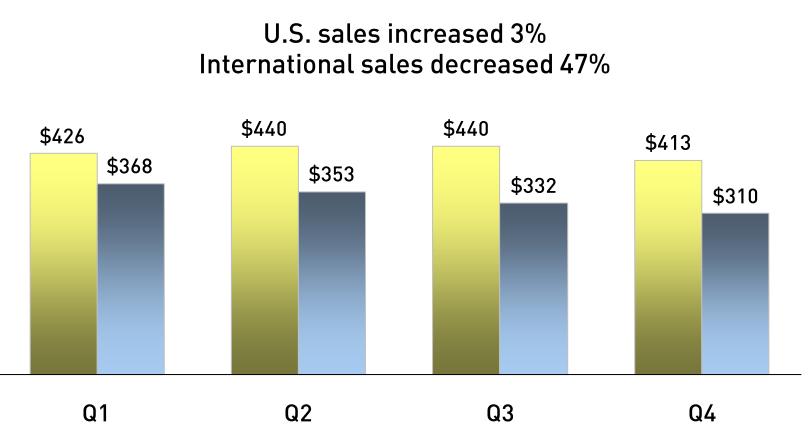
#### Millions

#### U.S. sales increased 12% International sales increased 24%



### Q4 Gemzar<sup>®</sup> Sales Decreased 25%

#### Millions



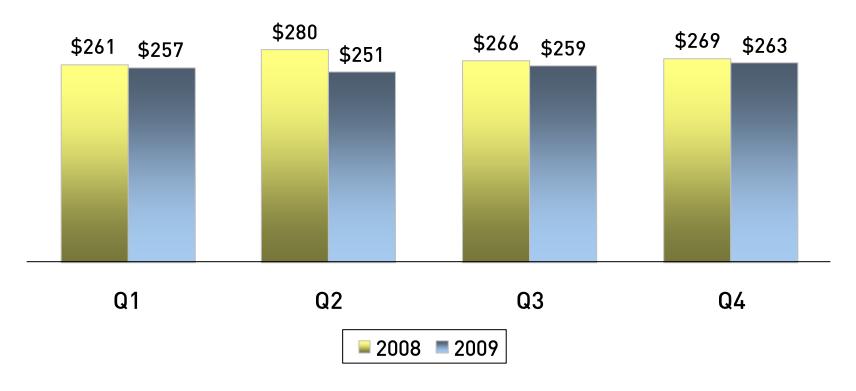
Note: Quarterly numbers may not add to year-to-date totals due to rounding.

2008 2009

### Q4 Evista<sup>®</sup> Sales Decreased 2%

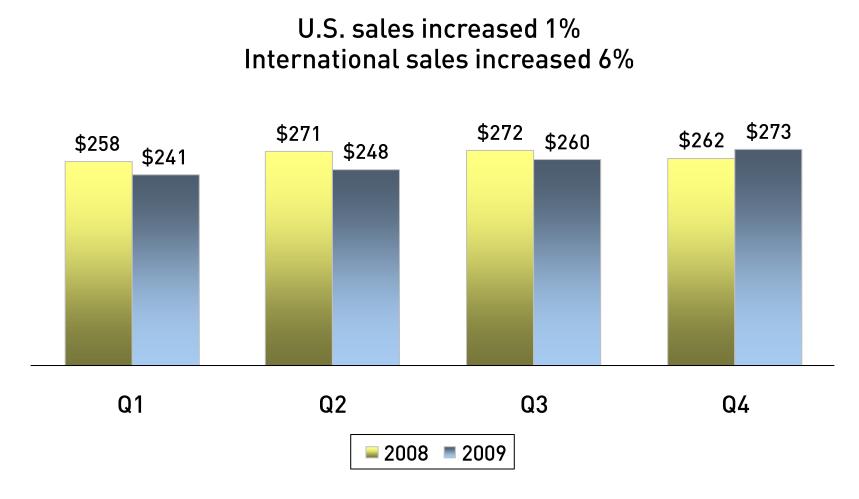
#### Millions

#### U.S. sales decreased 2% International sales decreased 2%



### Q4 Humulin<sup>®</sup> Sales Increased 4%

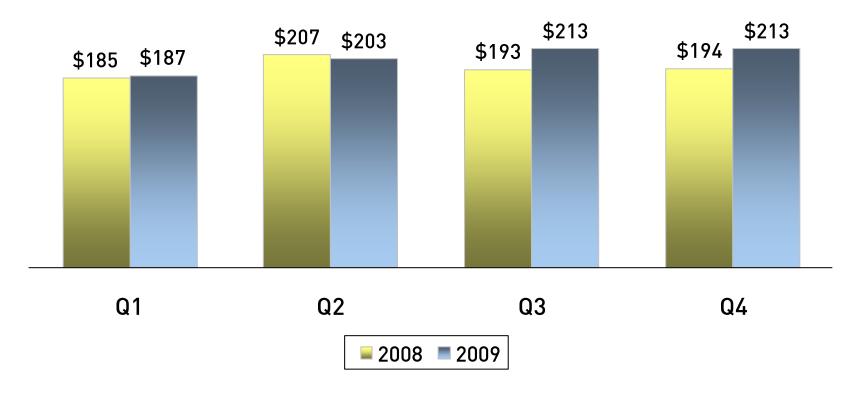
#### Millions



### Q4 Forteo<sup>®</sup> Sales Increased 9%

#### Millions

#### U.S. sales increased 3% International sales increased 20%



### Q4 Byetta<sup>®</sup> Worldwide Sales \$203.6 Million

#### Millions

#### Worldwide sales increased 9% Lilly revenue increased 17%



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.

### Q4 Strattera<sup>®</sup> Sales Increased 10%

#### Millions

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

