# Eli Lilly and Company Fourth Quarter Financial Review January 31st, 2012



## Agenda

#### Key Recent Events, Financial Results and Pipeline Update

- Ronika Pletcher, Director, Investor Relations
- Ilissa Rassner, Director, Investor Relations

#### Financial Guidance, Key Future Events and 2011 Summary

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

**Question and Answer Session** 

### 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.

# Beyond the Quarterly Financial Results

Key events since the last earnings call

#### Regulatory:

- Received European Commission approval for and submitted an sNDA to the FDA for – use of Alimta as a continuation maintenance therapy in patients with advanced nonsquamous non-small cell lung cancer after initial treatment with Alimta plus cisplatin
- Received FDA approval for use of Erbitux in combination with chemotherapy as a first-line treatment for recurrent locoregional or metastatic squamous cell carcinoma of the head and neck
- FDA approved Jentadueto, the linagliptin plus metformin fixed-dose combination for treatment of adults with type 2 diabetes
- FDA approved Amylin's Bydureon as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes
- Submitted Amyvid, a Positron Emission Tomography (PET) imaging agent, under investigation for the detection of beta-amyloid plaque in the brains of living patients to the European Medicines Agency (EMA)
- Announced the withdrawal of Xigris in all markets following results of the PROWESS-SHOCK study

## Beyond the Quarterly Financial Results

Key events since the last earnings call (cont.)

#### **Business Development:**

- Announced agreement with Amylin to terminate the exenatide alliance
- Announced acquisition of ChemGen Corp., a privately-held company specializing in innovative feed enzyme products for animal health
- Entered into a six-month agreement with Prasco Laboratories to supply authorized generic olanzapine upon the natural patent expiration for Zyprexa in the U.S. in October 2011

#### Clinical:

- The solanezumab DMC recommended continuing both pivotal Phase 3 trials without modification, stating that futility was not met, and recommended two additional ECGs be added to the open-label follow-on study
- Initiated Phase 3 development of our novel basal insulin analog for type 1 and type 2 diabetes
- Initiated Phase 3 development of our anti-IL-17 monoclonal antibody in psoriasis
- Presented positive Phase 2 results at AHA for evacetrapib in patients with hypercholesterolemia or low HDL-C

### 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

### 2011 Income Statements (Non-GAAP)

Millions; except per share data

	Q4 2011	Growth	Year	Growth
Total Revenue	\$6,047	(2)%	\$24,286	5%
Gross Margin Percent	78.1%	(2.0)pp	79.1%	(2.0)pp
Total Operating Expense*	3,489	2%	12,901	8%
Operating Income	1,236	(19)%	6,318	(7)%
Other Income / (Deductions)	(27)	(32)%	(179)	NM
Effective Tax Rate	19.9%	2.9pp	20.0%	(2.6)pp
Net Income	\$969	(22)%	\$4,913	(6)%
Diluted EPS	\$0.87	(22)%	\$4.41	(7)%

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

### 2011 Income Statements (Reported)

Millions; except per share data

	Q4 2011	Growth	Year	Growth
Total Revenue	\$6,047	(2)%	\$24,286	5%
Gross Margin Percent	78.1%	(2.0)pp	79.1%	(2.0)pp
Total Operating Expense*	3,656	4%	13,690	12%
Operating Income	1,069	(26)%	5,528	(15)%
Other Income / (Deductions)	(27)	(32)%	(179)	NM
Effective Tax Rate	17.6%	0.6pp	18.7%	(3.6)pp
Net Income	\$858	(27)%	\$4,348	(14)%
Diluted EPS	\$0.77	(27)%	\$3.90	(15)%

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

**Note:** See slide 20 for a complete list of charges.

### **EPS Reconciliation**

	Q4 2011	Growth	Year	Growth
EPS (reported)	\$0.77	(27%)	\$3.90	(15%)
In-process research and development charge associat with the Boehringer Ingelheim collaboration	ed -		0.23	
Special charge related to Xigris withdrawal	0.05		0.05	
Restructuring charges	0.05		0.24	
EPS (non-GAAP)	\$0.87	(22%)	\$4.41	(7%)

Note: Numbers may not add due to rounding.

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

			Q4 2011		
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$2,879.8	(18)%	-	11%	(6)%
Europe	1,083.0	<del>(7)%</del>	1%	<u>(10)%</u>	(16)%
Japan	590.1	(1)%	10%	<u> 19%</u>	27%
ROW	835.6	(4)%	(3)%	11%	5%
Total Pharma	5,388.5	(12)%	1%	7%_	(4)%
Animal Health	468.2	1%	(0)%	10%	10%
Net Product Sales	5,856.7	(11)%	1%	7%	(3)%
Collab/Other Revenue	189.9	(0)%	-	24%	24%
Total Revenue	\$6,046.6	(11)%	1%	8%	(2)%
			Full Year 20	11	
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$11,527.5	(3)%		3%	(1)%
Europe	5,007.1	(3)%	6%	1%_	4%
Japan	2,055.6	(2)%	12%	21%	31%
ROW	3,336.0	(3)%	3%	10%	10%
Total Pharma	21,926.2	(3)%	3%	5%	4%
Animal Health	1,678.6	2%	1%	18%	21%
Net Product Sales	23,604.8	(3)%	3%	5%	5%
Collab/Other Revenue	681.7	(0)%	-	8%	8%
Total Revenue	\$24,286.5	(3)%	2%	<b>6</b> %	5%
Note: Numbers may not add due	to rounding.				

# Effect of Foreign Exchange on 2011 Results (Non-GAAP)

Year-on-Year Growth

	Q4 2011		20	11	
	With FX	w/o FX	With FX	w/o FX	
Total Revenue	(2)%	(3)%	5%	3%	
Cost of Sales	7%	7%	16%	6%	
Gross Margin	(5)%	(5)%	3%	2%	
Operating Expense (R&D plus SG&A)	2%	1%	8%	6%	
Operating Income	(19)%	(20)%	(7)%	(6)%	
EPS	(22)%	(23)%	(7)%	(6)%	

# Effect of Foreign Exchange on 2011 Results (Reported)

Year-on-Year Growth

	Q4 2011		20	11	
	With FX	w/o FX	With FX	w/o FX	
Total Revenue	(2)%	(3)%	5%	3%	
Cost of Sales	7%	7%	16%	6%	
Gross Margin	(5)%	(5)%	3%	2%	
Operating Expense (R&D plus SG&A)	4%	4%	12%	11%	
Operating Income	(26)%	(27)%	(15)%	(14)%	
EPS	(27)%	(28)%	(15)%	(14)%	

# Lilly NME Pipeline

January 17, 2012

New Chemical Entity (NCE)

New Biotech Entity (NBE)

Movement since

p70 S6 inh	CXCR4 MAb	_	СВ		i iluse o	Arxxant
	Phase 1		Pha		Phase 3	Reg Review
diabetes	FGFR inh cancer	IL-1 β MAb CV disease	TGF-β R1 inh cancer	Survivin ASO cancer	Ramucirumab solid tumors	Liprotamase EPI
diabetes	JAK2 inh cancer	RON MAb cancer	SARM/Tadalafil erectile dys	Cixutumumab cancer	Necitumumab* squamous NSCLC	Florbetapir β-amyloid imag
diabetes	Gem prodrug cancer	GP75 MAb cancer	JAK1/JAK2 RA	PDGFRα MAb cancer	Enzastaurin DLBCL	
bone healing	p38 MAP inh cancer	VEGFR3 MAb cancer	Evacetrapib atherosclerosis	VEGFR1 MAb cancer	Dulaglutide diabetes	
migraine prev	Chk1 inh cancer	CSF1R MAb cancer	MR Antagonist CRD	eIF-4E ASO cancer	Empagliflozin* diabetes	
osteoarthritis	Hepcidin MAb anemia	Hedgehog antag cancer	TGF-β MAb CRD	CXCR4 pept inh cancer	New Insulin* Glargine Product	
depression	Ferroportin MAb anemia	CDK 4/6 inh cancer	11βHSD1 inh diabetes	Litronesib cancer	Novel Basal Insulin Analog*	
bipolar disorder	CV disease	c-Met inh cancer	Gluc-R antag diabetes	Chk1 inh cancer	Solanezumab Alzheimer's	
depression	obesity	NOTCH inh cancer	Blosozumab osteoporosis	GSK3 cancer	Edivoxetine depression	
β-secretase inh Alzheimer's		p70/AKT inh cancer	mGlu2 PotCys migraine prev	Tasisulam cancer	Pomaglumetad schizophrenia	Attriti
			Myostatin MAb disuse atrophy	c-Met MAb cancer	BAFF MAb Iupus/RA	
			_	N.	IL-17 MAb psoriasis	Achiev milesto

\* commercial collaborations

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# Key Future Events in 2012

Red text – potential 2012 data disclosure

#### Potential U.S. regulatory actions:

- Alimta continuation maintenance in nonsquamous non-small cell lung cancer
- Erbitux for 1st-line non-small cell lung cancer
- Erbitux for 1st-line metastatic colorectal cancer
- Amyvid for detection of beta amyloid plaque

#### Potential Phase 3 trial initiation:

Evacetrapib (CETP inhibitor)

#### Expected clinical trial completion:

- Solanezumab Phase 3 trials in Alzheimer's
- Effient Phase 3 trial in ACS-medical management
- Alimta Phase 3 PARAMOUNT and POINTBREAK trials
- Initial dulaglutide Phase 3 trials in type 2 diabetes <sup>2</sup>
- Initial empagliflozin Phase 3 trials in type 2 diabetes <sup>1, 2</sup>
- JAK1/JAK2 Phase 2b study in RA

#### Data disclosures of completed trials:

- anti-IL-17 monoclonal antibody Phase 2 data in psoriasis (journal article)
- Novel basal insulin analog Phase 2 data in type 1 and type 2 diabetes <sup>1</sup>
  - 1 in collaboration with Boehringer Ingelheim
  - 2 external data disclosure expected in 2013

### 2012 Guidance

Millions, except per share amounts

Total Revenue \$21.8 to \$22.8 billion

Gross Margin % of Revenue Approximately 77%

Mktg, Selling & Admin. \$7.4 to \$7.8 billion

Research & Development \$5.0 to \$5.3 billion

Other Income/(Expense) \$(50) - \$100 million

Tax Rate Approximately 21%

Earnings per Share \$3.10 - \$3.20

Capital Expenditures Approximately \$800 million

For complete reconciliation to reported guidance, please see slide 16 of this presentation and our earnings press release dated Jan. 31, 2012.

# Earnings per Share Expectations

	2012	2011	Growth
EPS (reported)	\$3.10-\$3.20	\$3.90	(18)%-(21)%
In-process research and development charges associated with the Boehringer Ingelheim collaboration	-	0.23	
Special charge related to Xigris withdrawal	-	0.05	
Restructuring charges	-	0.24	
EPS (non-GAAP)	\$3.10-\$3.20	\$4.41	(27)%-(30)%

Note: Numbers may not add due to rounding.

# 2011 Summary

#### **Financial Performance:**

- 5% revenue growth, despite the impact of Gemzar and Zyprexa generics
- Operating expenses grew faster than revenue due to the pharma manufacturers' fee and expenses from our diabetes partnership with Boehringer Ingelheim
- Removed \$1 billion from projected 2011 expenses and reduced approximately 5,600 headcount (since mid-2009)
- Generated \$7 billion of operating cash flow, easily covering capital expenditures of \$0.7 billion and dividend payment of roughly \$2.2 billion
- We remain on track to meet, or exceed, our mid-term financial projections

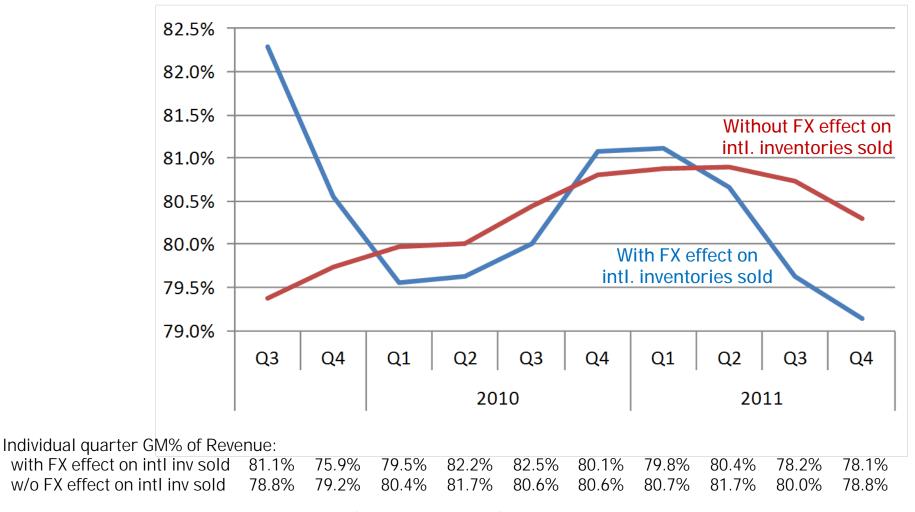
#### Pipeline Performance:

- 12 molecules in Phase 3 development, exceeding goal of 10 by year-end 2011
- Advanced 4 molecules into Phase 3, 8 into Phase 2 and 10 into Phase 1
- Strengthened diabetes franchise through strategic collaboration with Boehringer Ingelheim, adding empagliflozin (in Phase 3) and linagliptin (now launched in multiple markets)
- We now have the most robust mid- to late-stage pipeline in our history

# 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.

### 2011 Income Statement Notes

#### Notes:

- Q4 2011 includes a charge of \$85.0 million pre-tax, or \$0.05 per share after-tax, for the withdrawal of Xigris as well as a charge of \$82.6 million pre-tax, or \$0.05 per share after-tax, for asset impairments and restructuring primarily associated with previously announced strategic actions.
- In addition to the Q4 charges listed above, 2011 YTD results include a charge of \$388.0 million pre-tax, or \$0.23 per share after-tax, for acquired IPR&D associated with the Boehringer Ingelheim collaboration as well as a charges totaling \$233.8 million pre-tax, or \$0.19 per share after-tax, for asset impairments and restructuring primarily associated with severance costs from previously announced strategic actions.
- Q4 2010 includes a charge of \$79.0 million pre-tax, or \$0.06 per share after-tax, for asset impairments and restructuring primarily associated with previously announced strategic actions.
- In addition to the Q4 charges listed above, 2010 YTD results include a charge of \$50.0 million pre-tax, or \$0.03 per share after-tax, for acquired IPR&D associated with the in-licensing of Axiron from Acrux Corporation as well as a charges totaling \$113.0 million pre-tax, or \$0.07 per share after-tax, for asset impairments and restructuring primarily associated with severance costs from previously announced strategic actions.

# Comparative EPS Summary 2010/2011

	1Q10	2Q10	3Q10	4Q10	2010	1011	2011	3Q11	4Q11	2011
Non-GAAP	1.18	1.24	1.21	1.11	4.74	1.24	1.18	1.13	0.87	4.41
Reported	1.13	1.22	1.18	1.05	4.58	0.95	1.07	1.11	0.77	3.90

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. 31, 2012.

# Other Income/(Expense)

#### Millions

	Q4 11	Q4 10	2011	2010
- Interest Expense	(\$50.0)	(\$43.2)	(\$186.0)	(\$185.5)
- Interest Income	24.4	14.0	79.9	51.9
Interest, net	(25.6)	(29.2)	(106.1)	(133.6)
- FX Gains / (Losses)	(4.7)	(21.4)	(6.2)	(46.0)
- Gains / (Losses) on Equity Investments	10.8	14.7	98.7	73.5
- Miscellaneous Income / (Expense)	(7.3)	(3.5)	(165.4)	101.1
Other Income/(Expense), net	(1.2)	(10.2)	(72.9)	128.6
Net Other Income/(Expense)	\$(26.8)	\$(39.4)	<u>\$(179.0)</u>	\$(5.0)

Note: Numbers may not add due to rounding.

# Q4 Cymbalta® Revenue Increased 20%

Millions

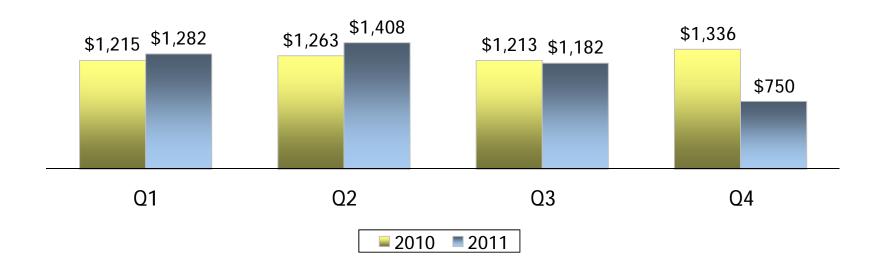
U.S. sales increased 19% International revenue increased 24%



# Q4 Zyprexa® Sales Decreased 44%

Millions

U.S. sales decreased 56% International sales decreased 32%



# Q4 Humalog® Sales Increased 21%

Millions

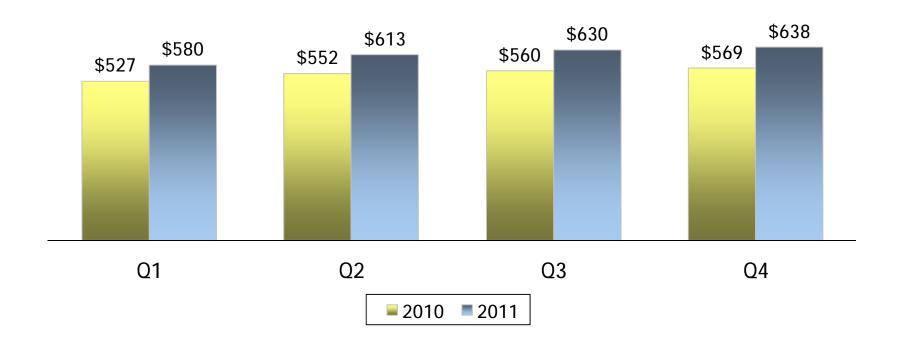
U.S. sales increased 26% International sales increased 13%



### Q4 Alimta® Sales Increased 12%

Millions

U.S. sales increased 7% International sales increased 16%



### Q4 Cialis® Sales Increased 6%

Millions

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



### Q4 Humulin® Sales Increased 20%

Millions

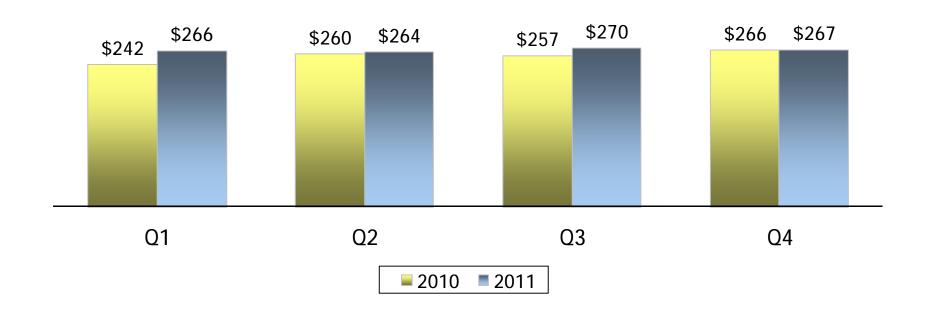
U.S. sales increased 41% International sales increased 5%



# Q4 Evista® Sales Essentially Flat

Millions

U.S. sales essentially flat International sales essentially flat



### Q4 Forteo® Sales Increased 16%

Millions

U.S. sales decreased 9% International sales increased 50%



### Q4 Strattera® Sales Increased 10%

Millions

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



### Q4 Exenatide Worldwide Sales \$177.3 Million

Millions

Worldwide sales increased 2% Lilly revenue increased 5%



### Q4 Gemzar® Sales Decreased 62%

Millions

U.S. sales decreased 101% International sales decreased 9%



## Q4 Effient® Worldwide Sales \$90.9 Million

Millions

