# Eli Lilly and Company Third Quarter Financial Review

October 20th, 2011



## Agenda

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

- Phil Johnson, Vice President, Investor Relations
- Ronika Pletcher, Director, Investor Relations

Zyprexa Update, Financial Guidance, Key Future Events and Q3 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 EC approval of Trajenta
- Received FDA approval of Cialis to treat the signs and symptoms of benign prostatic hyperplasia (BPH) and for the treatment of BPH and erectile dysfunction (ED), when the conditions occur simultaneously
- Received FDA approval of Byetta as add-on therapy with insulin glargine
- Received CHMP positive opinion 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
- Submitted reply to FDA's Complete Response Letter for Bydureon; assigned PDUFA of January 28, 2012
- Submitted reply to FDA's Complete Response Letter for Amyvid, a Positron Emission Tomography (PET) imaging agent under investigation for the detection of beta-amyloid plaque in the brains of living patients
- Submitted sBLA for Erbitux in first-line metastatic colorectal cancer.

#### **Business Development:**

- Entered into a collaboration with Lupin Limited under which Lupin will promote and distribute Lilly's Humulin range of products in India and Nepal
- Entered into a collaboration in India with Boehringer Ingelheim under which Lilly will co-promote linagliptin (once approved) and Boehringer Ingelheim will co-promote Humalog
- Launched Open Innovation Drug Discovery, a new platform designed to help build the company's pipeline and, from a philanthropic perspective, identify molecules that may have application for treating MDR-TB

#### Legal:

• The U.S. Court of Appeals for the Federal Circuit overturned a prior ruling by the U.S. District Court for the District of New Jersey, ruling in favor of Lilly and upholding the method-of-use patent for Strattera (expiration May 2017)

#### Industry:

• The America Invents Act was signed into law, a modernization of U.S. patent law that should improve U.S. competitiveness by aligning patent laws more closely to those of other countries

# **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 Statement (Non-GAAP)

Millions; except per share data

	Q3 2011	Q3 2010	Growth
Total Revenue	6,148	5,655	9%
Gross Margin	78.2%	82.5%	(4.3)pp
Total Operating Expense*	3,199	2,915	10%
Operating Income	1,611	1,753	(8)%
Other Income / (Deductions)	(83)	(22)	NM
Effective Tax Rate	17.9%	22.5%	(4.6)pp
Net Income	\$1,254	\$1,341	(7)%
Diluted EPS	\$1.13	\$1.21	(7)%

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

## 2011 Income Statement (Reported)

Millions; except per share data

	Q3 2011	Q3 2010	Growth
Total Revenue	6,148	5,655	9%
Gross Margin	78.2%	82.5%	(4.3)pp
Total Operating Expense*	3,224	2,974	8%
Operating Income	1,586	1,693	(6)%
Other Income / (Deductions)	(83)	(22)	NM
Effective Tax Rate	17.7%	22.0%	(4.3)pp
Net Income	\$1,236	\$1,303	(5)%
Diluted EPS	\$1.11	\$1.18	(6)%

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

Notes: Q3 2011 includes a charge of \$25.2 million (pretax), or \$0.02 (after-tax) while Q3 2010 includes a charge of \$59.5 million (pretax), or \$0.03 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.

## **EPS Reconciliation**

	Q3 2011	Q3 2010	Growth
EPS (reported)	\$1.11	\$1.18	(6%)
Restructuring charges	0.02	0.03	
EPS (non-GAAP)	\$1.13	\$1.21	(7%)

Note: Numbers may not add due to rounding.

## Effect of Price/Rate/Volume on Revenue

	Q3 2011	Q3 2011 vs. Q3 2010					
Pharmaceuticals	Amount	Price	FX Rate	Volume	Total		
U.S.	\$2,887.1	2%	-	(0)%	2%		
Europe	1,288.9	(1)%	13%	2%	14%		
Japan	521.1	(1)%	12%	20%	31%		
ROW	823.5	(4)%	5%	5%	7%		
Total Pharma	5,520.6	0%	5%	3%	8%		
Animal Health	451.0	2%	3%	22%	28%		
Net Product Sales	5,971.7	0%	5%	4%	9%		
Collab/Other Revenue	176.2	0%	0%	5%	5%		
Total Revenue	\$6,147.9	0%	4%	4%	9%		

Note: Numbers may not add due to rounding.

# Effect of Foreign Exchange on 2011 Results

(Non-GAAP)

Year-on-Year Growth

	Q3 2	2011	YTD:	2011
	With FX	w/o FX	With FX	w/o FX
Total Revenue	9%	4%	8%	5%
Cost of Sales	35%	8%	20%	6%
Gross Margin	3%	3%	5%	5%
Operating Expense (R&D plus SG&A)	10%	7%	11%	8%
Operating Income	(8)%	(2)%	(3)%	(1)%
EPS	(7)%	(1)%	(2)%	(0)%

# Effect of Foreign Exchange on 2011 Results

(Reported)

Year-on-Year Growth

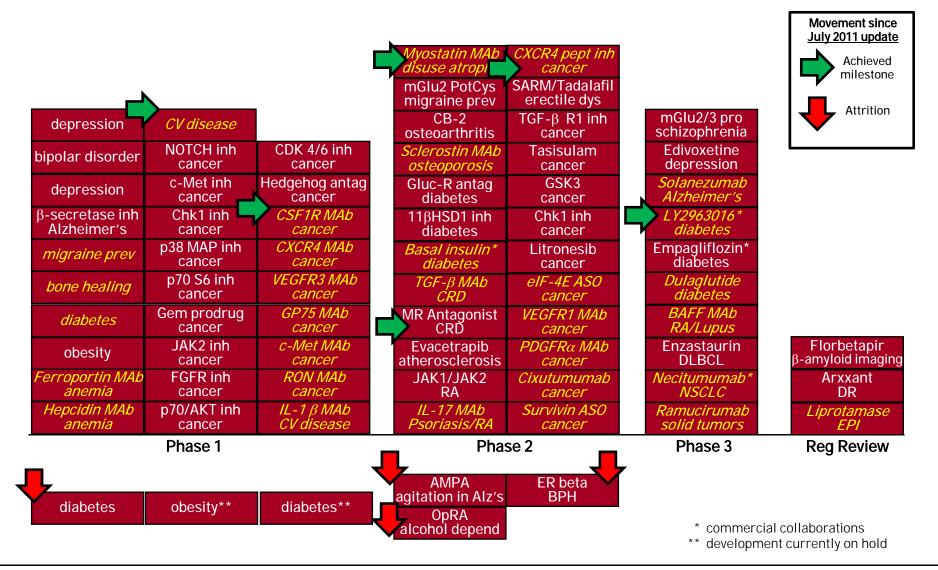
	Q3 2	2011	YTD	2011
	With FX	w/o FX	With FX	w/o FX
Total Revenue	9%	4%	8%	5%
Cost of Sales	35%	8%	20%	6%
Gross Margin	3%	3%	5%	5%
Operating Expense (R&D plus SG&A)	8%	5%	16%	13%
Operating Income	(6)%	0%	(12)%	(10)%
EPS	(6)%	1%	(11)%	(10)%

# Lilly NME Pipeline

October 10, 2011

New Chemical Entity (NCE)

New Biotech Entity (NBE)



# **Zyprexa Patent Expiration Update**

- Timing of patent expiration in major markets:
  - Europe in September 2011
     [April 2011 in Spain, Hungary, Czech Republic, Slovakia and Bulgaria.]
  - U.S. in October 2011
  - Japan in December 2015
- Rapid and significant sales erosion anticipated, likely causing Q4 results to differ substantially from YTD results:
  - Significant negative effect on sales
  - Downward pressure on gross margin as a percent of revenue
  - Sales and marketing expenses largely removed prior to patent expiration;
     operations sized to support remaining neuroscience products

### 2011 Guidance

#### Millions, except per share amounts

Total Revenue

Gross Margin % of Revenue

Mktg, Selling & Admin.

Research & Development

Other Income/(Expense)

Tax Rate (reported)

Tax Rate (non-GAAP)

EPS (reported)

Reconciling Items (estimated) (excludes any potential future items)

EPS (non-GAAP)

Capital Expenditures

Mid-single digit increase

Declining

High-single digit increase

Low-single digit increase

\$(175) - \$(225)

Approximately 19.5% Approximately 20%

\$3.89 - \$3.94

\$0.41

\$4.30 - \$4.35

Approximately \$700

For complete reconciliation to reported guidance, please see slide 15 of this presentation and our earnings press release dated Oct. 20, 2011.

# Earnings per Share Expectations

	2011	2010	Growth
Earnings per share (reported)	\$3.89-\$3.94	\$4.58	(14)%-(15)%
Restructuring charges	0.18	0.13	
In-process research and development charges associated with the Boehringer Ingelheim (2011) and Acrux (2010) agreements	0.23	0.03	
EPS (non-GAAP)	\$4.30-\$4.35	\$4.74	(8)%-(9)%

Note: Numbers may not add due to rounding.

# Key Future Events in 2011 and 2012

#### Potential regulatory actions:

- In the U.S.:
  - Erbitux for 1st-line head and neck cancer
  - Bydureon for type 2 diabetes
  - Tradjenta plus metformin fixed dose combination for type 2 diabetes
  - Alimta continuation maintenance in nonsquamous non-small cell lung cancer
  - Erbitux for 1<sup>st</sup>-line non-small cell lung cancer
  - Erbitux for 1st-line metastatic colorectal cancer
  - Amyvid for detection of beta amyloid plaque
- Alimta continuation maintenance in nonsquamous NSCLC in Europe

#### Expected clinical trial completion:

- Solanezumab Phase 3 trials in Alzheimer's
- Dulaglutide Phase 3 trials in type 2 diabetes
- JAK1/JAK2 Phase 2b study in RA
- Effient Phase 3 in ACS-MM
- Empagliflozin Phase 3 trials in type 2 diabetes
- Alimta Phase 3 PARAMOUNT and POINTBREAK trials

#### Potential Phase 3 trial initiation:

- Innovative basal analog insulin
- anti-IL-17 monoclonal antibody
- CETP inhibitor

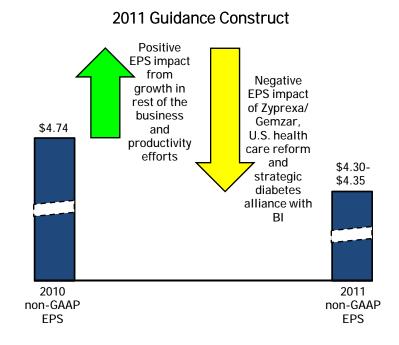
#### Presentation of clinical trial data:

- anti-IL-17 monoclonal antibody:
  - Phase 2 RA data at ACR
  - Phase 2 psoriasis data at Gene to Clinic
- CETP inhibitor Phase 2 data at AHA
- Potential data disclosures in 2012:
  - Innovative basal analog insulin Phase 2 data in type 1 and type 2 diabetes
  - Solanezumab Phase 3 data in Alzheimer's
  - JAK1/JAK2 Phase 2b data in RA
  - Effient Phase 3 trial in ACS-MM
  - Alimta Phase 3 PARAMOUNT and POINTBREAK trials

Black text – 2011 event Red text – 2012 event

# **Q3 2011 Summary**

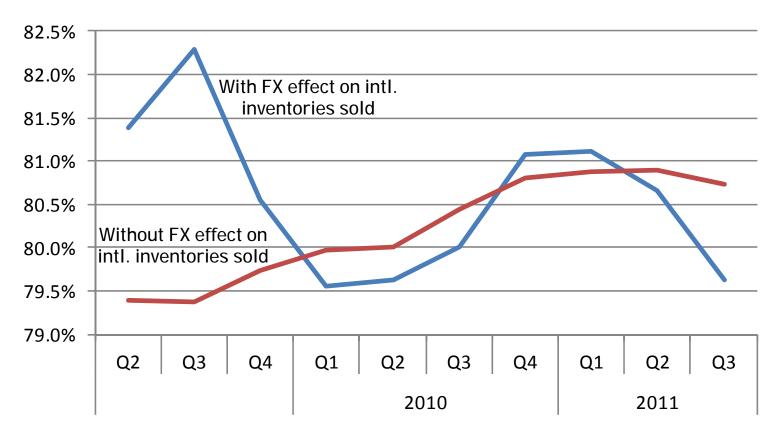
- Advancing the pipeline:
  - Ten molecules currently in Phase 3 development
  - Could have 12 molecules in Phase 3 by the end of 2011
- Tracking to achieve 2011 headcount and expense containment goals
- Q3 non-GAAP financial results:
  - Revenue, OPEX and EPS growth of 9%, 10% and -7%, respectively
- Excluding Gemzar outside of Japan, U.S. health care reform and investments for the BI alliance, the rest of the business generated:
  - Revenue growth of 15%
  - OPEX growth of 3% (2% on a reported basis)
  - Mid twenties EPS growth (high twenties growth on a reported basis)



# Supplementary Slides

# Gross Margin % - Moving Annual Total

Pro-forma non-GAAP



Individual quarter GM% of Revenue:

with FX effect on intl inv sold 82.1% 81.1% 75.9% 79.5% 82.5% 80.1% 79.8% 80.4% 78.2% 82.2% 81.7% 78.8% 79.2% 80.4% 81.7% 80.6% 80.7% 81.7% w/o FX effect on intl inv sold 80.6% 80.0%

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 2010/2011

	1Q10	2010	3Q10	4Q10	2010	1Q11	2011	3Q11	4Q11	2011
Non-GAAP	1.18	1.24	1.21	1.11	4.74	1.24	1.18	1.13		
Reported	1.13	1.22	1.18	1.05	4.58	0.95	1.07	1.11		

Note: Numbers may not add due to rounding.

For complete reconciliation to reported earnings, please see slide 8 of this presentation and our earnings press release dated Oct. 20, 2011.

# Q3 Other Income/(Loss)

#### Millions

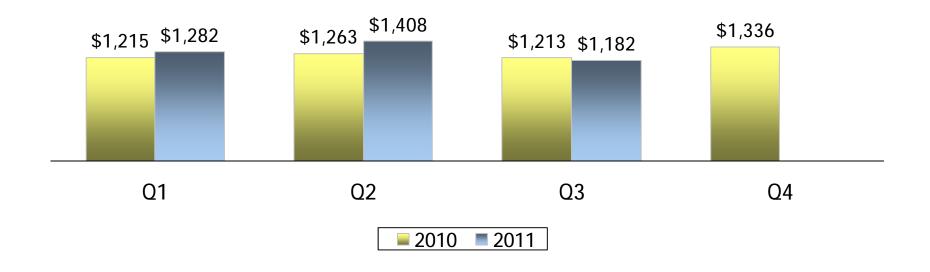
	Q3 11	Q3 10
- Interest Expense	(\$45.0)	(\$47.2)
- Interest Income	22.2	16.3
Interest, net	(22.8)	(30.9)
- FX Gains / (Losses)	9.8	(6.5)
- Gains / (Losses) on Equity Investments	11.6	(0.2)
- Miscellaneous Income / (Loss)	(82.0)	15.9
Miscellaneous Income/(Loss), net	(60.6)	9.2
Net Other Income (Loss)	<u>\$(83.4)</u>	<u>\$(21.7)</u>

Note: Numbers may not add due to rounding.

# Q3 Zyprexa® Sales Decreased 3%

Millions

U.S. sales decreased 7% International sales increased 2%



# Q3 Cymbalta® Revenue Increased 29%

Millions

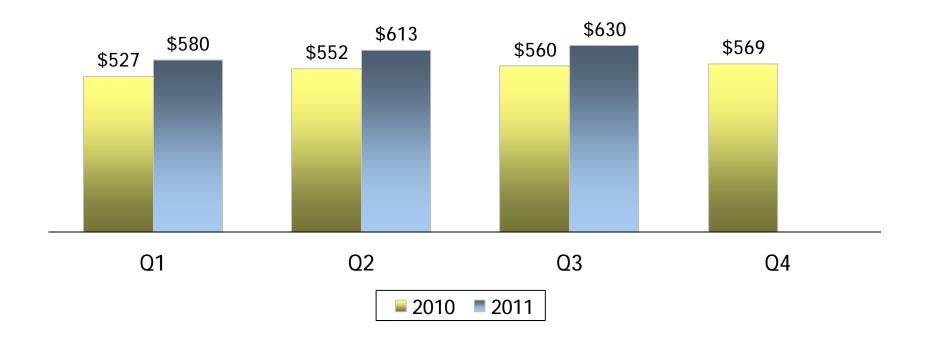
U.S. sales increased 26% International revenue increased 42%



## Q3 Alimta<sup>®</sup> Sales Increased 12%

Millions

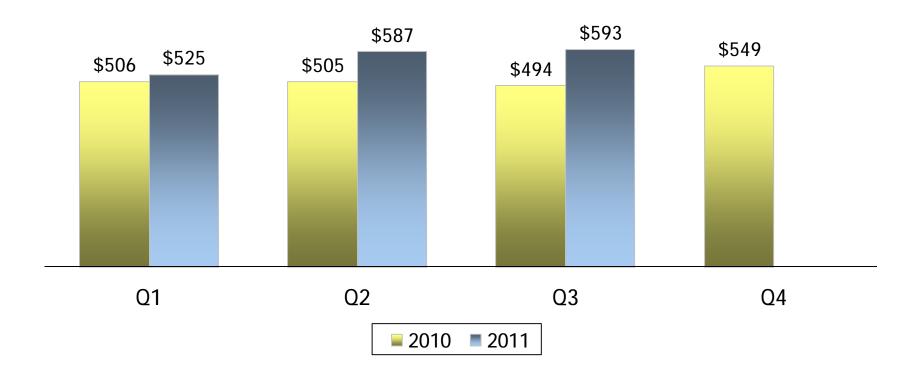
U.S. sales increased 5% International sales increased 18%



# Q3 Humalog<sup>®</sup> Sales Increased 20%

Millions

U.S. sales increased 20% International sales increased 21%



## Q3 Cialis® Sales Increased 16%

Millions

U.S. sales increased 10% International sales increased 19%



## Q3 Humulin® Sales Increased 8%

Millions

U.S. sales increased 18% International sales increased 1%



## Q3 Evista® Sales Increased 5%

Millions

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



## Q3 Forteo® Sales Increased 20%

Millions

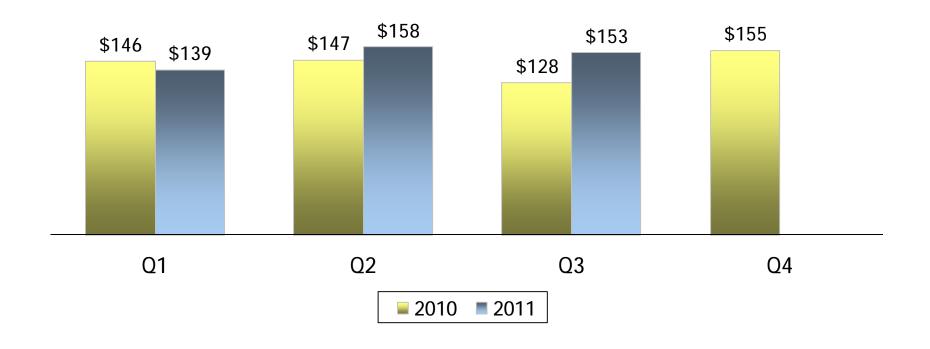
U.S. sales decreased 7% International sales increased 60%



## Q3 Strattera® Sales Increased 20%

Millions

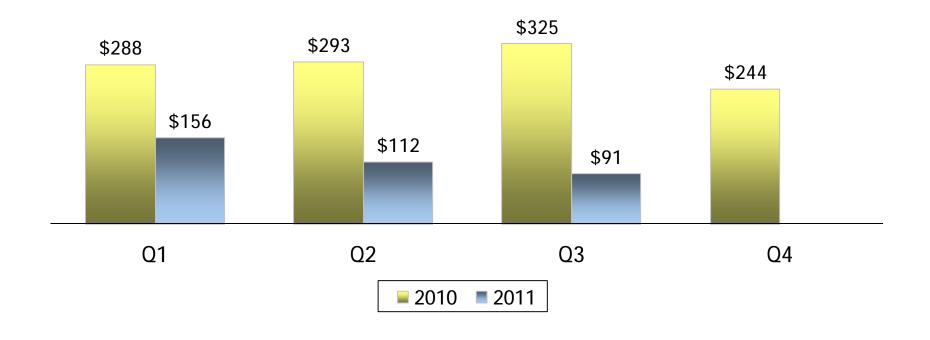
U.S. sales increased 13% International sales increased 33%



## Q3 Gemzar® Sales Decreased 72%

Millions

U.S. sales decreased 102% International sales decreased 9%



# Q3 Byetta® Worldwide Sales \$171.0 Million

Millions

Worldwide sales increased 1% Lilly revenue increased 4%



## Q3 Effient® Worldwide Sales \$83.5 Million

Millions

