# **Q2 2014 Financial Review**

July 24th, 2014



# Agenda

### Introduction and Key Recent Events

John Lechleiter, Chairman, President and Chief Executive Officer

### Q2 Financial Results, Key Future Events and Financial Guidance

- Phil Johnson, Vice President, Investor Relations
- Derica Rice, Executive Vice President, Global Services and Chief Financial Officer

### Summary

John Lechleiter, President, Chief Executive Officer and Chairman

#### **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 factors including, but not limited to, 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.

# Key Events Since the Last Earnings Call

#### Commercial:

 Launched Cyramza<sup>™</sup> in the U.S. as a single-agent treatment for patients with advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinumcontaining chemotherapy.

#### Regulatory:

- The European Commission approved empagliflozin, or Jardiance®, indicated in the treatment of type 2 diabetes mellitus to improve glycemic control in adults.
- Boehringer Ingelheim resubmitted the NDA for empagliflozin; FDA assigned a Class 1 (2-month) review.
- Boehringer Ingelheim submitted the fixed-dose combination of empagliflozin and metformin in Europe.
- Europe's CHMP recommended approval of Lilly and Boehringer Ingelheim's new insulin glargine product for the treatment of type 1 and type 2 diabetes.
- Submitted a sBLA in the U.S. for ramucirumab as combination therapy in patients with advanced gastric cancer (RAINBOW); in Europe, data from RAINBOW have been incorporated in the submission dossier.
- Disclosed that FDA assigned Fast Track status to necitumumab for first-line squamous NSCLC.

#### Clinical:

- At the ASCO meeting, presented detailed Phase 3 data from the REVEL trial of Cyramza in second-line NSCLC and from the SQUIRE trial of necitumumab in first-line squamous NSCLC as well as additional Phase 1 data for abemaciclib in NSCLC and breast cancer.
- At the ADA meeting, presented detailed data for three Phase 3 trials of dulaglutide: AWARD-6 head-to-head versus Victoza® and AWARD-2 and -4 head-to-head versus Lantus® with or without mealtime insulin.
- Announced positive, top-line results from three Phase 3 trials of basal insulin peglispro (BIL) in patients with type 2 diabetes; each trial showed a statistically superior reduction in HbA1c compared with Lantus; U.S. and European regulatory submissions are expected by the end of Q1 2015.
- Announced that the Phase 3 REACH trial of ramucirumab as monotherapy in patients with hepatocellular cancer did not meet its primary endpoint of overall survival.

# Key Events Since the Last Earnings Call

#### **Business Development/Other:**

- Announced a co-discovery and co-development collaboration with Immunocore Limited for novel T cell-based cancer therapies.
- Completed the acquisition of Lohmann Animal Health, a global leader in poultry vaccines.
- Announced an agreement with Sanofi to pursue regulatory approval of nonprescription Cialis® (tadalafil) in the United States, Europe, Canada and Australia.
- The English High Court ruled that the vitamin dosage regimen patent for Alimta® would not be infringed by a generic competitor that stated its intent to market alternative salt forms of pemetrexed in several European countries upon expiry of the Alimta compound patents in 2015. Lilly has appealed this ruling.
- Based on the U.S. Supreme Court ruling in Akamai vs. Limelight Networks, Teva and APP filed an unopposed motion asking
  the Court of Appeals to remand the Alimta case back to the District Court to consider the issue of infringement; no dates
  have been set
- A Brazilian Labor Court ruled against the company's local subsidiary in a case alleging some employees were exposed to hazardous materials at a manufacturing facility; we strongly disagree with the ruling and have filed an appeal.
- Repurchased \$145 million of stock in Q2 2014 under recently-authorized \$5 billion share repurchase program.

### **Comparison Measures**

### "Reported" results

Include all financial results as reported in accordance with GAAP

#### "Non-GAAP" measures

- Start with "Reported" results
- Include adjustments for items such as:
  - Asset impairment, restructuring and other special charges
  - Acquired in-process R&D charges and other income and expenses from business development activities

# 2014 Income Statement – Reported

Millions; except per share data

	Q2 2014	Growth	June YTD	Growth
Total Revenue	\$4,936	(17)%	\$9,619	(17)%
Gross Margin Percent	75.9%	(4.4)pp	74.9%	(5.0)pp
Total Operating Expense*	2,859	(12)%	5,485	(13)%
Operating Income	887	(41)%	1,721	(41)%
Other Income / (Deductions)	54	NM	110	NM
Effective Tax Rate	22.0%	1.6pp	20.2%	(0.3)pp
Net Income	<u>\$733</u>	(39)%	\$1,461	<u>(47)%</u>
Diluted EPS	\$0.68	(39)%	\$1.36	(46)%

<sup>\*</sup> Includes research and development expense, selling, marketing and administrative expense, acquired in-process research and development charges, and asset impairment, restructuring and other special charges.

Note: See slide 21 for a complete list of charges.

# Reconciliation of GAAP Reported to Non-GAAP Adjusted Information; certain line items (unaudited)

Millions; except per share data

Q2	201	14

	GAAP Reported	Adjust- ments	Non-GAAP Adjusted	Non-GAAP Adjusted Growth
Total Revenue	\$4,936	-	\$4,936	(17)%
Gross Margin	75.9%	-	75.9%	(4.4)pp
Total Operating Expense	2,859	-	2,859	(11)%
Operating Income	887	-	887	(43)%
Other Income / (Expense)	54	-	54	NM
Effective Tax Rate	22.0%	-	22.0%	1.5pp
Net Income	\$733	-	\$733	(42)%
Diluted EPS	\$0.68	-	\$0.68	(41)%

Note: Numbers may not add due to rounding.

# Reconciliation of GAAP Reported to Non-GAAP Adjusted Information; certain line items (unaudited)

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Millions; except per share data

	June YID						
	GAAP Reported	Adjust- ments	Non-GAAP Adjusted	Non-GAAP Adjusted Growth			
Total Revenue	\$9,619	-	\$9,619	(17)%			
Gross Margin	74.9%	-	74.9%	(5.0)pp			
Total Operating Expense	5,485	(31)	5,453	(12)%			
Operating Income	1,721	31	1,753	(42)%			
Other Income / (Expense)	110	-	110	NM			
Effective Tax Rate	20.2%	0.2%	20.4%	2.3pp			
Net Income	\$1,461	\$22	\$1,483	(41)%			
Diluted EPS	\$1.36	\$0.02	\$1.38	(40)%			

Note: Numbers may not add due to rounding; see slide 21 for a complete list of charges.

### **EPS Reconciliation**

	Q2 2014	Q2 2013	Growth	YTD 14	YTD 13	Growth
EPS (reported)	\$0.68	\$1.11	(39)%	\$1.36	\$2.53	(46)%
Asset impairment, restructuring and other special charges	-	0.04		0.02	0.06	
Income from the transfer of exenatide commercial rights					(0.29)	
EPS (non-GAAP)	\$0.68	\$1.16	(41)%	\$1.38	\$2.30	(40)%

Note: Numbers may not add due to rounding.

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

#### Q2 2014

Pharmaceuticals	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$2,047.7	2%		(36)%	(33)%	(33)%
ACE*	1,195.0	(3)%	4%	2%	2%_	(1)%
Japan	428.9	(1)%	(4)%	(10)%	(15)%	(11)%
<b>Emerging Markets</b>	662.8	1%	(4)%	7%	4%	8%
Total Pharma	4,334.4	1%	(0)%	(20)%	(20)%	(20)%
Animal Health	601.2	1%	(0)%	10%_	11%	11%
Total Revenue	\$4,935.6	1%	(0)%	(17)%	(17)%	(17)%

#### June YTD 2014

Pharmaceuticals	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$3,824.3	(4)%		(31)%	(35)%	(35)%
ACE*	2,380.0	(3)%	2%	1%	1%	(1)%
Japan	966.0	(2)%	(10)%	13%	(0)%	10%
<b>Emerging Markets</b>	1,319.7	1%	(5)%	10%	6%	11%
Total Pharma	8,490.1	(3)%	(1)%	(15)%	(19)%	(18)%
Animal Health	1,128.6	2%	(1)%	7%_	8%_	9%
Total Revenue	\$9,618.7	(3)%	(1)%	(13)%	(17)%	(16)%

Note: Numbers may not add due to rounding.

<sup>\*</sup> includes Australia/New Zealand, Canada and Europe CER = growth using constant exchange rates

# Effect of Foreign Exchange on 2014 Results

Year-on-Year Growth

	Q2 2	2014	June YT	D 2014
	With FX	w/o FX	With FX	w/o FX
Total Revenue	(17)%	(17)%	(17)%	(16)%
Cost of Sales	2%	(2)%	4%	(2)%
Gross Margin	(21)%	(20)%	(22)%	(19)%
Reported Operating Expense	(12)%	(12)%	(13)%	(12)%
Reported Operating Income	(41)%	(38)%	(41)%	(34)%
Reported EPS	(39)%	(36)%	(46)%	(40)%
Non-GAAP Operating Expense	(11)%	(10)%	(12)%	(11)%
Non-GAAP Operating Income	(43)%	(40)%	(42)%	(35)%
Non-GAAP EPS	(41)%	(39)%	(40)%	(33)%

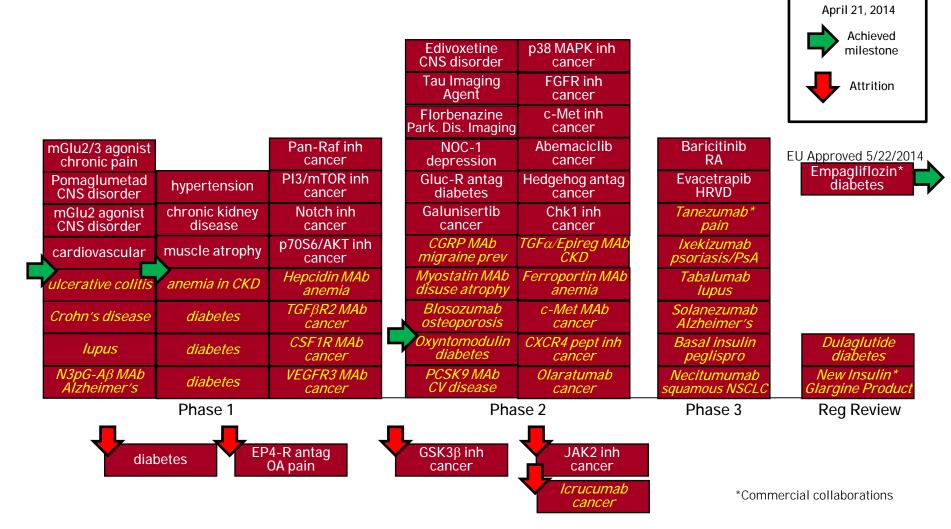
# Lilly NME Pipeline

July 17, 2014

New Chemical Entity (NCE)

New Biotech Entity (NBE)

Movement since



# **Key Events in 2014**

#### Potential Phase 3 initiations:

- · CDK4/6 (abemaciclib) for cancer
- **√**
- Blosozumab for osteoporosis

#### Potential Phase 3 data internal readouts:



- Basal insulin peglispro for type 1 and type 2 diabetes (topline press release for type 1 trials expected in Q3)
- Ramucirumab for second-line metastatic colorectal cancer
- Ixekizumab for psoriasis
- · Tabalumab for lupus
- First trial of baricitinib in rheumatoid arthritis

#### Potential Phase 3 data external disclosures:

- **√**+.
- AWARD-2 and AWARD-4 of dulaglutide for type 2 diabetes
  - + AWARD-6 of dulaglutide for type 2 diabetes
- **√+.** N
  - New insulin glargine product for type 1 and type 2 diabetes<sup>1</sup> (ELEMENT1 and ELEMENT2)
  - Necitumumab for first-line squamous NSCLC (SQUIRE)
- Ramucirumab as combination therapy for second-line gastric cancer (RAINBOW)
- Ramucirumab for second-line NSCLC (REVEL)
- **√**.
- Ramucirumab for second-line hepatocellular cancer (REACH)

#### Potential regulatory submissions:

- Basal insulin peglispro for type 1 and type 2 diabetes (by Q1 '15)
- 1
- Empagliflozin + linagliptin FDC for type 2 diabetes<sup>1</sup>
- Empagliflozin + metformin IR FDC for type 2 diabetes<sup>1</sup> (submitted in EU; U.S. expected H2 '14)
  - · Necitumumab for first-line squamous NSCLC



- Ramucirumab as combination therapy for second-line gastric cancer
- Ramucirumab for second-line NSCLC



Ramucirumab for second-line hepatocellular cancer

#### Potential regulatory actions:



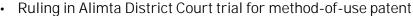
- Empagliflozin for type 2 diabetes<sup>1</sup> (approved in EU; U.S. pending)
- Dulaglutide for type 2 diabetes



- Ramucirumab as monotherapy for second-line gastric cancer
- New insulin glargine product<sup>1</sup>

#### Other:







- Evista U.S. patent expiration (March)
- Cymbalta® EU data package exclusivity expiration
- Partial clinical hold resolution for tanezumab<sup>2</sup> (now expected in 2015)
  - 1 in collaboration with Boehringer Ingelheim
  - 2 in collaboration with Pfizer

### 2014 Guidance

	Prior	Current
Total Revenue	\$19.4 to \$20.0 billion	\$19.4 to \$20.0 billion
Gross Margin % of Revenue	Approx. 73%	Approx. 73%
Mktg, Selling & Admin.	\$6.3 to \$6.6 billion	\$6.3 to \$6.6 billion
Research & Development	\$4.4 to \$4.7 billion	\$4.4 to \$4.7 billion
Other Income/(Expense)	\$100 - \$200 million	\$100 - \$200 million
Tax Rate	Approx. 19%	Approx. 19%
Minimum Net Income	\$2.9 billion	\$2.9 billion
Earnings per Share (non-GAAP) Earnings per Share (GAAP)	\$2.72 - \$2.80 \$2.70 - \$2.78	\$2.72 - \$2.80 \$2.67 - \$2.75
Minimum Operating Cash Flow	\$4 billion	\$4 billion
Capital Expenditures	Approx. \$1.3 billion	Approx. \$1.2 billion

# **Earnings per Share Expectations**

	2014	2013	Growth
EPS (reported)	\$2.67-\$2.75	\$4.32	(36)%-(38)%
Acquired in-process research and development charges	0.03	0.03	
Asset impairment, restructuring and other special charges	0.02	0.08	
Income related to termination of the exenatide collaboration with Amylin	<del>-</del>	(0.29)	
EPS (non-GAAP)	\$2.72-\$2.80	\$4.15	(33)%-(34)%

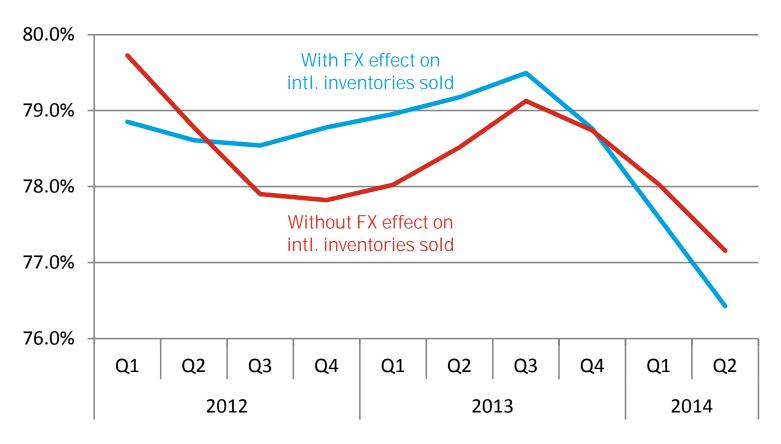
Note: Numbers may not add due to rounding.

# **Q2 2014 Summary**

- H1 financial performance places us on track to meet full-year guidance:
  - Effect of patent expirations in-line with expectations
  - Operating expenses declined 11%
  - Cyramza launched in Q2; more launches expected in H2
- Continued pipeline advancement strengthens our confidence in our innovation-based strategy
- Positioned to return to growth and expand margins in 2015 and beyond

# Supplementary Slides

# **Gross Margin % - Moving Annual Total**



Individual quarter GM% of Revenue:

with FX effect on intl inv sold 78.6% 79.5% 77.9% 79.0% 79.3% 80.3% 79.2% 76.1% 73.9% 75.9% w/o FX effect on intl inv sold 78.3% 77.9% 76.4% 78.5% 79.1% 79.9% 79.0% 77.0% 75.8% 76.5%

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 2013/2014

1Q13	2Q13	3Q13	4Q13	2013	1Q14	2Q14	3Q14	4Q14	2014
1.14	1.16	1.11	0.74	4.15	0.70	0.68			
1.42	1.11	1.11	0.67	4.32	0.68	0.68			
1	.14	.14 1.16	.14 1.16 1.11	.14 1.16 1.11 0.74	.14 1.16 1.11 0.74 4.15	.14 1.16 1.11 0.74 4.15 0.70	.14 1.16 1.11 0.74 4.15 0.70 0.68	.14 1.16 1.11 0.74 4.15 0.70 0.68	.14 1.16 1.11 0.74 4.15 0.70 0.68

Note: Numbers may not add due to rounding.

For a complete reconciliation to reported earnings, see slide 21 of this presentation and our earnings press release dated July 24, 2014.

### **2014 Income Statement Notes**

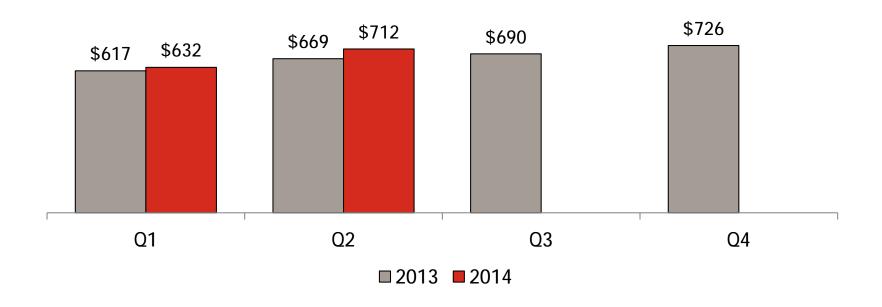
#### Notes:

- The first quarter 2014 non-GAAP financial statements have been adjusted to eliminate a charge of \$31.4 million (pretax), or EPS of \$0.02 (after-tax), associated with restructuring to reduce the company's cost structure.
- The second quarter 2013 non-GAAP financial statements have been adjusted to eliminate a charge of \$63.5 million (pretax), or EPS of \$0.04 (after-tax), primarily related to costs associated with the decision to close a packaging and distribution facility in Germany.
- In addition, 2013 YTD non-GAAP financial statements have been adjusted to eliminate income of \$495.4 million (pretax), or EPS of \$0.29 (after-tax), related to the transfer of exenatide commercial rights in markets outside the U.S. to Amylin and a charge of \$21.7 million (pretax), or EPS of \$0.01 (after-tax), associated with severance costs from actions the company is taking, primarily outside the U.S., to reduce its cost structure.

### Q2 Alimta Sales Increased 6%

Millions

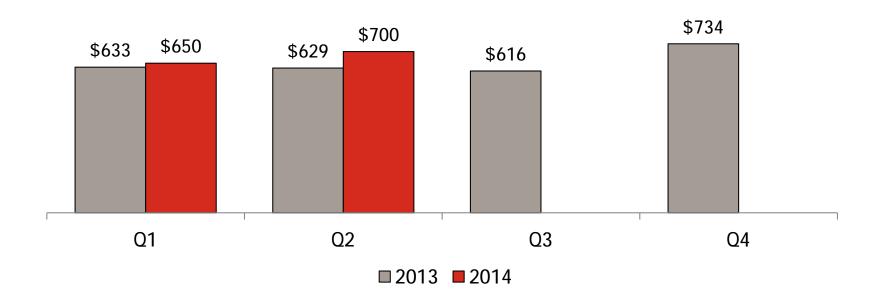
U.S. sales increased 5% International sales increased 7%



# Q2 Humalog<sup>®</sup> Sales Increased 11%

Millions

U.S. sales increased 17% International sales increased 4%



### Q2 Animal Health Sales Increased 11%

Millions

U.S. sales increased 3% International sales increased 21%



### Q2 Cialis Sales Increased 7%

Millions

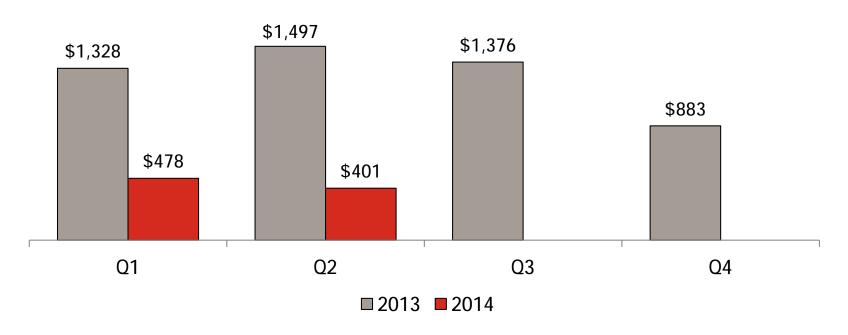
U.S. sales increased 24% International sales decreased 4%



# Q2 Cymbalta Sales Decreased 73%

Millions

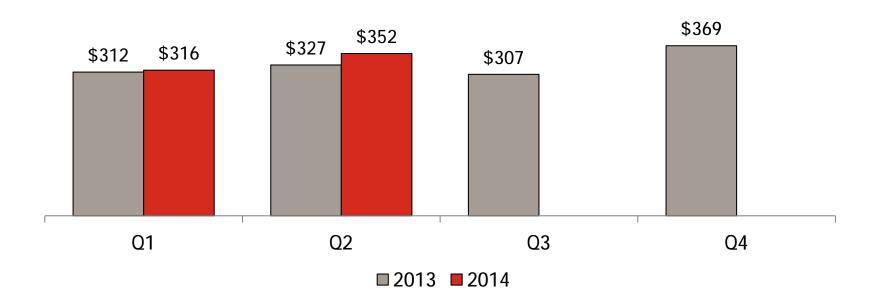
U.S. sales decreased 91% International sales increased 3%



### Q2 Humulin® Sales Increased 8%

Millions

U.S. sales increased 15% International sales increased 1%



### Q2 Forteo® Sales Increased 4%

Millions

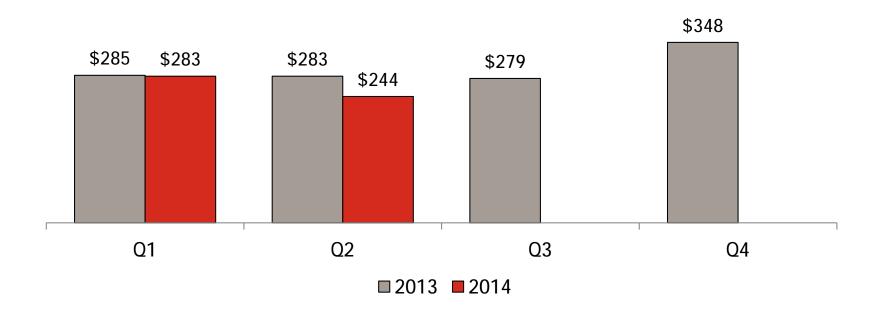
U.S. sales increased 10% International sales were flat



# Q2 Zyprexa® Sales Decreased 14%

Millions

U.S. sales increased 103% International sales decreased 23%



### Q2 Strattera® Sales Increased 17%

Millions

U.S. sales increased 26% International sales increased 3%



### Q2 Effient® Sales Decreased 3%

Millions

U.S. sales decreased 3% International sales decreased 1%



### Q2 Evista Sales Decreased 61%

Millions

U.S. sales decreased 72% International sales decreased 33%

