# Q1 2015 Financial Review

April 23<sup>rd</sup>, 2015



### Agenda

### Introduction and Key Recent Events

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

### Q1 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

#### 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® in the U.S. for second-line metastatic non-small cell lung cancer;
- · Launched Cyramza in the European Union for second-line gastric cancer;
- Launched Humalog® 200 units/ml KwikPen™ in the European Union; and
- Along with Boehringer Ingelheim, launched Glyxambi® (empagliflozin/linagliptin) tablets in the U.S.

#### Regulatory:

- In collaboration with Boehringer Ingelheim:
  - received FDA approval of Glyxambi (empagliflozin/linagliptin) tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes when both empagliflozin and linagliptin are appropriate treatments; and
  - received a positive opinion from Europe's CHMP recommending approval of a single-pill combination therapy with empagliflozin/metformin hydrochloride for the treatment of adults with type 2 diabetes.
- Cyramza (ramucirumab):
  - received approval from Japan's MHLW for treatment of patients with unresectable, advanced or recurrent gastric cancer; launch expected in mid-2015;
  - submitted in the U.S. and the European Union for second-line metastatic colorectal cancer; and
  - submitted in the European Union for second-line non-small cell lung cancer.
- Submitted ixekizumab to the FDA for the treatment of moderate-to-severe plaque psoriasis; and

## Key Events Since the Last Earnings Call

#### Regulatory:

• Announced removal of the FDA partial clinical hold for tanezumab; Phase 3 trials in multiple pain indications to start in 2015; triggered \$200 million payment to Pfizer.

#### Clinical:

- Along with Incyte Corporation, announced that the primary endpoint of improved ACR20 response compared to placebo after 12 weeks of treatment was met in the Phase 3 RA-BUILD study of baricitinib patients with moderately-to-severely active rheumatoid arthritis who had an inadequate response to, or were intolerant of, at least one conventional disease-modifying antirheumatic drug (cDMARD);
- Presented detailed results at the American Academy of Dermatology meeting from the Phase 3 UNCOVER-1 study evaluating ixekizumab in patients with moderate-to-severe plaque psoriasis;
- Announced positive top-line results from the Phase 3 SPIRIT-P1 study evaluating ixekizumab in patients with active psoriatic arthritis who were naïve to biologic disease-modifying antirheumatic drugs;
- Completed enrollment of EXPEDITION3, a Phase 3 study evaluating solanezumab as a potential treatment for patients with mild Alzheimer's disease; last patient visit is now expected in October 2016;
- Announced that the ACCELERATE Phase 3 study evaluating evacetrapib in approximately 12,000 people
  with high-risk atherosclerotic cardiovascular disease will be extended by approximately six months; last
  patient visit is now expected in July 2016; and
- Announced that regulatory submission of basal insulin peglispro will be delayed in order to generate additional clinical data to further understand and characterize the potential effects, if any, of changes in liver fat observed with BIL treatment in the Phase 3 trials; submission is likely to occur after 2016.

## Key Events Since the Last Earnings Call

#### Development/Other:

- Announced a collaboration with Hanmi Pharmaceutical Co., Ltd. for the development and commercialization of Hanmi's oral Bruton's tyrosine kinase (BTK) inhibitor, HM71224, for the treatment of autoimmune and other diseases; Lilly will receive worldwide rights excluding China, Hong Kong, Taiwan, and Korea;
- Announced a collaboration with Innovent Biologics, Inc. for the development and commercialization in China
  of three investigational cancer treatments; in addition, Lilly will be responsible for the development and
  commercialization outside of China for a pre-clinical immuno-oncology molecule and for up to three preclinical bispecific immuno-oncology molecules from Innovent;
- Announced an agreement with Bristol-Myers Squibb for the transfer back to Lilly of the North American rights to Erbitux®. These rights were scheduled to return to Lilly in September 2018 and are now expected to be transitioned in Q4 2015;
- The German Court of Appeal ruled that the company's vitamin regimen patent for Alimta® (pemetrexed disodium) would not be infringed by a generic competitor that intends to market a dipotassium salt form of pemetrexed in Germany once the compound patent expires in December 2015; the company has asked for permission to appeal this ruling to the German Supreme Court; and
- Repurchased \$311 million of stock in Q1 2015 under outstanding \$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
  - Amortization of intangible assets

# 2015 Income Statement - Reported

Millions; except per share data

	Q1 2015	Q1 2014	Growth
Total Revenue	4,645	4,683	(1)%
Gross Margin	74.3%	73.9%	0.4pp
Total Operating Expense*	2,927	2,626	11%
Operating Income	525	835	(37)%
Other Income / (Deductions)	93	56	66%
Effective Tax Rate	14.3%	18.3%	(4.0)pp
Net Income	<u>\$529</u>	<u>\$728</u>	(27)%
Diluted EPS	\$0.50	\$0.68	(26)%

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

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

Millions; except per share data

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	GAAP Reported	Adjust- ments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
Total Revenue	\$4,645	-	\$4,645	(6)%
Gross Margin	74.3%	3.9%	78.2%	3.6pp
Total Operating Expense	2,927	(400)	2,527	(7)%
Operating Income	525	580	1,105	15%
Other Income / (Expense)	93	-	93	NM
Effective Tax Rate	14.3%	8.6%	22.9%	<i>3.0pp</i>
Net Income	\$529	\$394	\$924	16%
Diluted EPS	\$0.50	\$0.37	\$0.87	18%

Note: Numbers may not add due to rounding; see slide 19 for a complete list of significant adjustments.

### **EPS Reconciliation**

	Q1 2015	Q1 2014	Growth
EPS (reported)	\$0.50	\$0.68	(26)%
Novartis Animal Health 2014 results	-	(0.03)	
Novartis Animal Health inventory step up	0.04	-	
Amortization of intangible assets	0.10	0.08	
Acquired in-process R&D	0.15	-	
Asset impairment, restructuring and other special charges	0.07	0.02	
EPS (non-GAAP)	\$0.87	\$0.74	18%

Note: Numbers may not add due to rounding; see slide 19 for more details on these significant adjustments.

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

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Pharmaceuticals	Amount	Price	FX Rate	Volume	_Total	CER
U.S.	\$1,840.7	10%		(5)%	4%	4%
ACE*	1,005.1	(3)%	(13)%	(0)%	(16)%	(3)%
Japan	416.2	0%	(12)%	(11)%	(23)%	(11)%
<b>Emerging Markets</b>	633.0	(2)%	(8)%	7%	(4)%	5%
Total Pharma	3,894.9	3%	(7)%	(3)%	(6)%	0%
Animal Health	749.8	3%_	(4)%_	44%	42%	46%
Total Revenue	<u>\$4,644.7</u>	3%	3% (6)% 3%		<u>(1)%</u>	<u> </u>
Non-GAAP:						
Animal Health	749.8	2%	(5)%_	0%_	(4)%	2%
Total Revenue	\$4,644.7	3%	(6)%	(2)%	(6)%	0%

Note: Numbers may not add due to rounding. Non-GAAP assumes the Novartis Animal Health acquisition occurred on January 1, 2014.

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

# Effect of Foreign Exchange on 2015 Results

01 2015

#### Year-on-Year Growth

	<u> </u>			
Reported:	With FX	w/o FX		
Total Revenue	(1)%	5%		
Cost of Sales	(2)%	22%		
Gross Margin	(0)%	(0)%		
Operating Expense	11%	15%		
Operating Income	(37)%	(50)%		
EPS	(26)%	(40)%		
Non-GAAP:				
Total Revenue	(6)%	0%		
Cost of Sales	(19)%	6%		
Gross Margin	(1)%	(1)%		
Operating Expense	(7)%	(3)%		
Operating Income	15%	4%		
EPS	18%	<b>7</b> %		

# Lilly NME Pipeline

April 17, 2015

New Chemical Entity (NCE)

New Biotech Entity (NBE)

7	D1 potentiator Parkinson's	Pomaglumetad schizophrenia	muscle atrophy
	BACE inhibitor Alzheimer's	mGlu2 agonist AD psychosis	Notch inh cancer
1	mGlu2/3 agonist chronic pain	hypertension	p70S6/AKT inh cancer
7	BTK inhibitor RA	chronic kidney disease	Pan-Raf inh cancer
	Blosozumab osteoporosis	diabetes	PI3/mT0R inh cancer
	rheumatoid arthritis	hypoglycemia	anemia in CKD
	ulcerative colitis	URI diabetes	diabetic nephropathy
	Crohn's disease	diabetes	MET/EGFR cancer
	lupus	diabetes	CSF1R MAb cancer
	N3pG-Aβ MAb Alzheimer's	diabetes	VEGFR3 MAb cancer
		Phase 1	

	Chk1 inh cancer
	Galunisertib cancer
au Imaging	p38 MAPK inh
orbenazine	cancer FGFR inh
	cancer
	c-Met inh cancer
uc-R antag diabetes	Hedgehog antag cancer
	CGRP MAb migraine prev
	Ferroportin MAb anemia
vntomodulin diabetes	c-Met MAb cancer
	CXCR4 pept inh cancer
α/ <b>Epireg MAb</b> CKD	Olaratumab cancer
	osano-PTH steoporosis vostatin MAb suse atrophy yntomodulin diabetes PCSK9 MAb CV disease ia/Epireg MAb

Movement since
January 23, 2015

Achieved
milestone

Attrition

New
molecule
Later phase
indication
terminated

Baricitinib
RA
Evacetrapib
HRVD
Tanezumab\*
pain
Solanezumab
Alzheimer's
Basal insulin
peglispro

Abemaciclib cancer

lxekizumab psoriasis Necitumumab squamous NSCLO

Reg Review

Phase 2 Phase 3

cardiovascular

\*Commercial collaborations

# **Key Events in 2015**

#### Potential Phase 3 initiations:

- Olaratumab for soft tissue sarcoma
- \*\* Ramucirumab for first-line gastric cancer
  - Ramucirumab for first-line EGFR mutation positive nonsmall cell lung cancer
  - Ramucirumab for second-line urothelial cancer
  - Ramucirumab for second-line hepatocelluar cancer
  - CGRP MAb for cluster headache
  - Tanezumab for pain <sup>1</sup>

#### Potential Phase 3 data internal readouts:

- Jardiance® CV outcomes trial for type 2 diabetes 2
- Ixekizumab for psoriatic arthritis
- +• Remaining trials of baricitinib in rheumatoid arthritis (BUILD Feb; BEAM and BEGIN H2 2015)

#### Potential Phase 3 data external disclosures:

- Ramucirumab for second-line metastatic colorectal cancer
  - Basal insulin peglispro for type 1 and type 2 diabetes
  - Jardiance CV outcomes trial for type 2 diabetes 2
- !xekizumab for psoriasis
  - Ixekizumab for psoriatic arthritis
  - Initial trials of baricitinib in rheumatoid arthritis
  - Two-year data from the EXPEDITION-EXT (extension) study of solanezumab in Alzheimer's disease

#### Potential regulatory submissions:

- √⁺
   Ramucirumab for second-line metastatic colorectal cancer
- Ramucirumab for second-line NSCLC (Europe)
- Basal insulin peglispro for type 1 and type 2 diabetes
  - Empagliflozin/linagliptin FDC for type 2 diabetes<sup>2</sup> (Europe)
- Ixekizumab for psoriasis
  - Baricitinib for rheumatoid arthritis

#### Potential regulatory actions:

- √⁺
   Ramucirumab for second-line gastric cancer (Japan)
  - Ramucirumab for second-line metastatic colorectal cancer
  - Necitumumab for first-line squamous NSCLC
  - Dulaglutide for type 2 diabetes (Japan)
  - Humalog U-200 Kwikpen for type 1 and type 2 diabetes (US)
- Empagliflozin/linagliptin FDC for type 2 diabetes 2 (US)
  - Empagliflozin/metformin IR FDC for type 2 diabetes 2

#### Other:

- Complete acquisition of Novartis Animal Health
- Partial clinical hold resolution for tanezumab 1
  - Rulings in ongoing Alimta patent litigation:
    - U.S.
    - ✓ Germany
      - UK
      - Japan
- 1 in collaboration with Pfizer
- 2 in collaboration with Boehringer Ingelheim

# 2015 Guidance

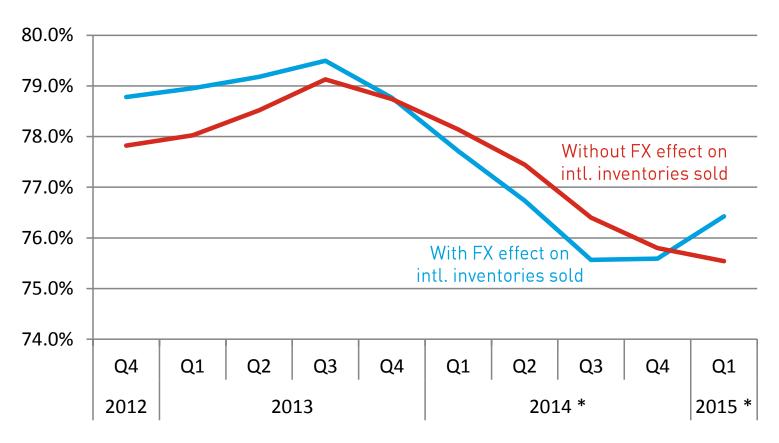
	Prior	Revised
Total Revenue	\$19.5 to \$20.0 billion	\$19.5 to \$20.0 billion
Gross Margin % of Revenue (non-GAAP) Gross Margin % of Revenue (GAAP)	Approx. 78.0% Approx. 75.0%	Approx. 78.0% Approx. 74.5%
Mktg, Selling & Admin. (non-GAAP) Mktg, Selling & Admin (GAAP)	\$6.3 to \$6.6 billion \$6.5 to \$6.8 billion	\$6.3 to \$6.6 billion \$6.4 to \$6.7 billion
Research & Development	\$4.7 to \$4.9 billion	\$4.7 to \$4.9 billion
Other Income/(Expense)	\$75 - \$125 million	\$75 - \$125 million
Tax Rate (non-GAAP) Tax Rate (GAAP)	Approx. 21.5% Approx. 18.5%	Approx. 21.5% Approx. 16.5%
Earnings per Share (non-GAAP) Earnings per Share (GAAP)	\$3.10 - \$3.20 \$2.40 - \$2.50	\$3.10 - \$3.20 \$2.21 - \$2.31
Capital Expenditures	Approx. \$1.3 billion	Approx. \$1.3 billion

## **Q1 2015 Summary**

- Remain on track to return to growth in 2015
  - solid underlying business performance
  - progress advancing our innovation-based strategy
  - revenue negatively affected by stronger U.S. Dollar and lingering effects of U.S. patent expirations for Cymbalta and Evista
- Continued pipeline advancement and restructuring of our cost base strengthens our confidence in our innovation-based strategy
  - One FDA approval so far in 2015:
    - o Glyxambi in Q1
  - Total non-GAAP operating expenses (SG&A + R&D) reduced by nearly
     \$200 million from Q1 2014 to Q1 2015
- Positioned to grow revenue and expand margins through the balance of this decade

# Supplementary Slides

# Gross Margin % - Moving Annual Total



Individual quarter GM% of Revenue\*:

76.1% with FX effect on intl inv sold 79.0% 79.3% 80.3% 79.2% 74.6% 76.7% 74.8% 76.3% 78.2% w/o FX effect on intl inv sold 78.5% 79.1% 79.9% 79.0% 77.0% 76.4% 77.2% 74.9% 74.7% 75.3%

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.

<sup>\* 2014</sup> and 2015 exclude amortization of intangibles from cost of sales and include Novartis Animal Health

### Q1 2015 Income Statement Notes

- First quarter 2015 non-GAAP information has been adjusted to eliminate:
  - inventory step-up costs associated with the acquisition of Novartis Animal Health totaling \$63.5 million (pretax), or \$0.04 per share (after-tax);
  - amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties totaling \$152.7 million (pretax), or \$0.10 per share (after-tax);
  - acquired in-process research and development costs totaling \$256.0 million (pretax), or \$0.15 per share (after-tax), comprised of a \$200.0 million payment to Pfizer following the FDA decision allowing the resumption of the Phase III clinical program for tanezumab and a \$56.0 million charge associated with a collaboration with Innovent to develop potential oncology therapies; and
  - costs associated with restructuring to reduce the company's cost structure, asset impairments, and integration costs associated with the acquisition of Novartis Animal Health totaling \$108.0 million (pretax), or \$0.07 per share (after-tax).
- First quarter 2014 non-GAAP information has been adjusted to eliminate:
  - the results of Novartis Animal Health as if the acquisition and the financing for the acquisition had occurred as of January 1, 2014 (see press release dated April 23, 2015 for details);
  - amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties totaling \$128.8 million (pretax), or \$0.08 per share (after-tax); and
  - costs primarily associated with restructuring to reduce the company's cost structure totaling \$31.4 million (pretax), or \$0.02 per share (after-tax).

# Comparative EPS Summary 2014/2015

	1Q14	2Q14	3Q14	4Q14	2014	1Q15	2Q15	3Q15	4Q15	2015
Non-GAAP	0.70	0.68	0.66	0.75	2.78	0.87				
Reported	0.68	0.68	0.47	0.40	2.23	0.50				

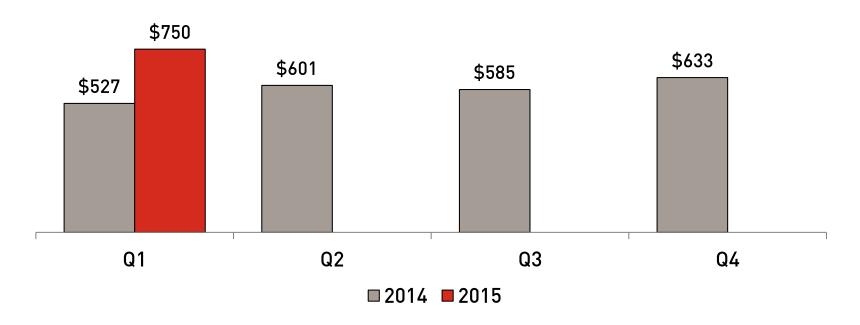
Note: Numbers may not add due to rounding.

For a complete reconciliation to reported earnings, see slide 19 and our earnings press release dated April 23, 2015.

### Q1 Animal Health Sales Increased 42%

Millions

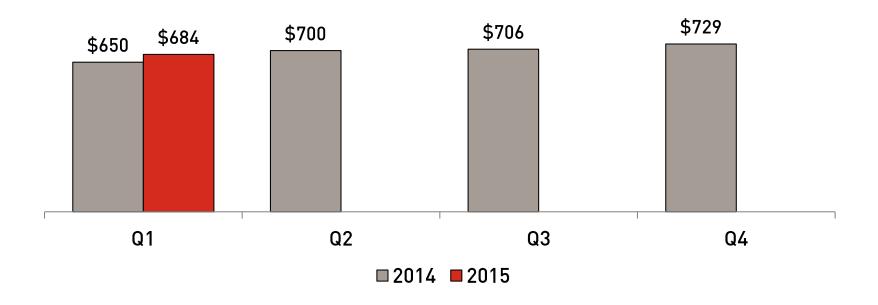
U.S. sales increased 16% International sales increased 79%



### Q1 Humalog Sales Increased 5%

Millions

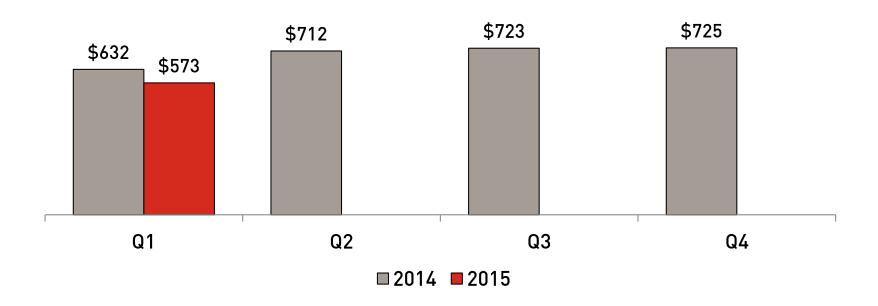
U.S. sales increased 12% International sales decreased 4%



### Q1 Alimta Sales Decreased 9%

Millions

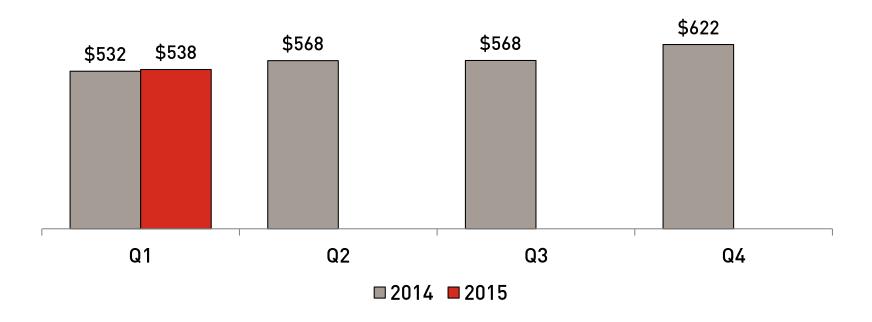
U.S. sales increased 3% International sales decreased 17%



### Q1 Cialis® Sales Increased 1%

Millions

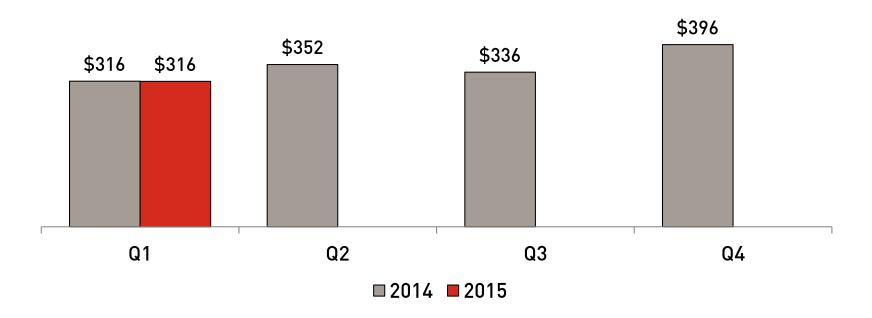
U.S. sales increased 20% International sales decreased 11%



# Q1 Humulin® Sales Essentially Flat

Millions

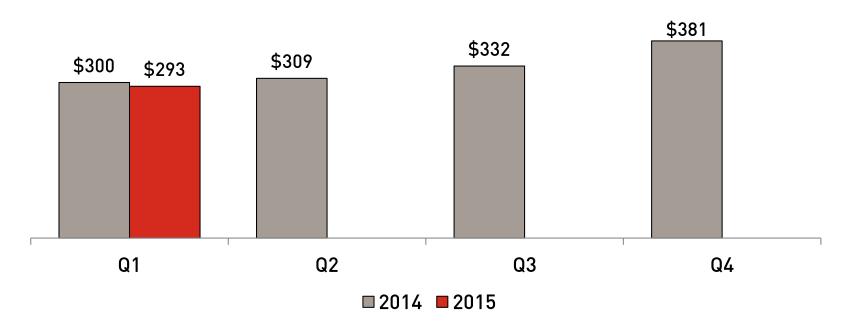
U.S. sales increased 16% International sales decreased 16%



### Q1 Forteo® Sales Decreased 2%

Millions

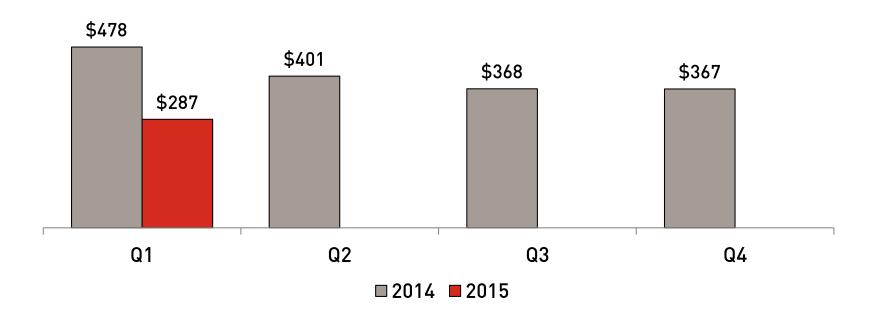
U.S. sales increased 21% International decreased 14%



# Q1 Cymbalta® Sales Decreased 40%

Millions

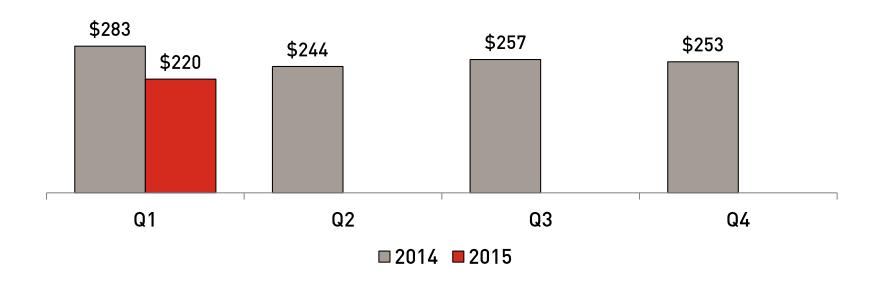
U.S. sales decreased 69% International sales decreased 23%



# Q1 Zyprexa® Sales Decreased 22%

Millions

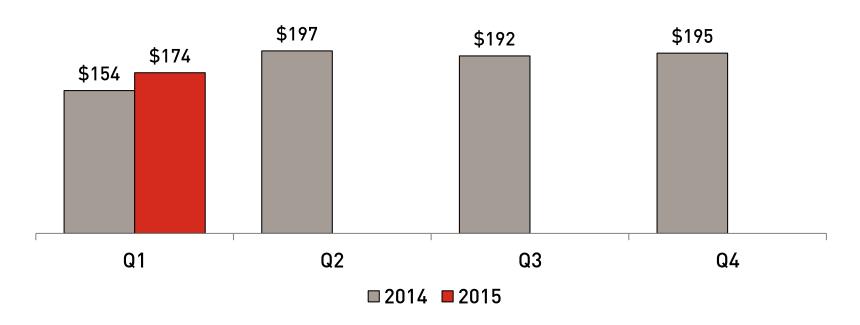
U.S. sales decreased 2% International sales decreased 25%



### Q1 Strattera® Sales Increased 13%

Millions

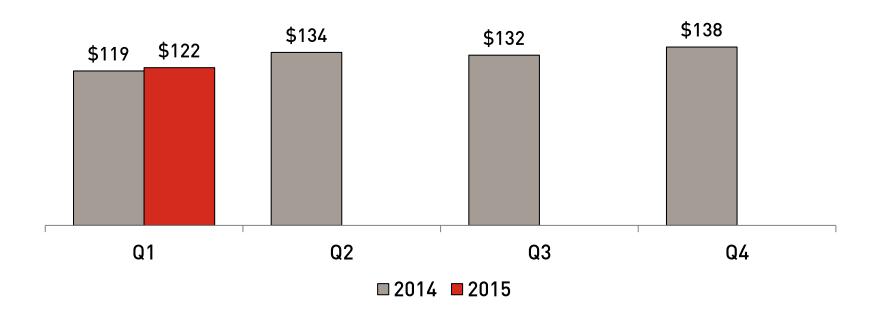
U.S. sales increased 31% International sales decreased 9%



### Q1 Effient® Sales Increased 2%

Millions

U.S. sales increased 8% International sales decreased 14%



### Q1 Evista® Sales Decreased 55%

Millions

U.S. sales decreased 75% International sales decreased 18%

