# Q1 2016 Financial Review

April 26, 2016



# Agenda

### **Introduction and Key Recent Events**

• John Lechleiter, Chairman, President and Chief Executive 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.



### **Strategic Objectives**

Progress since the last earnings call

- Excluding FX, revenue grew 8%
- Volume growth of 7%
- New products drove5pp of volume growth

 Returned over \$800m to shareholders in Q1 via dividend and share repurchase

**Expand** Grow Revenue Margins **Deploy Capital** Sustain Flow to Create Value of Innovation

- Non-GAAP OPEX % of revenue up slightly vs. Q1 2015
- Revised guidance implies 200-250bp decrease in non-GAAP OPEX % vs. 2015
- BACE inhibitor moved to Phase 3
- Taltz® (ixekizumab) approved and launched in U.S.
- Olaratumab submitted in U.S. and Europe



# Key Events Since the Last Earnings Call

#### Commercial:

- Launched Cyramza® (ramucirumab) in Europe for locally advanced or metastatic NSCLC and for metastatic colorectal cancer;
- Launched Portrazza™ (necitumumab) in Europe for locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing squamous NSCLC;
- Launched Taltz (ixekizumab) in the U.S. for the treatment of moderate-to-severe plaque psoriasis; and
- Launched Humulin® R U-500 KwikPen® in the U.S.

### Regulatory:

- Received U.S. Food and Drug Administration (FDA) approval for Taltz (ixekizumab) injection 80 mg/mL for the treatment of moderate-tosevere plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy;
- Received European Commission approval, following a positive CHMP opinion, for ixekizumab for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy;

### Regulatory (cont.):

- Received European Commission authorization to market Portrazza, in combination with gemcitabine and cisplatin chemotherapy, for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing squamous non-small cell lung cancer who have not received prior chemotherapy;
- Submitted once-daily baricitinib for the treatment of moderatelyto-severely active rheumatoid arthritis in Japan;
- Submitted olaratumab for soft tissue sarcoma in both the U.S. and European Union;
- Within the Boehringer Ingelheim and Lilly Diabetes Alliance, submitted the once-daily, fixed-dose combination tablet of empagliflozin and metformin XR to the U.S. FDA; and
- Received approval for Imrestor<sup>™</sup> (pegbovigrastim injection) in the U.S. for the reduction in the incidence of clinical mastitis; Imrestor is a protein alternative to antibiotics that helps support the natural function of a dairy cow's immune system during the critical time around calving, when the risk for mastitis is heightened.



# Key Events Since the Last Earnings Call

#### Clinical:

- Announced an amendment to the EXPEDITION3 trial of solanezumab in mild Alzheimer's disease to include a single primary endpoint of cognition (ADAS-Cog 14); functional outcomes will be evaluated as key secondary endpoints using both the ADCS-iADL and the FAQ;
- Along with AstraZeneca, announced that AMARANTH, a Phase 2/3 study of AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for early Alzheimer's disease, will continue to the Phase 3 portion of the Phase 2/3 seamless trial; and
- Along with Boehringer Ingelheim, announced plans to conduct two outcome trials investigating the diabetes medicine Jardiance® (empagliflozin) for the treatment of people with chronic heart failure; the trials are targeted to begin within the next 12 months and are planned to enroll people with chronic heart failure both with and without type 2 diabetes.

### **Business Development/Other (cont.):**

- Modified existing baricitinib agreement to provide Incyte the right to develop and commercialize ruxolitinib (Jakafi®), its JAK1/JAK2 inhibitor, for graft-versus-host disease; Lilly retains rights to develop and commercialize baricitinib in this disease;
- Elanco licensed rights to Aratana's Galliprant®, an FDA-approved therapeutic for the control of pain and inflammation associated with osteoarthritis in dogs; the agreement grants Elanco exclusive rights to develop, manufacture, market and commercialize Galliprant globally, and co-promote the product with Aratana in the United States:
- The UK High Court decided the Alimta® (pemetrexed disodium)
  vitamin regimen patent would not presently be infringed by Actavis
  marketing pemetrexed trometamol in the UK, France, Italy and
  Spain with instructions to dilute the product only with dextrose
  solution. Lilly plans to seek permission to appeal this decision to
  the UK Court of Appeal; and
- Repurchased \$300 million of stock in Q1 2016; \$2.65 billion remains under outstanding \$5 billion share repurchase program; also distributed over \$500 million to shareholders via the dividend.



### **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



## 2016 Income Statement – Reported

Millions; except per share data

	Q1 2016	Q1 2015	Change
Total Revenue	4,865	4,645	5%
Gross Margin	72.8%	74.3%	(1.5)pp
Total Operating Expense*	2,826	2,927	(3)%
Operating Income	716	525	36%
Other Income / (Expense)	(149)	93	NM
Effective Tax Rate	22.4%	14.3%	8.1pp
Net Income	\$440	\$529	(17)%
Diluted EPS	\$0.41	\$0.50	(18)%



<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.

NM – not meaningful

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

Millions; except per share data

Q1 2016
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				Non-GAAP	
	GAAP	Adjust-	Non-GAAP	Adjusted	
	Reported	<u>ments</u>	<u>Adjusted</u>	<u>Change</u>	
Total Revenue	\$4,865	-	\$4,865	5%	
Gross Margin	72.8%	3.5%	76.3%	(1.9)pp	
Total Operating Expense	2,826	(133)	2,693	7%	
Operating Income	716	304	1,020	(8)%	
Other Income / (Expense)	(149)	204	55	(41)%	
Effective Tax Rate	22.4%	(4.5)%	17.9%	(5.0)pp	
Net Income	\$440	\$442	\$882	(4)%	
Diluted EPS	\$0.41	\$0.42	\$0.83	(5)%	

Note: Numbers may not add due to rounding; see slide 23 for a complete list of significant adjustments.

NM – not meaningful



## **EPS Reconciliation**

	Q1 2016	Q1 2015	Change
EPS (reported)	\$0.41	\$0.50	(18)%
Amortization of intangible assets	0.11	0.10	
Asset impairment, restructuring and other special charges	0.11	0.07	
Acquired in-process R&D	-	0.15	
Venezuela charge	0.19	-	
Novartis Animal Health inventory step up		0.04	
EPS (non-GAAP)	\$0.83	\$0.87	(5)%

Note: Numbers may not add due to rounding; see slide 23 for more details on these significant adjustments.



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

Q1 2016

Pharmaceuticals	Amount	Price_	FX Rate	Volume	Total	CER
U.S.	\$2,163.2	4%	-	13%	17%	17%
EuCan*	911.6	(3)%	(6)%	5%	(5)%	1%
Japan	482.0	(4)%	2%	18%	16%	14%
<b>Emerging Markets</b>	553.7	0%	(10)%	(8)%	(17)%	(7)%
Total Pharma	4,110.5	1%	(3)%	8%	6%	8%
Animal Health	754.6	1%	(4)%	3%	1%	5%
Total Revenue	\$4,865.1	1%	(3)%	7%	5%	8%

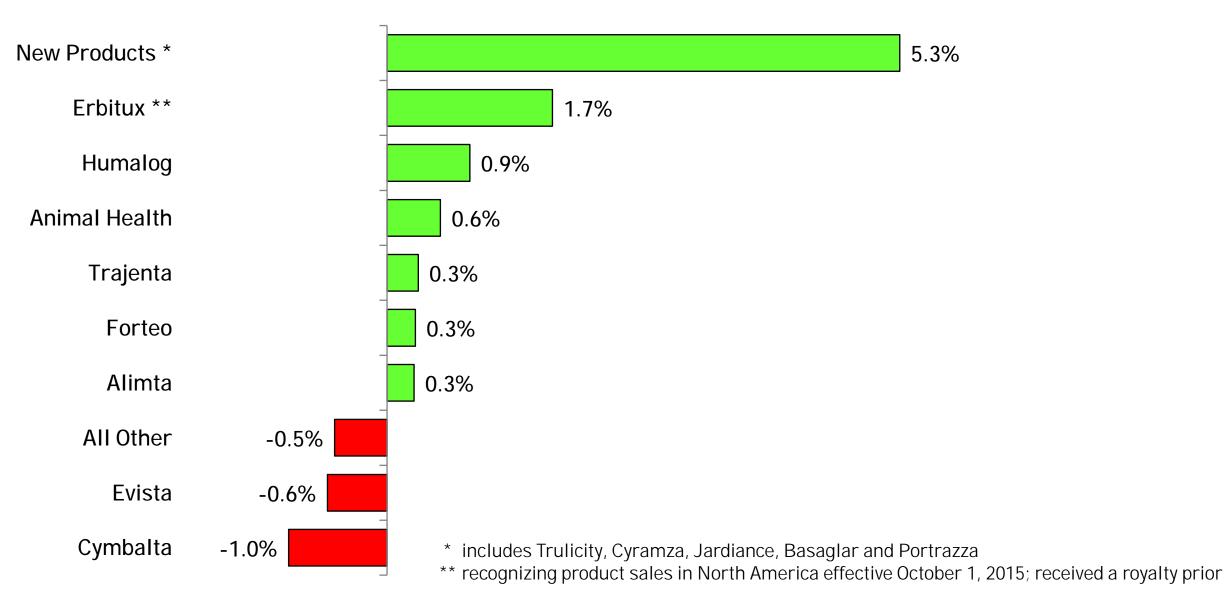
Note: Numbers may not add due to rounding.



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

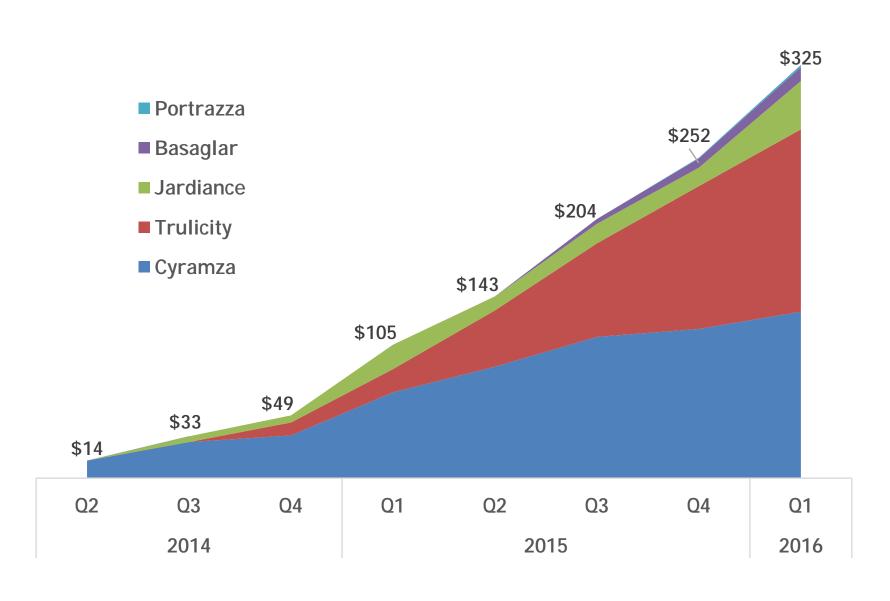
# New Products Driving WW Volume Growth

#### Contribution to WW Volume Growth Rate of 7%



Lilly

## **Update on New Product Launch Progress**



Note: Jardiance is sold by Boehringer Ingelheim; Lilly records as revenue its share of Jardiance gross margin

Not for promotional use

#### Trulicity®:

- 70%+ access in both commercial and Part D
- U.S. TRx SOM 17% and growing
- GLP-1 class TRx growing over 30% in U.S.

#### Cyramza:

- Strong uptake of gastric in Japan
- Launched NSCLC and mCRC in Europe during Q1

#### Jardiance:

- NBRx SOM grew from 15% in Q1 2015 to 28% in Q1 2016
- SGLT2 class TRx growing over 45% in U.S.
- EMPA-REG OUTCOME® under regulatory review

### Basaglar®:

- Basal SOM: Slovakia 17%, Japan 11% and Germany 2%
- U.S. launch scheduled for December 15, 2016

#### Portrazza:

- Launch in U.S. in Q4 2015
- Launched in Europe in early Q2 2016



# Effect of Foreign Exchange on 2016 Results

Year-on-Year Growth

	Rep	orted	Non-	GAAP
	With FX	w/o FX	With FX	w/o FX
Total Revenue	5%	8%	5%	8%
Cost of Sales	11%	9%	14%	12%
Gross Margin	3%	7%	2%	7%
Operating Expense	(3)%	(1)%	7%	9%
Operating Income	36%	73%	(8)%	1%
EPS	(18)%	37%	(5)%	5%



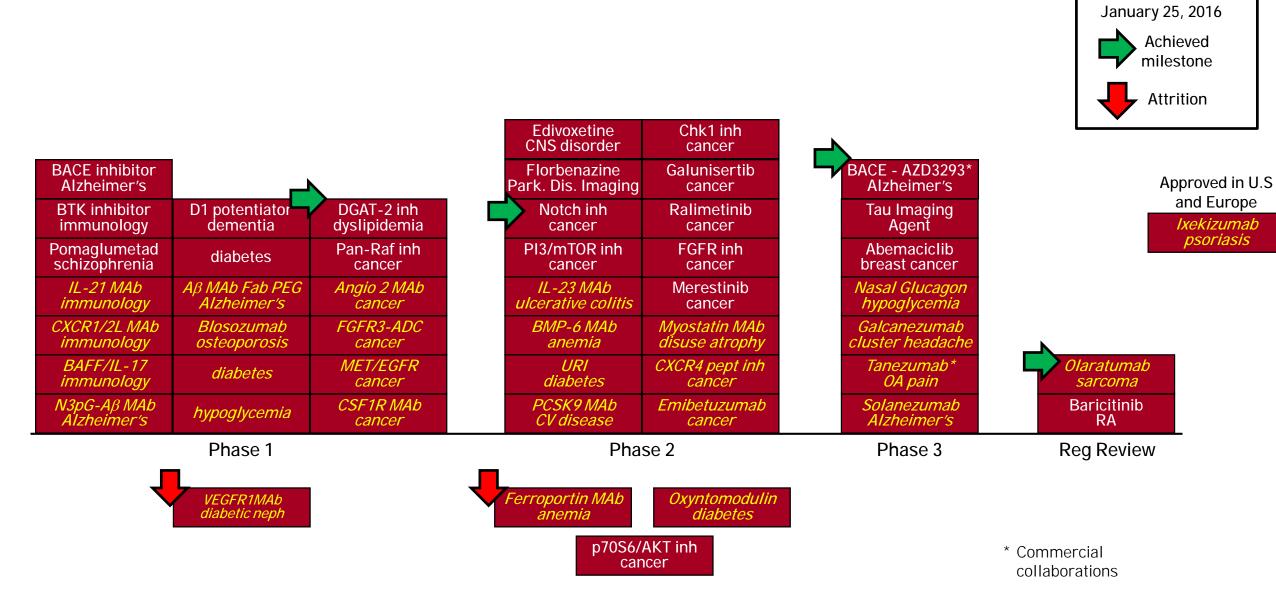
# Lilly NME Pipeline

April 19, 2016

New Chemical Entity (NCE)

New Biotech Entity (NBE)

Movement since



Lilly

# Lilly Select NILEX Pipeline

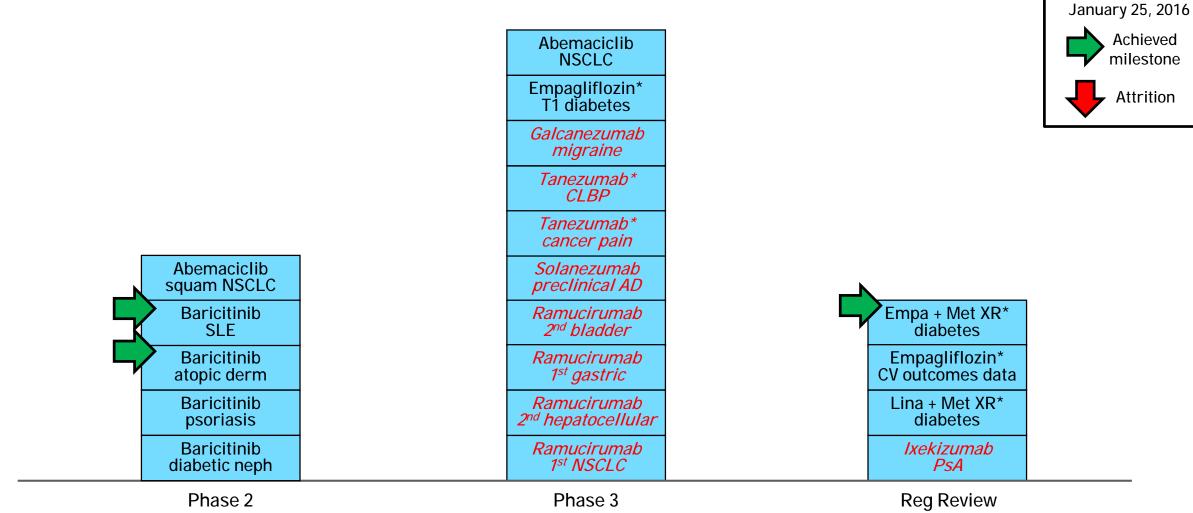
April 19, 2016

**Chemical Entity (NCE)** 

Biotech Entity (NBE)

Movement since

Select NILEX in Phase 2 development or later for NMEs that have progressed to Phase 3 or launched for a lead indication



\* Commercial collaborations



# **Key Events in 2016**

#### Potential Phase 3 initiations:

- ✓ \* BACE inhibitor for Alzheimer's disease ¹
- √\* CGRP MAb for migraine prevention
  - Ixekizumab for axial spondyloarthritis
  - Solanezumab for prodromal Alzheimer's disease
  - Ultra-rapid insulin for diabetes

#### Potential Phase 3 data internal readouts:

- Abemaciclib single-agent Phase 2 breast cancer
- CGRP MAb for cluster headache
- Ixekizumab for psoriatic arthritis (SPIRIT-P2)
- Ixekizumab for psoriasis H2H vs ustekinumab (IXORA-S)
- · Solanezumab for mild Alzheimer's disease

#### Potential Phase 3 data external disclosures:

- Abemaciclib single-agent Phase 2 breast cancer
- Baricitinib RA-BEYOND study (long-term extension)
- Linagliptin type 2 diabetes albuminuria study (MARLINA)<sup>2</sup>

1 in collaboration with AstraZeneca2 in collaboration with Boehringer Ingelheim

#### Potential regulatory submissions:

- √\* Olaratumab for soft-tissue sarcoma (US√\*/EU√\*)
- √\* Baricitinib for rheumatoid arthritis (US√\*/EU√\*/J√\*)
- √\*• Empagliflozin/metformin XR<sup>2</sup> (US)

#### Potential regulatory actions:

- Olaratumab for soft-tissue sarcoma (US)
- ✓\*• Necitumumab for first-line squamous NSCLC (EU)
- √\* Cyramza for second-line NSCLC (EU√\*/J)
- √\* Cyramza for second-line mCRC (EU√\*/J)
- √\*• Ixekizumab for psoriasis (US√\*/EU√\*)
  - Ixekizumab for psoriasis and psoriatic arthritis (J)
  - Empagliflozin CV outcomes data<sup>2</sup> (US/EU)
  - Empagliflozin/linagliptin FDC for type 2 diabetes <sup>2</sup> (EU)
  - Linagliptin/metformin XR<sup>2</sup> (US)

#### Other:

- Pediatric exclusivity for Effient®
- Pediatric exclusivity for Cialis®
- Rulings in ongoing Alimta patent litigation:
  - U.S.
- ✓ UK



### 2016 Guidance

Gross Margin % of Revenue (non-GAAP) Gross Margin % of Revenue (GAAP)

Mktg, Selling & Admin.

Research & Development

Other Income/(Expense) (non-GAAP)
Other Income/(Expense) (GAAP)

Tax Rate (non-GAAP)
Tax Rate (GAAP)

Earnings per Share (non-GAAP) Earnings per Share (GAAP)

Capital Expenditures

#### Prior

\$20.2 to \$20.7 billion

Approx. 77.0% Approx. 74.0%

\$6.0 to \$6.2 billion

\$4.8 to \$5.0 billion

\$0 - \$75 million

\$0 - \$75 million

Approx. 22.5%

Approx. 21.0%

\$3.45 - \$3.55

\$2.83 - \$2.93

Approx. \$1.1 billion

#### Revised

\$20.6 to \$21.1 billion

Approx. 76.0% Approx. 73.0%

\$6.1 to \$6.3 billion

\$4.9 to \$5.1 billion

#### unchanged

\$(200) - \$(125) million

Approx. 21.0% unchanged

\$3.50 - \$3.60

\$2.68 - \$2.78

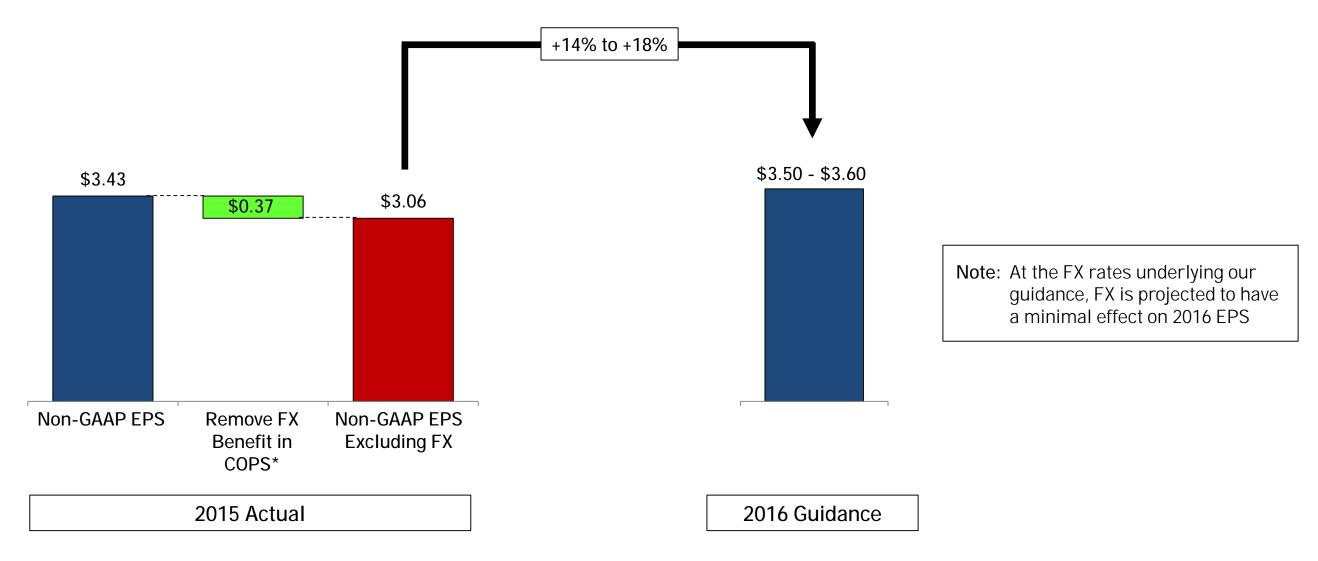
unchanged

#### FX rates for revised guidance:

- Euro at 1.13
- Yen at 113
- Pound at 1.44



### 2016 Non-GAAP EPS Guidance vs. 2015 Actual



<sup>\*</sup> effect of foreign exchange on international inventories sold



## Summary

- Revenue growth of 8% on a constant currency basis with 5pp of growth driven by new products
- Pipeline milestones included: approval of Taltz, submission of olaratumab and initiation of Phase 3 for our BACE inhibitor
- Strong momentum behind our innovation-based strategy; continued execution key to creating value for all our stakeholders, including shareholders
- We continue to make substantial progress on each of our strategic goals:
  - Excluding FX, revenue Grow Expand • Volume growth of 7% Margins Revenue 5pp of volume growth **Deploy Capital** Sustain Flow shareholders in Q1 via to Create Value of Innovation
    - Non-GAAP OPEX % of revenue up slightly vs. Q1 2015
    - Revised guidance implies 200-250bp non-GAAP OPEX % decrease vs. 2015
    - BACE inhibitor moved to Phase 3
    - Taltz (ixekizumab) approved and launched in U.S.
    - Olaratumab submitted in U.S. and Europe



grew 8%

New products drove

Returned \$800m to

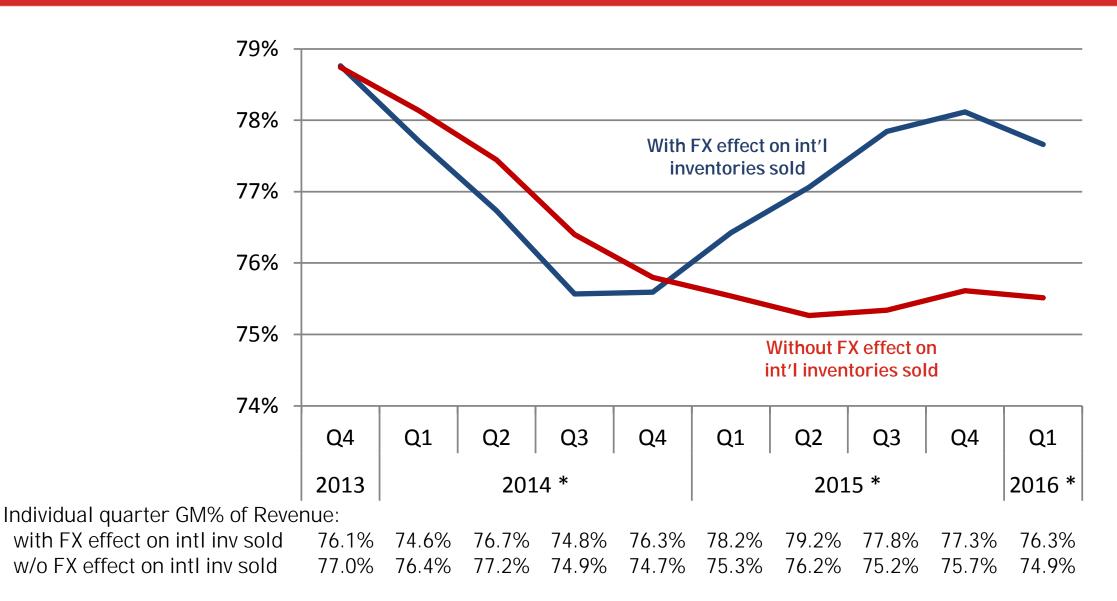
dividend and share

repurchase

# Supplementary Slides



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



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.

\* Excludes amortization of intangibles from cost of sales and includes Novartis Animal Health



### Q1 2016 Income Statement Notes

- Q1 2016 non-GAAP information has been adjusted to eliminate:
  - amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties totaling \$172.5 million (pretax), or \$0.11 per share (after-tax);
  - charges associated with asset impairments related to the closure of an animal health manufacturing facility in Ireland and integration costs related to the acquisition of Novartis Animal Health totaling \$131.4 million (pretax), or \$0.11 per share (after-tax); and
  - a charge related to the impact of the Venezuelan financial crisis, including the significant deterioration of the bolivar, totaling \$203.9 million (pretax), or \$0.19 per share (after-tax).
- •Q1 2015 non-GAAP information has been adjusted to eliminate:
  - 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);
  - 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);
  - 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 an FDA decision allowing the resumption of the Phase 3 clinical trials for tanezumab and a \$56.0 million charge associated with a collaboration with Innovent to develop potential oncology therapies; and
  - inventory step-up costs associated with the acquisition of Novartis Animal Health totaling \$63.5 million (pretax), or \$0.04 per share (after-tax).



# Comparative EPS Summary 2015/2016

	1Q15	2Q15	3Q15	4Q15	2015	1016	2Q16	3Q16	4Q16	2016
Non-GAAP	0.87	0.90	0.89	0.78	3.43	0.83				
Reported	0.50	0.56	0.75	0.45	2.26	0.41				

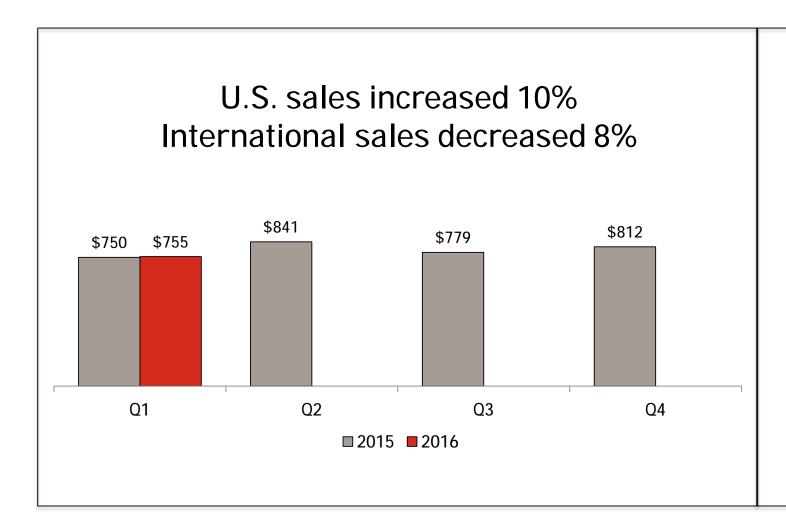
Note: Numbers may not add due to rounding.

For a complete reconciliation to reported earnings, see slide 23 and our earnings press release dated April 26, 2016.



### Q1 2016 Animal Health Sales Increased 1%

### Millions



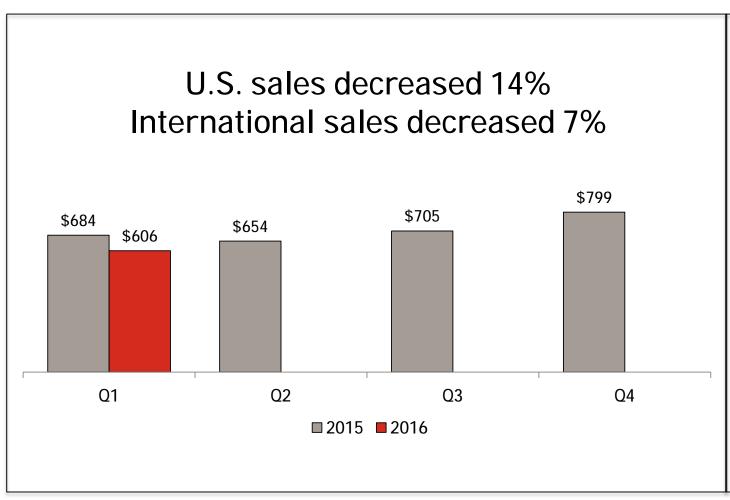
	<u>Q1 Sales</u>	<u>Change</u>	<u>Performance</u>	<u>Rate</u>
U.S. Food And Other	\$249.7	8%	8%	0%
U.S. Companion	142.7	14%	14%	0%
OUS Food And Other	272.8	(7)%	1%	(8)%
OUS Companion	89.4	(10)%	(3)%	(7)%
WW Animal Health	\$754.6	1%	5%	(4)%

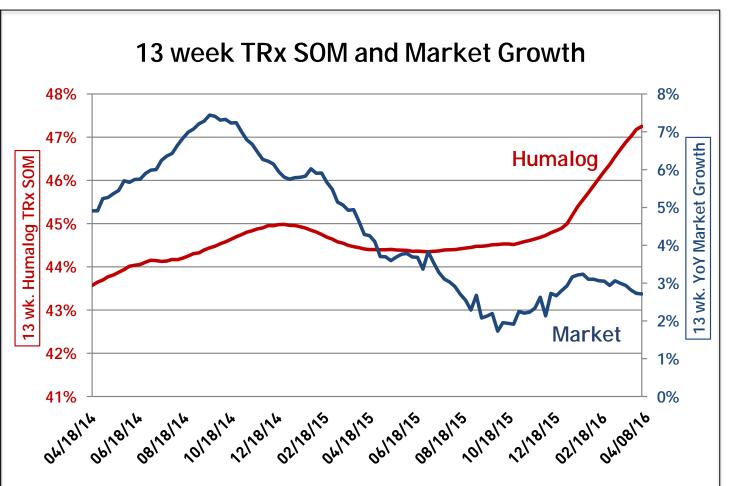
- U.S. food animal growth driven by beef and poultry business
- U.S. companion animal growth driven by launches of Interceptor® Plus and Osurnia®



# Q1 2016 Humalog® Sales Decreased 11%

### Millions



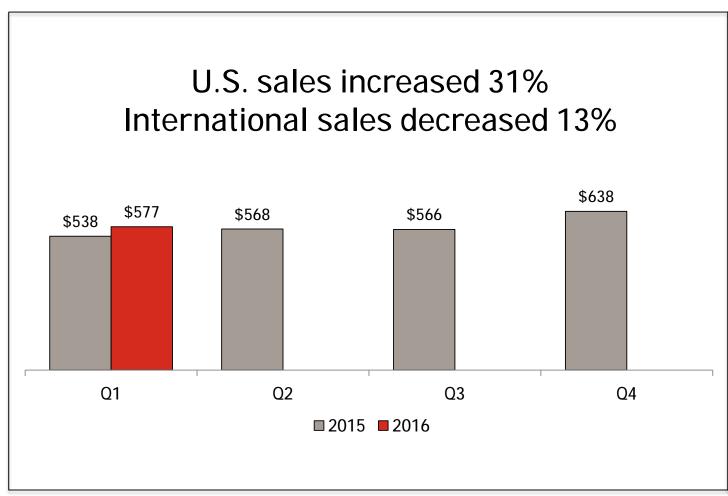


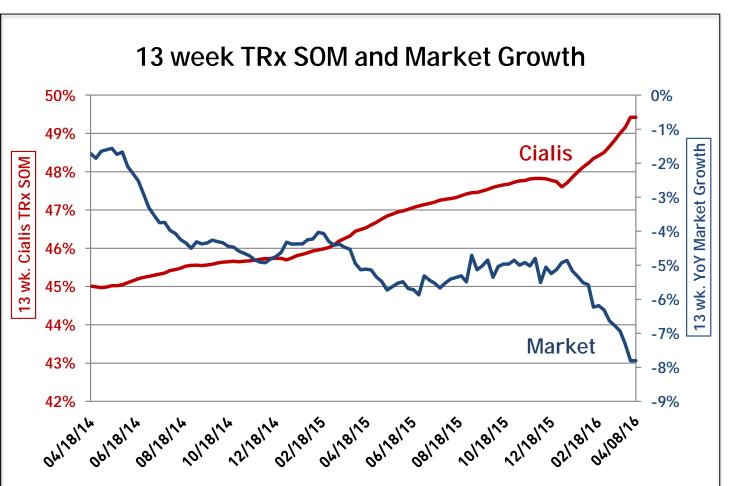
Source: IMS Health NPA TRx, weekly data April 8, 2016



### Q1 2016 Cialis Sales Increased 7%

### Millions



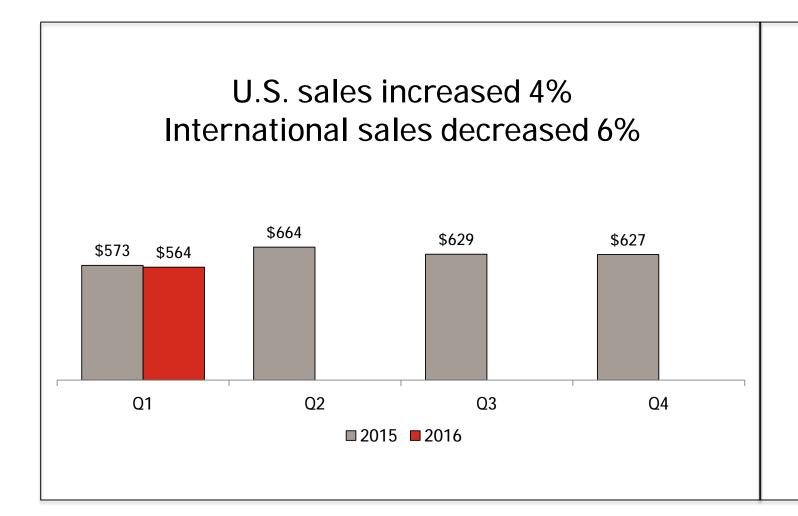


Source: IMS Health NPA TRx, weekly data April 8, 2016



### Q1 2016 Alimta Sales Decreased 2%

### Millions



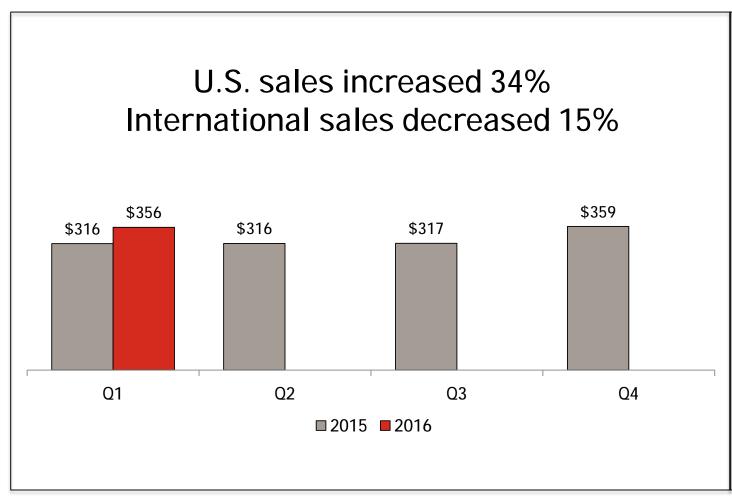
	<u>Q1 Sales</u>	<u>Change</u>	<u>Performance</u>	<u>Rate</u>
U.S. Alimta	\$263.1	4%	4%	0%
OUS Alimta	301.1	(6)%	(1)%	(5)%
WW Alimta	\$564.2	(2)%	1%	(3)%

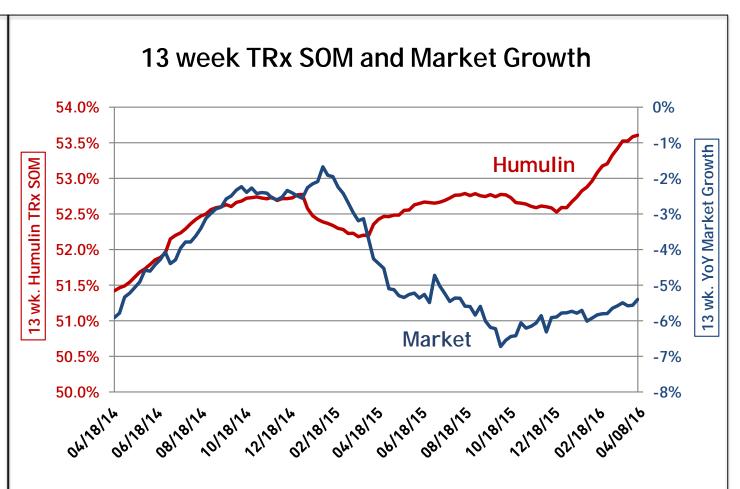
- U.S. sales increased due to wholesaler buying patterns
- OUS sales decreased due to unfavorable FX rates, lower realized prices, partially offset by increased volume
- German Supreme Court hearing set for mid-2016



### Q1 2016 Humulin Sales Increased 13%

### Millions



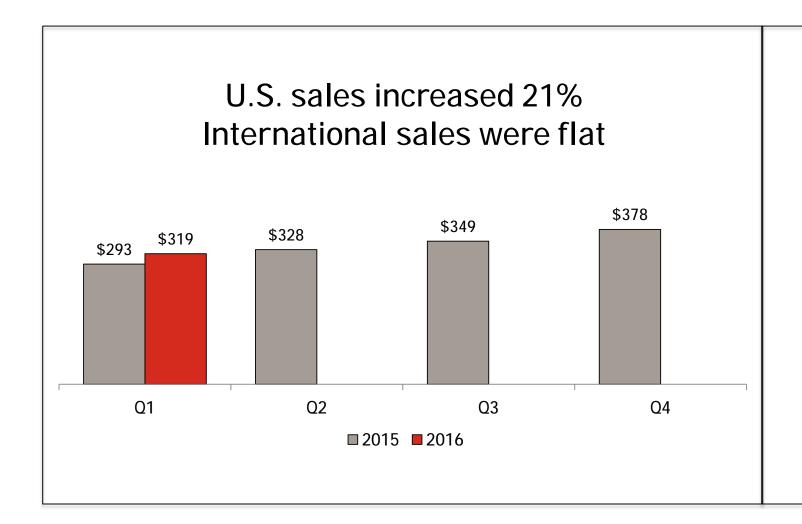


Source: IMS Health NPA TRx, weekly data April 8, 2016



### Q1 2016 Forteo® Sales Increased 9%

#### Millions



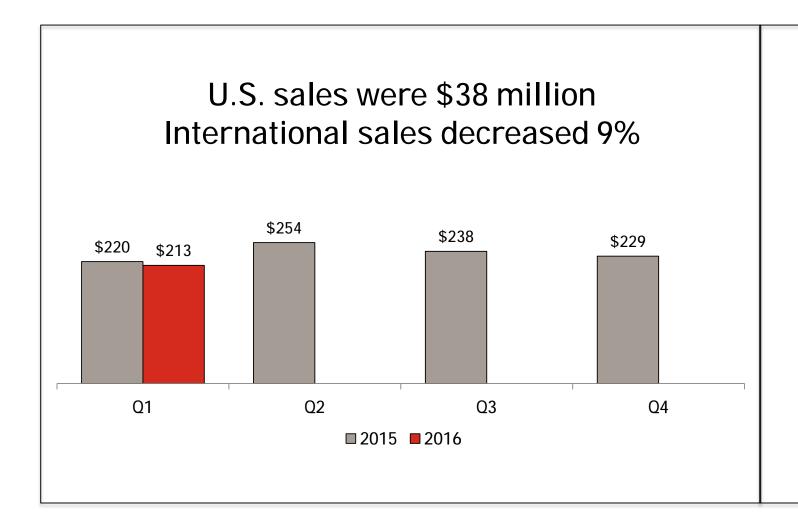
	<u>Q1 Sales</u>	<u>Change</u>	<u>Performance</u>	<u>Rate</u>
U.S. Forteo	\$148.1	21%	21%	0%
OUS Forteo	170.5	(0)%	4%	(4)%
WW Forteo	\$318.6	9%	11%	(2)%

- U.S. sales increase driven by higher realized prices
- OUS sales flat as lower realized prices and the unfavorable impact of foreign exchange rates were essentially offset by increased volume
- Lower OUS realized prices driven by price revision in Japan



# Q1 2016 Zyprexa® Sales Decreased 3%

#### Millions



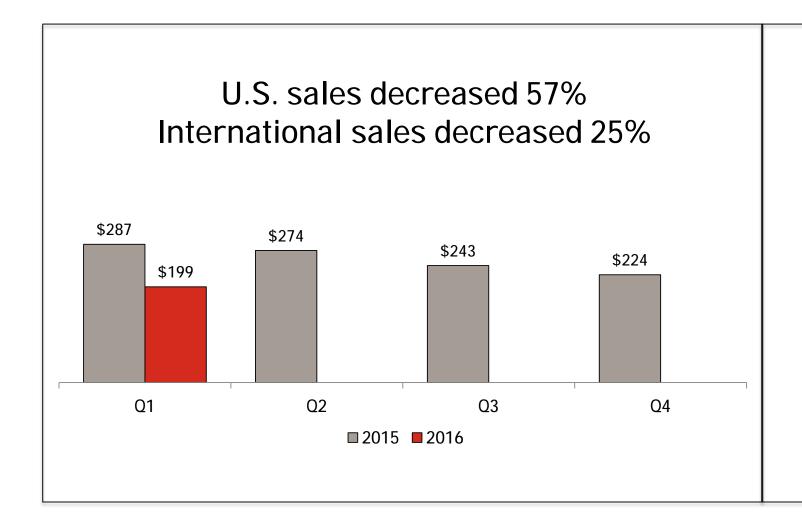
	Q1 Sales	<u>Change</u>	<u>Performance</u>	<u>Rate</u>
U.S. Zyprexa	\$37.9	43%	43%	0%
OUS Zyprexa	174.9	(9)%	(7)%	(3)%
WW Zyprexa	\$212.8	(3)%	(1)%	(2)%

 Japan Zyprexa Q1 sales were \$93.6 million, relatively flat compared to Q1 2015; patent exclusivity expired last December; generic competition expected beginning mid-2016



# Q1 2016 Cymbalta® Sales Decreased 31%

### Millions



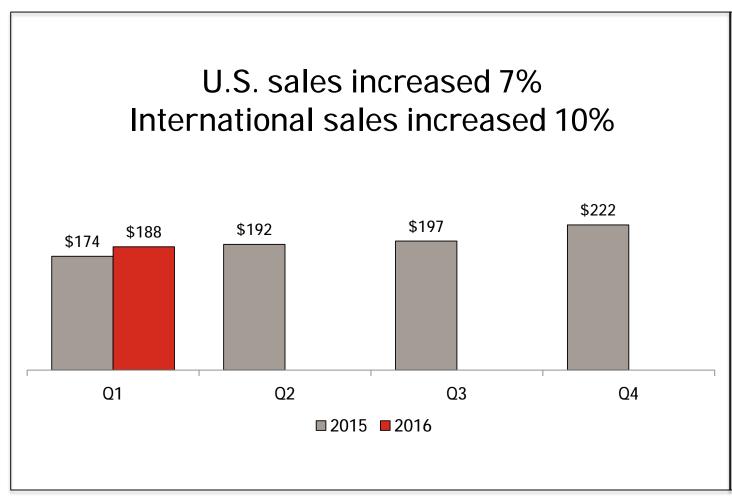
	<u>Q1 Sales</u>	<u>Change</u>	<u>Performance</u>	<u>Rate</u>
U.S. Cymbalta	\$23.3	(57)%	(57)%	0%
OUS Cymbalta	175.4	(25)%	(20)%	(4)%
WW Cymbalta	\$198.7	(31)%	(27)%	(3)%

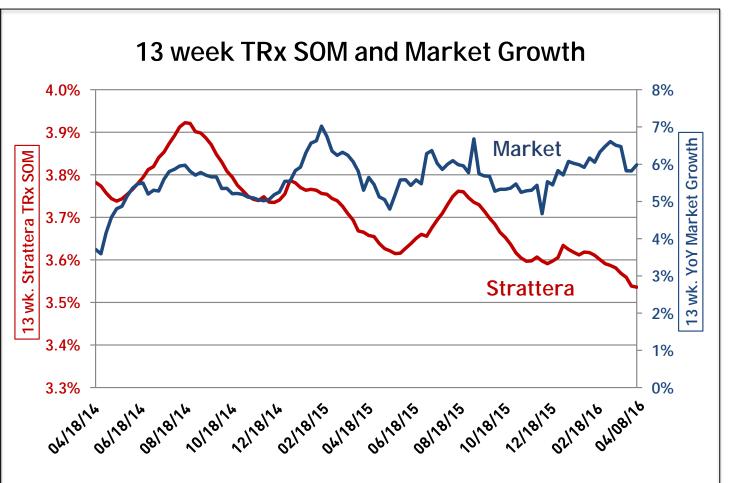
• OUS sales decrease driven by the loss of exclusivity in Europe in 2014 and FX.



### Q1 2016 Strattera® Sales Increased 8%

### Millions



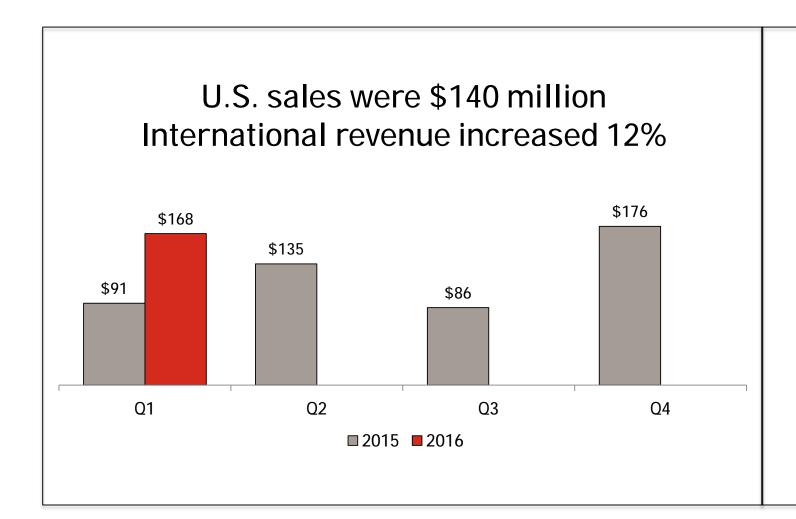


Source: IMS Health NPA TRx, weekly data April 8, 2016



### Q1 2016 Erbitux® Revenue Increased 90%

### Millions



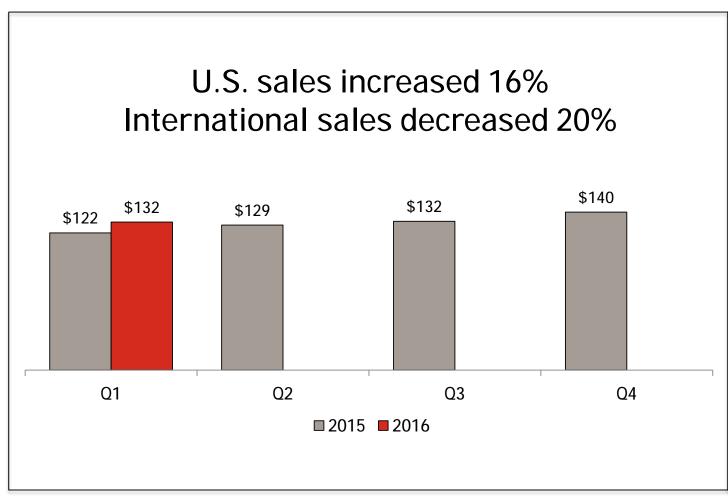
	<u>Q1 Sales</u>	<u>Change</u>	<u>Performance</u>	<u>Rate</u>
U.S. Erbitux	\$140.3	121%	121%	0%
OUS Erbitux	27.8	12%	11%	2%
WW Erbitux	\$168.1	90%	90%	0%

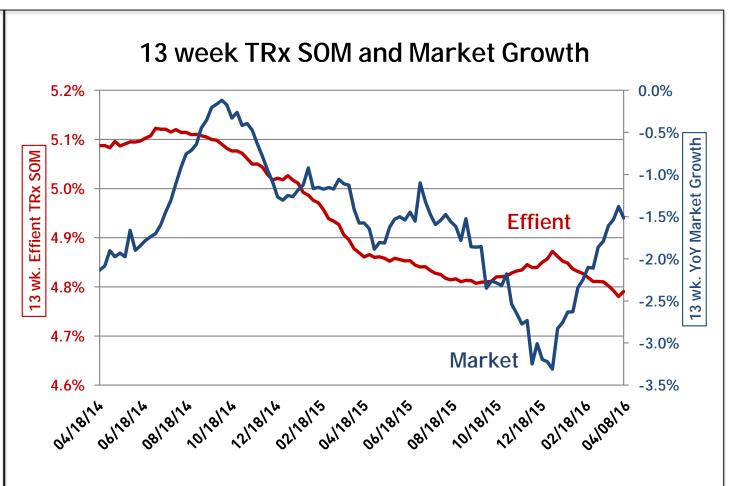
 U.S. sales increase driven by the take back of North American commercialization rights from Bristol-Myers Squibb effective October 1, 2015



### Q1 2016 Effient Sales Increased 8%

### Millions



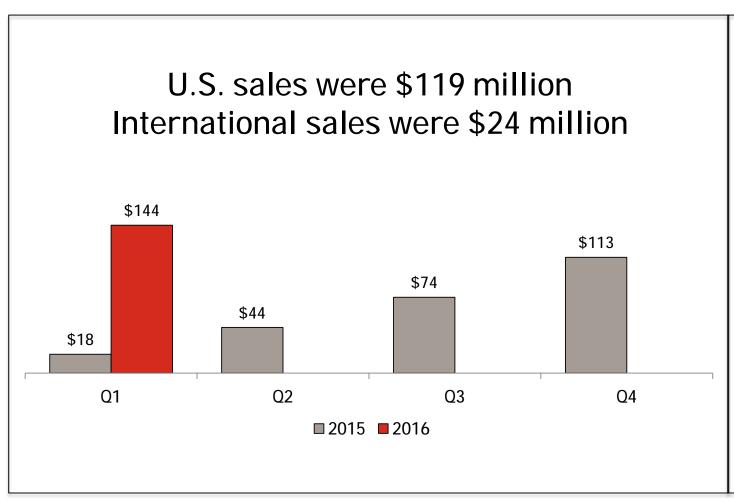


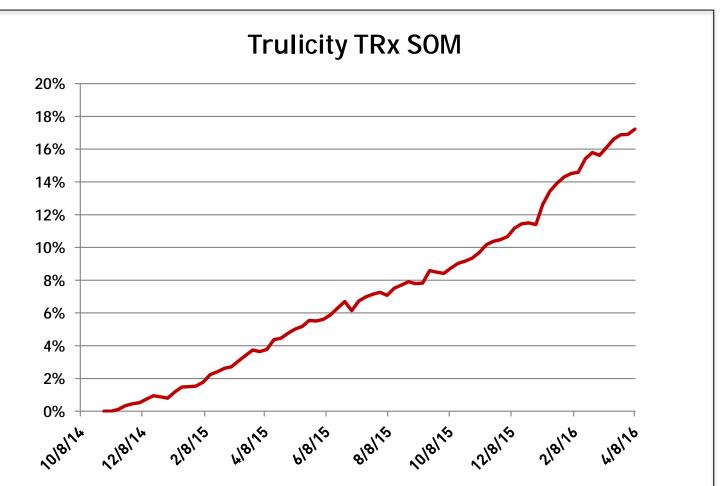
Source: IMS Health NPA TRx, weekly data April 8, 2016



# Q1 2016 Trulicity Sales Were \$144 Million

### Millions



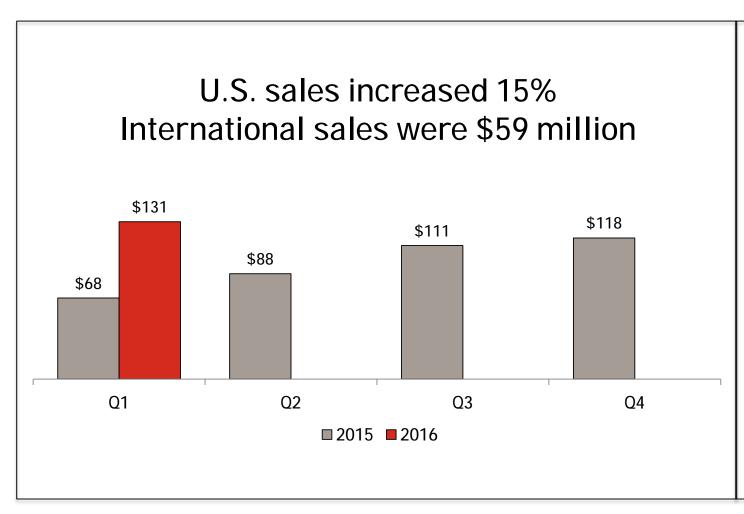


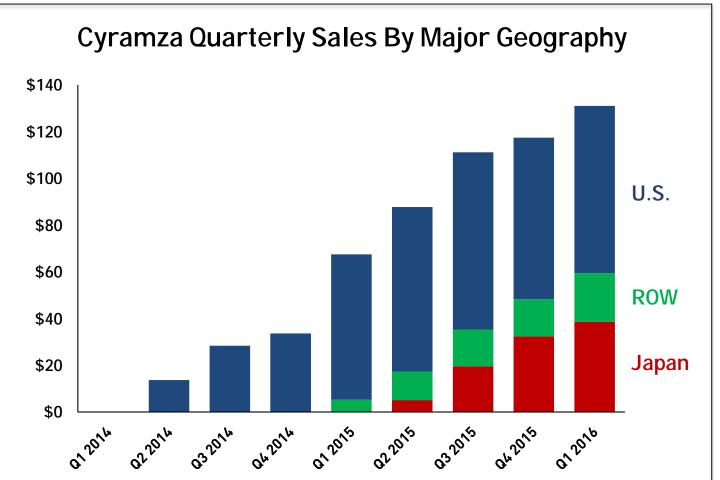
Source: IMS Health NPA TRx, weekly data April 8, 2016



## Q1 2016 Cyramza Sales Increased 94%

### Millions

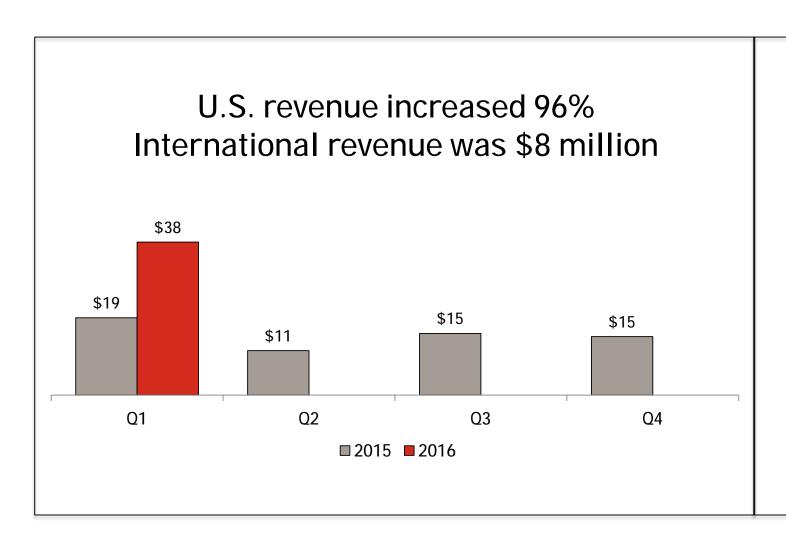


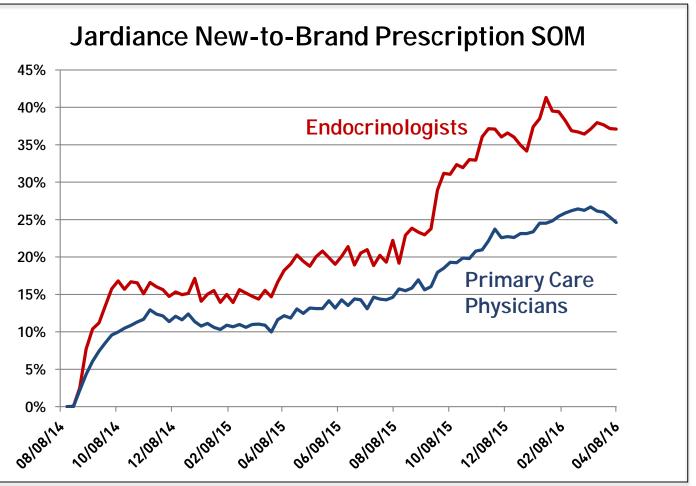




### Q1 2016 Jardiance Revenue Increased 99%

### Millions



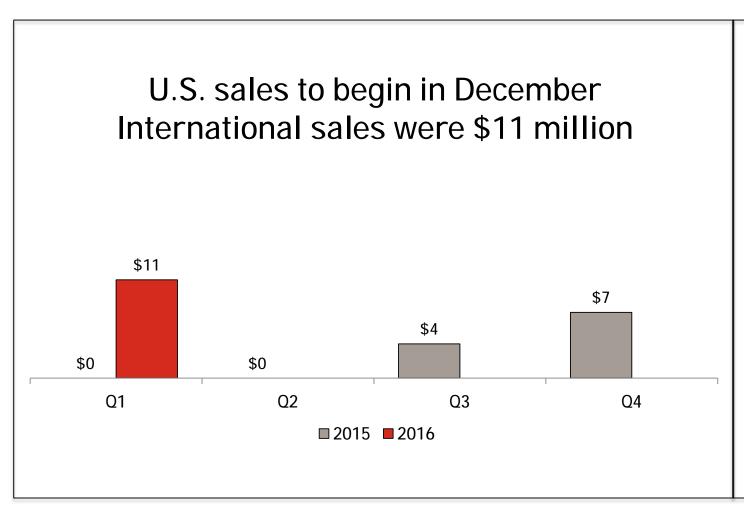


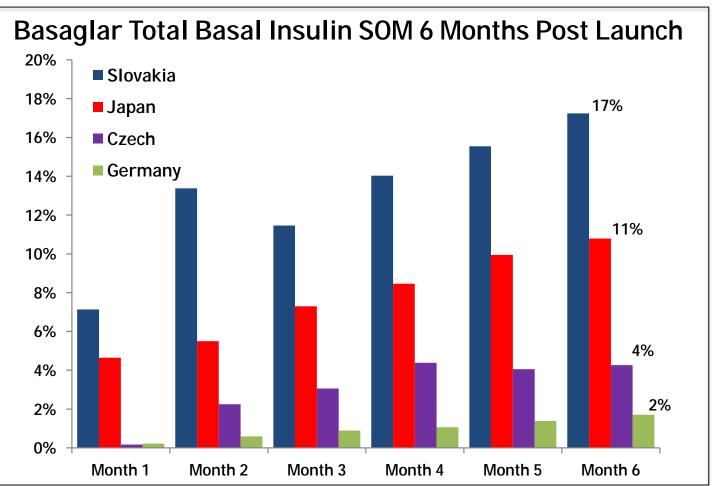
Source: IMS Health NPA NBRx, weekly data April 8, 2016



# Q1 2016 Basaglar Sales Were \$11 Million

### Millions



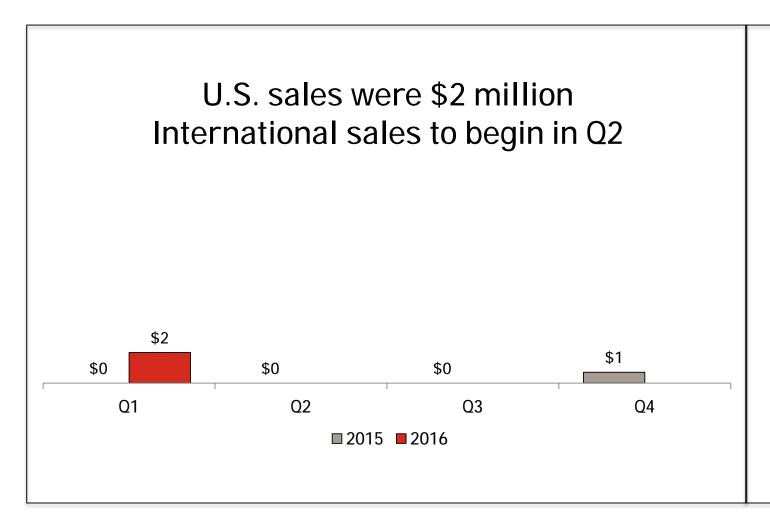


Sources: IMS Health; Slovak Republic Pharmaceutical Index, IMS MIDAS Insulin Units Share (Japan), Czech Republic Pharmaceutical Index, IMS PharmaScope National (Germany); monthly data February 2016



### Q1 2016 Portrazza Sales Were \$2 Million

### Millions



- Launched in the U.S. in December 2015
- Initial launches in Europe began in early Q2



Silly -

