# Q1 2017 FINANCIAL REVIEW

## **APRIL 25, 2017**





### **INTRODUCTION AND KEY RECENT EVENTS**

Dave Ricks, President and Chief Executive Officer

## **Q1 FINANCIAL RESULTS, KEY FUTURE EVENTS, FINANCIAL GUIDANCE**

**Phil Johnson**, Vice President, Investor Relations

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

### **QUESTION AND ANSWER SESSION**

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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.

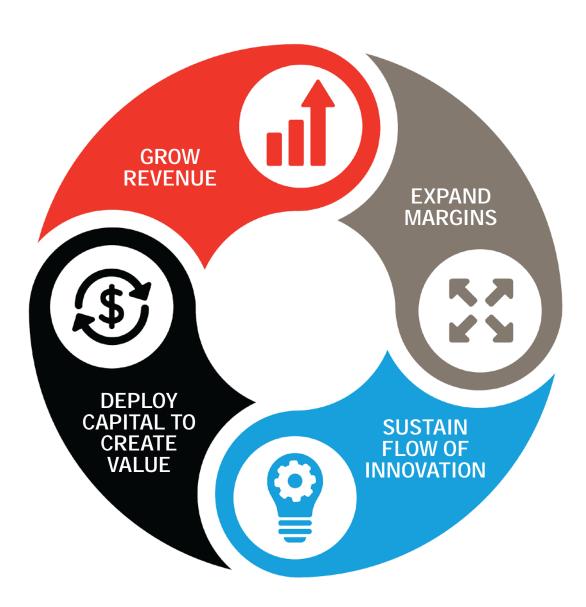
For additional information about the factors that affect the company's business, please see the company's latest Forms 10-K and 10-Q filed with the Securities and Exchange Commission.

The company undertakes no duty to update forward-looking statements.



# **STRATEGIC OBJECTIVES**

**PROGRESS SINCE THE LAST EARNINGS CALL** 



## **GROW REVENUE**

Revenue growth of 7%

Pharmaceutical volume growth of 9%

New products drove 10.1pp of volume growth

## DEPLOY CAPITAL TO CREATE VALUE

**Closed CoLucid acquisition** 

Paid over \$500 million via dividend

**OPEX % of revenue decreased** nearly 220bp vs. Q1 2016

## SUSTAIN FLOW **OF INNOVATION**

Launch of Olumiant<sup>®</sup> in EU

Baricitinib U.S. delay given FDA complete response letter

Positive Phase 3 readouts from MONARCH 2, MONARCH 3, IXORA-S, and RAINFALL studies



## **EXPAND MARGINS**

### Excluding FX on international inventories sold, GM % increased nearly 220bp vs. Q1 2016

# **KEY EVENTS SINCE THE LAST EARNINGS CALL**

### COMMERCIAL

- In collaboration with Boehringer Ingelheim, launched Synjardy<sup>®</sup> XR tablets in the U.S. for adults with type 2 diabetes (T2D); and
- Launched Olumiant (baricitinib) in Europe for adults with moderate-to-severe active rheumatoid arthritis.

### REGULATORY

- Received European Commission (EC) approval of Olumiant for the treatment of moderate-to-severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more diseasemodifying antirheumatic drugs;
- Received a complete response letter from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) for baricitinib for the treatment of moderate-to-severe rheumatoid arthritis indicating the FDA is unable to approve the application in its current form;
- Received FDA approval of an update to the Trulicity<sup>®</sup> label to include combination use with basal insulin in adults with T2D; and
- In collaboration with Boehringer Ingelheim, received EC approval of an update to the Synjardy label to include a change to the indication statement as well as data on the reduction of risk of cardiovascular (CV) death in patients with T2D and established CV disease when treated with empagliflozin.

### **CLINICAL**

- Announced that the MONARCH 2 study of abemaciclib met its primary endpoint demonstrating that women with HR+, HER2- advanced breast cancer who had relapsed or progressed after endocrine therapy experienced a statistically significant improvement in progression-free survival (PFS) when treated with abemaciclib plus fulvestrant compared to placebo plus fulvestrant; Lilly intends to begin global regulatory submission of these results in Q2 2017;
- Announced that the MONARCH 3 study of abemaciclib met its primary endpoint at an interim analysis demonstrating that women with HR+, HER2- advanced breast cancer who had not received prior systemic therapy experienced a statistically significant improvement in PFS when treated with abemaciclib plus an aromatase inhibitor compared to placebo plus an aromatase inhibitor; improvement was also shown in a key secondary endpoint of objective response rate; Lilly intends to begin global regulatory submissions of these results in Q3 2017;
- Announced that the RAINFALL study of ramucirumab in first-line gastric cancer met its primary endpoint of improved PFS; as expected, the trial will continue until overall survival (OS) data are mature in 2018;
- At the American Academy of Dermatology Annual Meeting, presented data from the IXORA-S study showing Taltz<sup>®</sup> (ixekizumab) demonstrated superior efficacy to Stelara<sup>®</sup> (ustekinumab) at 24 weeks in patients with moderate-tosevere plaque psoriasis; and
- Along with Boehringer Ingelheim, announced initiation of two Phase 3 studies investigating empagliflozin for the treatment of adults with chronic heart failure: the trials will enroll adults with and without T2D as well as with preserved ejection fraction or reduced ejection fraction.

# **KEY EVENTS SINCE THE LAST EARNINGS CALL**

### **BUSINESS DEVELOPMENT & OTHER**

- Completed the acquisition of CoLucid Pharmaceuticals, adding lasmiditan, a potential first-in-class, non-vasoconstrictive migraine treatment, to our pain management pipeline;
- The Japan IP High Court confirmed the decisions of the Japan Patent Office and ruled in Lilly's favor in the invalidation trials initiated by Sawai regarding Lilly's vitamin regimen patents for Alimta<sup>®</sup>; if the patents are ultimately upheld through all challenges they could provide intellectual property protection for Alimta in Japan until June 2021;
- Announced plans to invest \$850 million in the company's U.S. operations in 2017, including research laboratories, manufacturing facilities, and administrative areas; and
- Distributed over \$500 million to shareholders via the dividend.



## **COMPARISON MEASURES**

## "REPORTED" RESULTS

Include all financial results as reported in accordance with Generally **Accepted Accounting Principles** (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



# **2017 INCOME STATEMENT - REPORTED**

Millions; except per share data

	Q1 2017	Change
Total Revenue	\$5,228	7%
Gross Margin	74.6%	1.8pp
Total Operating Expense*	3,854	36%
Operating Income	46	(94)%
Other Income (Expense)	15	NM
Effective Tax Rate	281.0%	NM
Net Income (Loss)	(\$111)	NM
Diluted EPS	(\$0.10)	NM

\* 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 2017			
				Non-GAAP
	GAAP	Adjust-	Non-GAAP	Adjusted
	Reported	ments	Adjusted	Change
Total Revenue	\$5,228	-	\$5,228	7%
Gross Margin	74.6%	3.5%	78.1%	1.8pp
Total Operating Expense	3,854	(1,073)	2,781	3%
Operating Income	46	1,258	1,304	28%
Other Income (Expense)	15	-	15	(72%)
Effective Tax Rate	281.0%	(259.8%)	21.2%	3.3pp
Net Income (Loss)	(\$111)	\$1,150	\$1,040	18%
Diluted EPS	(\$0.10)	\$1.09	\$0.98	18%

Note: Numbers may not add due to rounding; see slide 22 for a complete list of significant adjustments.

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## RECONCILIATION OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION; CERTAIN LINE ITEMS (UNAUDITED)

### Millions; except per share data

	<u>Q1 2017</u>	<u>Q1 2016</u>	Change
EPS (reported)	(\$0.10)	\$0.41	NM
Amortization of intangible assets	0.11	0.11	
Asset impairment, restructuring, and other special charges	0.16	0.11	
Venezuela charge	-	0.19	
Acquired in-process R&D	0.81	-	
BI Vetmedica inventory step up	0.01	-	
EPS (non-GAAP)	\$0.98	\$0.83	18%

Note: Numbers may not add due to rounding; see slide 22 for more details on these significant adjustments.

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# **EFFECT OF PRICE/RATE/VOLUME ON REVENUE**

### Millions

Q1 2017

Pharmaceuticals	Amount	Price	FX Rate	Volume	Total
U.S.	\$2,519.7	4%	-	12%	16%
Europe	765.3	(4%)	(4%)	3%	(5%)
Japan	504.5	(4%)	2%	6%	5%
Rest of World	669.4	(3%)	(2%)	7%	2%
Total Pharma	4,459.0	1%	(1%)	9%	8%
Animal Health	769.4	(0%)	(0%)	2%	2%
Total Revenue	\$5,228.3	0%	(1%)	8%	7%

Note: Numbers may not add due to rounding.

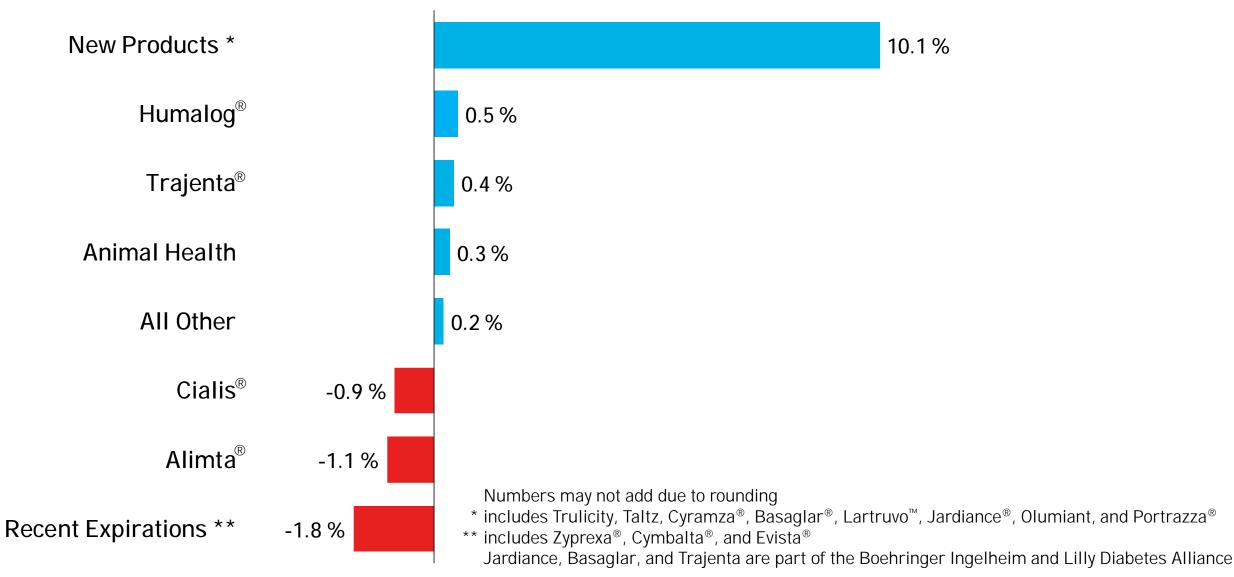
CER = price change + volume change



 CER
16%
(1%)
3%
4%
9%
2%
8%

## **NEW PRODUCTS DRIVING WW REVENUE GROWTH**

### Contribution to 8% Q1 WW Volume Growth

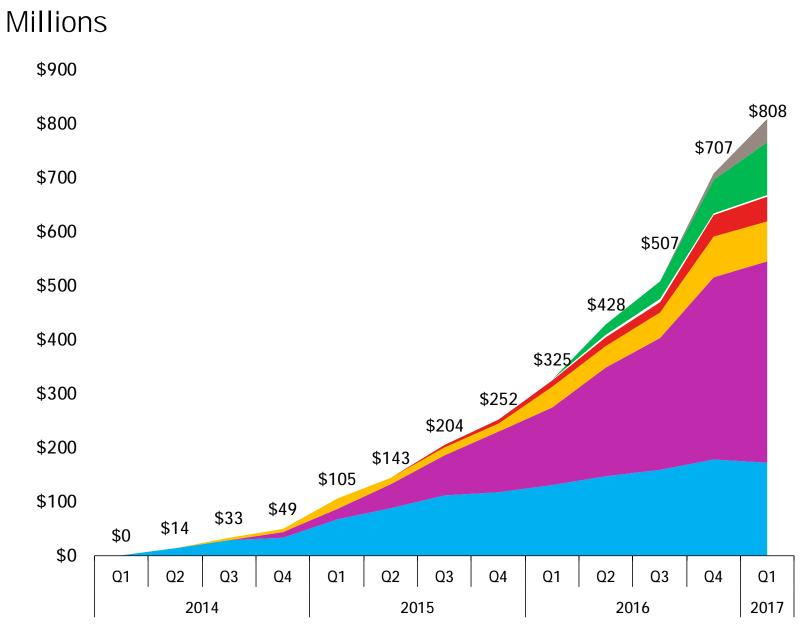


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# **UPDATE ON NEW PRODUCT LAUNCH PROGRESS**



Note: Jardiance is sold by Boehringer Ingelheim; Lilly records as revenue its share of Jardiance gross margin Jardiance and Basaglar are part of the Boehringer Ingelheim and Lilly Diabetes Alliance

### TRULICITY

- U.S. NBRx SOM among Endos similar to Victoza<sup>®</sup>
- GLP-1 class TRx growing ~25% in U.S. due to PCP adoption

### **CYRAMZA**

- 57% SOM in 2<sup>nd</sup>-line metastatic gastric cancer in Japan
- Competitive pressure in NSCLC in the U.S. from IO agents

### **JARDIANCE**

- Market leader in U.S. NBRx SOM among Endos

### TALTZ

- U.S. NBRx Derm SOM nearly 14%; strong IL-17A class growth
- Global launches continue

### BASAGLAR

- U.S. NBRx over 20%, surpassing Tresiba and Toujeo
- Basal DoT SOM over 16% in Japan and nearing 4% in Europe

### LARTRUVO

- Strong early uptake in U.S. with positive KOL feedback
- · European launches ongoing

### OLUMIANT

- European launches ongoing
- U.S. FDA issued complete response letter

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• New CV indication driving increase in SGLT-2 new patient starts

## **EFFECT OF FOREIGN EXCHANGE ON 2017 RESULTS**

### Year-on-Year Growth

	Q1 2017		
Reported	With FX	w/o FX	
Total Revenue	7%	8%	
Cost of Sales	0%	1%	
Gross Margin	10%	11%	
Operating Expense	36%	37%	
Operating Income	(94)%	(100)%	
EPS	NM	NM	

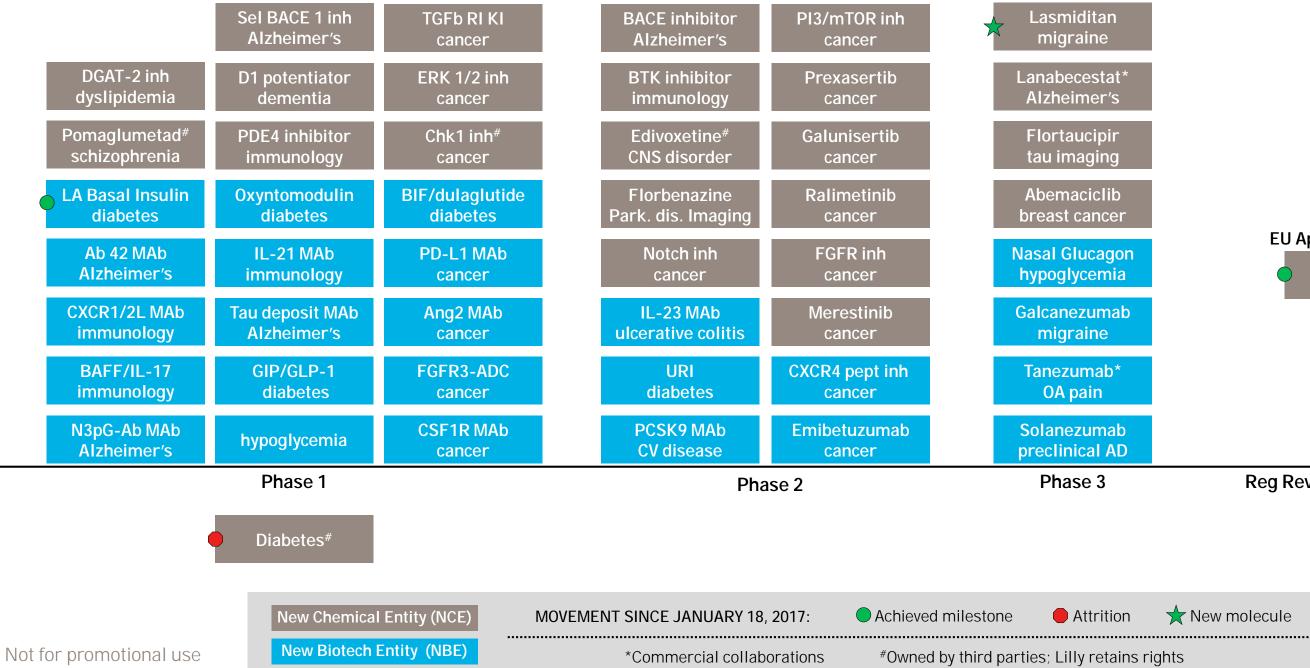
### Non-GAAP

Total Revenue	7%	8%
Cost of Sales	(1)%	(0)%
Gross Margin	10%	11%
Operating Expense	3%	4%
Operating Income	28%	32%
EPS	18%	22%





## LILLY NME PIPELINE APRIL 18, 2017





### EU Approved 2/13/2017

Baricitinib RA

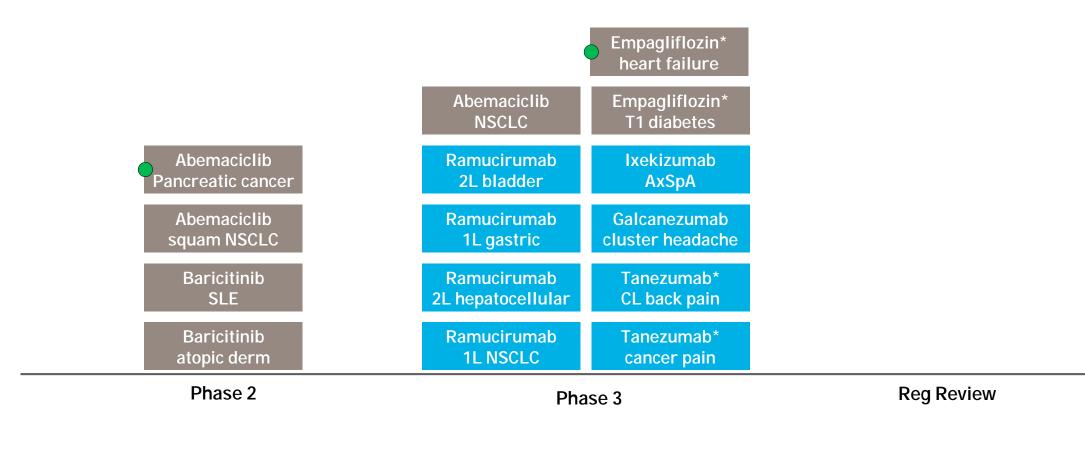
### **Reg Review**

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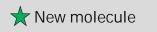
# LILLY SELECT NILEX PIPELINE

APRIL 18, 2017

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







# **POTENTIAL KEY EVENTS 2017**

### PHASE 3 INITIATIONS

Ultra-rapid insulin for diabetes

Baricitinib for psoriatic arthritis

Generation for heart failure (HFrEF) <sup>1</sup>

Empagliflozin for heart failure (HFpEF)<sup>1</sup>

### PHASE 3 DATA INTERNAL READOUTS

Flortaucipir (18F AV-1451) tau imaging agent Abemaciclib JUNIPER study

🔗 Ramucirumab RAINFALL 1L gastric (initial PFS readout)

Alimta+platinum+Keytruda in 1L nonsquamous NSCLC (KN-189)<sup>2</sup>

### PHASE 3 DATA EXTERNAL DISCLOSURES

Galcanezumab for migraine prevention

Lasmiditan SPARTAN study

Abemaciclib MONARCH 2 study

Abemaciclib MONARCH 3 study

Ramucirumab RANGE study in 2L bladder cancer (PFS readout)

### **REGULATORY SUBMISSIONS**

Galcanezumab for migraine prevention (US) Abemaciclib for advanced breast cancer (MONARCH 1) (US) Abemaciclib + fulvestrant for 2L breast cancer (MONARCH 2) (US/EU/J) Abemaciclib + Als for 1L breast cancer (MONARCH 3) (US/EU/J) Fruguitinib for 3L metastatic colorectal cancer (China) ✓ Ixekizumab for psoriatic arthritis (US)

### **REGULATORY ACTIONS**

Baricitinib for rheumatoid arthritis (US 2/EU /J) Ixekizumab for psoriatic arthritis (US) Alimta+carbo+Keytruda in 1L nonsquamous NSCLC (KN-021G) (US)<sup>2,3</sup>

### **OTHER**

Closing of BI US animal health vaccines acquisition

Closing of CoLucid Pharmaceuticals acquisition

Pediatric exclusivity for Cialis

Rulings in ongoing Alimta patent litigation:

**W**US CAFC

**US IPRs** IJΚ

Germany

🧭 Japan

<sup>1</sup> in collaboration with Boehringer Ingelheim <sup>2</sup> in collaboration with Merck <sup>3</sup> KN-021G is a Merck sBLA filing for Keytruda<sup>®</sup>



## **2017 GUIDANCE**

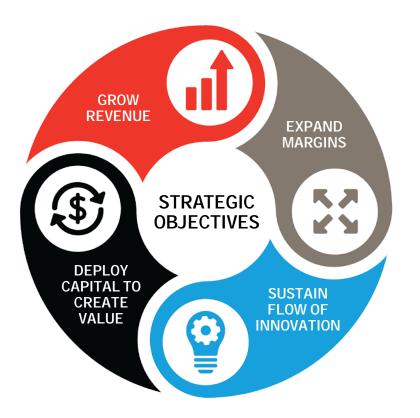
	Prior	Current
Total Revenue	\$21.8 to \$22.3 billion	unchanged
Gross Margin % of Revenue (GAAP)	Approx. 73.5%	unchanged
Gross Margin % of Revenue (non-GAAP)	Approx. 77.0%	unchanged
Marketing, Selling & Administrative	\$6.4 to \$6.6 billion	unchanged
Research & Development	\$4.9 to \$5.1 billion	unchanged
Other Income/(Expense)	\$0 - \$100 million	unchanged
ax Rate (GAAP)	Approx. 24.5%	unchanged
ax Rate (non-GAAP)	Approx. 22.0%	unchanged
Earnings per Share (GAAP)	\$2.69 to \$2.79	\$2.60 to \$2.70
Earnings per Share (non-GAAP)	\$4.05 to \$4.15	unchanged
Capital Expenditures	Approx. \$1.2 billion	unchanged



# rates for current guidance: Euro at 1.07 Yen at 111 Pound at 1.25

## SUMMARY

- Continued momentum with our innovation-based strategy
- Eight product launches since 2014, two more launches possible by year end 2018
- Raising expectations for outcomes and delivering value to the healthcare system, leading to volume-based revenue growth and expanding margins
- Focused on continued execution of strategy to create value for all our stakeholders



### **GROW REVENUE**

Minimum average annual revenue growth of 5% in constant currency from 2015 through 2020

### DEPLOY CAPITAL TO CREATE VALUE

Fund existing marketed and pipeline products

Bolster growth prospects via business development in focus areas

Annual dividend increases

### **EXPAND MARGINS**

Excluding FX on int'l inventories sold, gross margin % to increase from 2015 through 2020

OPEX % of revenue of 50% or less in 2018

### SUSTAIN FLOW OF INNOVATION

Potential to launch 20+ new molecules in 10 years (2014-2023)

On average, could launch 2+ new indications or line extensions per year

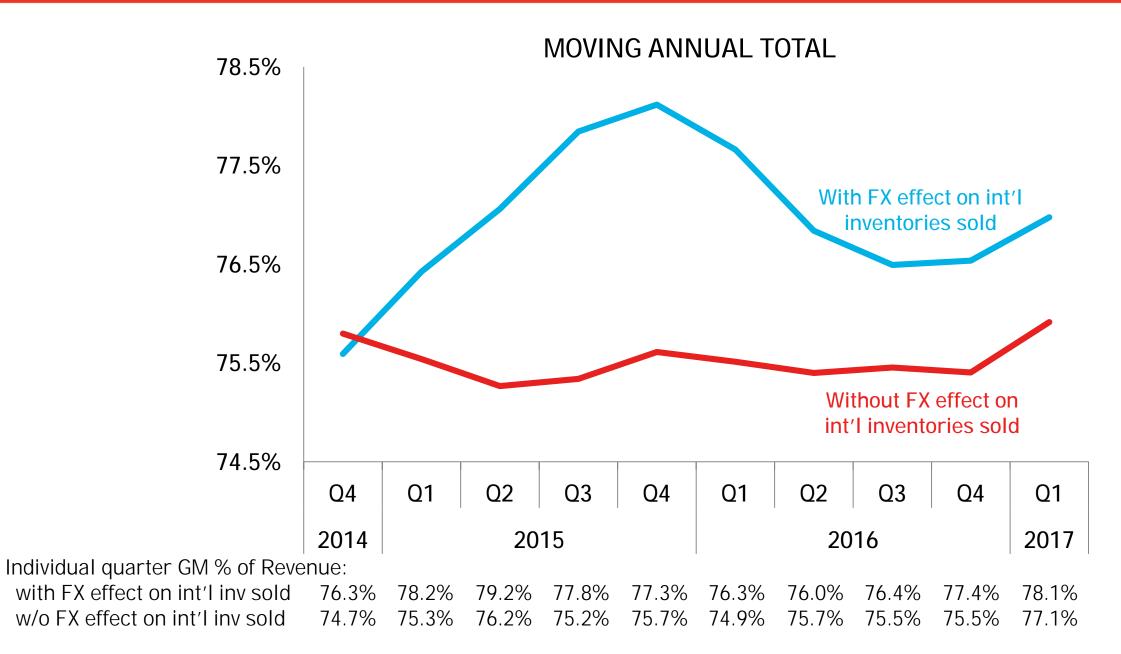


# Supplementary Slides

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## **NON-GAAP GROSS MARGIN % OF REVENUE**



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. Not for promotional use



# **Q1 2017 INCOME STATEMENT NOTES**

### Q1 2017 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 \$176.1 million (pretax), or \$0.11 per share (after-tax);
- an acquired in-process research and development charge related to the acquisition of CoLucid Pharmaceuticals totaling \$857.6 million (pretax), or \$0.81 per share (after-tax);
- inventory step-up costs associated with the acquisition of Boehringer Ingelheim Vetmedica's U.S. feline, canine, and rabies vaccine portfolio totaling \$10.4 million (pretax), or \$0.01 per share (after-tax); and
- charges primarily related to severance costs incurred as a result of actions taken to reduce the company's cost structure, as well as integration costs related to the acquisition of Novartis Animal Health, totaling \$213.9 million, or \$0.16 per share (after-tax).

### 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).

## **COMPARATIVE EPS SUMMARY 2016/2017**

	1016	2016	3Q16	4Q16	2016	1017	2017	3017	4Q17
Reported	0.41	0.71	0.73	0.73	2.58	(0.10)			
Non-GAAP	0.83	0.86	0.88	0.95	3.52	0.98			

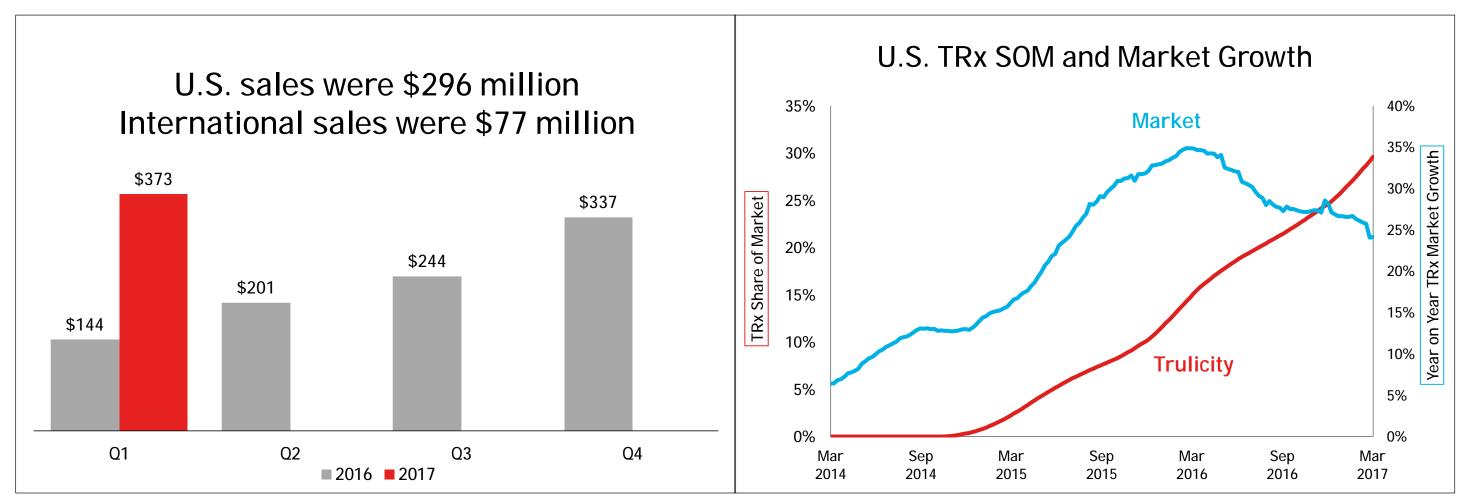
Note: Numbers may not add due to rounding.

For a complete reconciliation to reported earnings, see slide 22 and our earnings press release dated April 25, 2017.



## 2017

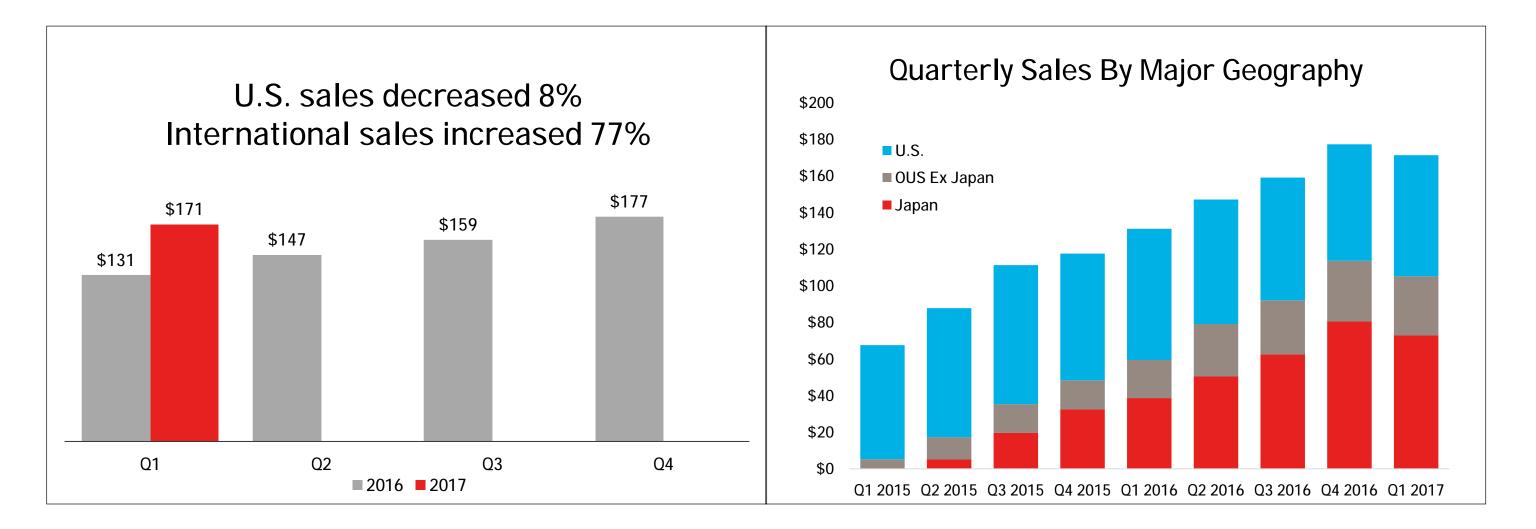
## Q1 2017 TRULICITY SALES WERE UP 160%



Lill

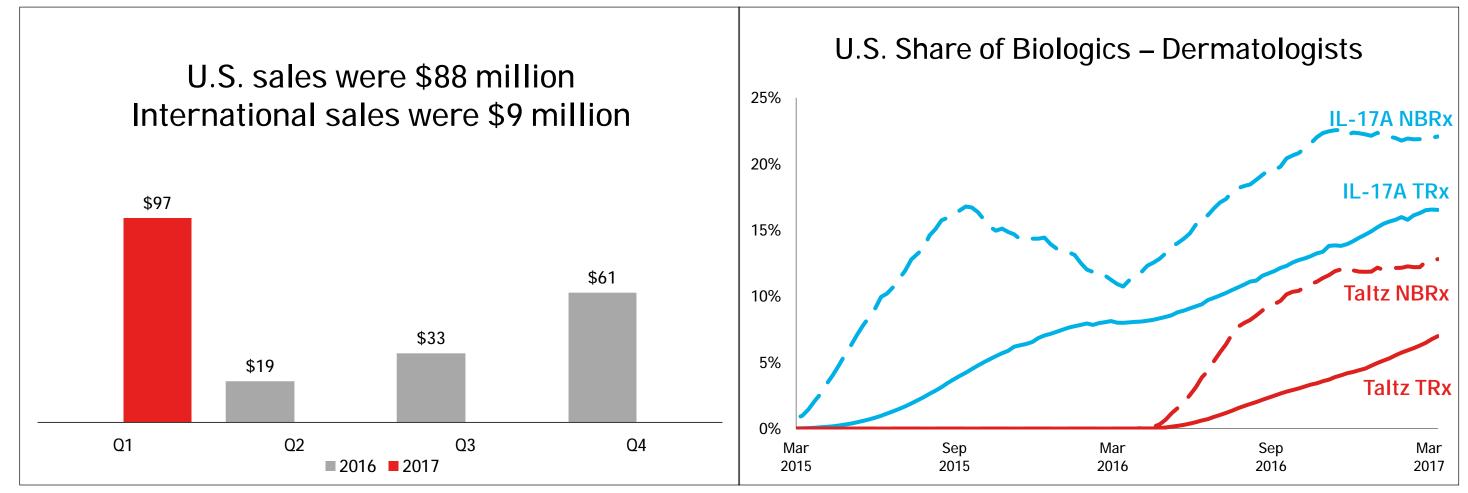
Source: QuintilesIMS Health NPA TRx 3MMA, weekly data March 31, 2017

## Q1 2017 CYRAMZA SALES INCREASED 31%





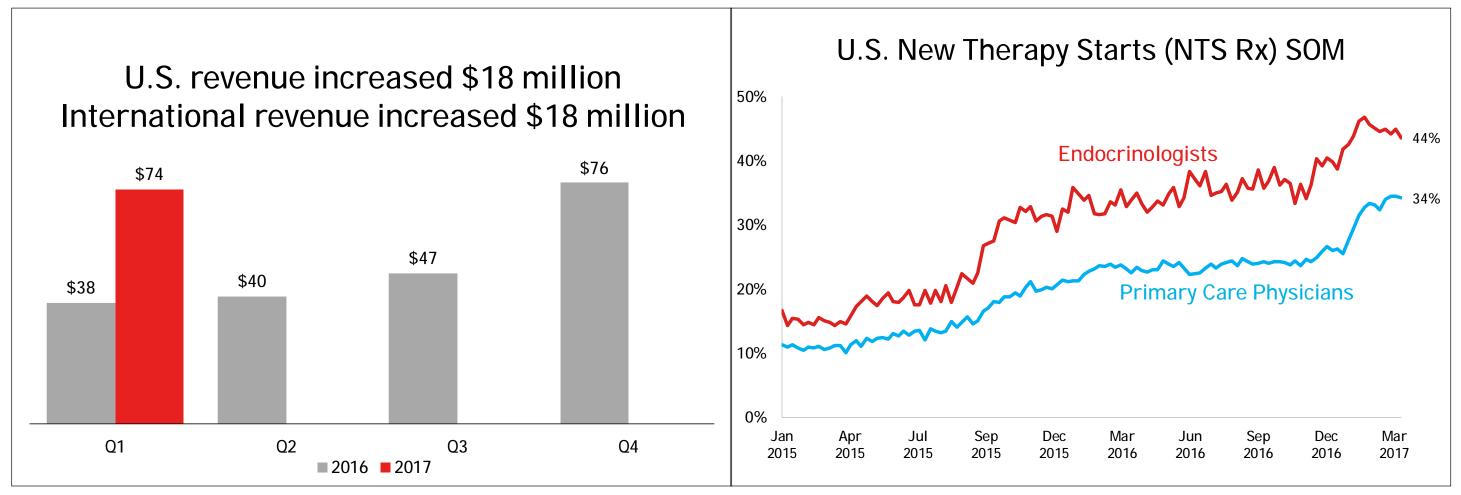
## Q1 2017 TALTZ SALES WERE \$97 MILLION



Source: QuintilesIMS Health NPA TRx and NBRx 3MMA, weekly data March 31, 2017

## **Q1 2017 JARDIANCE REVENUE WAS \$74 MILLION**

### Millions



Source: QuintilesIMS Health NPA NTS Rx 3MMA, weekly data March 31, 2017

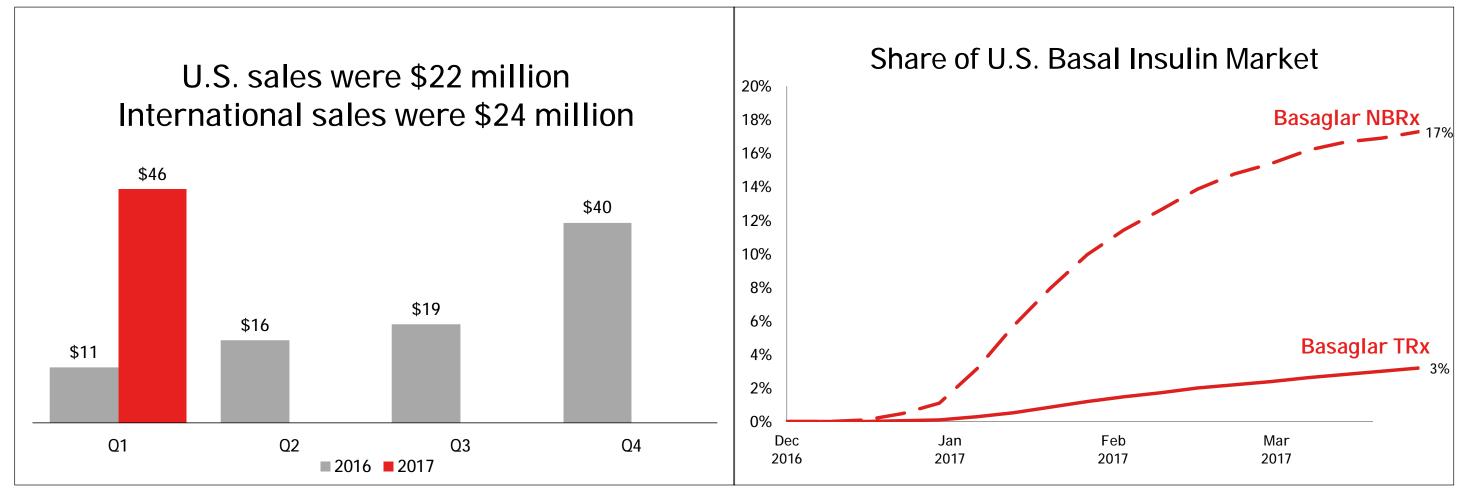
Note: Jardiance is part of the Boehringer Ingelheim and Lilly Diabetes Alliance





## Q1 2017 BASAGLAR SALES WERE \$46 MILLION

### Millions

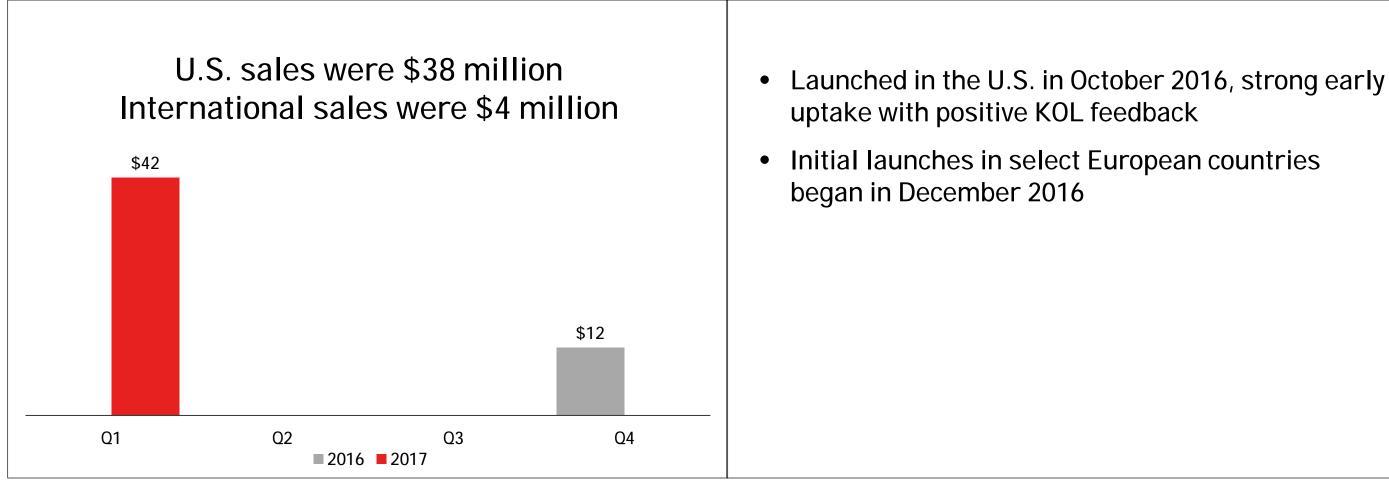


Source: QuintilesIMS Health NPA TRx and NBRx 1MMA, weekly data March 31, 2017

Note: Basaglar is part of the Boehringer Ingelheim and Lilly Diabetes Alliance



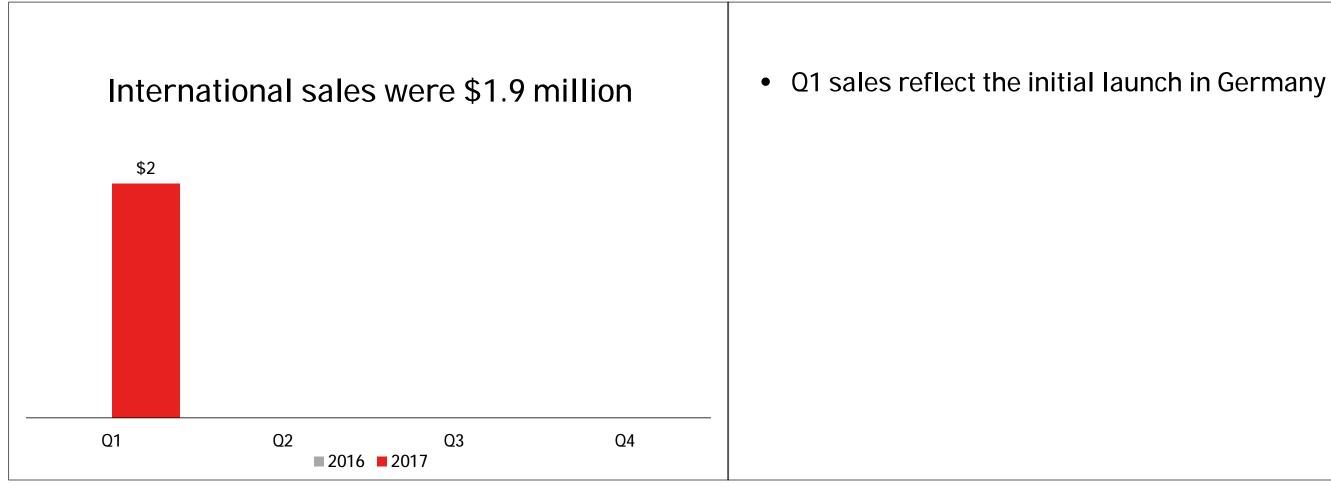
# **Q1 2017 LARTRUVO SALES WERE \$42 MILLION**





## **Q1 2017 OLUMIANT SALES WERE \$2 MILLION**

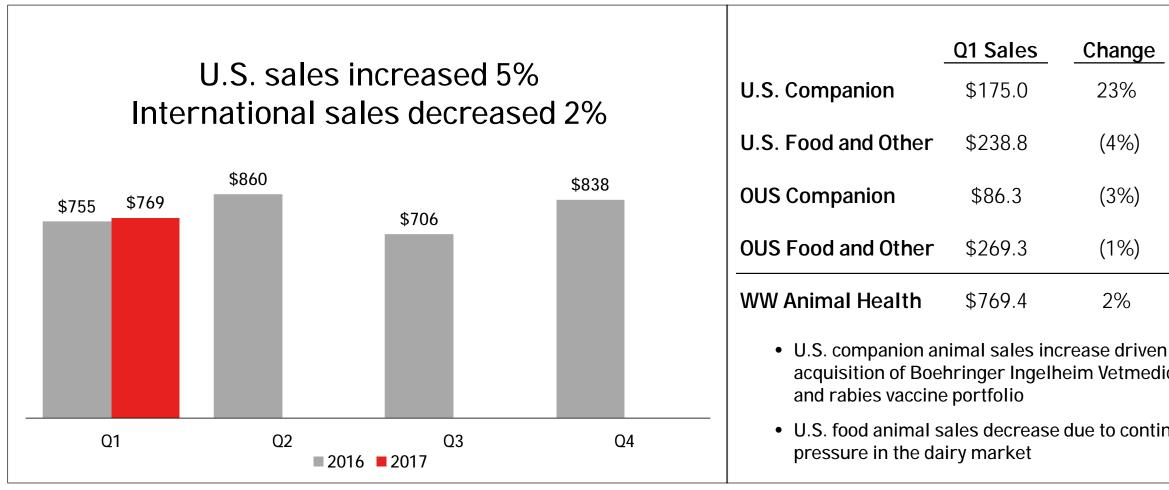
### Millions



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## **Q1 2017 ANIMAL HEALTH SALES INCREASED 2%**

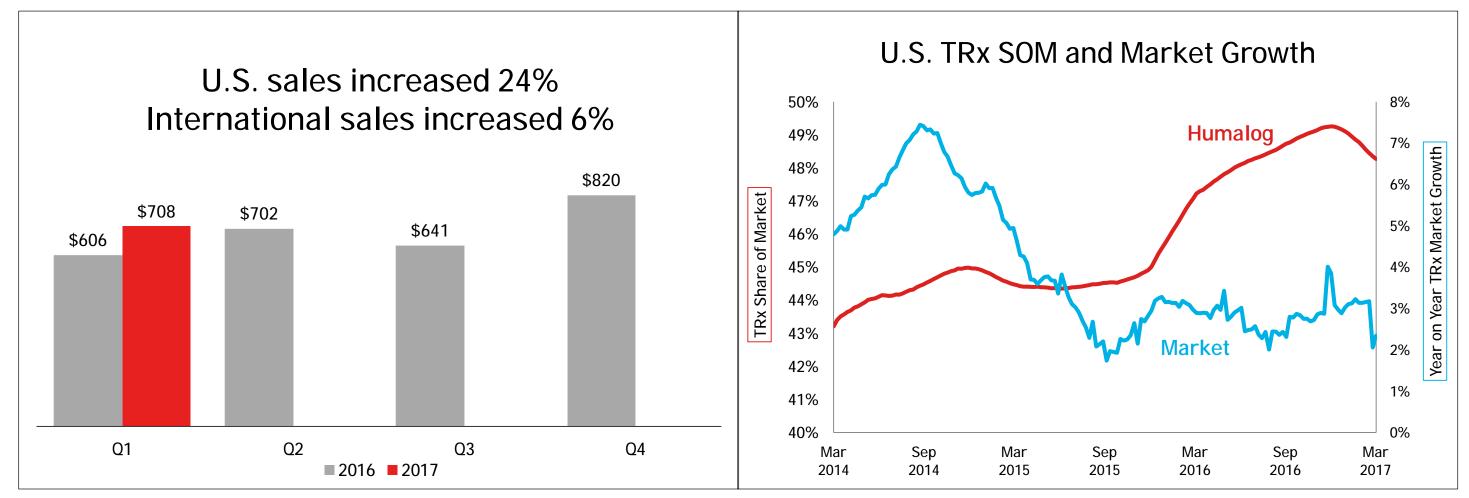






Performance	Rate			
23%	_			
(4%)	-			
(2%)	(1%)			
(1%)	(0%)			
2%	(0%)			
h by revenue from the ica's U.S. feline, canine,				
nued economic				

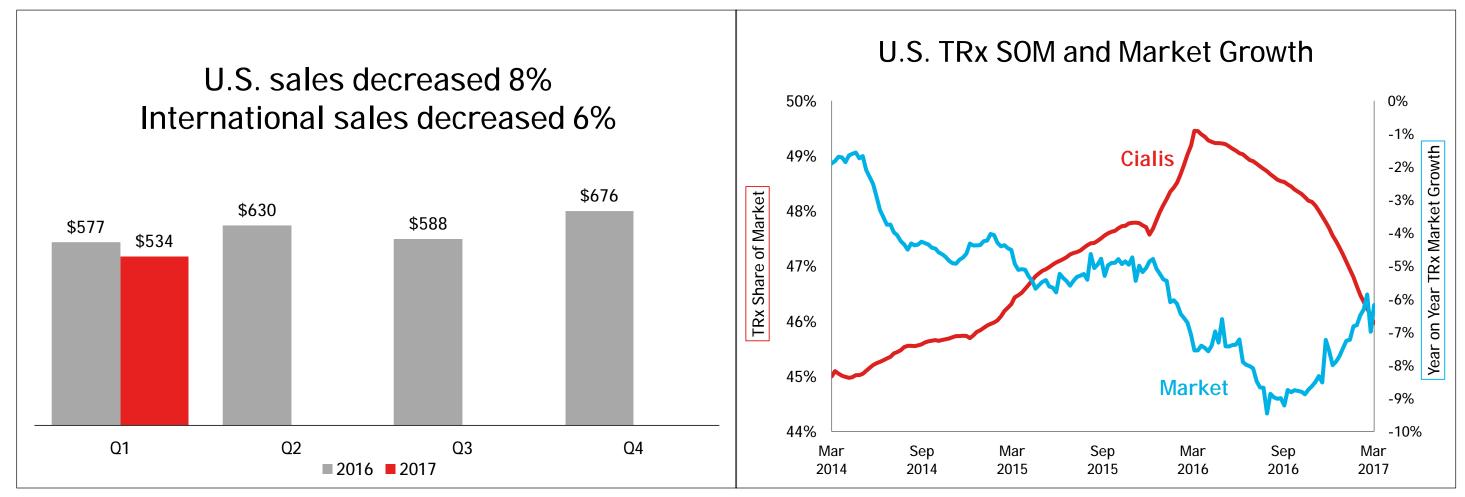
## Q1 2017 HUMALOG SALES INCREASED 17%



Lilly

Source: QuintilesIMS Health NPA TRx 3MMA, weekly data March 31, 2017

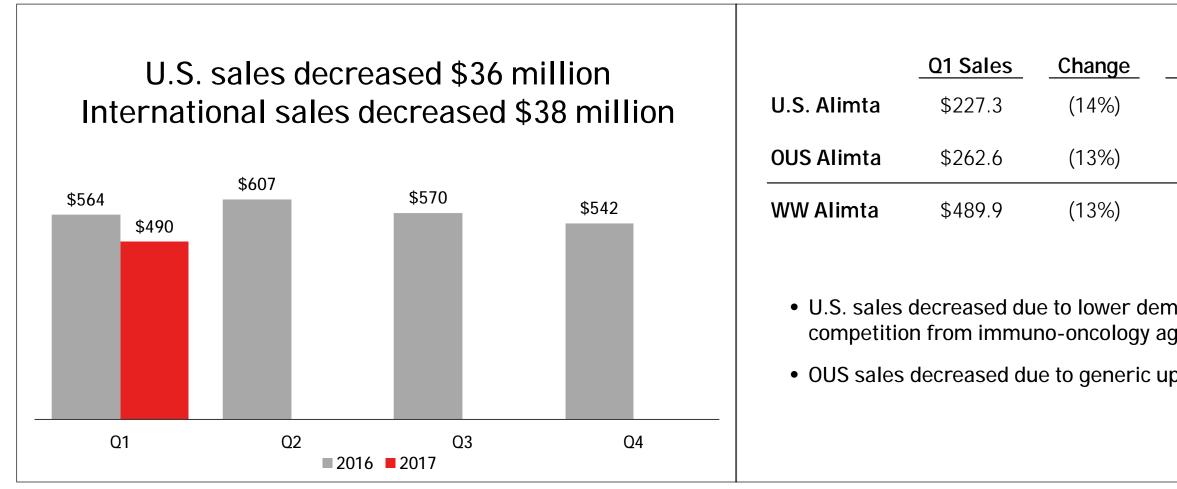
## Q1 2017 CIALIS SALES DECREASED 7%



Lill

Source: QuintilesIMS Health NPA TRx 3MMA, weekly data March 31, 2017

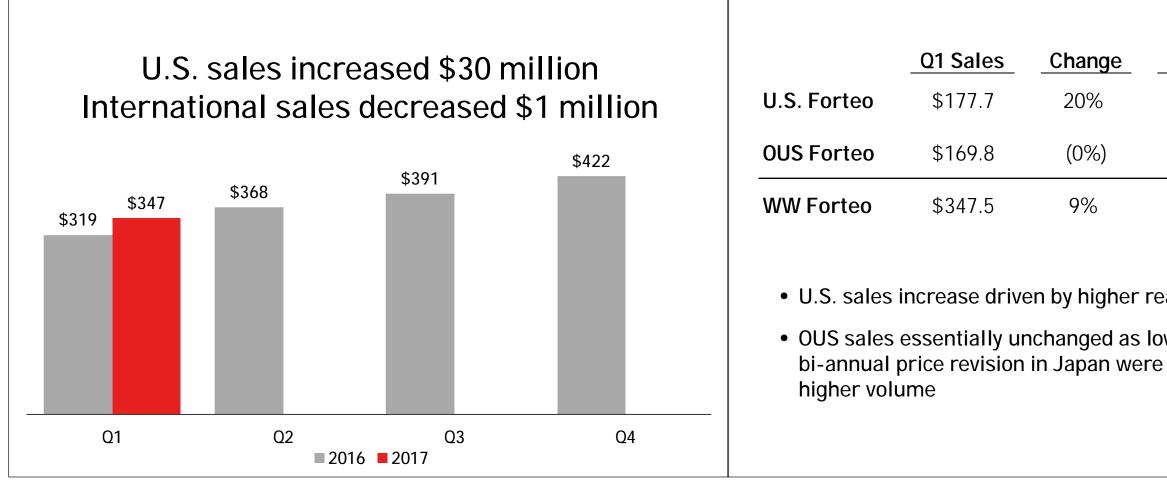
## Q1 2017 ALIMTA SALES DECREASED 13%



Lill

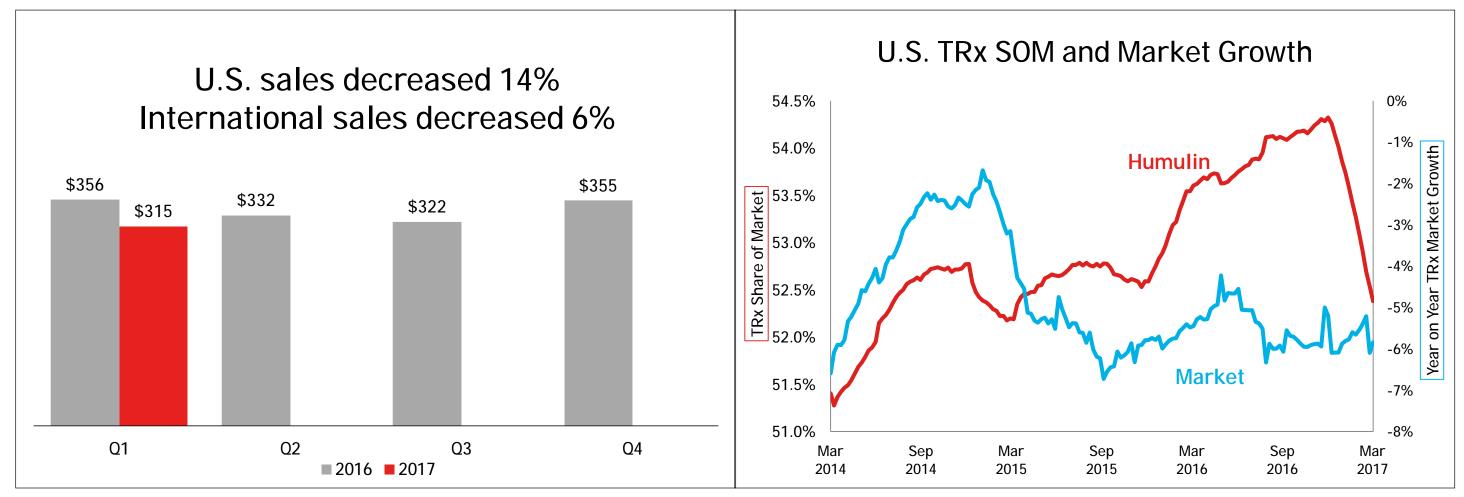
Performance	Rate
(14%)	-
(11%)	(2%)
(12%)	(1%)
nand, primarily f gents ptake and lower	

## Q1 2017 FORTEO<sup>®</sup> SALES INCREASED 9%



Dorformanco	Rate
Performance 20%	
(1%)	0%
9%	0%
ealized prices ower prices due t mostly offset by	

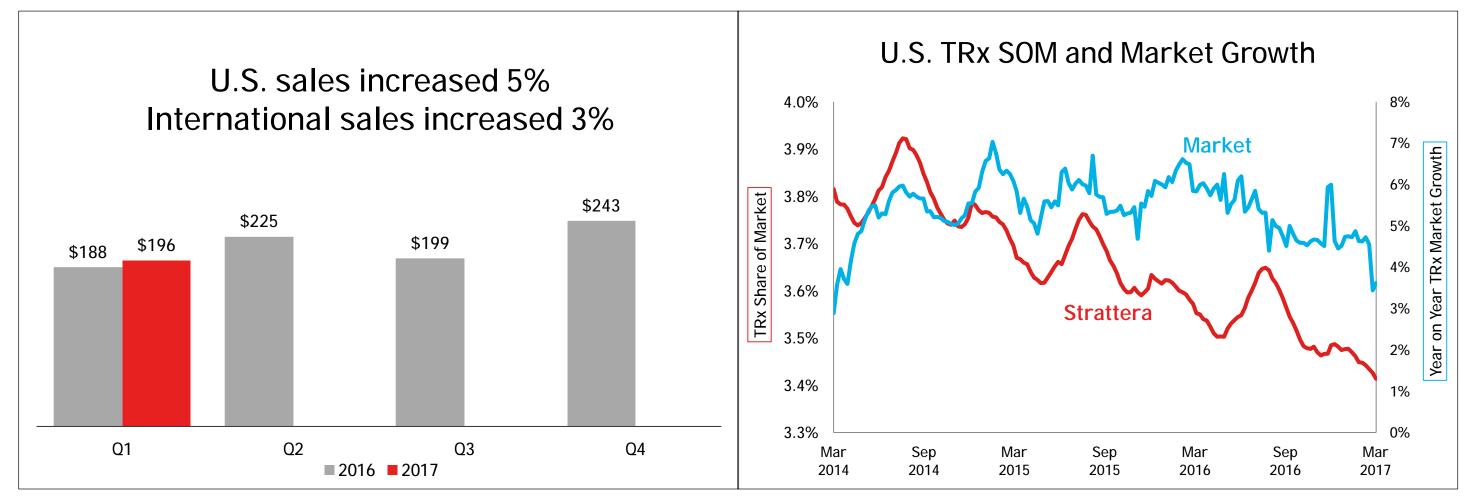
# Q1 2017 HUMULIN<sup>®</sup> SALES DECREASED 12%



Lill

Source: QuintilesIMS Health NPA TRx 3MMA, weekly data March 31, 2017

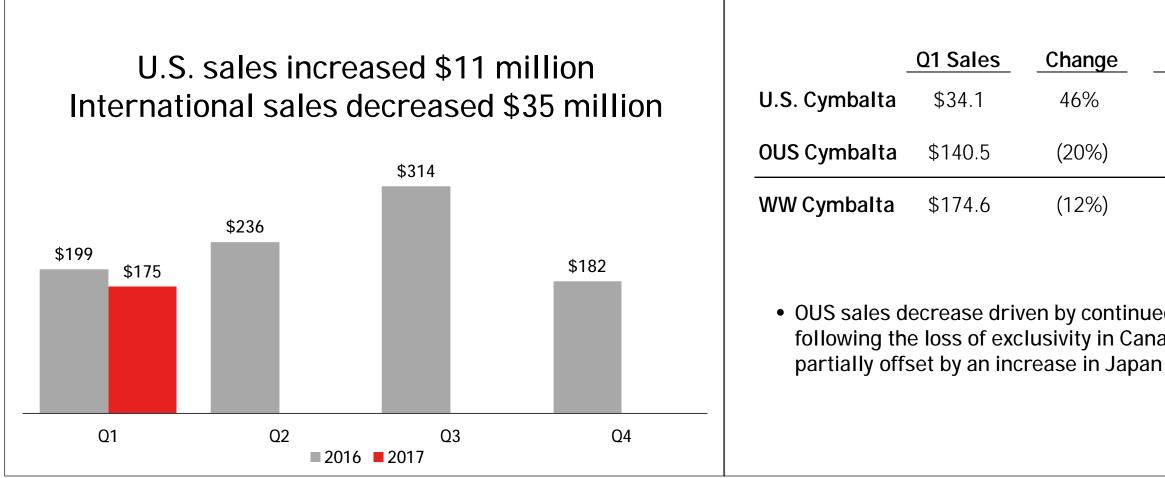
## Q1 2017 STRATTERA® SALES INCREASED 4%



Lill

Source: QuintilesIMS Health NPA TRx 3MMA, weekly data March 31, 2017

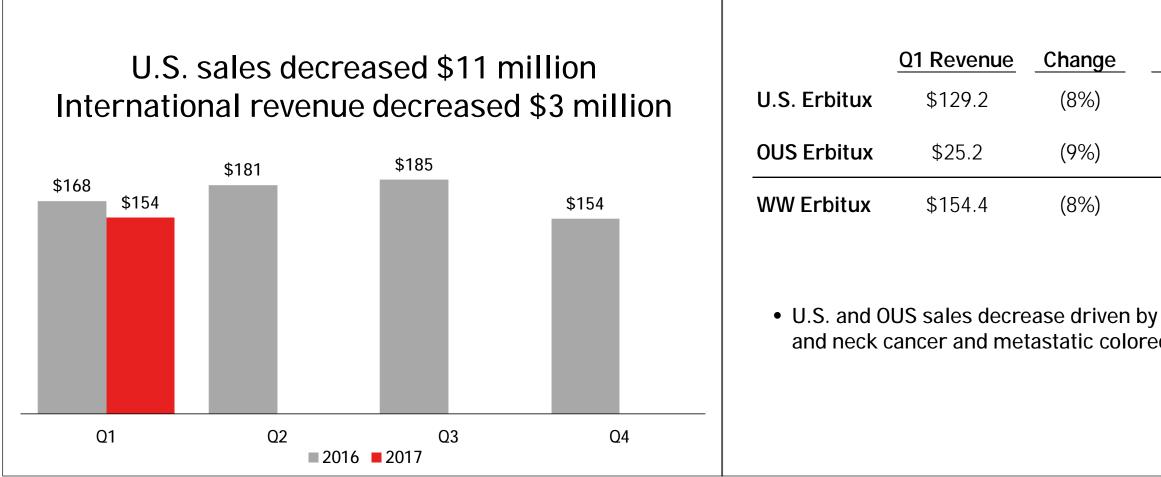
## Q1 2017 CYMBALTA SALES DECREASED 12%



Lill

Performance	Rate
46%	-
(20%)	(0%)
(12%)	(0%)
ed sales erosion ada and Europe, 1	

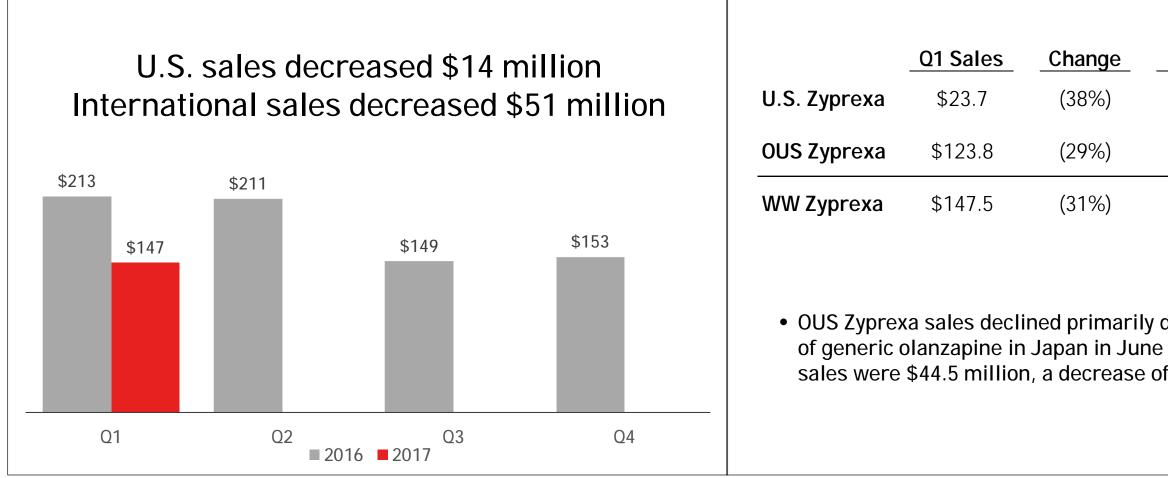
# Q1 2017 ERBITUX<sup>®</sup> REVENUE DECREASED 8%



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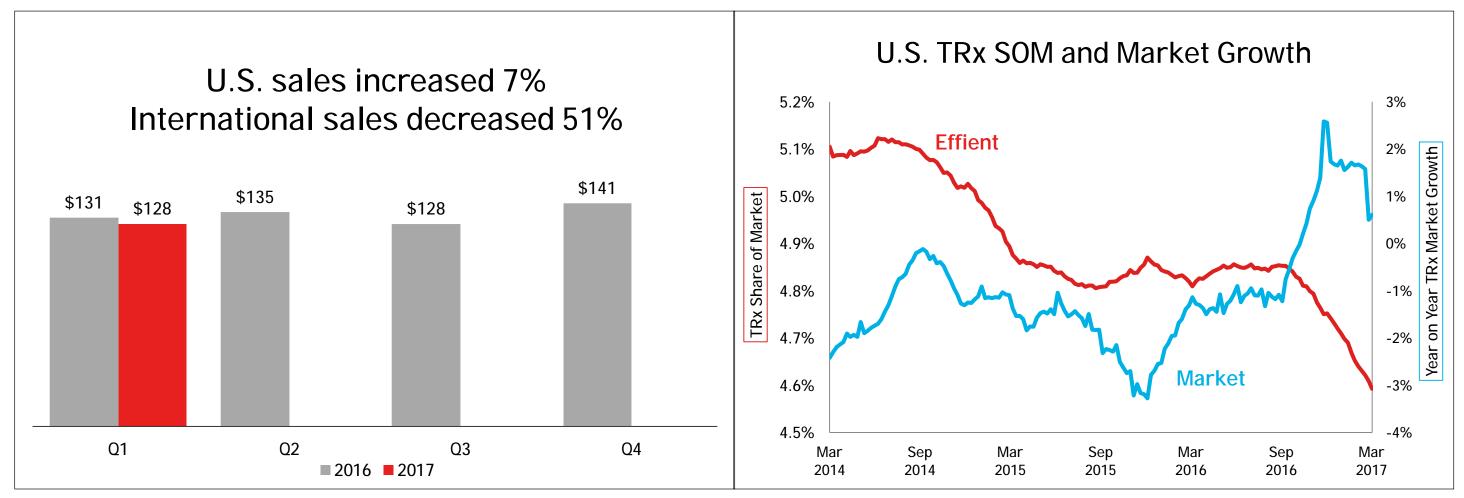
Deufeumenee	Data
Performance (8%)	Rate
(10%)	1%
(8%)	0%
competition in ectal cancer indi	

## Q1 2017 ZYPREXA SALES DECREASED 31%



Performance	Rate	
(38%)	-	
(28%)	(1%)	
(30%)	(1%)	
due to the introduction 2016; Japan Zyprexa f 52%		

## Q1 2017 EFFIENT<sup>®</sup> SALES DECREASED 3%



Lill

Source: QuintilesIMS Health NPA TRx 3MMA, weekly data March 31, 2017

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