

# Eli Lilly and Company Third Quarter 2013 Financial Review

October 23<sup>rd</sup>, 2013

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*Lilly*  
Answers That Matter.

# Agenda

## Key Recent Events, Financial Results and Pipeline Update

- Phil Johnson, Vice President, Investor Relations
- Travis Coy, Director, Investor Relations

## Key Future Events, Financial Guidance and 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 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.

# Beyond the Quarterly Financial Results

## Key events since the last earnings call

### Clinical:

- Announced that the Phase 3 study, SQUIRE, investigating necitumumab in patients with stage IV metastatic squamous non-small cell lung cancer met its primary endpoint of increased overall survival
- Announced that the Phase 3 study, RAINBOW, investigating ramucirumab in combination with paclitaxel in patients with advanced gastric cancer that was refractory to, or progressive after, initial chemotherapy met its primary endpoint of increased overall survival
- Announced that the Phase 3 study, ROSE, investigating ramucirumab in women with locally recurrent or metastatic breast cancer did not meet its primary endpoint of increased progression-free survival

### Regulatory/Commercial:

- Ramucirumab as a single agent for advanced gastric cancer:
  - Completed the rolling BLA submission in the United States; received Priority Review designation
  - Submitted the marketing authorization application in the European Union
- Dulaglutide for type 2 diabetes:
  - Submitted a BLA in the United States
  - Submitted the marketing authorization application in the European Union
- Along with Boehringer Ingelheim, submitted empagliflozin for type 2 diabetes in Japan
- Final decision by the Centers for Medicare and Medicaid Services for Coverage with Evidence Development for the use of beta-amyloid PET imaging agents, including Amyvid™

### Other:

- Lilly's Board of Directors authorized a \$5 billion share repurchase plan

# Comparison Measures

Results shown two ways to aid analysis

## “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
  - In-process R&D charges and other income and expenses from business development activities

# 2013 Income Statement (Reported)

Millions; except per share data

	<u>Q3 2013</u>	<u>Growth</u>	<u>Sept YTD</u>	<u>Growth</u>
Total Revenue	\$5,773	6%	\$17,304	4%
Gross Margin Percent	79.2%	1.3pp	79.6%	0.9pp
Total Operating Expense*	3,030	(4)%	9,313	(1)%
Operating Income	1,545	42%	4,470	22%
Other Income / (Deductions)	(31)	NM	510	(30)%
<i>Effective Tax Rate</i>	<i>20.5%</i>	<i>(8.7)pp</i>	<i>20.5%</i>	<i>(5.3)pp</i>
<b>Net Income</b>	<b><u>\$1,203</u></b>	<b><u>(9)%</u></b>	<b><u>\$3,957</u></b>	<b><u>21%</u></b>
<b>Diluted EPS</b>	<b>\$1.11</b>	<b>(6)%</b>	<b>\$3.64</b>	<b>25%</b>

\* Includes Research and Development expense, Selling, Marketing and Administrative expense and asset impairment, restructuring and other special charges.

Note: See slide 20 for a complete list of charges.

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

Millions; except per share data

	Q3 2013			
	<u>GAAP Reported</u>	<u>Adjust- ments</u>	<u>Non-GAAP Adjusted</u>	<u>Non-GAAP Adjusted Growth</u>
Total Revenue	\$5,773	-	\$5,773	6%
Gross Margin	79.2%	-	79.2%	1.3pp
Total Operating Expense	3,030	-	3,030	(2)%
Operating Income	1,545	-	1,545	36%
Other Income / (Deductions)	(31)	-	(31)	NM
<i>Effective Tax Rate</i>	<i>20.5%</i>	-	<i>20.5%</i>	<i>(1.6)pp</i>
Net Income	\$1,203	-	\$1,203	35%
Diluted EPS	\$1.11	-	\$1.11	41%

Note: Numbers may not add due to rounding.

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

Millions; except per share data

September YTD 2013

	GAAP Reported	Adjust- ments	Non-GAAP Adjusted	Non-GAAP Adjusted Growth
Total Revenue	\$17,304	-	\$17,304	4%
Gross Margin	79.6%	-	79.6%	0.9pp
Total Operating Expense	9,313	(85)	9,228	(1)%
Operating Income	4,470	85	4,555	22%
Other Income / (Deductions)	510	(495)	14	NM
<i>Effective Tax Rate</i>	<i>20.5%</i>	<i>(1.6)%</i>	<i>18.9%</i>	<i>(4.1)pp</i>
Net Income	\$3,957	\$(252)	\$3,706	31%
Diluted EPS	\$3.64	\$(0.23)	\$3.41	34%

Note: Numbers may not add due to rounding.



# EPS Reconciliation

	<u>Q3 2013</u>	<u>Q3 2012</u>	<u>Growth</u>	<u>YTD 13</u>	<u>YTD 12</u>	<u>Growth</u>
EPS (reported)	\$1.11	\$1.18	(6)%	\$3.64	\$2.92	25%
Asset impairment, restructuring and other special charges	-	0.04		0.06	0.05	
Income related to termination of the exenatide collaboration with Amylin	-	(0.43)		(0.29)	(0.43)	
EPS (non-GAAP)	<u>\$1.11</u>	<u>\$0.79</u>	<u>41%</u>	<u>\$3.41</u>	<u>\$2.54</u>	<u>34%</u>

Note: Numbers may not add due to rounding.

# Effect of Price/Rate/Volume on Revenue

## Q3 2013

Pharmaceuticals	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
U.S.	\$3,006.9	11%	-	(0)%	11%	11%
ACE*	1,142.0	(2)%	3%	4%	5%	2%
Japan	489.6	(2)%	(21)%	11%	(12)%	9%
Emerging Markets	603.8	(2)%	(4)%	5%	(1)%	3%
Total Pharma	5,242.3	5%	(2)%	2%	6%	8%
Animal Health	530.3	(1)%	(1)%	13%	11%	12%
<b>Total Revenue</b>	<b>\$5,772.6</b>	<b>5%</b>	<b>(2)%</b>	<b>3%</b>	<b>6%</b>	<b>8%</b>

## September YTD 2013

Pharmaceuticals	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
U.S.	\$8,924.9	12%	-	(3)%	8%	8%
ACE*	3,454.5	(2)%	1%	(0)%	(1)%	(2)%
Japan	1,454.9	(2)%	(18)%	12%	(9)%	9%
Emerging Markets	1,896.9	(1)%	(3)%	6%	2%	5%
Total Pharma	15,731.2	6%	(2)%	0%	4%	6%
Animal Health	1,573.2	(1)%	(1)%	6%	6%	7%
<b>Total Revenue</b>	<b>\$17,304.3</b>	<b>5%</b>	<b>(2)%</b>	<b>1%</b>	<b>4%</b>	<b>6%</b>

Note: Numbers may not add due to rounding.

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

# Effect of Foreign Exchange on 2013 Results

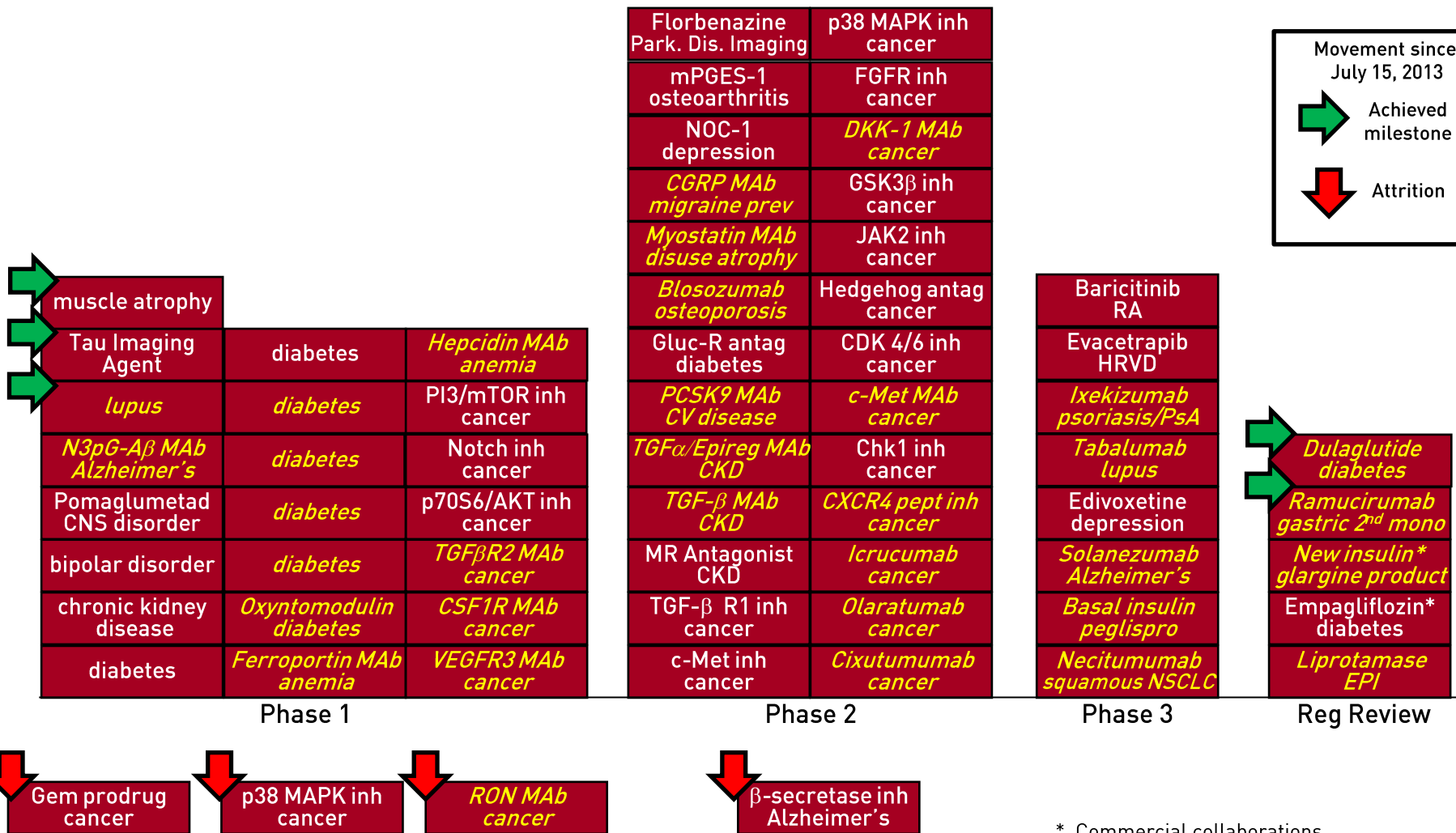
## Year-on-Year Growth

	Q3 2013		Sept YTD 2013	
	With FX	w/o FX	With FX	w/o FX
Total Revenue	6%	8%	4%	6%
Cost of Sales	(0)%	(4)%	(1)%	(3)%
Gross Margin	8%	12%	5%	8%
Reported Operating Expense	(4)%	(3)%	(1)%	(0)%
Reported Operating Income	42%	54%	22%	30%
Reported EPS	(6)%	2%	25%	32%
Non-GAAP Operating Expense	(2)%	(1)%	(1)%	(0)%
Non-GAAP Operating Income	36%	47%	22%	29%
Non-GAAP EPS	41%	52%	34%	43%

# Lilly NME Pipeline

October 16, 2013

New Chemical Entity (NCE)  
New Biotech Entity (NBE)



\* Commercial collaborations

# Key Events in 2013

## Potential Phase 3 data external disclosure / **internal readouts:**

- ✓+ • Initial trials of dulaglutide for type 2 diabetes
- ✓+ • Initial trials of empagliflozin for type 2 diabetes<sup>1</sup>
- Initial trials of basal insulin peglispro for type 1 and type 2 diabetes
- ✓+ • Trials of new insulin glargine product for type 1 and type 2 diabetes<sup>1</sup>
- ✓+ • Ramucirumab as monotherapy for second-line gastric cancer (ASCO-GI in January)
- ✓- • Ramucirumab for breast cancer
- ✓+ • Ramucirumab as combination therapy for second-line gastric cancer
- ✓- • Enzastaurin for DLBCL
- ✓+ • Necitumumab for first-line squamous NSCLC
- Initial trials of edivoxetine as adjunctive therapy for major depressive disorder
- ✓- • Additional analyses of Phase 3 trials of tabalumab for rheumatoid arthritis

## Potential regulatory submissions:

- ✓+ • Dulaglutide for type 2 diabetes
- ✓+ • Empagliflozin for type 2 diabetes<sup>1</sup>
- ✓+ • New insulin glargine product for type 1 and type 2 diabetes<sup>1</sup>
- ✓+ • Ramucirumab as monotherapy for second-line gastric cancer<sup>2</sup>
- ✓- • Enzastaurin for DLBCL

## Other:

- ✓+ • Initiation of new pivotal trial for solanezumab in patients with mild AD
- ✓ • Alimta® District Court trial for method-of-use patent (August)
- Cymbalta® U.S. patent expiration (December)

1 in collaboration with Boehringer Ingelheim  
2 FDA rolling submission underway

# 2013 Guidance

	<u>Prior</u>	<u>Current</u>
Total Revenue	\$22.6 to \$23.4 billion	\$22.6 to \$23.4 billion
Gross Margin % of Revenue	Approx. 79%	Approx. 79%
Mktg, Selling & Admin.	\$7.0 to \$7.2 billion	\$7.0 to \$7.2 billion
Research & Development	\$5.3 to \$5.5 billion	\$5.3 to \$5.5 billion
Other Income/(Expense) (non-GAAP)	\$(50) - \$100 million	\$(50) - \$100 million
Other Income/(Expense) (GAAP)	\$440 - \$590 million	\$440 - \$590 million
Tax Rate (non-GAAP)	Approx. 19.0%	Approx. 19.0%
Tax Rate (GAAP)	Approx. 20.5%	Approx. 20.5%
Earnings per Share (non-GAAP)	\$4.05 - \$4.15	\$4.10 - \$4.15
Earnings per Share (GAAP)	\$4.28 - \$4.38	\$4.33 - \$4.38
Capital Expenditures	Approx. \$900 million	Approx. \$1.0 billion
Q4 2013 U.S. Cymbalta Sales	n.a.	Approx. \$500 million

# Earnings Per Share Expectations

	<u>2013</u>	<u>2012</u>	<u>Growth</u>
EPS (reported)	\$4.33-\$4.38	\$3.66	18%-20%
Asset impairment, restructuring and other special charges	0.06	0.16	
Income related to termination of the exenatide collaboration with Amylin	<u>(0.29)</u>	<u>(0.43)</u>	
EPS (non-GAAP)	<u><u>\$4.10-\$4.15</u></u>	<u><u>\$3.39</u></u>	<u><u>21%-22%</u></u>

Note: Numbers may not add due to rounding.

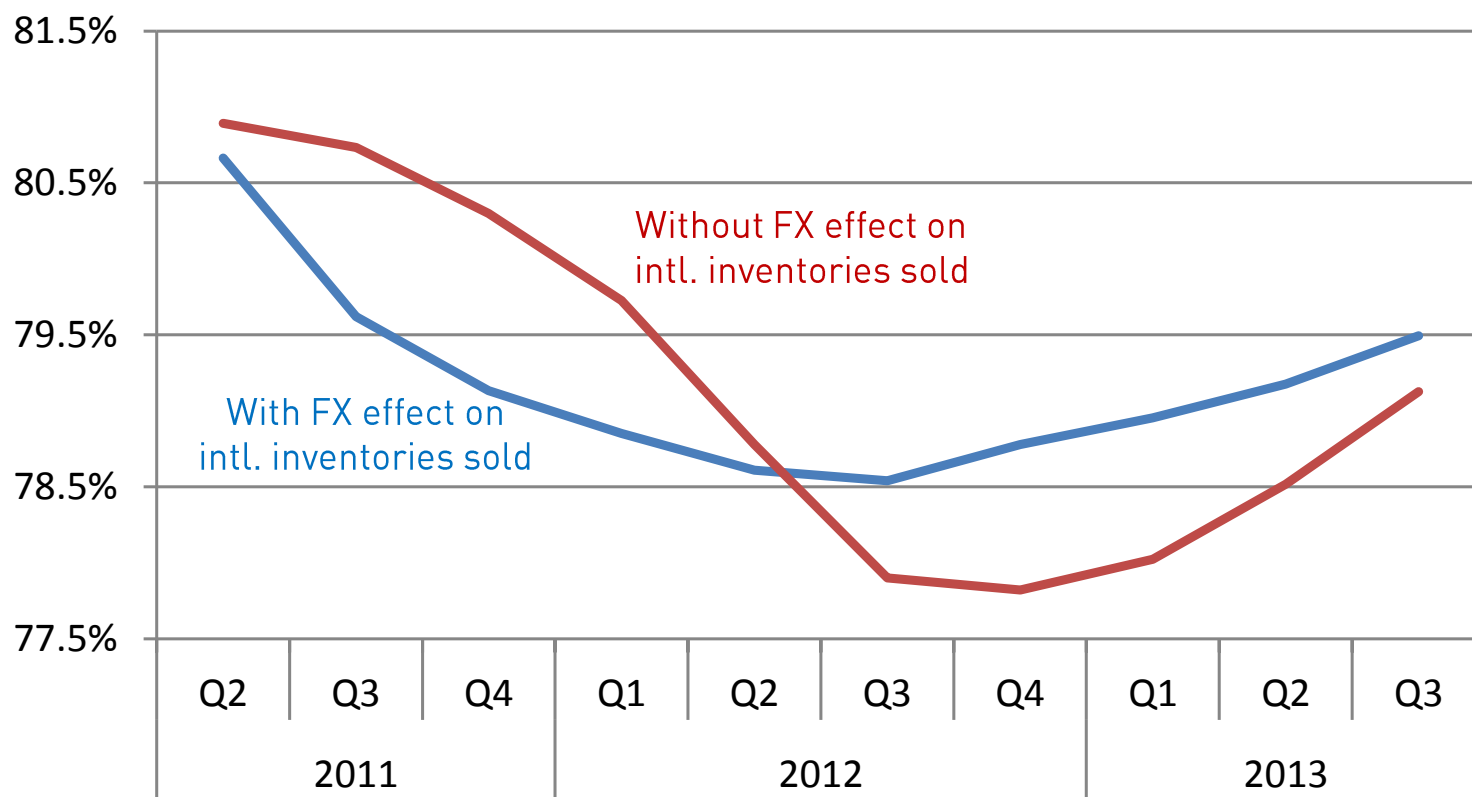
# Q3 2013 Summary

- **Solid financial performance and continued pipeline advancement in Q3**
- **Continued implementation of our strategy moving forward**
  - Advancing our pipeline
  - Driving strong performance of our marketed brands and key growth areas
  - Increasing productivity and reducing our cost structure
- **Committed to return cash to our shareholders**
  - Maintaining our dividend, at least at its current level, in 2014 and beyond
  - Repurchasing shares under our recently-authorized \$5 billion program
- **Poised to drive revenue growth and expand margins post-2014**
  - Expect to launch our next wave of innovation starting in 2014
  - Will continue to generate and disseminate important data throughout 2014



# Supplementary Slides

# Gross Margin % - Moving Annual Total



Individual quarter GM% of Revenue:

with FX effect on intl inv sold	80.4%	78.2%	78.1%	78.6%	79.5%	77.9%	79.0%	79.3%	80.3%	79.2%
w/o FX effect on intl inv sold	81.7%	80.0%	78.8%	78.3%	77.9%	76.4%	78.5%	79.1%	79.9%	79.0%

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 2012/2013

	1Q12	2Q12	3Q12	4Q12	2012	1Q13	2Q13	3Q13	4Q13	2013
Non-GAAP	0.92	0.83	0.79	0.85	3.39	1.14	1.16	1.11		
Reported	0.91	0.83	1.18	0.74	3.66	1.42	1.11	1.11		

Note: Numbers may not add due to rounding.

For a complete reconciliation to reported earnings, see slide 20 of this presentation and our earnings press release dated October 23, 2013.

# 2013 Income Statement Notes

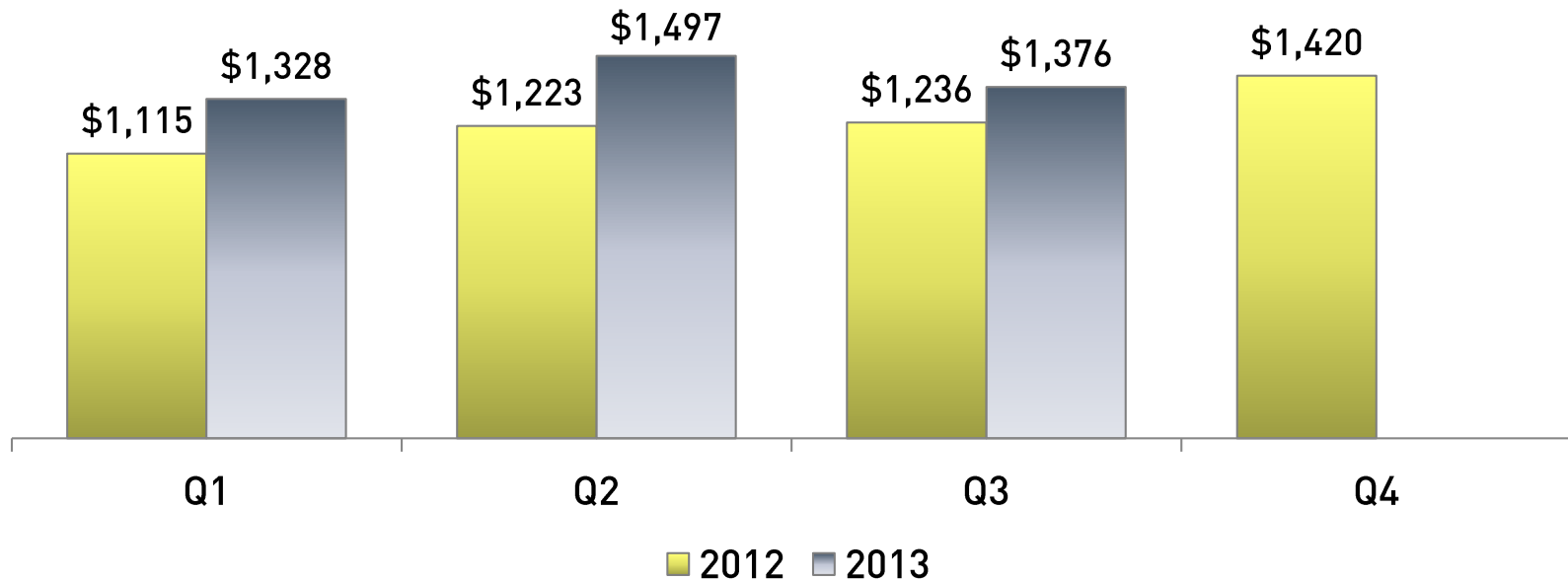
## Notes:

- There are no adjustments to third quarter 2013 non-GAAP financial statements.
- The third quarter 2012 non-GAAP financial statements have been adjusted to eliminate income of \$787.8 million (pretax), or \$0.43 per share (after-tax) related to the early payment by Amylin of the exenatide revenue sharing obligation as well as a charge of \$53.3 million (pretax), or EPS of \$0.04 (after-tax), related to an asset impairment of a delivery device platform.
- The year-to-date 2013 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, a charge of \$63.5 million (pretax), or EPS of \$0.04 (after-tax), primarily related to the anticipated closure of a packaging and distribution facility in Germany, 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 and global workforce.
- In addition, the year-to-date 2012 non-GAAP financial statements have been adjusted to eliminate a charge of \$23.8 million (pretax), or EPS of \$0.01 (after-tax) primarily related to the withdrawal of Xigris®.

# Q3 Cymbalta Sales Increased 11%

Millions

U.S. sales increased 15%  
International sales decreased 2%

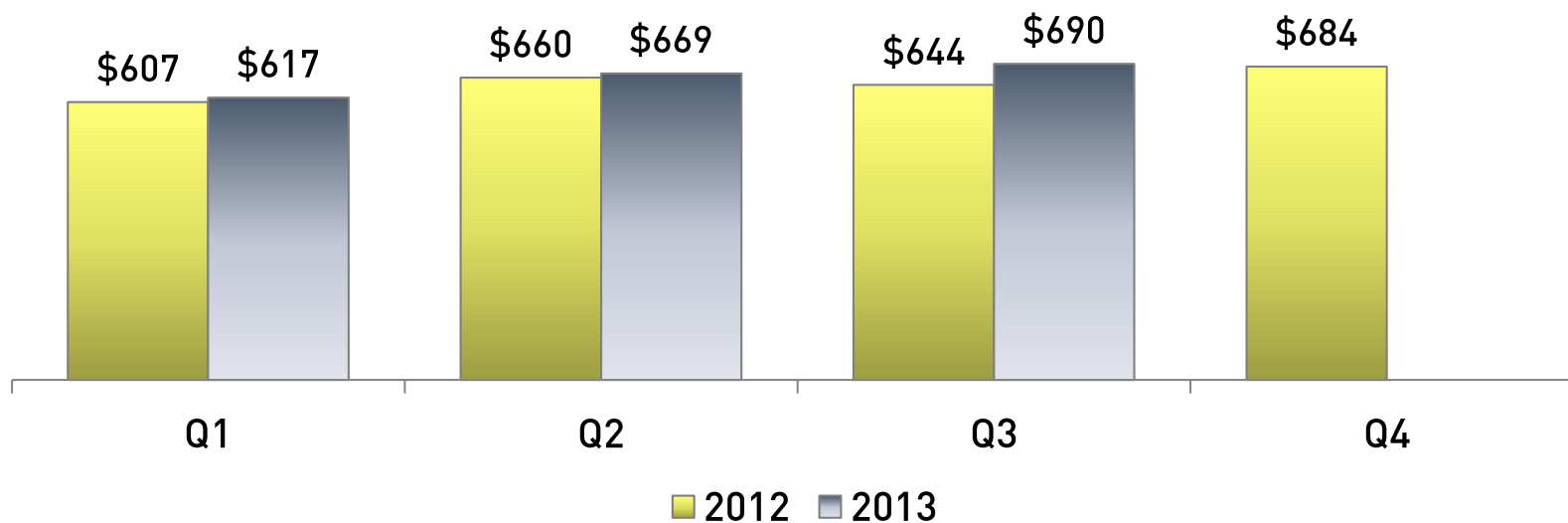


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Alimta Sales Increased 7%

Millions

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

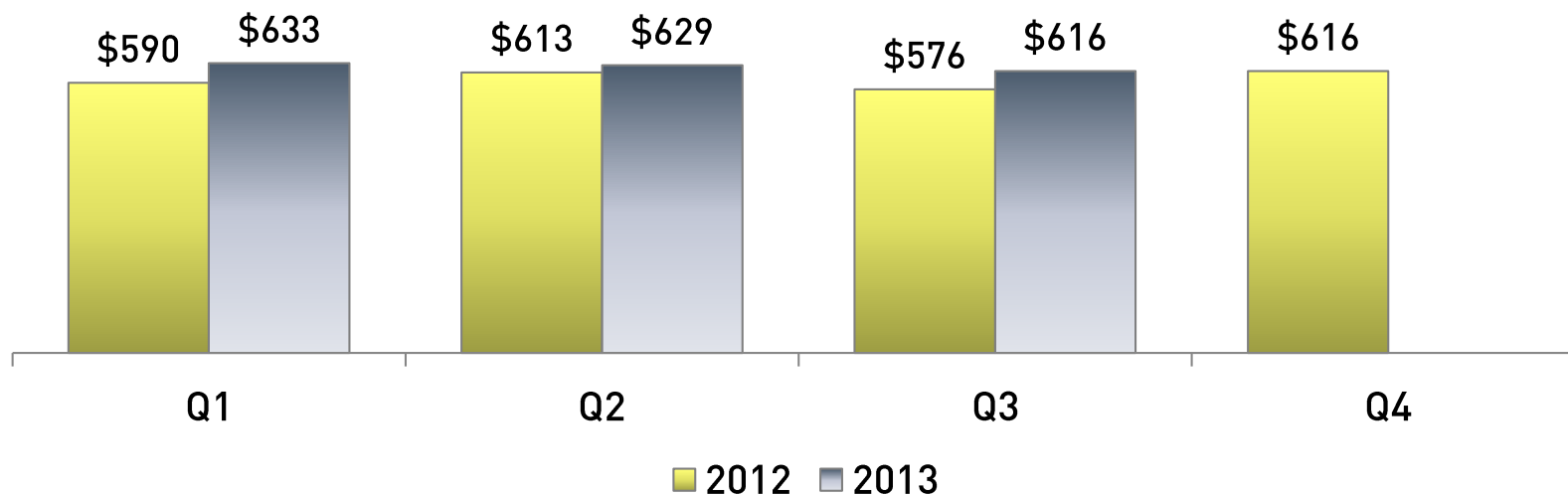


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Humalog<sup>®</sup> Sales Increased 7%

Millions

U.S. sales increased 6%  
International sales increased 8%

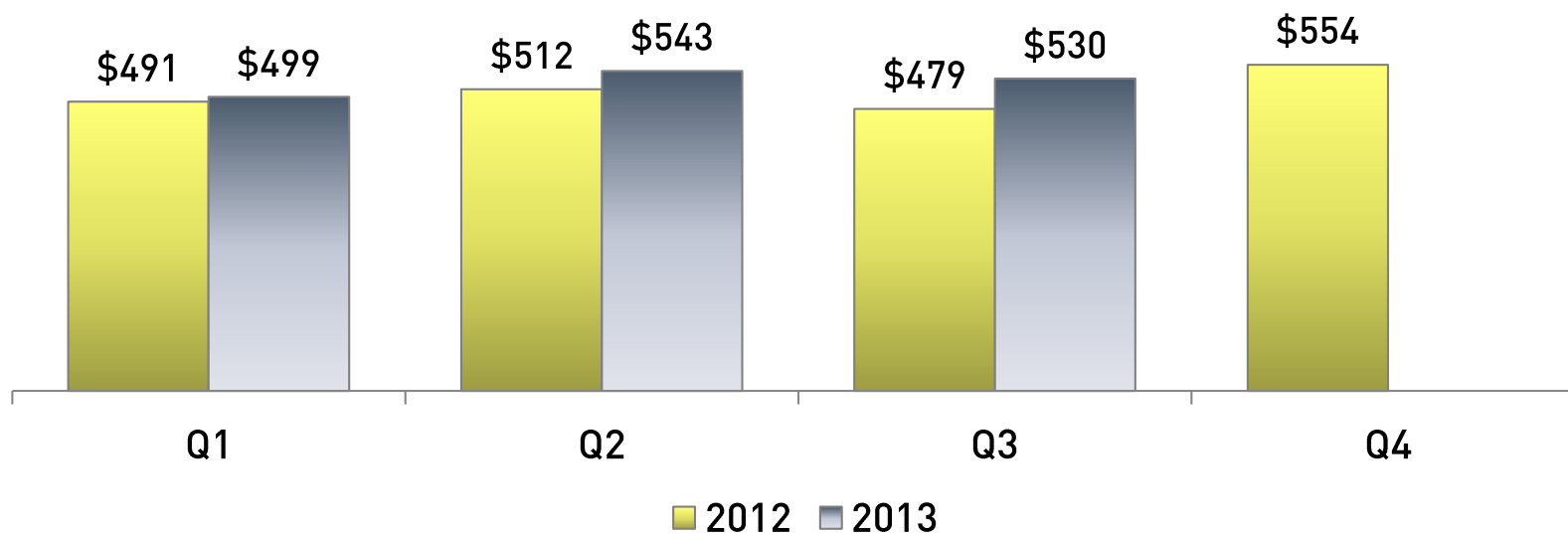


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Animal Health Sales Increased 11%

Millions

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



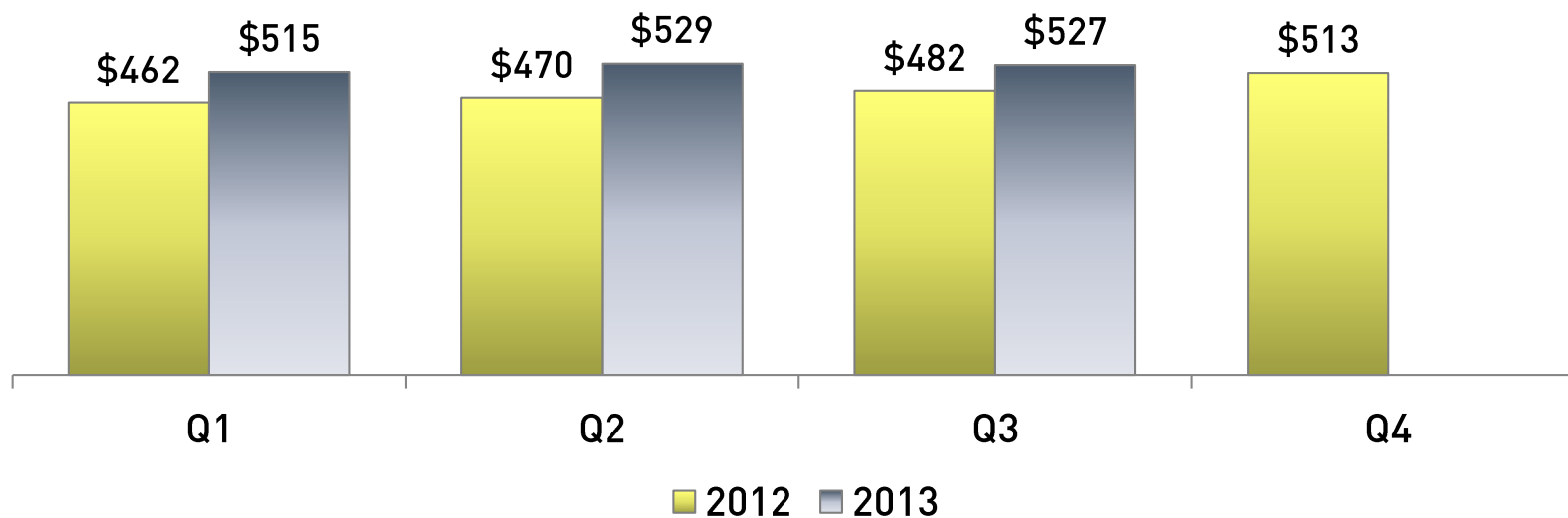
Note: Quarterly numbers may not add to year-to-date totals due to rounding.



# Q3 Cialis<sup>®</sup> Sales Increased 9%

Millions

U.S. sales increased 14%  
International sales increased 6%

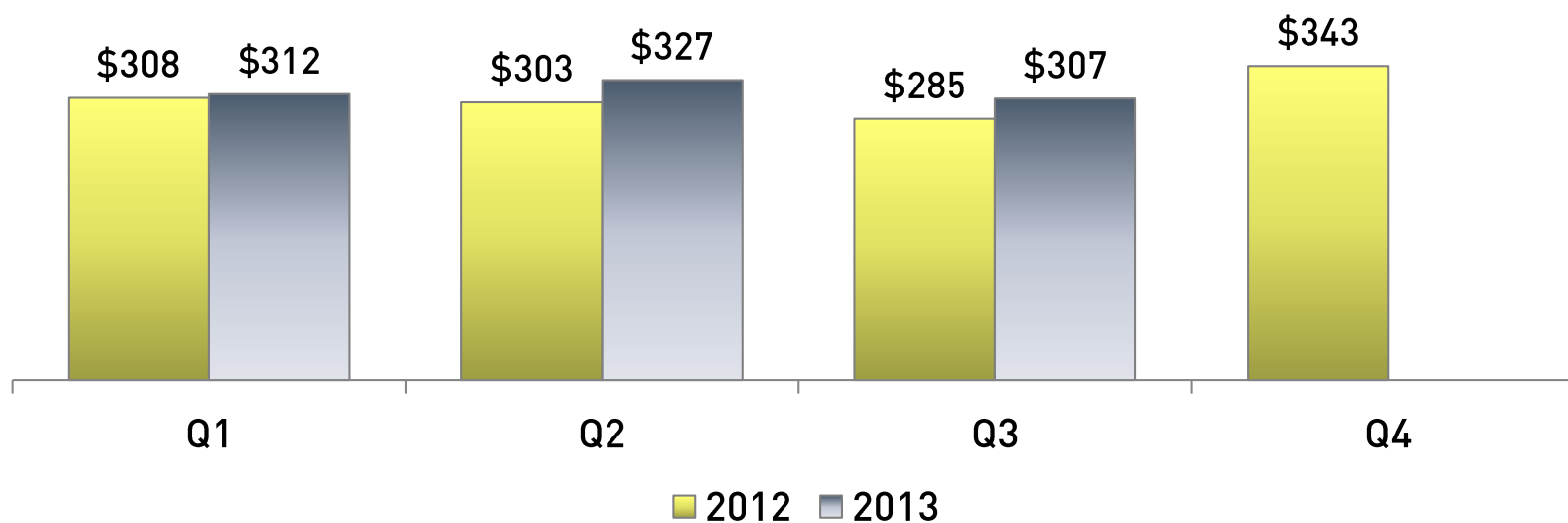


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Humulin<sup>®</sup> Sales Increased 8%

Millions

U.S. sales increased 22%  
International sales decreased 5%

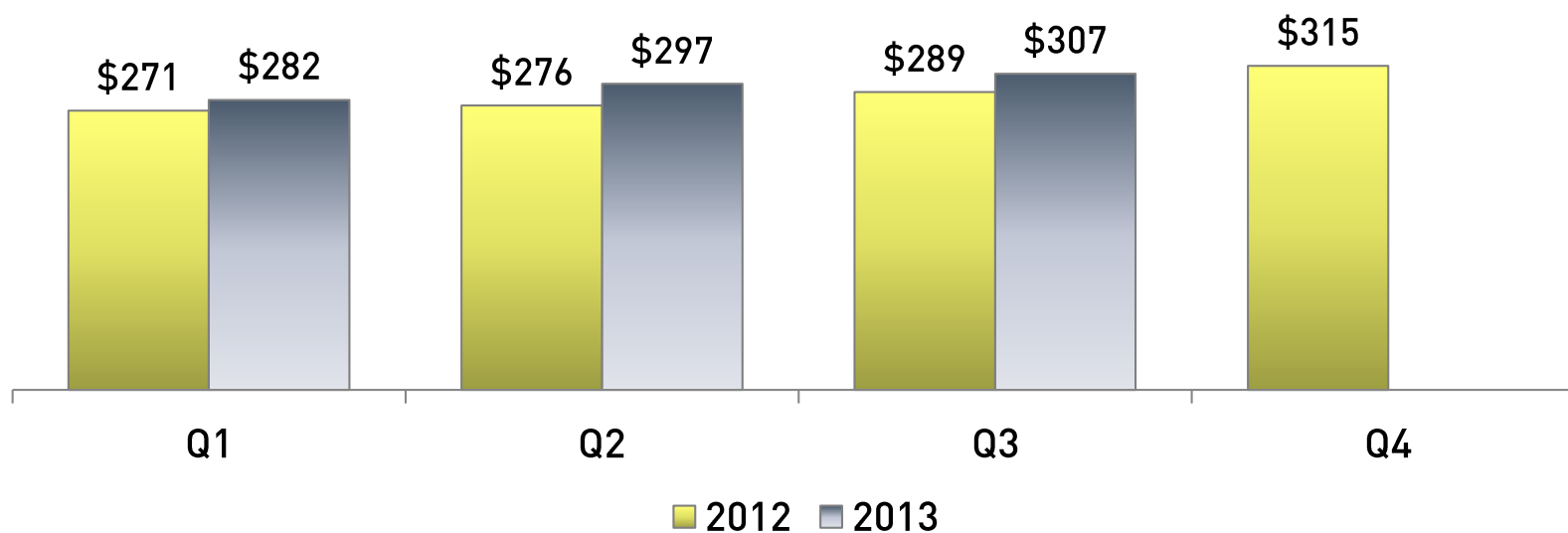


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Forteo<sup>®</sup> Sales Increased 6%

Millions

U.S. sales essentially flat  
International sales increased 11%

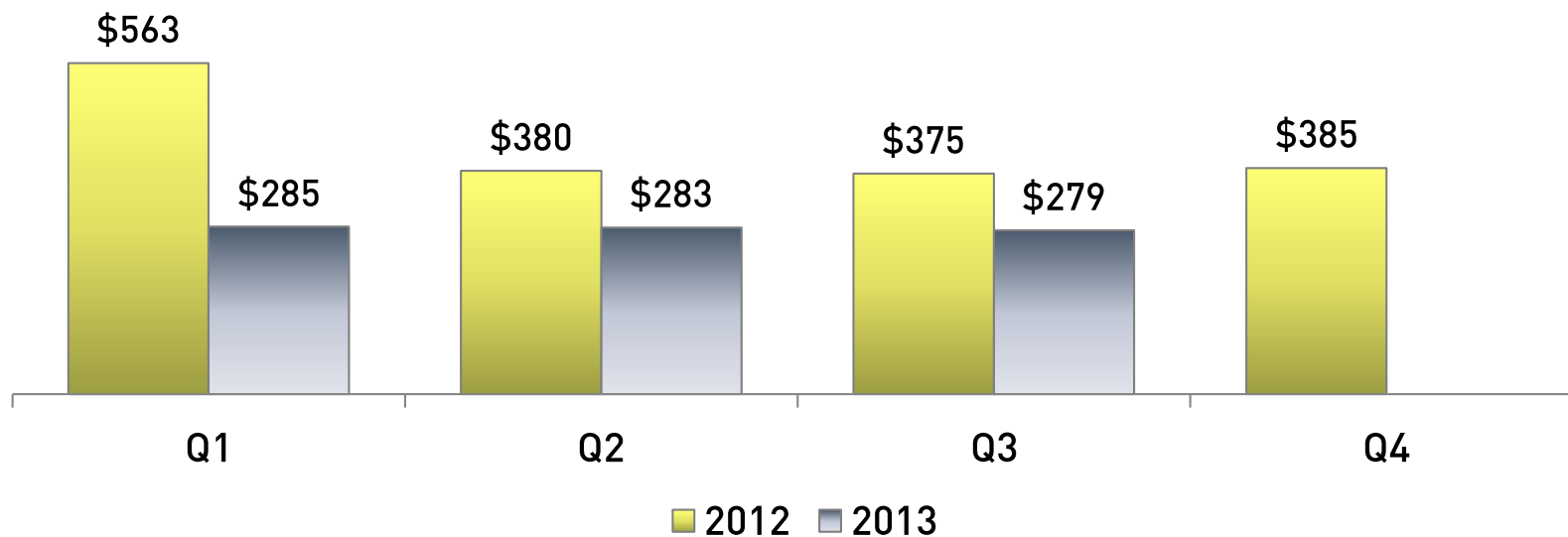


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Zyprexa<sup>®</sup> Sales Decreased 26%

Millions

U.S. sales decreased 51%  
International sales decreased 20%

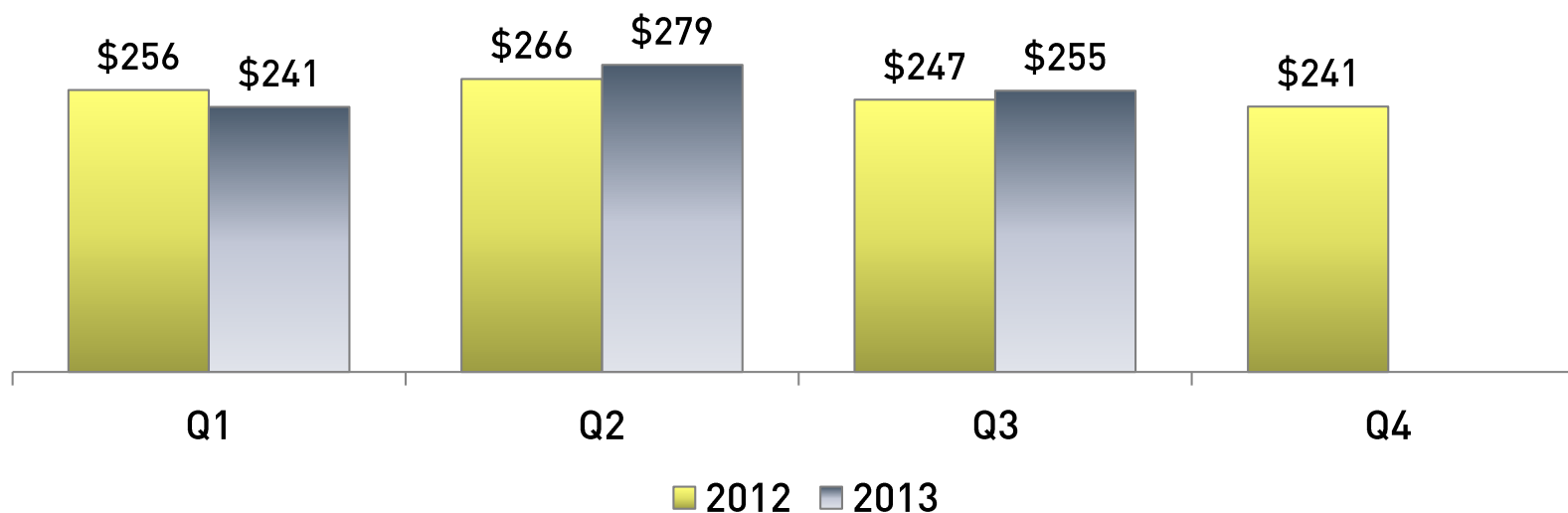


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Evista<sup>®</sup> Sales Increased 3%

Millions

U.S. sales increased 14%  
International sales decreased 19%

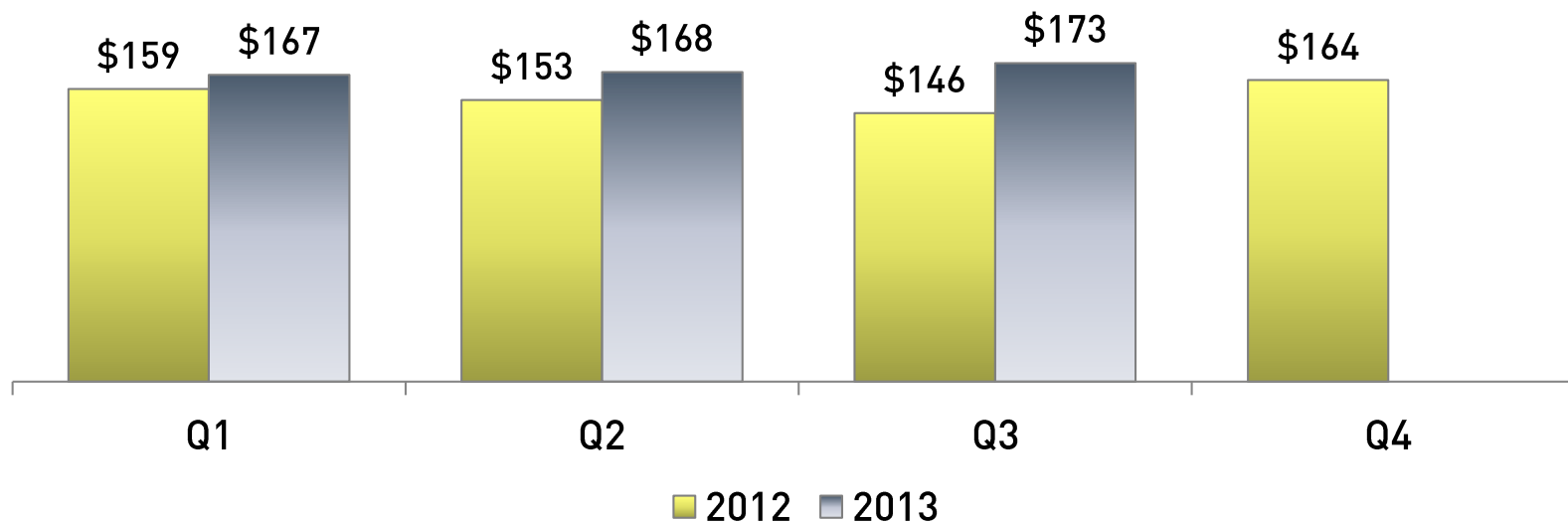


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Strattera<sup>®</sup> Sales Increased 19%

Millions

U.S. sales increased 23%  
International sales increased 12%

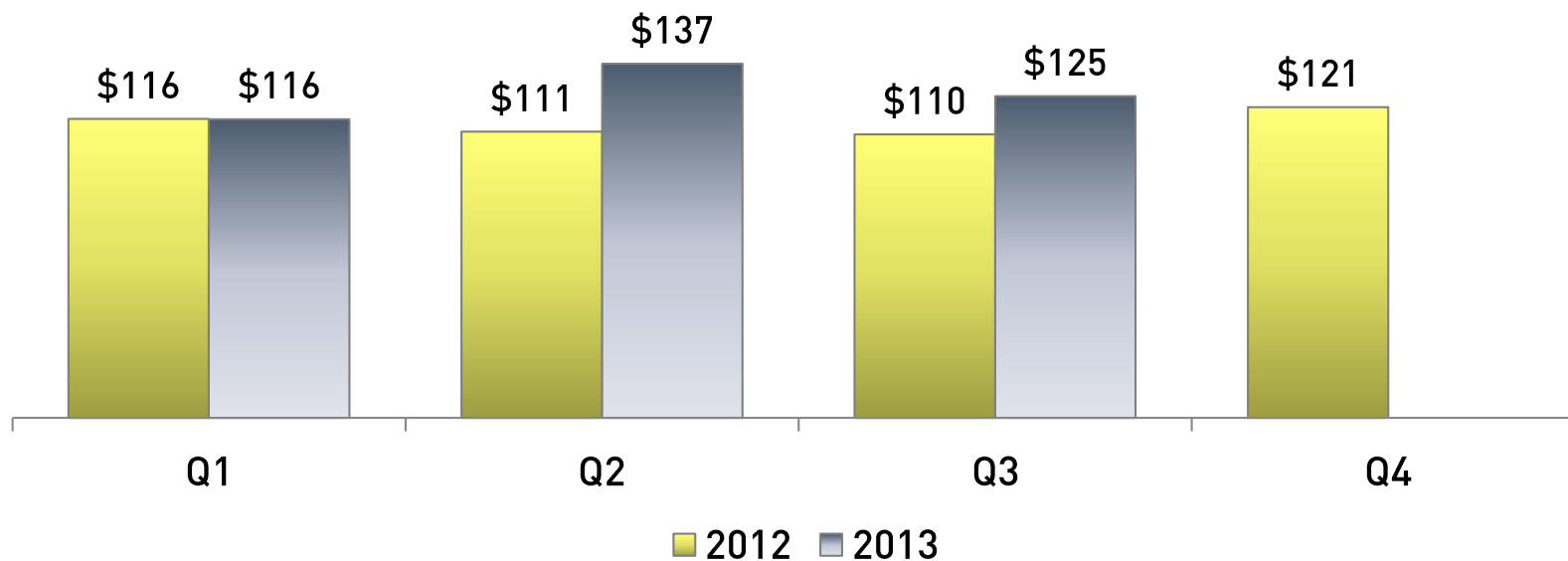


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q3 Effient<sup>®</sup> Sales Increased 14%

Millions

U.S. sales increased 15%  
International sales increased 10%



Note: Quarterly numbers may not add to year-to-date totals due to rounding.