

Eli Lilly and Company First Quarter 2014 Financial Review

April 24th, 2014

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Lilly
Answers That Matter.

Agenda

Introduction and Key Recent Events

- John Lechleiter, President, Chief Executive Officer and Chairman

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

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

Regulatory:

- FDA approved CYRAMZA™ for the treatment of advanced gastric cancer or gastro-esophageal junction adenocarcinoma, as a single-agent after prior fluoropyrimidine- or platinum-containing chemotherapy
- FDA issued a complete response letter for the empagliflozin NDA; continue to expect FDA action in 2014
- Europe's CHMP issued a positive opinion recommending approval of empagliflozin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes
- Submitted an NDA to the FDA for a combination tablet of empagliflozin and linagliptin (Tradjenta®) for the treatment of adults with type 2 diabetes
- FDA issued a complete response letter for the NDA of Humalog U-200 KwikPen; resubmission expected in H2 2014

Clinical:

- Announced that the REVEL trial, a Phase 3 study comparing ramucirumab plus docetaxel to placebo plus docetaxel as second-line treatment in patients with non-small cell lung cancer, met its primary endpoint of improved overall survival
- Presented Phase 1 results of our CDK 4/6 inhibitor, bemaciclib, in advanced metastatic breast cancer; Phase 3 program in breast cancer to begin in mid-2014
- Announced that AWARD-6, a Phase 3 study comparing once-weekly dulaglutide 1.5mg to once-daily liraglutide 1.8mg, met its primary endpoint of non-inferiority in the reduction of HbA1c from baseline at 26 weeks

Key Events Since the Last Earnings Call

Business Development/Other:

- Announced agreement to acquire Novartis Animal Health for approximately \$5.4 billion, creating the second-largest global animal health player
- Announced agreement to acquire Lohmann Animal Health, a global leader in the supply of poultry vaccines
- The U.S. District Court for the Southern District of Indiana upheld the vitamin dosage regimen patent for Alimta®
- The Regional Court of Düsseldorf, Germany ruled in Lilly's favor on the issue of infringement of the vitamin dosage regimen patent for Alimta
- Sanofi filed a lawsuit alleging Lilly's new insulin glargine product infringes certain Sanofi patents; filing of the lawsuit invokes a stay on FDA approval for a period of 30 months, or until a court finds in favor of Lilly, whichever is sooner
- U.S. patent protection for Evista® expired on March 2nd
- In an Actos® product liability case in Louisiana, a jury found in favor of the plaintiffs and awarded compensatory and punitive damages. Lilly disagrees with the verdict and intends to vigorously challenge this outcome. After this verdict was entered, Takeda notified Lilly that it was reserving its right to challenge its obligations to defend and indemnify Lilly with respect to this case only. Lilly believes it is entitled to full defense and indemnification of its losses and expenses related to this case and in all other U.S. cases.
- Repurchased \$55 million of stock in Q1 2014 under recently-authorized \$5 billion share repurchase program

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
 - Acquired in-process R&D charges and other income and expenses from business development activities

2014 Income Statement (Reported)

Millions; except per share data

	<u>Q1 2014</u>	<u>Q1 2013</u>	<u>Growth</u>
Total Revenue	4,683	5,602	(16)%
Gross Margin	73.9%	79.3%	(5.4)pp
Total Operating Expense*	2,626	3,022	(13)%
Operating Income	835	1,422	(41)%
Other Income / (Deductions)	56	529	(89)%
<i>Effective Tax Rate</i>	<i>18.3%</i>	<i>20.7%</i>	<i>(2.4)pp</i>
Net Income	<u>\$728</u>	<u>\$1,548</u>	(53)%
Diluted EPS	\$0.68	\$1.42	(52)%

* 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 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

	Q1 2014			
	<u>GAAP Reported</u>	<u>Adjustments</u>	<u>Non-GAAP Adjusted</u>	<u>Non-GAAP Adjusted Growth</u>
Total Revenue	\$4,683	-	\$4,683	(16)%
Gross Margin	73.9%	-	73.9%	(5.4)pp
Total Operating Expense	2,626	(31)	2,594	(14)%
Operating Income	835	31	866	(40)%
Other Income / (Expense)	56	-	56	66%
<i>Effective Tax Rate</i>	<i>18.3%</i>	<i>0.4%</i>	<i>18.7%</i>	<i>3.2pp</i>
Net Income	\$728	\$22	\$750	(40)%
Diluted EPS	\$0.68	\$0.02	\$0.70	(39)%

Note: Numbers may not add due to rounding.

EPS Reconciliation

	<u>Q1 2014</u>	<u>Q1 2013</u>	<u>Growth</u>
EPS (reported)	\$0.68	\$1.42	(52)%
Asset impairment, restructuring and other special charges	0.02	0.01	
Income from the transfer of exenatide commercial rights	<u>-</u>	<u>(0.29)</u>	<u></u>
EPS (non-GAAP)	<u><u>\$0.70</u></u>	<u><u>\$1.14</u></u>	<u><u>(39)%</u></u>

Note: Numbers may not add due to rounding.

Effect of Price/Rate/Volume on Revenue

	Q1 2014					
	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
Pharmaceuticals						
U.S.	\$1,776.7	(11)%	-	(26)%	(37)%	(37)%
ACE*	1,185.0	(2)%	1%	1%	(0)%	(1)%
Japan	537.2	(4)%	(17)%	37%	16%	33%
Emerging Markets	656.8	2%	(6)%	13%	8%	15%
Total Pharma	4,155.7	(7)%	(2)%	(10)%	(19)%	(16)%
Animal Health	527.4	4%	(1)%	3%	6%	7%
Total Revenue	\$4,683.1	(6)%	(2)%	(8)%	(16)%	(14)%

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 2014 Results



Year-on-Year Growth

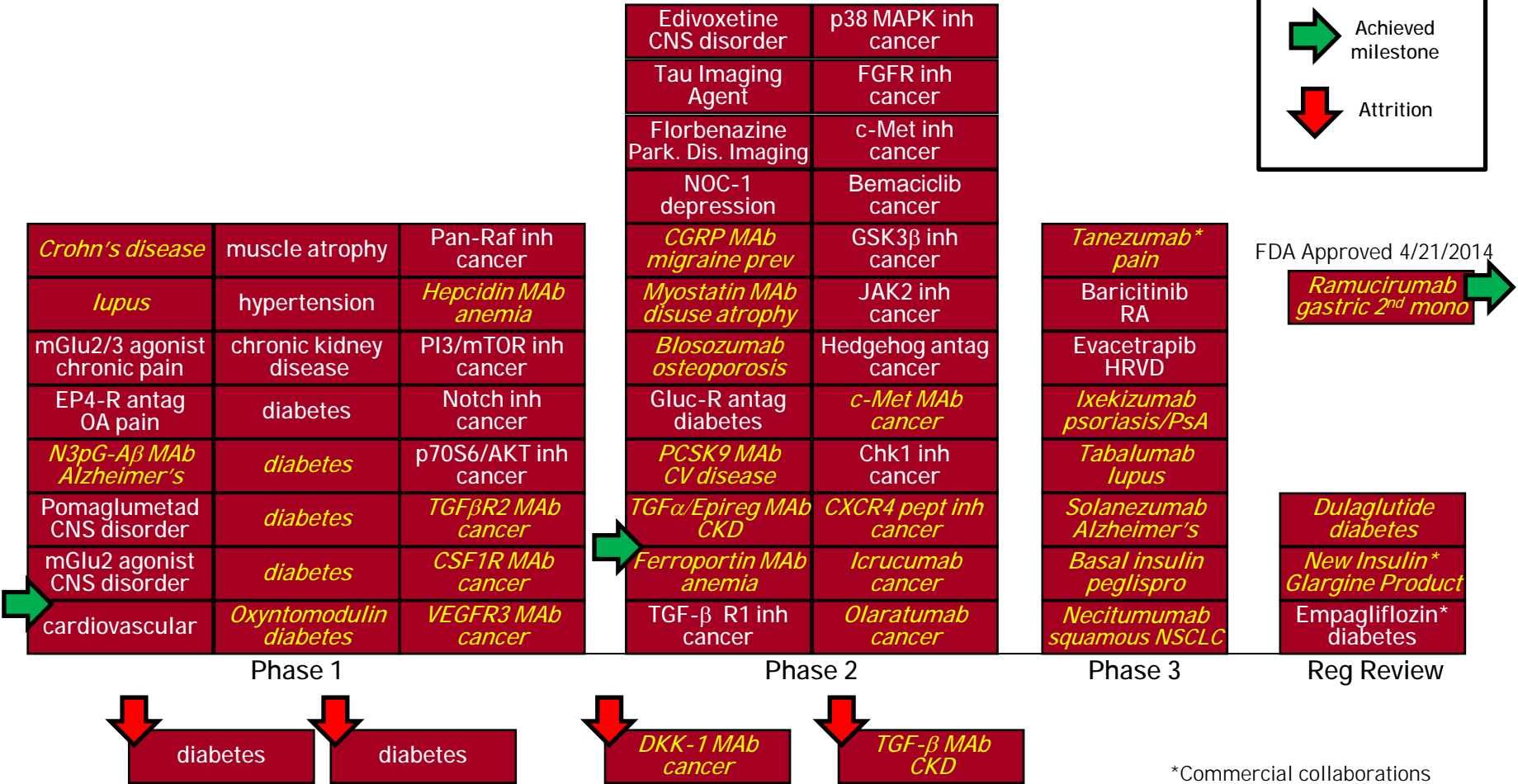
	Q1 2014	
	With FX	w/o FX
Total Revenue	(16)%	(14)%
Cost of Sales	6%	(1)%
Gross Margin	(22)%	(18)%
Reported Operating Expense	(13)%	(12)%
Reported Operating Income	(41)%	(30)%
Reported EPS	(52)%	(44)%
Non-GAAP Operating Expense	(14)%	(12)%
Non-GAAP Operating Income	(40)%	(29)%
Non-GAAP EPS	(39)%	(29)%

Lilly NME Pipeline

April 21, 2014

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

Movement since January 23, 2014
 Achieved milestone
 Attrition



*Commercial collaborations

Key Events in 2014

Potential Phase 3 initiations:

- CDK4/6 (bemaciclib) for cancer
- Blosozumab for osteoporosis

Potential Phase 3 data internal readouts:

- Basal insulin peglispro for type 1 and type 2 diabetes
- 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 ²
- New insulin glargine product for type 1 and type 2 diabetes ¹ (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) ²
- Ramucirumab for second-line hepatocellular cancer (REACH)

Potential regulatory submissions:

- Basal insulin peglispro for type 1 and type 2 diabetes
- ✓+ Empagliflozin + linagliptin FDC for type 2 diabetes ¹
- Empagliflozin + metformin IR FDC for type 2 diabetes ¹
- 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 ¹
- Dulaglutide for type 2 diabetes
- ✓+ Ramucirumab as monotherapy for second-line gastric cancer
- New insulin glargine product ¹

Other:

- ✓+ Ruling in Alimta District Court trial for method-of-use patent
- ✓ Evista U.S. patent expiration (March)
- Cymbalta® EU data package exclusivity expiration
- Partial clinical hold resolution for tanezumab ³ (now expected in 2015)

¹ in collaboration with Boehringer Ingelheim

² detailed data at future medical meetings

³ in collaboration with Pfizer

2014 Guidance

	<u>Prior</u>	<u>Current</u>
Total Revenue	\$19.2 to \$19.8 billion	\$19.4 to \$20.0 billion
Gross Margin % of Revenue	Approx. 74%	Approx. 73%
Mktg, Selling & Admin.	\$6.2 to \$6.5 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. 20%	Approx. 19%
Minimum Net Income	\$3 billion	\$2.9 billion
Earnings per Share (non-GAAP)	\$2.72 - \$2.80	\$2.72 - \$2.80
Earnings per Share (GAAP)	\$2.72 - \$2.80	\$2.70 - \$2.78
Minimum Operating Cash Flow	\$4 billion	\$4 billion
Capital Expenditures	Approx. \$1.3 billion	Approx. \$1.3 billion

Earnings Per Share Expectations

	<u>2014</u>	<u>2013</u>	<u>Growth</u>
EPS (reported)	\$2.70-\$2.78	\$4.32	(36)%-(38)%
Acquired in-process research and development charge associated with CGRP antibody acquisition	-	0.03	
Asset impairment, restructuring and other special charges	0.02	0.08	
Income related to termination of the exenatide collaboration with Amylin	-	(0.29)	
EPS (non-GAAP)	<u>\$2.72-\$2.80</u>	<u>\$4.15</u>	<u>(33)%-(34)%</u>

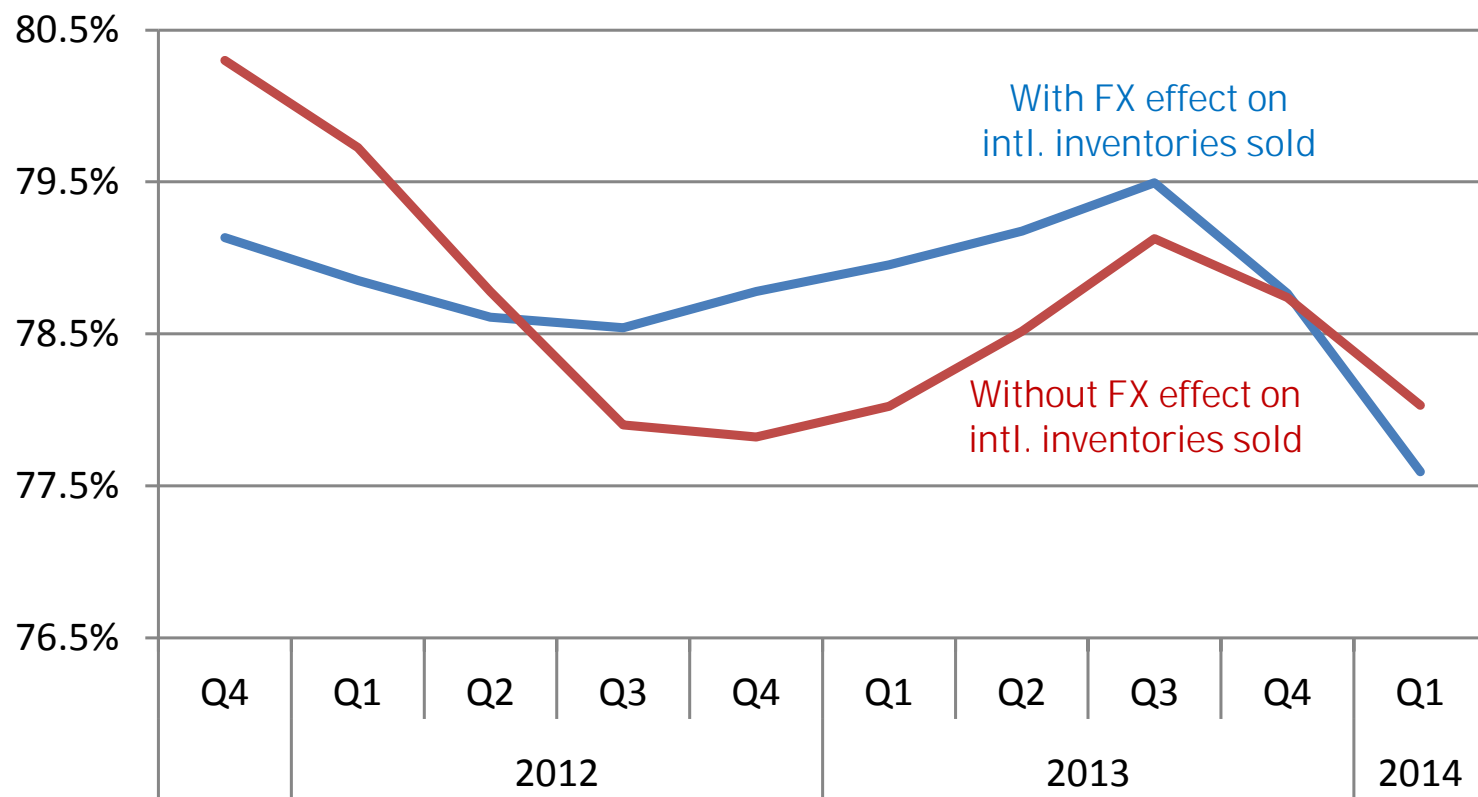
Note: Numbers may not add due to rounding.

Q1 2014 Summary

- **Significant progress implementing our strategy:**
 - Advancing our pipeline
 - Driving strong performance of our marketed brands and key growth areas
 - Increasing productivity and reducing our cost structure
- **Effect of patent expirations in-line with expectations**
- **Q1 financial performance places us on track to meet full-year guidance:**
 - Growth engines continue to perform well
 - Operating expenses declined 14%
- **Diligent preparation has positioned Lilly to continue to:**
 - invest in our pipeline, including new product launches
 - pay the dividend at least at its current level
 - recapitalize our physical asset base
 - reinvest in our business through opportunistic business development
 - return excess cash to shareholders through share repurchases

Supplementary Slides

Gross Margin % - Moving Annual Total



Individual quarter GM% of Revenue:

with FX effect on intl inv sold	78.1%	78.6%	79.5%	77.9%	79.0%	79.3%	80.3%	79.2%	76.1%	73.9%
w/o FX effect on intl inv sold	78.8%	78.3%	77.9%	76.4%	78.5%	79.1%	79.9%	79.0%	77.0%	75.8%

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
Non-GAAP	1.14	1.16	1.11	0.74	4.15	0.70				
Reported	1.42	1.11	1.11	0.67	4.32	0.68				

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 April 24, 2014.

2014 Income Statement Notes

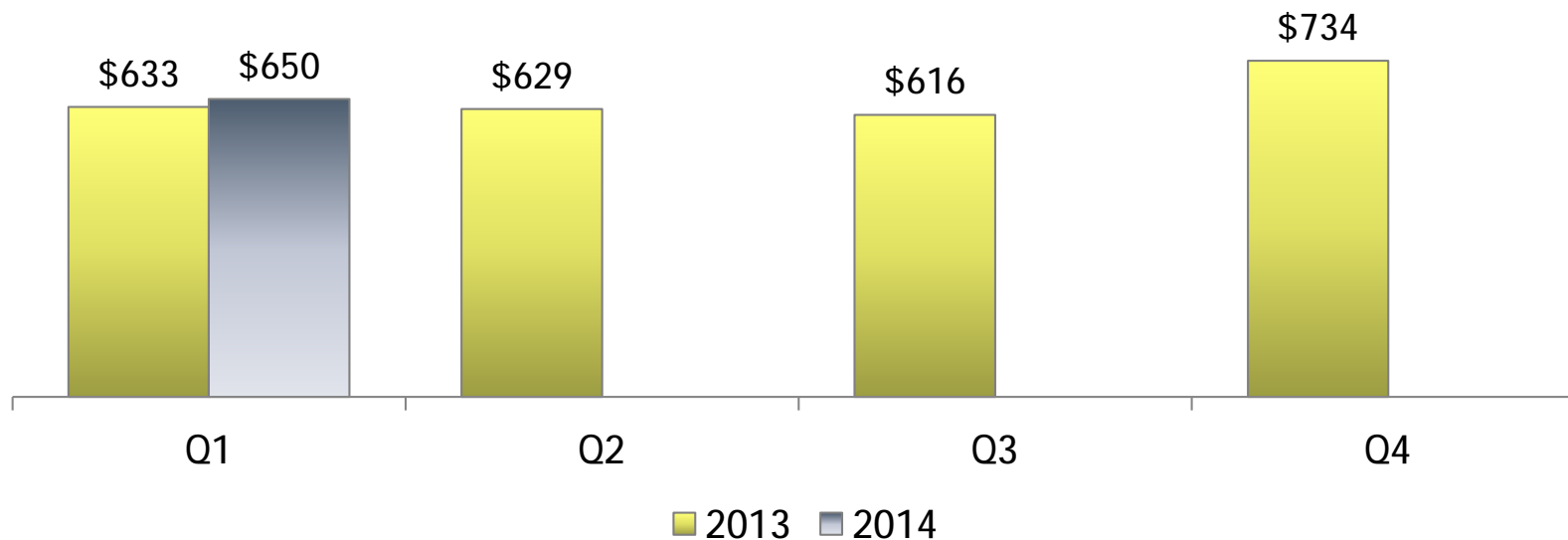
Notes:

- 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 first-quarter 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 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.

Q1 Humalog[®] Sales Increased 3%

Millions

U.S. sales decreased 1%
International sales increased 8%

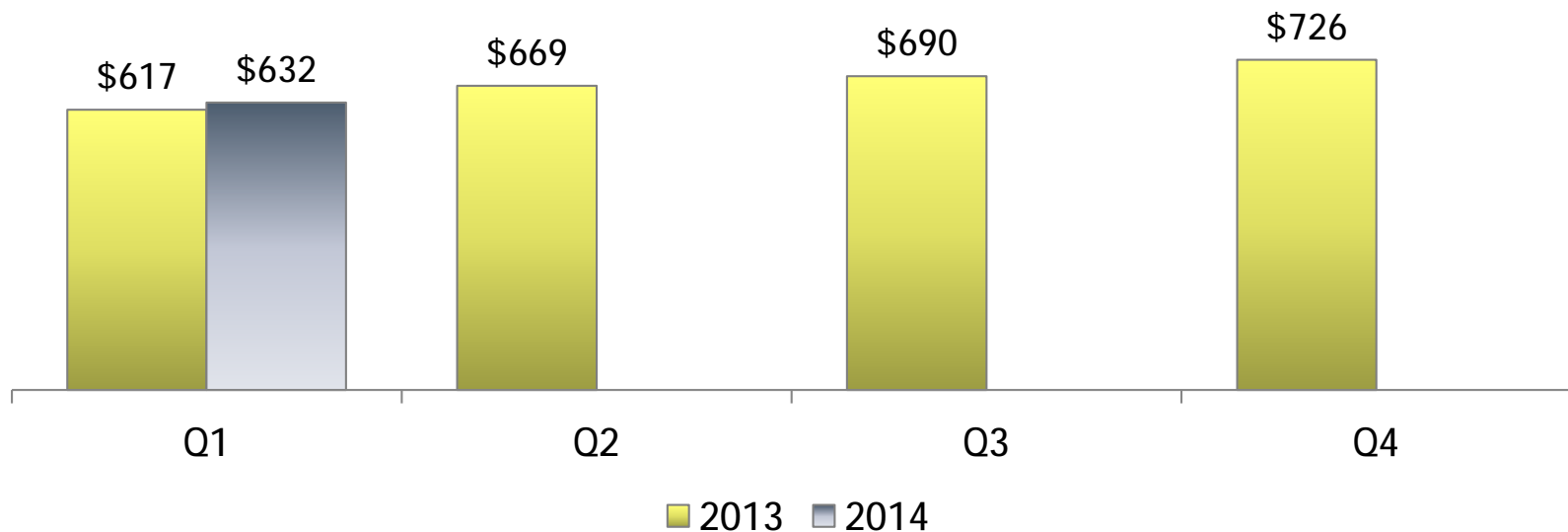


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Alimta Sales Increased 2%

Millions

U.S. sales decreased 6%
International sales increased 9%

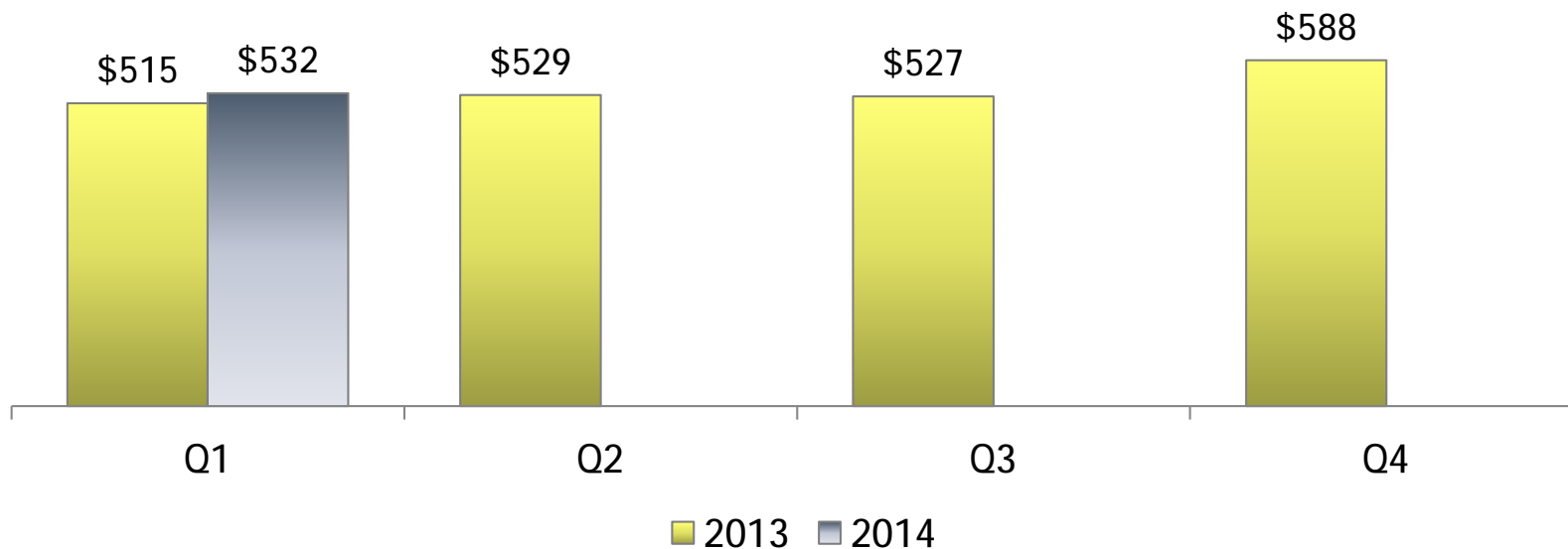


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Cialis[®] Sales Increased 3%

Millions

U.S. sales decreased 4%
International sales increased 9%

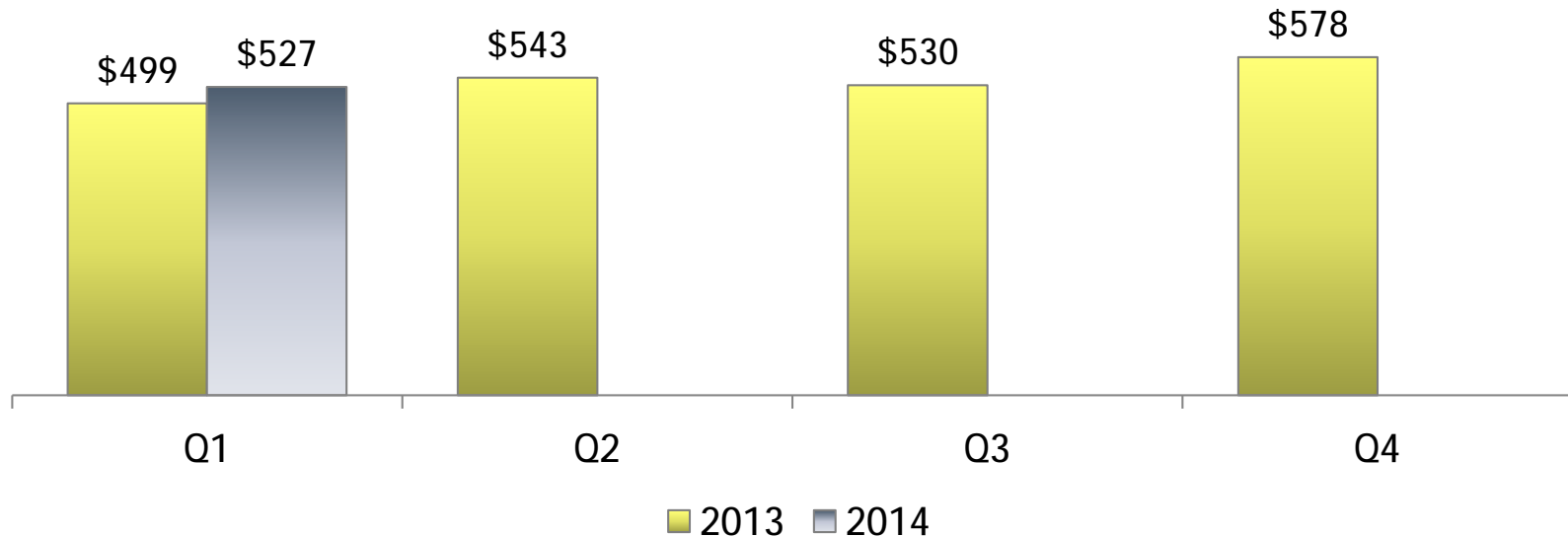


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Animal Health Sales Increased 6%

Millions

U.S. sales increased 4%
International sales increased 8%

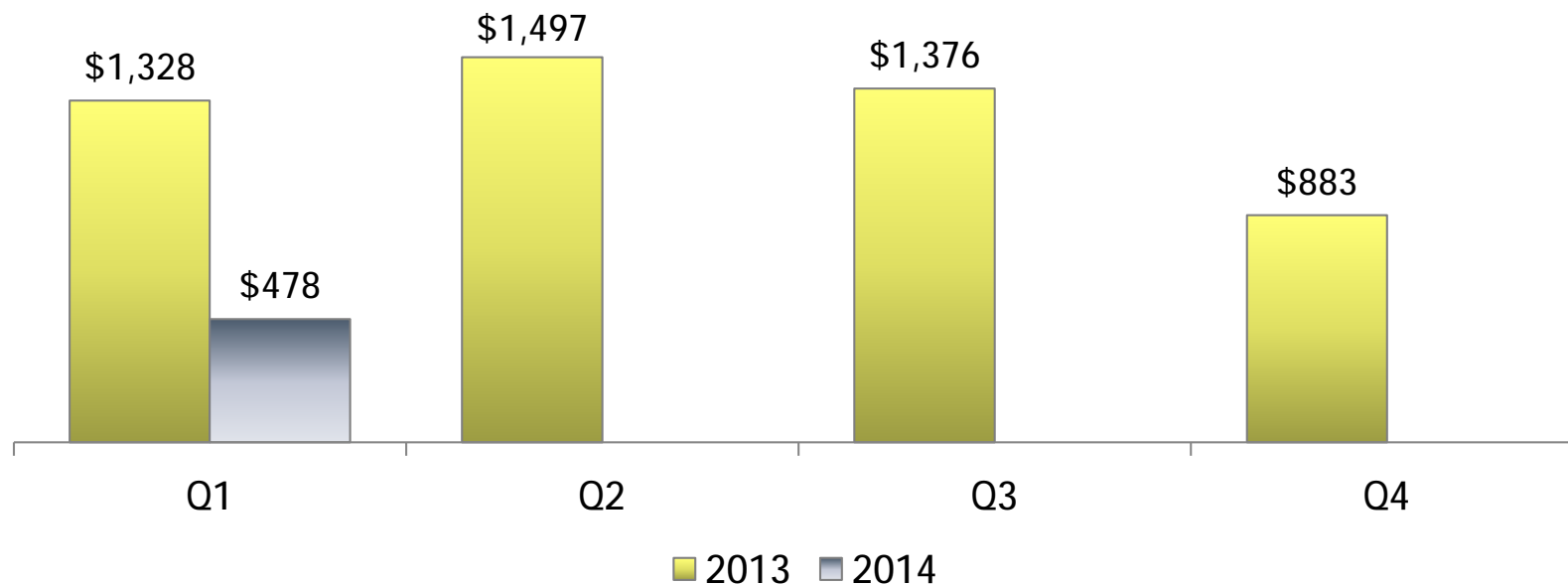


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Cymbalta Sales Decreased 64%

Millions

U.S. sales decreased 83%
International sales increased 11%

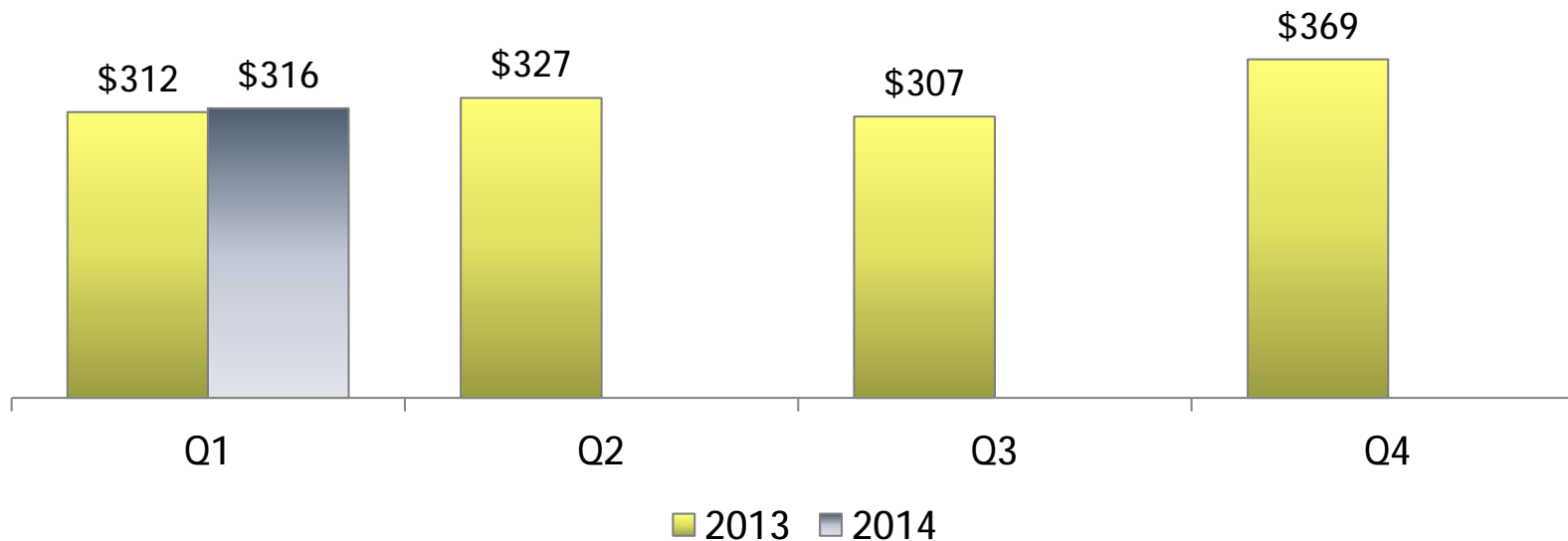


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Humulin[®] Sales Increased 1%

Millions

U.S. sales decreased 5%
International sales increased 9%

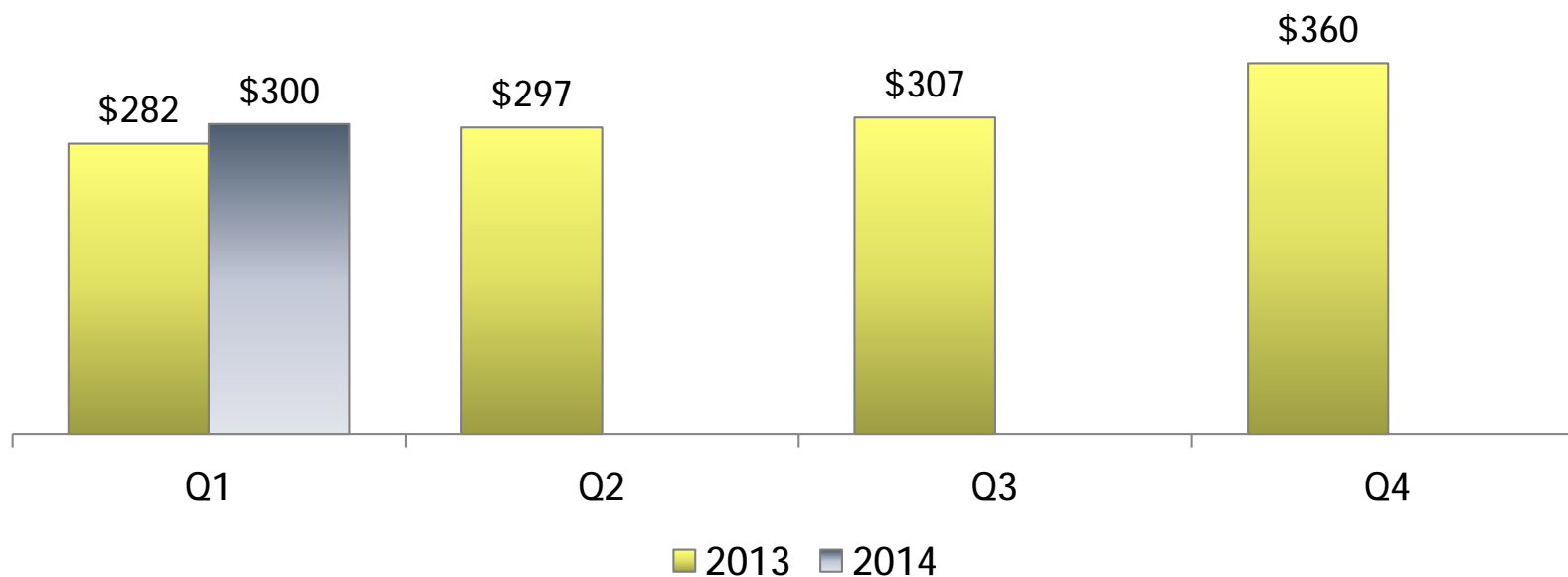


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Forteo[®] Sales Increased 7%

Millions

U.S. sales decreased 10%
International sales increased 17%

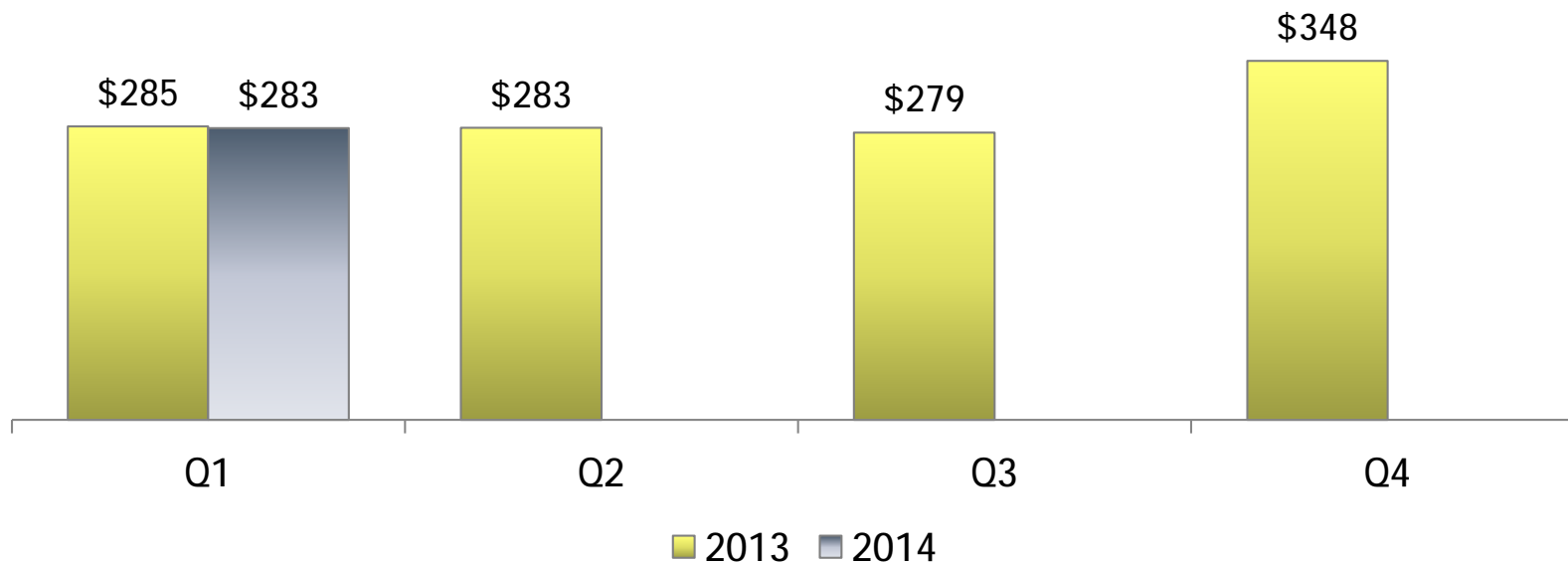


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Zyprexa[®] Sales Decreased 1%

Millions

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

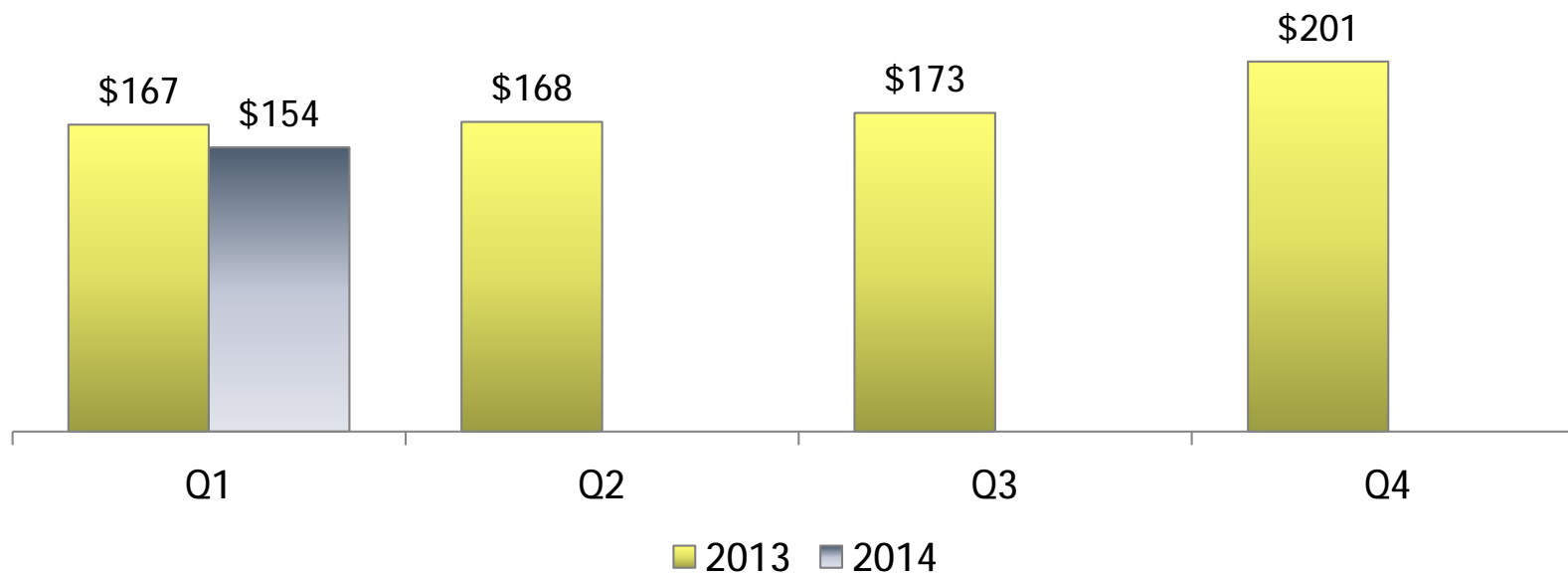


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Strattera[®] Sales Decreased 7%

Millions

U.S. sales decreased 21%
International sales increased 17%

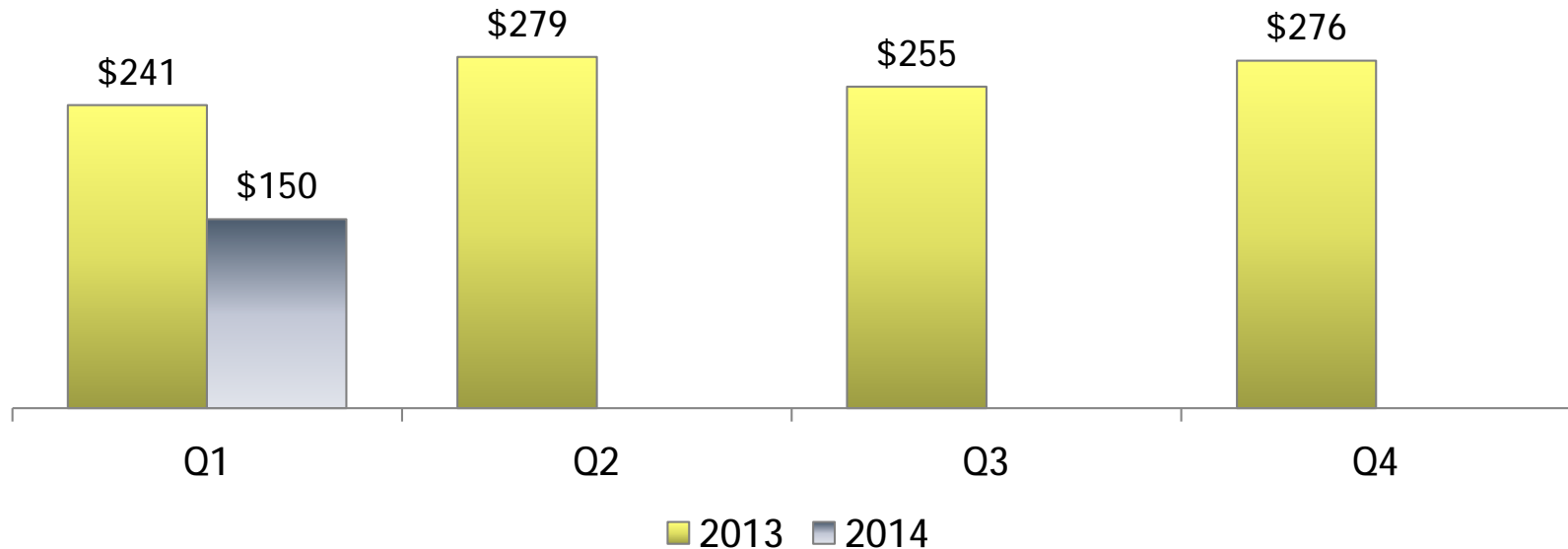


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Evista Sales Decreased 38%

Millions

U.S. sales decreased 43%
International sales decreased 25%

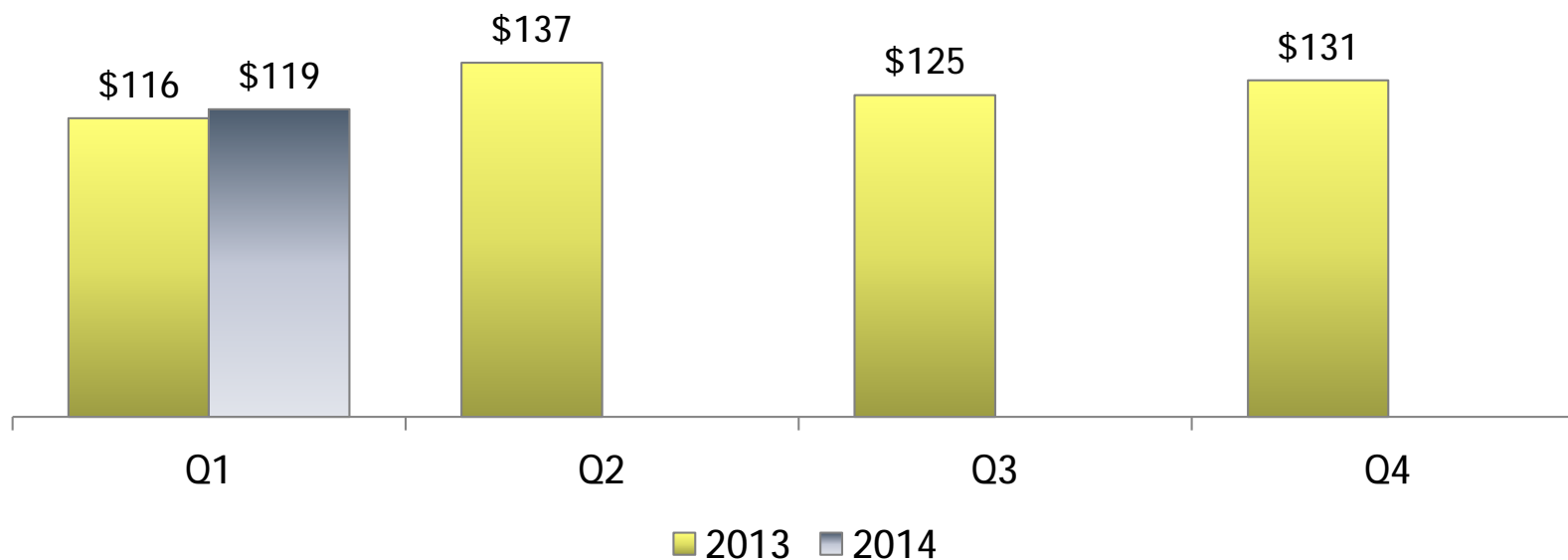


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

Q1 Effient[®] Sales Increased 3%

Millions

U.S. sales increased 5%
International sales decreased 2%



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