

# Eli Lilly and Company Fourth Quarter 2012 Financial Review

January 29<sup>th</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
- Ilissa Rassner, Director, Investor Relations

## Key Future Events, Oncology Update, Financial Guidance and Summary

- Susan Mahony, Senior Vice President and President, Lilly Oncology
- 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

### Regulatory:

- Received European Commission approval for:
  - Cialis<sup>®</sup> for once-daily use for the treatment of the signs and symptoms of BPH;
  - Amyvid<sup>™</sup> for the PET imaging of beta-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive impairment; and
  - Along with our partner Boehringer Ingelheim, Trajenta<sup>®</sup> for use in combination with insulin in adults with type 2 diabetes.
- Received regulatory approval in Japan for Erbitux<sup>®</sup> for the treatment of patients with head and neck cancer;
- Received regulatory approval in Canada for Erbitux for the treatment of patients with first-line EGFR-expressing metastatic colorectal cancer.

### Clinical:

- Presented additional data from the EXPEDITION studies at CTAD;
- Announced that we plan to conduct an additional Phase 3 study of solanezumab in patients with mild Alzheimer's disease;
- Presented Phase 2 data in rheumatoid arthritis at ACR for tabalumab and, along with Incyte, for baricitinib;
- Announced that one of three Phase 3 trials of tabalumab for the treatment of rheumatoid arthritis would be discontinued to due insufficient efficacy seen at an interim analysis;
- Along with Boehringer Ingelheim, announced that primary endpoints were met in four Phase 3 trials of empagliflozin for the treatment of patients with type 2 diabetes.

# Beyond the Quarterly Financial Results

## Key events since the last earnings call (cont.)

### **Business Development:**

- Announced that Lilly will assume sole worldwide development and commercialization rights to our novel basal insulin analog;
- Announced that Lilly will assume sole North American and Japanese development and commercialization rights for necitumumab.

### **Other:**

- Reached agreement with the SEC to settle issues related to compliance with the U.S. Foreign Corrupt Practices Act;
- Announced that Lilly will discontinue manufacturing operations in Mexico City by mid-2015;
- Completed \$419 million remaining on existing share repurchase program;
- Authorized a new \$1.5 billion share repurchase program. Completed \$400 million of this new plan in 2012 and anticipate completing the remaining \$1.1 billion during 2013.

# Comparison Measures

Results shown two ways to aid analysis

## “Reported” results

- Include all financial results as reported in accordance with GAAP

## “Non-GAAP” results

- Start with “Reported” results
- Include adjustments for items such as:
  - Restructuring charges, asset impairments and special charges
  - In-process R&D charges from business development activities

# 2012 Income Statement (Non-GAAP)

Millions; except per share data

	<u>Q4 2012</u>	<u>Growth</u>	<u>Year</u>	<u>Growth</u>
Total Revenue	\$5,957	(1)%	\$22,603	(7)%
Gross Margin Percent	79.0%	0.9pp	78.8%	(0.3)pp
Total Operating Expense*	3,441	(1)%	12,792	(1)%
Operating Income	1,268	3%	5,015	(21)%
Other Income / (Deductions)	(52)	94%	(114)	(36)%
<i>Effective Tax Rate</i>	<i>22.3%</i>	<i>2.4pp</i>	<i>22.8%</i>	<i>2.8pp</i>
Net Income	\$945	(2)%	\$3,784	(23)%
Diluted EPS	\$0.85	(2)%	\$3.39	(23)%

\* Includes Research and Development expense and Selling, Marketing and Administrative expense.

# 2012 Income Statement (Reported)

Millions; except per share data

	<u>Q4 2012</u>	<u>Growth</u>	<u>Year</u>	<u>Growth</u>
Total Revenue	\$5,957	(1)%	\$22,603	(7)%
Gross Margin Percent	79.0%	0.9pp	78.8%	(0.3)pp
Total Operating Expense*	3,645	(0)%	13,073	(5)%
Operating Income	1,064	(0)%	4,734	(14)%
Other Income / (Deductions)	(52)	94%	674	n.m.
<i>Effective Tax Rate</i>	<i>18.3%</i>	<i>0.7pp</i>	<i>24.4%</i>	<i>5.7pp</i>
Net Income	\$827	(4)%	\$4,089	(6)%
Diluted EPS	\$0.74	(4)%	\$3.66	(6)%

\* Includes Research and Development expense, Selling, Marketing and Administrative expense and other charges.

Note: See slide 21 for a complete list of charges.

# EPS Reconciliation

	<u>Q4 2012</u>	<u>Q4 2011</u>	<u>Growth</u>	<u>Year 12</u>	<u>Year 11</u>	<u>Growth</u>
<b>EPS (reported)</b>	<b>\$0.74</b>	<b>\$0.77</b>	<b>(4)%</b>	<b>\$3.66</b>	<b>\$3.90</b>	<b>(6)%</b>
In-process research and development charges associated with Boehringer Ingelheim collaboration	-	-		-	0.23	
Asset impairment, restructuring and other special charges	0.11	0.10		0.16	0.29	
Income from early payment of Amylin financial obligations	-	-		(0.43)	-	
<b>EPS (non-GAAP)</b>	<b><u>\$0.85</u></b>	<b><u>\$0.87</u></b>	<b><u>(2)%</u></b>	<b><u>\$3.39</u></b>	<b><u>\$4.41</u></b>	<b><u>(23)%</u></b>

Note: Numbers may not add due to rounding.

# Effect of Price/Rate/Volume on Revenue

	Q4 2012				
	Amount	Price	FX Rate	Volume	Total
Pharmaceuticals					
U.S.	\$2,802.7	7%	-	(10)%	(3)%
Europe	1,010.2	1%	(4)%	(3)%	(7)%
Japan	603.8	(10)%	(4)%	16%	2%
ROW	829.1	(2)%	(0)%	1%	(1)%
Total Pharma	5,245.8	3%	(1)%	(4)%	(3)%
Animal Health	554.1	(0)%	(1)%	19%	18%
Net Product Sales	5,799.9	2%	(1)%	(2)%	(1)%
Collab/Other Revenue	157.4	0%	-	(17)%	(17)%
Total Revenue	\$5,957.3	2%	(1)%	(3)%	(1)%

	Full Year 2012				
	Amount	Price	FX Rate	Volume	Total
Pharmaceuticals					
U.S.	\$10,650.0	8%	-	(16)%	(8)%
Europe	3,920.9	(6)%	(6)%	(10)%	(22)%
Japan	2,194.9	(7)%	0%	14%	7%
ROW	3,168.1	(2)%	(3)%	0%	(5)%
Total Pharma	19,933.9	2%	(2)%	(9)%	(9)%
Animal Health	2,036.5	2%	(2)%	21%	21%
Net Product Sales	21,970.4	2%	(2)%	(7)%	(7)%
Collab/Other Revenue	633.0	0%	-	(7)%	(7)%
Total Revenue	\$22,603.4	2%	(2)%	(7)%	(7)%

Note: Numbers may not add due to rounding.

# Effect of Foreign Exchange on 2012 Results (Non-GAAP)

## Year-on-Year Growth

	Q4 2012		2012	
	With FX	w/o FX	With FX	w/o FX
Total Revenue	(1)%	(0)%	(7)%	(5)%
Cost of Sales	(6)%	1%	(5)%	7%
Gross Margin	(0)%	(1)%	(7)%	(8)%
Operating Expense <i>(R&amp;D plus SG&amp;A)</i>	(1)%	(1)%	(1)%	0%
Operating Income	3%	(1)%	(21)%	(26)%
EPS	(2)%	(6)%	(23)%	(29)%

# Effect of Foreign Exchange on 2012 Results (Reported)

## Year-on-Year Growth

	Q4 2012		2012	
	With FX	w/o FX	With FX	w/o FX
Total Revenue	(1)%	(0)%	(7)%	(5)%
Cost of Sales	(6)%	1%	(5)%	7%
Gross Margin	(0)%	(1)%	(7)%	(8)%
Operating Expense <i>(R&amp;D, SG&amp;A and sign. items)</i>	(0)%	0%	(5)%	(3)%
Operating Income	(0)%	(4)%	(14)%	(21)%
EPS	(4)%	(8)%	(6)%	(13)%



# Key Events in 2012

Red text – potential 2012 data disclosure

## Potential U.S. regulatory actions:

- ✓+ • Linagliptin plus metformin fixed-dose combination for type 2 diabetes <sup>1</sup>
- ✓+ • Alimta<sup>®</sup> continuation maintenance (PARAMOUNT) in nonsquamous non-small cell lung cancer
- ✓- • Erbitux for 1st-line non-small cell lung cancer
- ✓+ • Erbitux for 1st-line metastatic colorectal cancer
- ✓+ • Amyvid for the detection of beta amyloid plaques
- ✓+ • Cymbalta<sup>®</sup> U.S. pediatric exclusivity

## Potential Phase 3 trial initiation:

- ✓+ • Evacetrapib (CETP inhibitor)
- ✓+ • Baricitinib (JAK1/JAK2 inhibitor)

✓ denotes that an event has occurred

<sup>1</sup> in collaboration with Boehringer Ingelheim

<sup>2</sup> external data disclosure expected in 2013

## Data disclosures, trials completing in '12:

- ✓-+ • Solanezumab Phase 3 trials in Alzheimer's (ANA in Oct)
- ✓- • Effient<sup>®</sup> Phase 3 trial in ACS-medical management (ESC in August)
- ✓+ • Alimta Phase 3 PARAMOUNT trial (ASCO in June)
- ✓- • Alimta Phase 3 POINTBREAK trial
- ✓+ • Initial empagliflozin Phase 3 trials in type 2 diabetes <sup>1, 2</sup>
- ✓+ • Initial dulaglutide Phase 3 trials in type 2 diabetes <sup>2</sup>
- ✓+ • Dulaglutide Phase 2 hemodynamic trial (ASH in May)
- ✓+ • Baricitinib Phase 2b trial in RA (12-week data at EULAR in June, 24-week data at ACR in November)
- ✓- • Pomaglumetad methionil pivotal trials for monotherapy in acute schizophrenia
- ✓+ • Ramucirumab Phase 3 gastric monotherapy trial

## Data disclosures, trials completed in '11:

- ✓+ • Ixekizumab Phase 2 data in psoriasis (data published in NEJM in March)
- ✓+ • Novel basal insulin analog Phase 2 data in type 1 and type 2 diabetes (ADA in June)

# 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 novel basal insulin analog 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**
- **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
- 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)

<sup>1</sup> in collaboration with Boehringer Ingelheim

# 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. 78%	Approx. 78%
Mktg, Selling & Admin.	\$7.1 to \$7.4 billion	\$7.1 to \$7.4 billion
Research & Development	\$5.2 to \$5.5 billion	\$5.2 to \$5.5 billion
Other Income/(Expense) (non-GAAP)	\$(150) - \$0 million	\$(150) - \$0 million
Other Income/(Expense) (GAAP)	\$340 - \$490 million	\$340 - \$490 million
Tax Rate (non-GAAP)	Approx. 21%	Approx. 19.5%
Tax Rate (GAAP)	Approx. 22.5%	Approx. 21%
Earnings per Share (non-GAAP)	\$3.75 - \$3.90	\$3.82 - \$3.97
Earnings per Share (GAAP)	\$4.03 - \$4.18	\$4.10 - \$4.25
Capital Expenditures	Approx. \$900 million	Approx. \$900 million

Note: 2013 guidance has been updated to include the discrete benefit related to 2012 from the American Taxpayer Relief Act of 2012. For a complete reconciliation to reported guidance, see slide 17 of this presentation and our earnings press release dated January 29, 2012.

# Earnings Per Share Expectations

	<u>2013</u>	<u>2012</u>	<u>Growth</u>
<b>EPS (reported)</b>	<b>\$4.10-\$4.25</b>	<b>\$3.66</b>	<b>12%-16%</b>
Asset impairment, restructuring and other special charges	-	0.16	
Income from early payment of Amylin revenue-sharing obligation	<u>(0.28)</u>	<u>(0.43)</u>	
<b>EPS (non-GAAP)</b>	<b><u><u>\$3.82-\$3.97</u></u></b>	<b><u><u>\$3.39</u></u></b>	<b><u><u>13%-17%</u></u></b>

Note: Numbers may not add due to rounding.

# 2012 Summary

## Continued implementation of our strategy:

- Replenishing and advancing our pipeline
- Driving strong performance of our marketed brands and key growth areas
- Increasing productivity and reducing our cost structure

## Financial Performance:

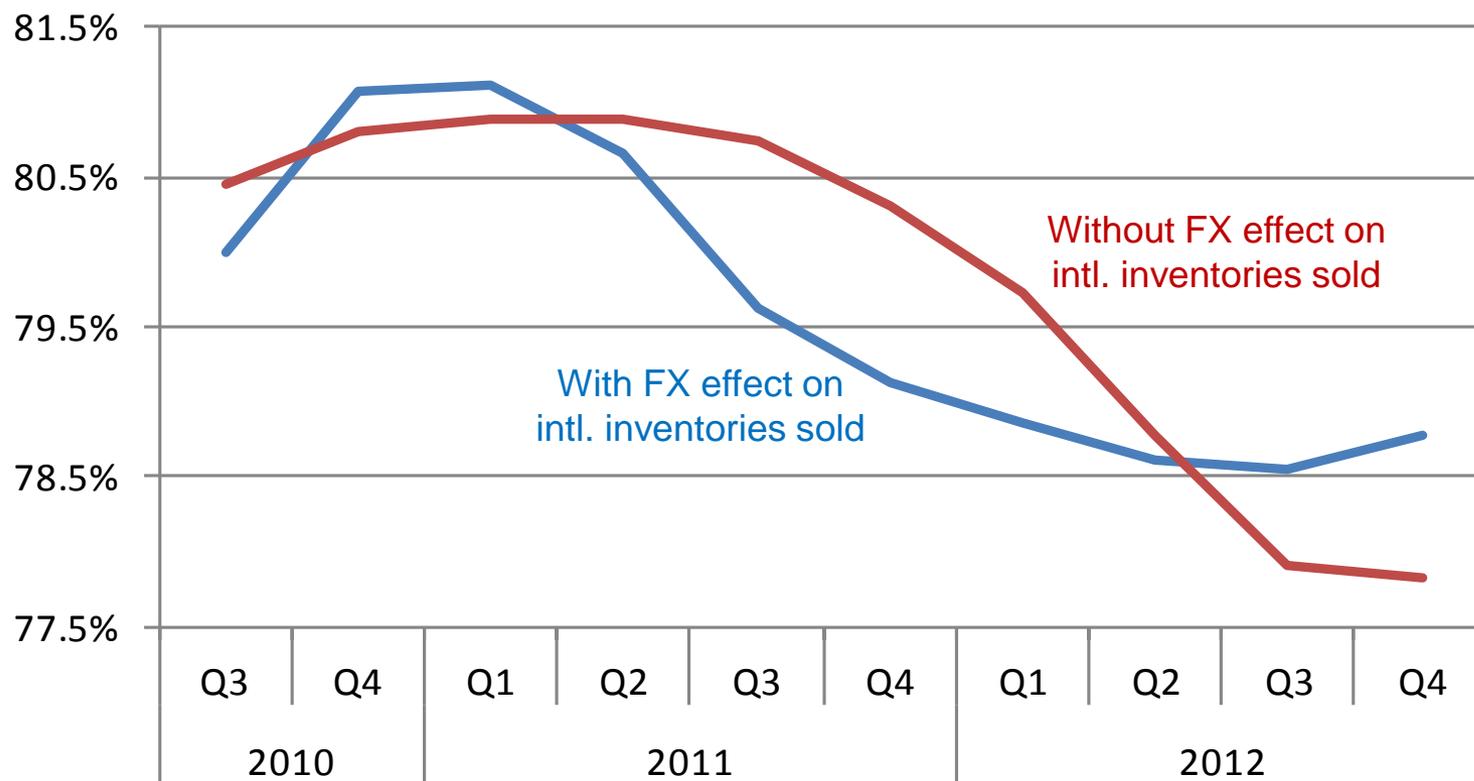
- Generated \$5 billion of operating cash flow, easily covering capital expenditures of \$0.9 billion and dividend payment of roughly \$2.2 billion
- Initiated \$1.5 billion share repurchase program
- We remain on track to meet, or exceed, our mid-term financial projections
  - At least \$20 billion in revenue
  - At least \$3 billion in net income
  - At least \$4 billion in operating cash flow

## Pipeline Performance:

- 13 molecules in Phase 3 and 23 molecules in Phase 2
- Advanced 12 molecules into Phase 1, eight into Phase 2, two into Phase 3 and launched Amyvid in the U.S.
- We now have the most robust mid- to late-stage pipeline in our history

# Supplementary Slides

# Gross Margin % - Moving Annual Total



Individual quarter GM% of Revenue:

with FX effect on intl inv sold	82.5%	80.1%	79.8%	80.4%	78.2%	78.1%	78.6%	79.5%	77.9%	79.0%
w/o FX effect on intl inv sold	80.6%	80.6%	80.7%	81.7%	80.0%	78.8%	78.3%	77.9%	76.4%	78.5%

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.

# 2012 Income Statement Notes

## Notes:

- The fourth-quarter 2012 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges totaling \$204.0 million (pretax), or \$0.11 per share (after-tax), primarily related to an intangible asset impairment for liprotamase and restructuring to reduce the company's cost structure and global workforce.
- The full-year 2012 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges of \$281.1 million (pretax), or \$0.16 per share (after-tax), primarily related to an intangible asset impairment for liprotamase, restructuring to reduce the company's cost structure and global workforce, the asset impairment of a product delivery device platform, and the withdrawal of Xigris<sup>®</sup>. Additionally, the full-year 2012 financial statements have been adjusted for income of \$787.8 million (pretax), or \$0.43 per share (after-tax) related to the early payment of the exenatide revenue-sharing obligation.
- The fourth-quarter 2011 financial statements have been adjusted to eliminate asset impairments, restructuring and other special charges totaling \$167.6 million (pretax), or \$0.10 per share (after-tax), primarily related to a special charge for the withdrawal of Xigris and restructuring to reduce the company's cost structure and global workforce.
- The full-year 2011 financial statements have been adjusted to eliminate asset impairments, restructuring, and other special charges of \$401.4 million (pretax), or \$0.29 per share (after-tax), primarily related to severance costs and a special charge for the withdrawal of Xigris. Additionally, the full-year 2011 financial statements have been adjusted for an acquired in-process research and development charge of \$388.0 million (pretax), or \$0.23 per share (after-tax), associated with the Boehringer Ingelheim diabetes collaboration. (Numbers do not add due to rounding.)

# Comparative EPS Summary 2011/2012

	1Q11	2Q11	3Q11	4Q11	2011	1Q12	2Q12	3Q12	4Q12	2012
Non-GAAP	1.24	1.18	1.13	0.87	4.41	0.92	0.83	0.79	0.85	3.39
Reported	0.95	1.07	1.11	0.77	3.90	0.91	0.83	1.18	0.74	3.66

Note: Numbers may not add due to rounding.

For a complete reconciliation to reported earnings, see slide 9 of this presentation and our earnings press release dated January 29, 2013.

# Other Income/(Deductions) – non-GAAP

Millions

	<u>Q4 2012</u>	<u>Q4 2011</u>	<u>YTD 2012</u>	<u>YTD 2011</u>
- Interest Expense	\$(42.6)	\$(50.0)	\$(177.8)	\$(186.0)
- Interest Income	26.1	24.4	105.0	79.9
Interest, net	(16.5)	(25.6)	(72.8)	(106.1)
- FX Gains / (Losses)	0.1	(4.7)	(26.0)	(6.2)
- Gains / (Losses) on Equity Investments	2.2	10.8	45.5	99.0
- Miscellaneous Income / (Loss)	(37.8)	(7.3)	(60.5)	(165.7)
Other Income, net	(35.5)	(1.2)	(41.0)	(72.9)
Net Other Income (Loss)	<u>\$(52.0)</u>	<u>\$(26.8)</u>	<u>\$(113.8)</u>	<u>\$(179.0)</u>

Note: Numbers may not add due to rounding.

# Other Income/(Deductions) – GAAP

Millions

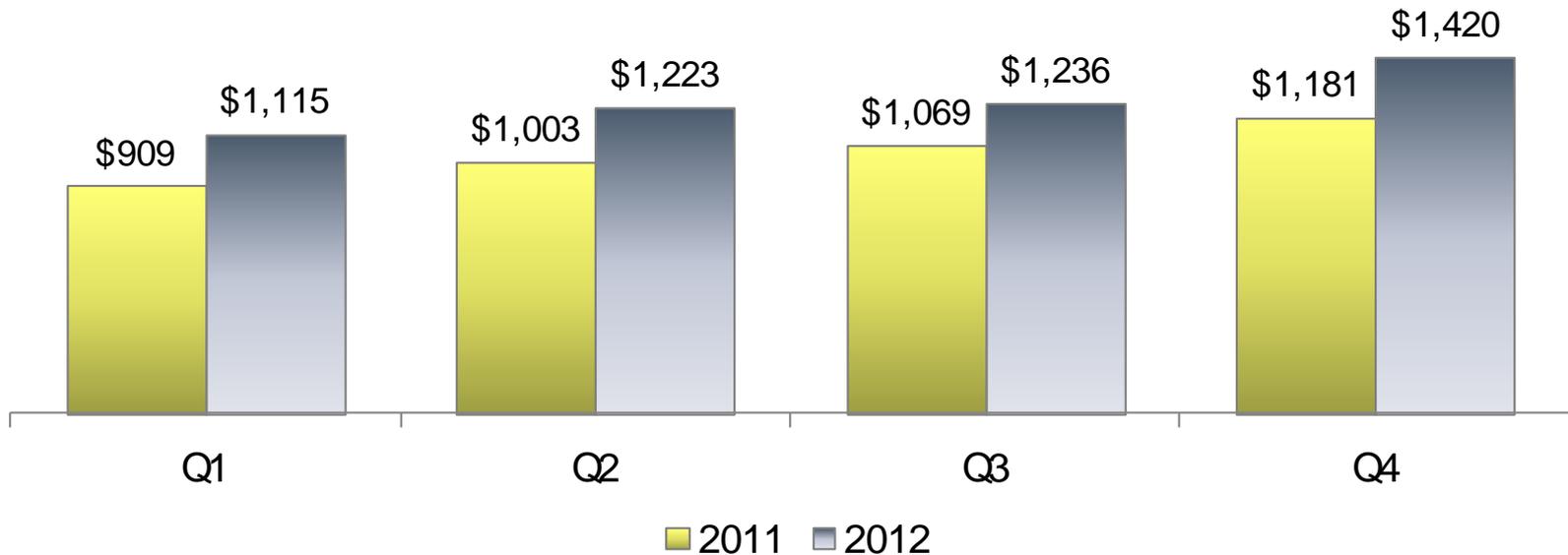
	<u>Q4 2012</u>	<u>Q4 2011</u>	<u>YTD 2012</u>	<u>YTD 2011</u>
- Interest Expense	\$(42.6)	\$(50.0)	\$(177.8)	\$(186.0)
- Interest Income	26.1	24.4	105.0	79.9
Interest, net	(16.5)	(25.6)	(72.8)	(106.1)
- FX Gains / (Losses)	0.1	(4.7)	(26.0)	(6.2)
- Gains / (Losses) on Equity Investments	2.2	10.8	45.5	99.0
- Miscellaneous Income / (Loss)	(37.8)	(7.3)	727.3	(165.7)
Other Income, net	<u>(35.5)</u>	<u>(1.2)</u>	<u>746.8</u>	<u>(72.9)</u>
Net Other Income (Loss)	<u>\$(52.0)</u>	<u>\$(26.8)</u>	<u>\$674.0</u>	<u>\$(179.0)</u>

Note: Numbers may not add due to rounding.

# Q4 Cymbalta Sales Increased 20%

Millions

U.S. sales increased 25%  
International sales increased 5%

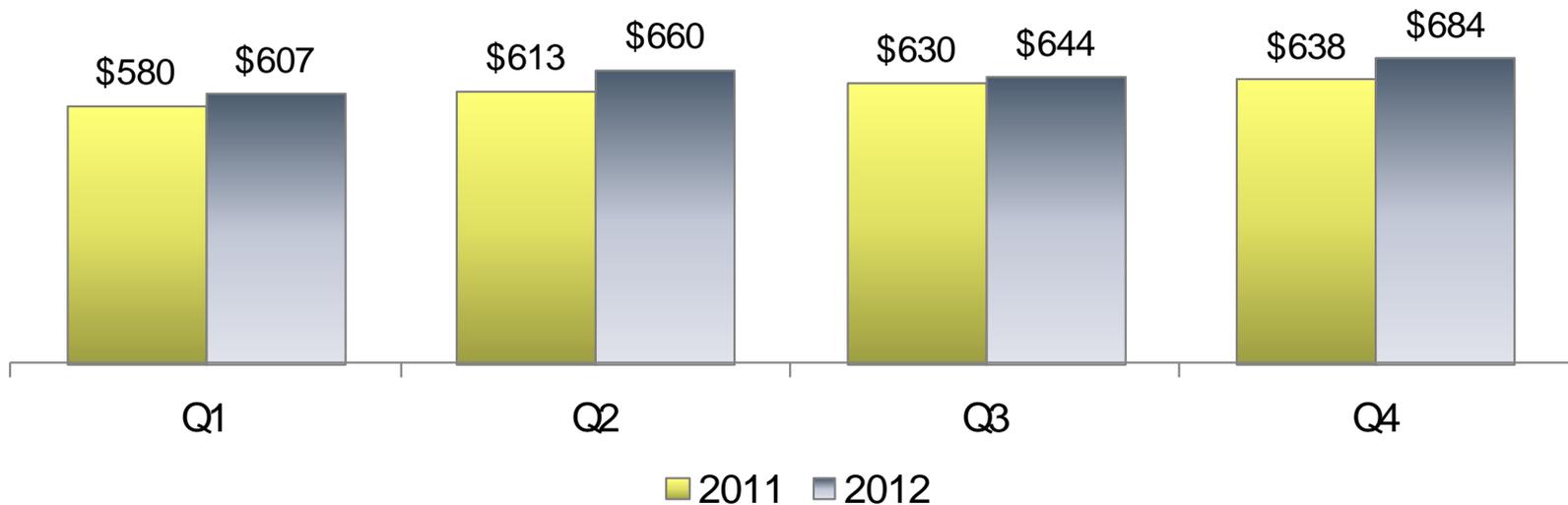


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Alimta Sales Increased 7%

Millions

U.S. sales increased 19%  
International sales flat

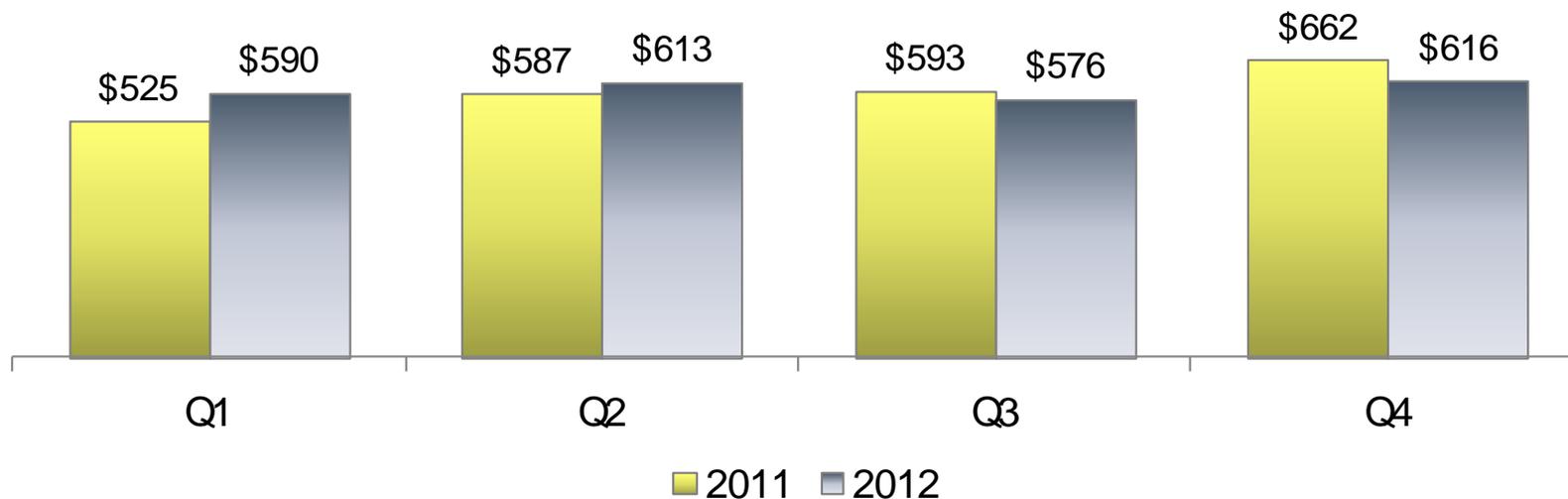


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Humalog<sup>®</sup> Sales Decreased 7%

Millions

U.S. sales decreased 19%  
International sales increased 12%

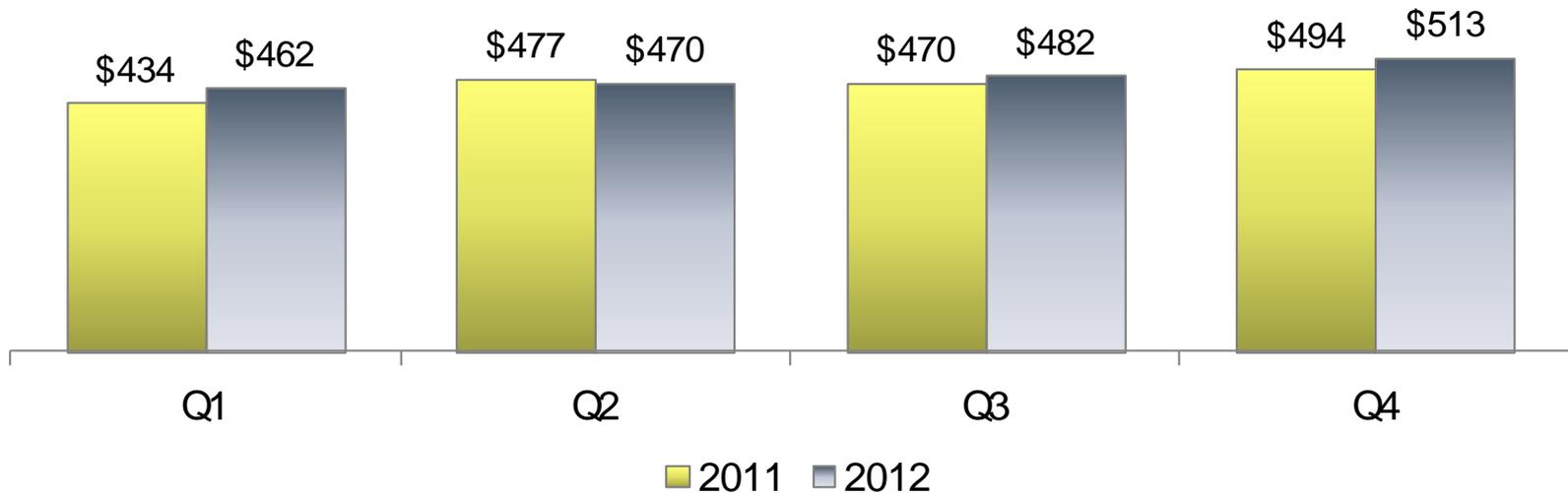


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Cialis Sales Increased 4%

Millions

U.S. sales increased 6%  
International sales increased 2%

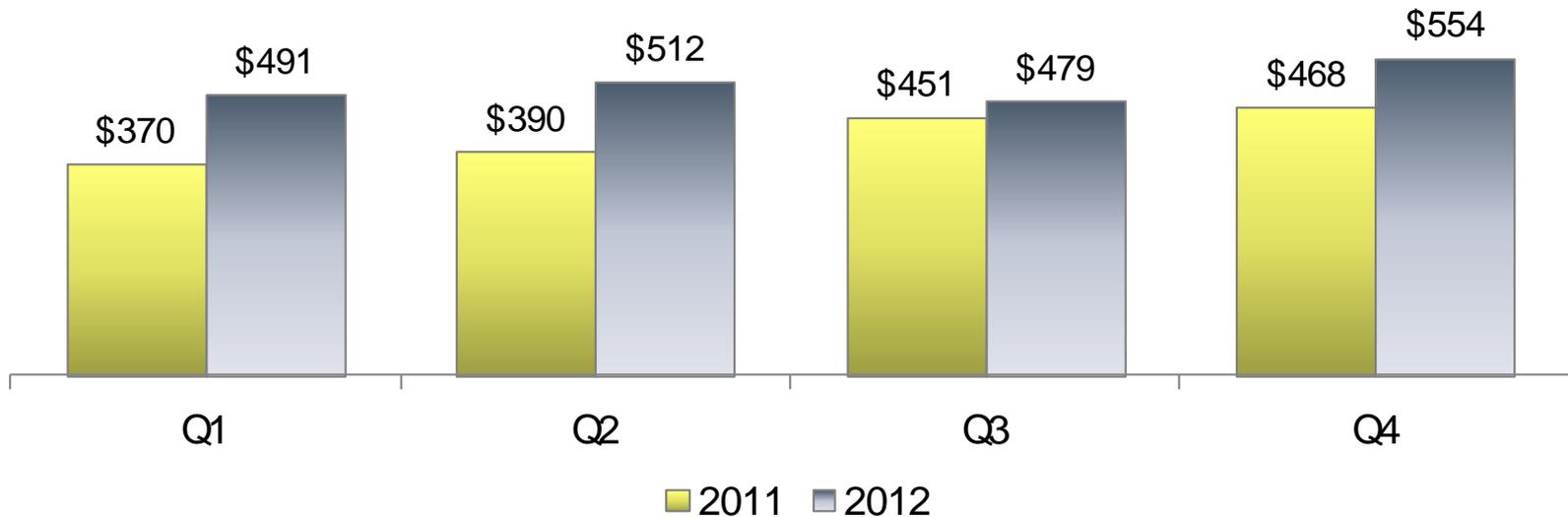


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Animal Health Sales Increased 18%

Millions

U.S. sales increased 31%  
International sales increased 5%

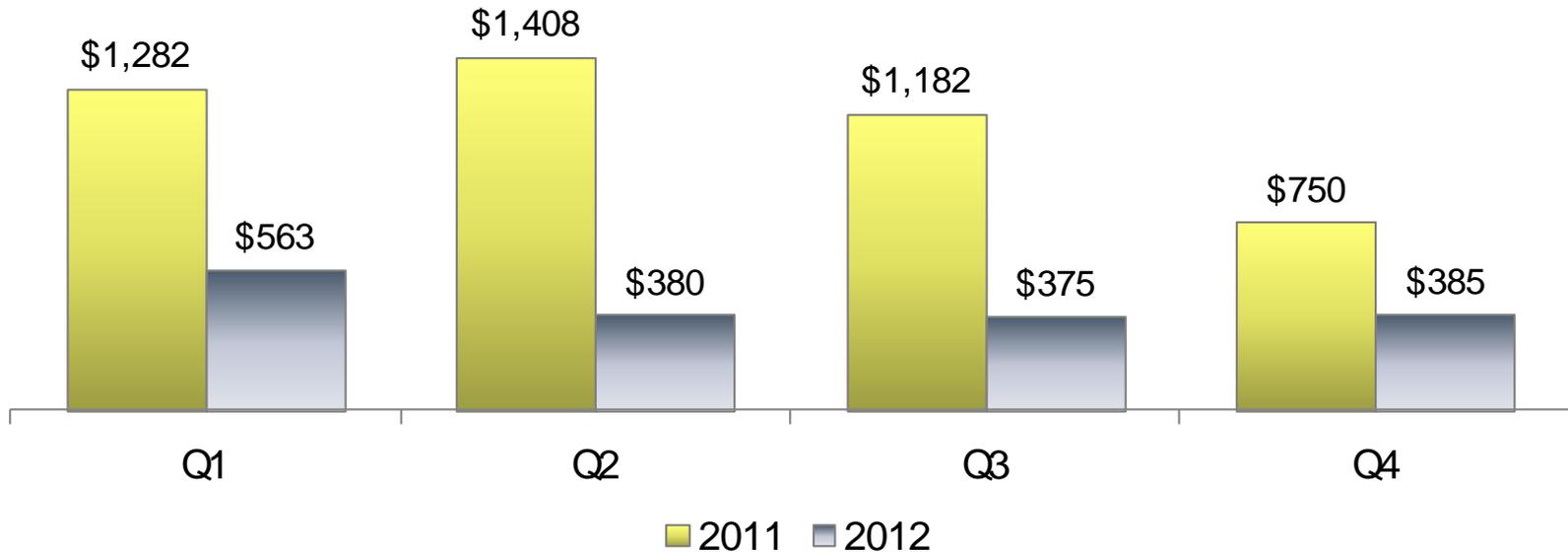


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Zyprexa<sup>®</sup> Sales Decreased 49%

Millions

U.S. sales decreased 80%  
International sales decreased 29%

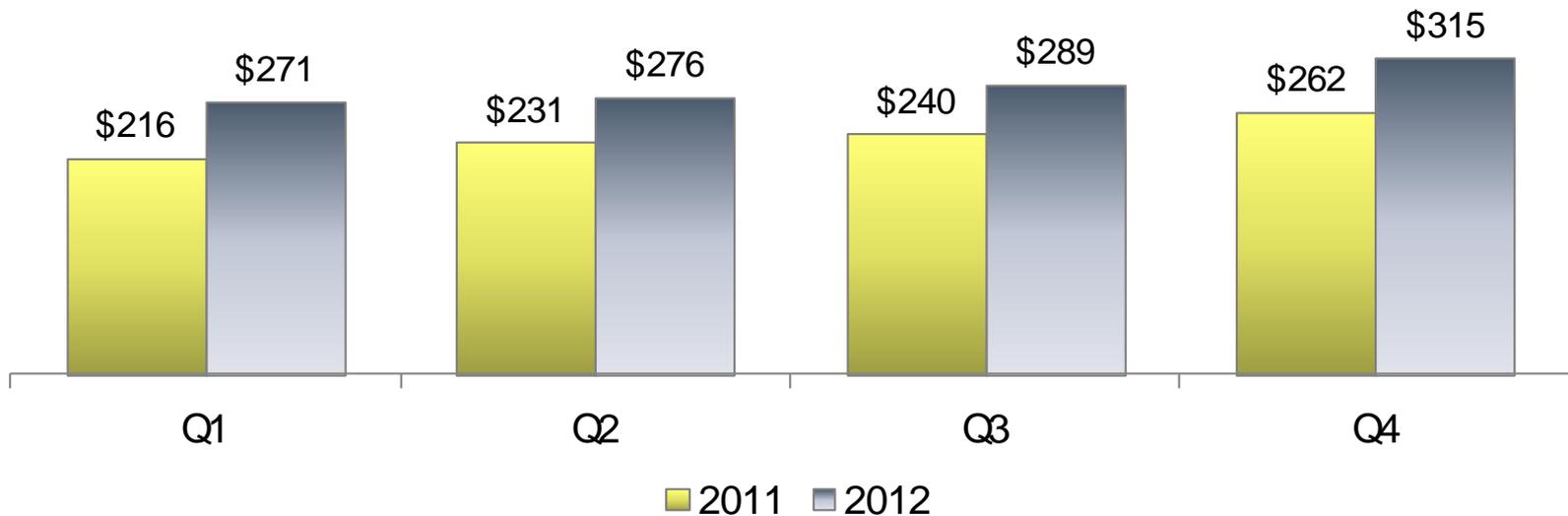


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Forteo<sup>®</sup> Sales Increased 20%

Millions

U.S. sales flat  
International sales increased 37%

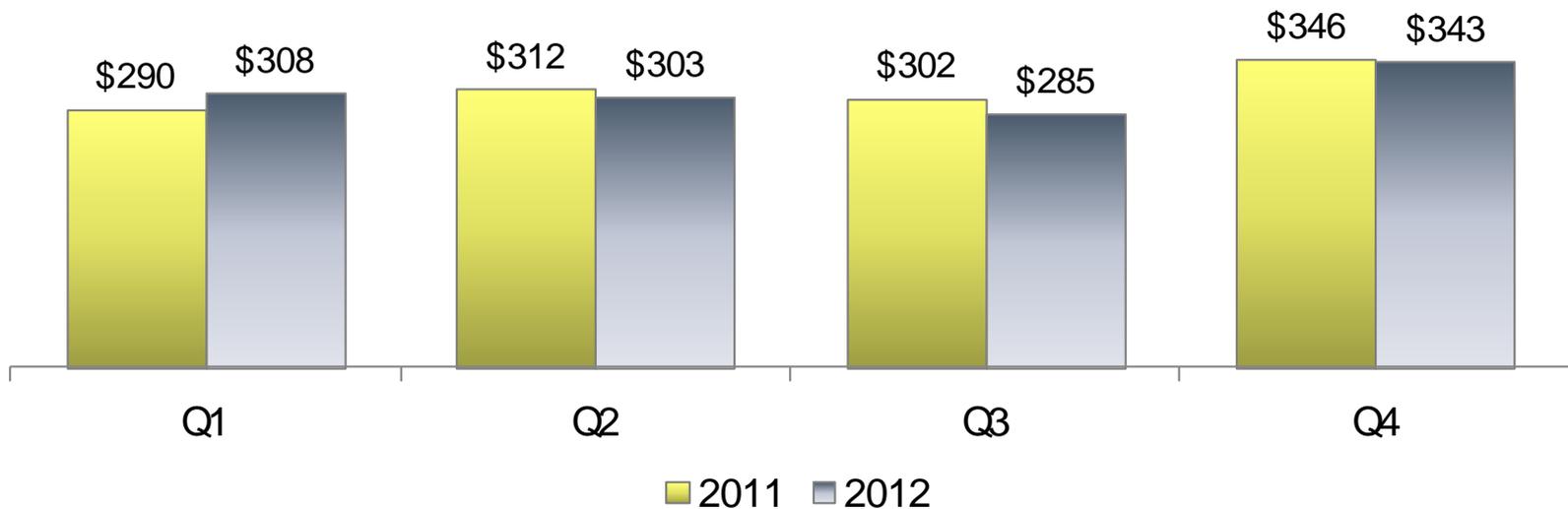


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Humulin<sup>®</sup> Sales Decreased 1%

Millions

U.S. sales decreased 4%  
International sales increased 2%

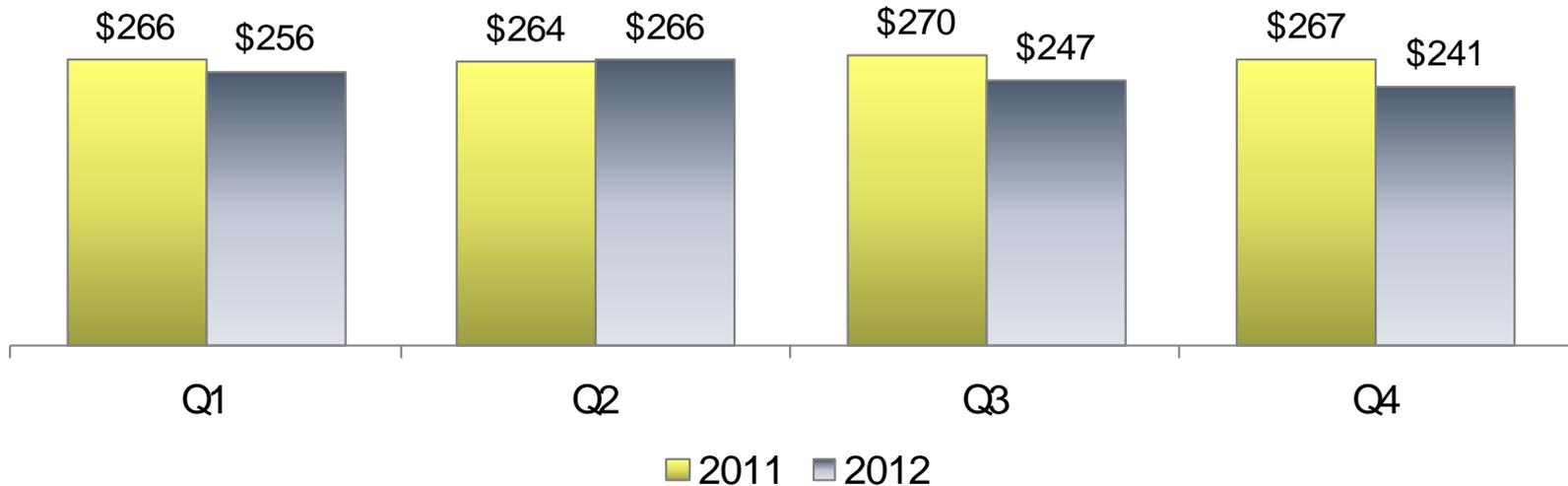


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Evista<sup>®</sup> Sales Decreased 10%

Millions

U.S. sales decreased 3%  
International sales decreased 25%

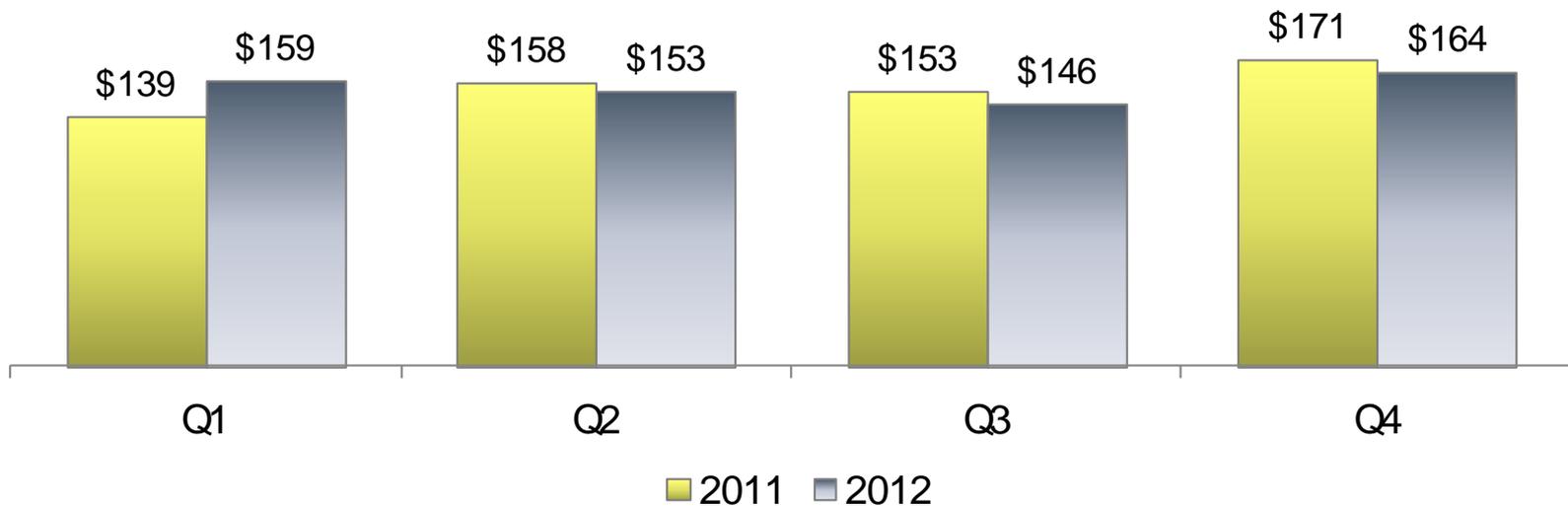


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Strattera<sup>®</sup> Sales Decreased 4%

Millions

U.S. sales decreased 14%  
International sales increased 15%

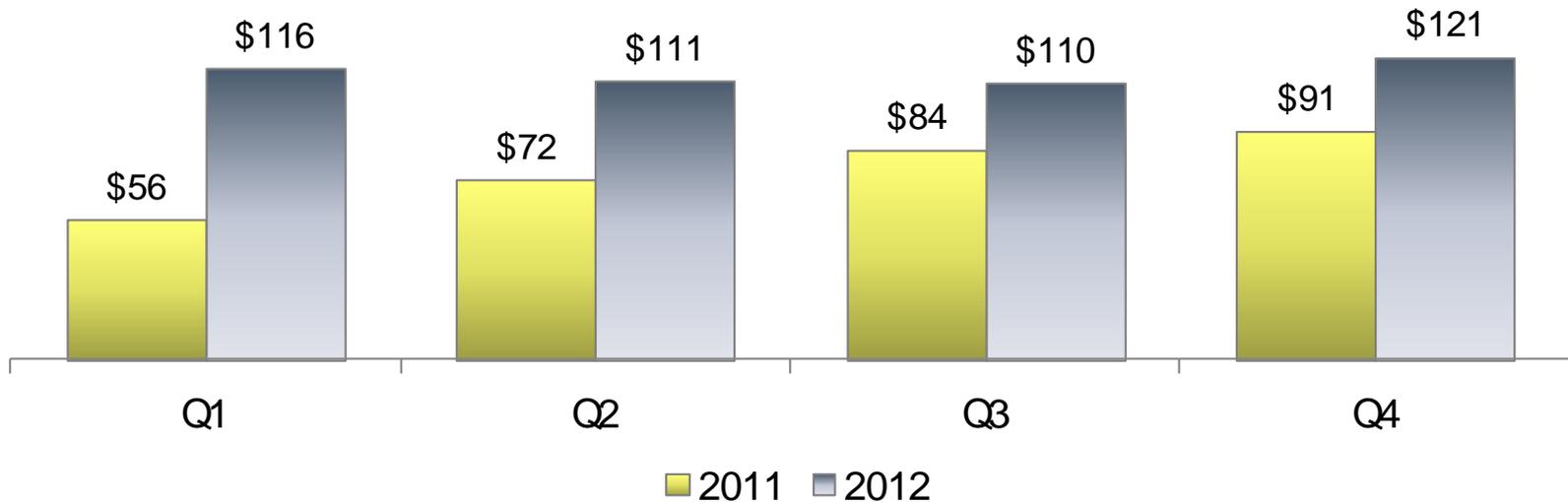


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Effient Sales Increased 33%

Millions

U.S. sales increased 31%  
International sales increased 37%

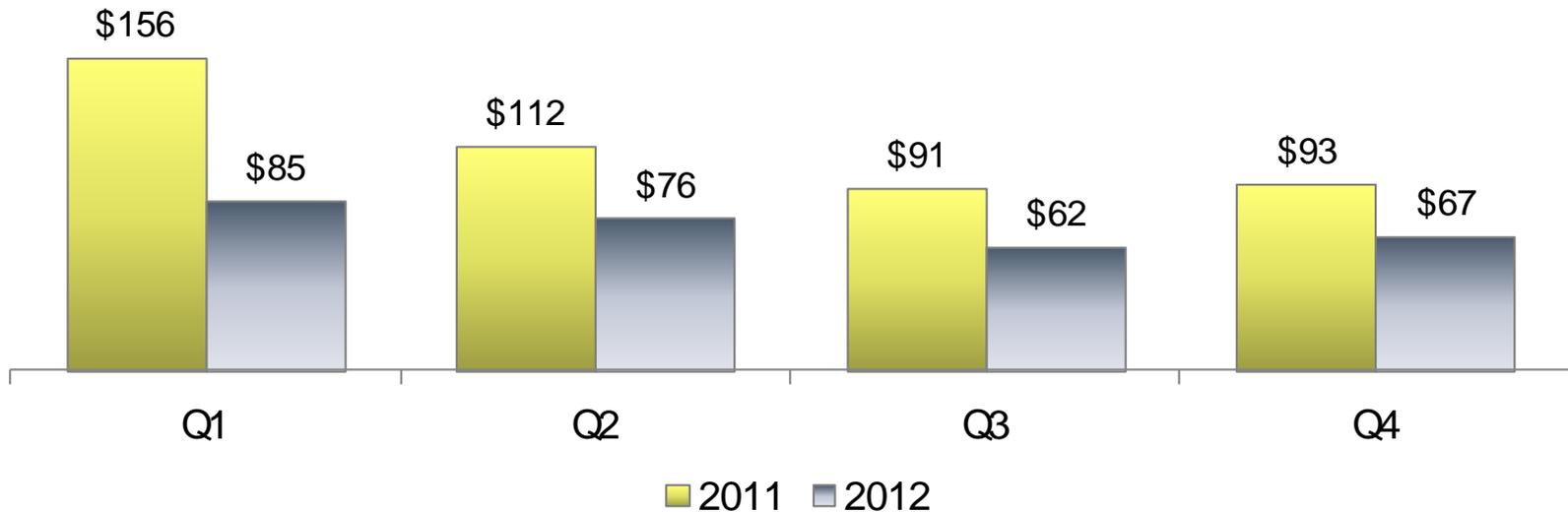


Note: Quarterly numbers may not add to year-to-date totals due to rounding.

# Q4 Gemzar<sup>®</sup> Sales Decreased 27%

Millions

U.S. sales were essentially \$0  
International sales decreased 29%



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