

Bank of New York Mellon Corp
Form 8-K
February 12, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) February 12, 2014

THE BANK OF NEW YORK MELLON CORPORATION

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction

of incorporation)

001-35651
(Commission

File Number)

13-2614959
(I.R.S. Employer

Identification No.)

Edgar Filing: Bank of New York Mellon Corp - Form 8-K

One Wall Street

New York, New York
(Address of principal executive offices)

10286
(Zip code)

Registrant's telephone number, including area code (212) 495-1784

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01. OTHER EVENTS.

On February 12, 2014, The Bank of New York Mellon Corporation (the Company) issued \$200,000,000 aggregate principal amount of the Company s Floating Rate Senior Medium-Term Notes Series G due 2019 (the Notes). The Notes were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-3 (File No. 333-189568). In connection with this issuance, the legal opinion as to the legality of the Notes is being filed as Exhibit 5.1 to this report.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) EXHIBITS.

Exhibit

Number	Description
5.1	Opinion of Craig T. Beazer.
23.1	Consent of Craig T. Beazer (included in Exhibit 5.1).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

The Bank of New York Mellon Corporation
(Registrant)

Date: February 12, 2014

By: /s/ Craig T. Beazer
Name: Craig T. Beazer
Title: Assistant Secretary

EXHIBIT INDEX

Number	Description	Method of Filing
5.1	Opinion of Craig T. Beazer.	Filed herewith
23.1	Consent of Craig T. Beazer.	Included in Exhibit 5.1
	\$	
62.7		
	Collaboration and other revenue	
79.3		
81.4		
148.9		
160.6		
	Total revenue	
	\$	
91.8		
	\$	
110.1		
	\$	
186.6		
	\$	
223.3		

Bristol-Myers Squibb Company

Pursuant to a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), relating to Erbitux, we are co-developing Erbitux in the U.S. and Canada with BMS, exclusively, and in Japan with BMS and Merck. Under this arrangement, Erbitux research and development and other costs are shared by both companies according to a predetermined ratio.

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties under the agreement. Collaborative reimbursements received by us for supply of clinical trial materials; for research and development; and for a portion of marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated condensed statement of operations. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in the U.S. and Canada, which is recorded in

collaboration and other revenue. Royalty expense paid to third parties, net of any reimbursements received, is recorded as a reduction of collaboration and other revenue.

We are responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient (API) for clinical and commercial use in the territory, and BMS will purchase all of its requirements of API for commercial use from us, subject to certain stipulations in the agreement. Sales of Erbitux to BMS for commercial use are reported in net product sales.

Merck KGaA

A development and license agreement with Merck with respect to Erbitux granted Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and co-exclusive rights with BMS and us in Japan. Merck also manufactures Erbitux for supply in its territory. We receive a royalty on the sales of Erbitux outside of the U.S. and Canada, which is included in collaboration and other revenue as earned. Collaborative reimbursements received for research and development and for marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated condensed statement of operations. Royalty expense paid to third parties, net of any royalty reimbursements received, is recorded as a reduction of collaboration and other revenue.

Effient®

We are in a collaborative arrangement with Daiichi Sankyo Company, Limited (Daiichi Sankyo) to develop, market, and promote Effient. We and Daiichi Sankyo have agreed to co-promote in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. Daiichi Sankyo has exclusive marketing rights in Japan and certain other territories. The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories. We record product sales in our exclusive and co-promotion territories. In our exclusive territories, we pay Daiichi Sankyo a royalty specific to these territories. Profit-share payments made to Daiichi Sankyo are recorded as marketing, selling, and administrative expenses. All royalties paid to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales. Effient sales were \$137.4 million and \$111.0 million for the quarters ended June 30, 2013 and 2012, respectively, and \$253.2 million and \$226.9 million for the six months ended June 30, 2013 and 2012, respectively.

Diabetes Collaboration

In January 2011, we and Boehringer Ingelheim entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Included are Boehringer Ingelheim's two oral diabetes agents, linagliptin and empagliflozin. Subsequently in 2011, linagliptin was approved and launched in the U.S. (trade name Tradjenta®), Japan (trade name Trazenta™), Europe (trade name Trajenta®), and other countries. Empagliflozin is currently under regulatory review in the U.S. and Europe. Also included in the agreement is our new insulin glargine product, which was submitted for regulatory review in Europe in June 2013, and an option granted to Boehringer Ingelheim to co-develop and co-commercialize our anti-TGF-beta monoclonal antibody, which is currently in Phase II clinical testing. Under the terms of the global agreement, we made an initial one-time payment to Boehringer Ingelheim of \$388.0 million and recorded an acquired in-process research and development (IPR&D) charge, which was included as expense in the first quarter of 2011 and was deductible for tax purposes.

In connection with the approval of linagliptin in the U.S., Japan, and Europe, in 2011 we paid \$478.7 million in success-based regulatory milestones, all of which were capitalized as intangible assets and are being amortized to cost of sales. We incurred milestone-related expenses of \$92.2 million in connection with regulatory submissions for empagliflozin in the U.S. and Europe during the first quarter of 2013. These regulatory submission milestones were recorded as research and development expenses. We may also pay up to 228.8 million euro in additional regulatory milestones for empagliflozin. In the future, we will be eligible to receive \$290.0 million in success-based regulatory milestones on our new insulin glargine product. Should Boehringer Ingelheim elect to opt in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, we would be eligible for up to \$525.0 million in opt-in and success-based regulatory milestone payments. The companies share ongoing development costs equally. The companies also share in the commercialization costs and gross margin for any product resulting from the collaboration that receives regulatory approval. We record our portion of the gross margin as collaboration and other revenue, and we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration. Revenue related to this collaboration was \$54.8 million and \$13.1 million for the quarters ended June 30, 2013 and 2012, respectively, and \$97.4 million and \$25.9 million for the six months ended June 30, 2013 and 2012, respectively.

Solanezumab

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby TPG funded a portion of the Phase III development of solanezumab. Under the agreement, TPG's obligation to fund solanezumab costs was not material and ended in the first half of 2011. In exchange for their funding, TPG may receive success-based sales milestones totaling approximately \$70 million and mid-single digit royalties that are contingent upon the successful development of solanezumab. The royalties relating to solanezumab would be paid for approximately ten years after launch of a product.

Baricitinib

In December 2009, we entered into a worldwide license and collaboration agreement with Incyte Corporation (Incyte) to acquire development and commercialization rights to its JAK inhibitor compound, now known as baricitinib, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. The agreement calls for payments of up to \$515.0 million associated with certain development and regulatory milestones as well as an additional \$150.0 million of potential sales-based milestones. Incyte also has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent if the product

is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. The agreement also provides Incyte with an option to co-promote in the United States. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. We made development milestone payments of \$49.0 million in 2010 related to Phase II trials of baricitinib. Upon initiation of Phase III trials for the treatment of rheumatoid arthritis in the fourth quarter of 2012, we incurred an additional milestone-related expense of \$50.0 million. These milestone payments were recorded as research and development expenses.

Summary of Collaboration-Related Commission and Profit-Share Payments

The aggregate amount of commission and profit-share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was \$55.2 million and \$45.9 million for the quarters ended June 30, 2013 and 2012, respectively, and \$100.4 million and \$92.7 million for the six months ended June 30, 2013 and 2012, respectively.

Amortization of Intangible Assets

We record, as finite-lived intangible assets, the cost of milestone payments associated with products approved for marketing, as well as the cost of rights to assets approved for marketing that were acquired in business combinations. We also record finite-lived intangible assets for the cost of licensed platform technologies that have alternative future uses in research and development; manufacturing technologies; and customer relationships from business combinations. Amortization expense related to these finite-lived intangibles was \$145.2 million and \$133.1 million for the quarters ended June 30, 2013 and 2012, respectively, and \$291.3 million and \$280.8 million for the six months ended June 30, 2013 and 2012, respectively.

Note 5: Asset Impairments, Restructuring, and Other Special Charges

We recognized asset impairments, restructuring, and other special charges of \$63.5 million and no charges for the quarters ended June 30, 2013 and 2012, respectively, and \$85.2 million and \$23.8 million for the six months ended June 30, 2013 and 2012, respectively. The 2013 charges related primarily to costs associated with the anticipated closure of a packaging and distribution facility in Germany and to severance costs for actions the company is taking, primarily outside the U.S., to reduce its cost structure and global workforce. The 2012 charges primarily relate to a change in our estimates of returned product related to the withdrawal of XigrisTM from the market during the fourth quarter of 2011.

Note 6: Financial Instruments

Financial instruments that potentially subject us to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-sciences products account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by our ongoing credit-review procedures and insurance. A large portion of our cash is held by a few major financial institutions. We monitor our exposures with these institutions and do not expect any of these institutions to fail to meet their obligations. Major financial institutions represent the largest component of our investments in corporate debt securities. In accordance with documented corporate policies, we limit the amount of credit exposure to any one financial institution or corporate issuer. We are exposed to credit-related losses in the event of nonperformance by counterparties to risk-management instruments but do not expect any counterparties to fail to meet their obligations given their high credit ratings.

Accounting Policy for Risk-Management Instruments

Our derivative activities are initiated within the guidelines of documented corporate risk-management policies and do not create additional risk because gains and losses on derivative contracts offset losses and gains on the assets, liabilities, and transactions being hedged. As derivative contracts are initiated, we designate the instruments individually as either a fair value hedge or a cash flow hedge. Management reviews the correlation and effectiveness of our derivatives on a quarterly basis.

For derivative contracts that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative contracts that are designated and qualify as cash flow hedges, the effective

portion of gains and losses on these contracts is reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings.

Hedge ineffectiveness is immediately recognized in earnings. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized currently in earnings during the period of change.

We may enter into foreign currency forward contracts to reduce the effect of fluctuating currency exchange rates (principally the euro, the British pound, and the Japanese yen). Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currencies. These contracts are recorded at fair value with the gain or loss recognized in other — net, (income) expense. We may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward contracts generally have maturities not exceeding 12 months. At June 30, 2013, we had outstanding foreign currency forward commitments to purchase 895.3 million U.S. dollars and sell 680.1 million euro, commitments to purchase 192.7 million euro and sell 253.9 million U.S. dollars, commitments to purchase 323.0 million U.S. dollars and sell 31.21 billion Japanese yen, commitments to purchase 251.6 million British pounds and sell 293.4 million euro, and commitments to purchase 170.0 million euro and sell 145.1 million British pounds, which will all settle within 30 days.

In the normal course of business, our operations are exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing, investing, and operating. We address a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact of fluctuations in interest rates on earnings. Our primary interest-rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest-rate exposures, we strive to achieve an acceptable balance between fixed- and floating-rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance.

Interest rate swaps or collars that convert our fixed-rate debt to a floating rate are designated as fair value hedges of the underlying instruments. Interest rate swaps or collars that convert floating-rate debt to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements. At June 30, 2013, substantially all of our total debt is at a fixed rate. We have converted approximately 60 percent of our fixed-rate debt to floating rates through the use of interest rate swaps.

We may enter into forward contracts and designate them as cash flow hedges to limit the potential volatility of earnings and cash flow associated with forecasted sales of available-for-sale securities.

The Effect of Risk-Management Instruments on the Consolidated Condensed Statement of Operations

The following effects of risk-management instruments were recognized in other—net, (income) expense:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Fair value hedges:				
Effect from hedged fixed-rate debt	\$ 144.3	\$ 97.6	\$ 213.3	\$ 31.7
Effect from interest rate contracts	(144.3) (97.6) (213.3) (31.7
Cash flow hedges:				
Effective portion of losses on interest rate contracts reclassified from accumulated other comprehensive loss	2.2	2.2	4.4	4.4
Net (gains) losses on foreign currency exchange contracts not designated as hedging instruments	(7.6) 18.0	(7.5) (14.8

The effective portion of net losses on equity contracts in designated cash flow hedging relationships recorded in other comprehensive income (loss) was \$10.1 million and \$8.9 million for the three and six months ended June 30, 2013, respectively. There were no equity contracts in designated cash flow hedging relationships in 2012.

During the next 12 months, we expect to reclassify from accumulated other comprehensive loss to earnings \$8.9 million of pretax net losses on cash flow hedges of the variability in expected future interest payments on our floating rate debt.

During the three and six months ended June 30, 2013 and 2012, net losses related to ineffectiveness, as well as net losses related to the portion of our risk-management hedging instruments, fair value hedges, and cash flow hedges that were excluded from the assessment of effectiveness, were not material.

Edgar Filing: Bank of New York Mellon Corp - Form 8-K

Fair Value of Financial Instruments

The following tables summarize certain fair value information at June 30, 2013 and December 31, 2012 for assets and liabilities measured at fair value on a recurring basis, as well as the carrying amount and amortized cost of certain other investments:

Description	Carrying Amount	Amortized Cost	Fair Value Measurements Using			Fair Value
			Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
June 30, 2013						
Cash and cash equivalents	\$3,786.5	\$3,786.5	\$3,724.7	\$61.8	\$	\$3,786.5
Short-term investments:						
U.S. government and agencies	\$84.5	\$84.5	\$84.5	\$	\$	\$84.5
Corporate debt securities	838.3	836.3		838.3		838.3
Other securities	1.7	1.7		1.7		1.7
Short-term investments	\$924.5	\$922.5				
Noncurrent investments:						
U.S. government and agencies	\$1,083.7	\$1,090.9	\$1,001.2	\$82.5	\$	\$1,083.7
Corporate debt securities	3,948.4	3,978.1		3,948.4		3,948.4
Mortgage-backed	629.3	646.0		629.3		629.3
Asset-backed	353.5	358.8		353.5		353.5
Other securities	7.8	8.1		7.8		7.8
Marketable equity	262.4	100.9	262.4			262.4
Equity method and other investments ⁽¹⁾	276.3	276.3				
Noncurrent investments	\$6,561.4	\$6,459.1				
December 31, 2012						
Cash and cash equivalents	\$4,018.8	\$4,018.8	\$3,964.4	\$54.4	\$	\$4,018.8
Short-term investments:						
U.S. government and agencies	\$150.2	\$150.2	\$150.2	\$	\$	\$150.2
Corporate debt securities	1,503.5	1,501.5		1,503.5		1,503.5
Other securities	11.8	11.8		11.8		11.8
Short-term investments	\$1,665.5	\$1,663.5				
Noncurrent investments:						
U.S. government and agencies	\$1,362.7	\$1,360.3	\$1,122.4	\$240.3	\$	\$1,362.7
Corporate debt securities	3,351.3	3,322.9		3,351.3		3,351.3
Mortgage-backed	668.1	677.7		668.1		668.1
Asset-backed	519.0	523.5		519.0		519.0
Other securities	3.3	3.3		3.3		3.3
Marketable equity	175.8	83.0	175.8			175.8
	233.1	233.1				

Equity method and other
investments⁽¹⁾

Noncurrent investments	\$6,313.3	\$6,203.8
------------------------	-----------	-----------

¹ Fair value not applicable

13

Edgar Filing: Bank of New York Mellon Corp - Form 8-K

Description	Carrying Amount	Fair Value Measurements Using			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Long-term debt, including current portion					
June 30, 2013	\$ (5,314.0)	\$	\$ (5,638.1)	\$	\$ (5,638.1)
December 31, 2012	(5,531.3)		(5,996.6)		(5,996.6)

Description	Carrying Amount	Fair Value Measurements Using			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
June 30, 2013					
Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Other receivables	\$ 12.4	\$	\$ 12.4	\$	\$ 12.4
Sundry	363.7		363.7		363.7
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	22.8		22.8		22.8
Other current liabilities	(5.4)		(5.4)		(5.4)
Equity contracts designated as hedging instruments:					
Sundry	0.6		0.6		0.6
Other current liabilities	(7.3)		(7.3)		(7.3)
Other noncurrent liabilities	(2.2)		(2.2)		(2.2)

December 31, 2012

Risk-management instruments					
Interest rate contracts designated as hedging instruments:					
Sundry	\$ 589.4	\$	\$ 589.4	\$	\$ 589.4
Foreign exchange contracts not designated as hedging instruments:					
Other receivables	11.0		11.0		11.0
Other current liabilities	(17.5)		(17.5)		(17.5)

Risk-management instruments above are disclosed on a gross basis. There are various rights of setoff associated with certain of the risk-management instruments above that are subject to an enforceable master netting arrangement or similar agreements. Although various rights of setoff and master netting arrangements or similar agreements may exist with the individual counterparties to the risk-management instruments above, individually, these financial rights are

not material.

We determine fair values based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities, or discounted cash flow analyses. The fair value of equity method investments and other investments is not readily available.

14

The table below summarizes the contractual maturities of our investments in debt securities measured at fair value as of June 30, 2013:

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	\$ 6,942.8	\$ 924.5	\$ 4,836.0	\$ 448.8	\$ 733.5

A summary of the fair value of available-for-sale securities in an unrealized gain or loss position and the amount of unrealized gains and losses (pretax) in accumulated other comprehensive loss follows:

	June 30, 2013	December 31, 2012
Unrealized gross gains	\$ 182.1	\$ 140.5
Unrealized gross losses	77.8	29.0
Fair value of securities in an unrealized gain position	2,768.3	5,246.0
Fair value of securities in an unrealized loss position	4,295.5	2,102.0

Other-than-temporary impairment losses on investment securities of \$5.2 million were recognized in the statement of operations for the six months ended June 30, 2013. No charges were recognized during the second quarter of 2013. Other-than-temporary impairment losses on investment securities of \$3.7 million and \$7.4 million were recognized in the statement of operations for the second quarter and first six months of 2012, respectively. For fixed-income securities, the amount of credit losses represents the difference between the present value of cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing the credit loss were the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration.

The securities in an unrealized loss position include fixed-rate debt securities of varying maturities. The value of fixed-income securities is sensitive to changes in the yield curve and other market conditions. Approximately 80 percent of the securities in a loss position are investment-grade debt securities. At this time, there is no indication of default on interest or principal payments for debt securities other than those for which an other-than-temporary impairment charge has been recorded. We do not intend to sell and it is not more likely than not we will be required to sell the securities in a loss position before the market values recover or the underlying cash flows have been received, and we have concluded that no additional other-than-temporary loss is required to be charged to earnings as of June 30, 2013.

Activity related to our investment portfolio, substantially all of which related to available-for-sale securities, was as follows:

	Three Months Ended		Six Months Ended	
	June 30, 2013	2012	June 30, 2013	2012
Proceeds from sales	\$3,587.6	\$1,251.9	\$6,939.7	\$3,635.3
Realized gross gains on sales	28.2	13.2	38.2	26.9
Realized gross losses on sales	5.4	2.5	7.9	5.2

Realized gains and losses on sales of investments are computed based upon specific identification of the initial cost adjusted for any other-than-temporary declines in fair value that were recorded in earnings.

Note 7: Stock-Based Compensation

Our stock-based compensation expense consists primarily of performance awards (PAs), shareholder value awards (SVAs), and restricted stock units (RSUs). We recognized pretax stock-based compensation cost of \$33.7 million and \$34.8 million for the quarters ended June 30, 2013 and 2012, respectively. During the first six months of 2013 and 2012, we recognized pretax stock-based compensation expense of \$68.8 million and \$65.8 million, respectively. PAs are granted to officers and management and are payable in shares of our common stock. The number of PA shares actually issued, if any, varies depending on the achievement of certain earnings per share targets over a

two-year period. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement period. As of June 30, 2013, the total remaining unrecognized compensation cost related to nonvested PAs amounted to \$36.7 million, which will be amortized over the weighted-average remaining requisite service period of approximately 15 months.

SVAs are granted to officers and management and are payable in shares of common stock at the end of a three-year period. The number of shares actually issued varies depending on our stock price at the end of the three-year vesting period compared to pre-established target prices. We measure the fair value of the SVA unit on the grant date using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables that determine the probability of satisfying the market condition stipulated in the award grant and calculates the fair value of the award. As of June 30, 2013, the total remaining unrecognized compensation cost related to nonvested SVAs amounted to \$76.8 million, which will be amortized over the weighted-average remaining requisite service period of approximately 24 months.

RSUs are granted to certain employees and are payable in shares of our common stock. RSU shares are accounted for at fair value based upon the closing stock price on the date of grant. The corresponding expense is amortized over the vesting period, typically three years. As of June 30, 2013, the total remaining unrecognized compensation cost related to nonvested RSUs amounted to \$83.3 million, which will be amortized over the weighted-average remaining requisite service period of 25 months.

Note 8: Shareholders' Equity

During the first quarter of 2013, we purchased the remaining \$1.10 billion of shares associated with our previously announced \$1.50 billion share repurchase program.

Note 9: Earnings Per Share

Unless otherwise noted in the footnotes, all per-share amounts are presented on a diluted basis, that is, based on the weighted-average number of outstanding common shares plus the effect of all potentially dilutive common shares (primarily contingently issuable shares and unexercised stock options).

Note 10: Income Taxes

We file income tax returns in the U.S. federal jurisdiction and various state, local, and non-U.S. jurisdictions. We are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations in most major taxing jurisdictions for years before 2007.

The U.S. examination of certain matters related to tax years 2008–2009 that were not settled as part of previous examinations remains in progress. Management believes it is reasonably possible the remaining 2008–2009 tax matters could be concluded within the next 12 months. However, resolution of these matters is still dependent upon a number of factors, including the potential for formal administrative and legal proceedings. As a result, it is not possible to estimate the range of the reasonably possible changes in unrecognized tax benefits that could occur within the next 12 months related to these years, nor is it possible to estimate reliably the total future cash flows related to these unrecognized tax benefits.

Note 11: Retirement Benefits

Net pension and retiree health benefit expense included the following components:

	Defined Benefit Pension Plans			
	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Components of net periodic benefit cost:				
Service cost	\$71.1	\$64.1	\$140.8	\$127.1
Interest cost	108.9	112.7	218.3	225.7
Expected return on plan assets	(174.8)	(170.3)	(349.7)	(341.4)
Amortization of prior service cost	2.6	0.8	5.2	1.7
Recognized actuarial loss	99.2	71.0	195.2	141.9
Net periodic benefit cost	\$107.0	\$78.3	\$209.8	\$155.0
	Retiree Health Benefit Plans			
	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Components of net periodic benefit cost:				
Service cost	\$15.1	\$15.9	\$30.2	\$32.3
Interest cost	23.3	28.5	46.7	57.0
Expected return on plan assets	(32.7)	(31.8)	(65.5)	(63.6)
Amortization of prior service cost	(5.9)	(8.8)	(12.8)	(17.5)
Recognized actuarial loss	23.2	24.6	46.2	48.3
Net periodic benefit cost	\$23.0	\$28.4	\$44.8	\$56.5

On a global basis, we have contributed approximately \$50 million required to satisfy minimum funding requirements to our defined benefit pension plans in 2013. In addition, we have contributed approximately \$300 million of discretionary funding to our global post-retirement benefit plans in 2013. During the remainder of 2013, we expect to make contributions to our defined benefit pension plans of approximately \$10 million to satisfy minimum funding requirements. We do not anticipate making any additional discretionary contributions in 2013.

Note 12: Contingencies

We are a party to various legal actions and government investigations. The most significant of these are described below. It is not possible to determine the outcome of these matters and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that, except as noted below with respect to the Alimta[®] Hatch-Waxman patent challenges, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Alimta Patent Litigation and Administrative Proceedings

We are engaged in the following U.S. patent litigation matters involving Alimta brought pursuant to procedures set out in the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984). Teva Parenteral Medicines, Inc. (Teva); APP Pharmaceuticals, LLC (APP); Barr Laboratories, Inc. (Barr); Pliva Hrvatska D.O.O. (Pliva); Accord Healthcare Inc. (Accord); and Apotex Inc. (Apotex) each submitted Abbreviated New Drug Applications (ANDAs) seeking approval to market generic versions of Alimta prior to the expiration of our vitamin dosage regimen patent (expiring in 2022) and alleging the patent is invalid.

In October 2010, we filed a lawsuit in the U.S. District Court for the Southern District of Indiana against Teva, APP, Pliva, and Barr seeking rulings that the patent is valid and infringed. Trial in this case is scheduled to begin in August 2013. In January 2012 and April 2012, we filed similar lawsuits in the same court against Accord and Apotex, respectively. A second lawsuit against Accord was filed in February 2013. The Accord and Apotex cases

have been consolidated by the court, with a trial scheduled in July 2014. In June 2013, Accord filed a petition requesting review of the patent by the U.S. Patent and Trademark Office, seeking a ruling that the claims in the patent are invalid. In addition, generic manufacturers have opposed the European Patent Office's decision to grant a vitamin dosage regimen patent, and are seeking revocation of that patent.

We believe the challenges to these patents are without merit and expect to prevail. However, it is not possible to determine the outcome of the challenges, and accordingly, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our future consolidated results of operations, liquidity, and financial position. We expect that a loss of exclusivity for Alimta would result in a rapid and severe decline in future revenues in the relevant market.

Byetta Product Liability Litigation

We have been named as a defendant in approximately 170 Byetta product liability lawsuits involving approximately 550 plaintiffs. Approximately 85 of these lawsuits, covering about 465 plaintiffs, are filed in California and coordinated in a Los Angeles Superior Court. We are aware of approximately 460 additional claimants who have not yet filed suit. The majority of the claims allege damages for pancreatitis. A smaller number of claimants allege that Byetta caused or contributed to their pancreatic cancer. We believe these claims are without merit and are prepared to defend against them vigorously.

Diethylstilbestrol Product Liability Litigation

In approximately 80 U.S. lawsuits against us involving approximately 80 claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed diethylstilbestrol (DES) during pregnancy in the 1950s and 1960s. Approximately 75 of these claimants allege that they were indirectly exposed in utero to the medicine and later developed breast cancer as a consequence. We believe these claims are without merit and are prepared to defend against them vigorously.

Prozac® Product Liability Litigation

We have been named as a defendant in 10 U.S. lawsuits primarily related to allegations that the antidepressant Prozac caused or contributed to birth defects in the children of women who ingested the drug during pregnancy. We are aware of approximately 380 additional claims related to birth defects, which have not yet been filed. We believe these claims are without merit and are prepared to defend against them vigorously.

Brazil–Employee Litigation

We have been named in a lawsuit brought by the Labor Attorney for 15th Region in the Labor Court of Paulinia, State of Sao Paulo, Brazil, alleging possible harm to employees and former employees caused by exposure to heavy metals at a former Lilly manufacturing facility in Cosmopolis, Brazil. We have also been named in approximately 30 lawsuits filed in the same court by individual former employees making similar claims. We believe these lawsuits are without merit and are prepared to defend against them vigorously.

Product Liability Insurance

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of product liability and related claims in the future. In the past several years, we have been unable to obtain product liability insurance due to a very restrictive insurance market. Therefore, for substantially all of our currently marketed products, we have been and expect that we will continue to be completely self-insured for product liability losses. The DES claims are covered by insurance, subject to deductibles and coverage limits. There is no assurance that we will be able to fully collect from our insurance carriers in the future.

Note 13: Other Comprehensive Income (Loss)

The following table summarizes the activity related to each component of other comprehensive income (loss) during the three months ended June 30, 2013:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at April 1, 2013	\$ 80.8	\$ 90.5	\$ (4,086.7)	\$ (99.0)	\$ (4,014.4)
Other comprehensive income (loss) before reclassifications	12.1	(23.0)	5.3	(5.8)	(11.4)
Net amount reclassified from accumulated other comprehensive loss	—	(0.5)	76.2	1.4	77.1
Net other comprehensive income (loss)	12.1	(23.5)	81.5	(4.4)	65.7
Balance at June 30, 2013	\$ 92.9	\$ 67.0	\$ (4,005.2)	\$ (103.4)	\$ (3,948.7)

The following table summarizes the activity related to each component of other comprehensive income (loss) during the six months ended June 30, 2013:

(Amounts presented net of taxes)	Foreign Currency Translation Gains (Losses)	Unrealized Net Gains (Losses) on Securities	Defined Benefit Pension and Retiree Health Benefit Plans	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance at January 1, 2013	\$ 426.8	\$ 72.5	\$ (4,195.2)	\$ (101.2)	\$ (3,797.1)
Other comprehensive income (loss) before reclassifications	(333.9)	(1.7)	37.7	(5.1)	(303.0)
Net amount reclassified from accumulated other comprehensive loss	—	(3.8)	152.3	2.9	151.4
Net other comprehensive income (loss)	(333.9)	(5.5)	190.0	(2.2)	(151.6)
Balance at June 30, 2013	\$ 92.9	\$ 67.0	\$ (4,005.2)	\$ (103.4)	\$ (3,948.7)

The tax effect on the unrealized net losses on securities was a benefit of \$11.6 million and \$1.8 million for the second quarter and first six months of 2013, respectively. The tax effect related to our defined benefit pension and retiree health benefit plans was an expense of \$42.1 million and \$89.1 million for the second quarter and first six months of 2013, respectively. The tax effect on the effective portion of cash flow hedges was not significant for the second quarter and first six months of 2013. Income taxes were not provided for foreign currency translation.

Reclassifications Out of Accumulated
Other Comprehensive Loss

Details about Accumulated Other Comprehensive Loss Components	Three Months Ended June 30, 2013	Six Months Ended June 30, 2013	Affected Line Item in the Consolidated Condensed Statements of Operations
Amortization of defined pension benefit items:			
Prior service costs	\$ 3.3	\$ 7.6	(1)
Actuarial gains (losses)	(122.4)	(241.4)	(1)

Edgar Filing: Bank of New York Mellon Corp - Form 8-K

Total before tax	(119.1)	(233.8)
Tax benefit	42.9		81.5	
Net of tax	(76.2)	(152.3)
Other, net of tax	(0.9)	0.9	Other—net, (income) expense
Total reclassifications for the period (net of tax)	\$(77.1)	\$(151.4)

¹ These accumulated other comprehensive loss components are included in the computation of net periodic pension cost (see Note 11).

Note 14: Other—Net, (Income) Expense

Other—net, (income) expense consisted of the following:

	Three Months Ended		Six Months Ended	
	June 30, 2013	2012	June 30, 2013	2012
Income related to transfer of exenatide commercial rights (Note 4)	\$—	\$—	\$(495.4)	\$—
Interest expense	40.3	43.0	80.6	88.3
Interest income	(29.7)	(27.2)	(53.3)	(53.3)
Other	(22.5)	0.7	(73.0)	27.5
Other—net, (income) expense	\$(11.9)	\$16.5	\$(541.1)	\$62.5

The increase in other—net, (income) expense for the first six months is primarily related to income recognized from the transfer to Amylin of exenatide commercial rights in all markets outside the United States during the first quarter of 2013. See Note 4 for additional information.

Note 15: Segment Information

We operate in two business segments—human pharmaceutical products and animal health. Our business segments are distinguished by the ultimate end user of the product—humans or animals. Performance is evaluated based on profit or loss from operations before income taxes.

	Three Months Ended		Six Months Ended	
	June 30, 2013	2012	June 30, 2013	2012
Segment revenue — to unaffiliated customers:				
Human pharmaceutical products:				
Neuroscience	\$2,004.5	\$1,824.5	\$3,853.4	\$3,728.2
Endocrinology	1,784.3	1,704.1	3,509.2	3,395.1
Oncology	808.1	846.8	1,572.3	1,650.6
Cardiovascular	731.3	646.9	1,425.3	1,284.9
Other pharmaceuticals	58.0	66.2	129.1	140.9
Total human pharmaceutical products	5,386.2	5,088.5	10,489.3	10,199.7
Animal health	543.5	512.2	1,042.4	1,003.0
Total segment revenue	\$5,929.7	\$5,600.7	\$11,531.7	\$11,202.7
Segment profits:				
Human pharmaceutical products	\$1,430.7	\$1,049.3	\$2,778.8	\$2,280.9
Animal health	147.7	136.4	277.0	263.9
Total segment profits	\$1,578.4	\$1,185.7	\$3,055.8	\$2,544.8
Reconciliation of total segment profits to consolidated income before taxes:				
Segment profits	\$1,578.4	\$1,185.7	\$3,055.8	\$2,544.8
Other profits (losses):				
Income related to transfer of exenatide commercial rights (Note 4)	—	—	495.4	—
Asset impairments, restructuring, and other special charges (Note 5)	(63.5)	—	(85.2)	(23.8)
Total consolidated income before taxes	\$1,514.9	\$1,185.7	\$3,466.0	\$2,521.0

For internal management reporting presented to the chief operating decision maker, certain costs are fully allocated to our human pharmaceutical products segment and therefore are not reflected in the animal health segment's profit. Such items include costs associated with treasury-related financing, global service centers, certain acquisition-related transaction costs, and inventory valuation adjustments.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations

Executive Overview

This section provides an overview of our financial results, recent product and late-stage pipeline developments, and legal, regulatory, and other matters affecting our company and the pharmaceutical industry. Earnings per share (EPS) data is presented on a diluted basis.

Financial Results

Worldwide total revenue increased 6 percent and 3 percent to \$5.93 billion and \$11.53 billion in the second quarter and first six months of 2013, respectively, primarily driven by growth in several products, including Cymbalta[®] and Cialis[®], partially offset by steep sales declines for Zyprexa[®] due to the loss of patent exclusivity in most major markets other than Japan. Net income for the second quarter and first six months of 2013 increased 31 percent and 42 percent to \$1.21 billion and \$2.75 billion, respectively. EPS for the second quarter and first six months of 2013 increased 34 percent and 46 percent to \$1.11 per share and \$2.53 per share, respectively, compared with the same periods of 2012. The increases in net income and EPS during the second quarter were driven by higher gross margin and lower marketing, selling, and administrative expenses and, to a lesser extent, higher other income and a lower effective tax rate, partially offset by higher asset impairment, restructuring, and other special charges as highlighted below. The increase in net income and EPS for the first six months of 2013 was also driven by the income recognized from the transfer to Amylin of exenatide commercial rights in all markets outside the U.S. as highlighted below, partially offset by higher research and development expenses. EPS also benefited from a lower number of shares outstanding in the second quarter and first six months of 2013 compared to the same respective periods of 2012. The following highlighted items affect comparisons of our financial results for the three and six months ended June 30, 2013 and 2012:

2013

Collaborations (Note 4)

- We recognized income in the first quarter of \$495.4 million (pretax), or \$0.29 per share, related to the transfer to Amylin of exenatide commercial rights in all markets outside the United States.

Asset Impairments, Restructuring, and Other Special Charges (Note 5)

• We recognized charges in the second quarter of \$63.5 million (pretax), or \$0.04 per share, primarily related to costs associated with the anticipated closure of a packaging and distribution facility in Germany.

• We recognized charges in the first quarter of \$21.7 million (pretax), or \$0.01 per share, related to severance costs for actions being taken, primarily outside the U.S., to reduce our cost structure and global workforce.

2012

Asset Impairments, Restructuring, and Other Special Charges (Note 5)

We recognized asset impairments, restructuring, and other special charges of \$23.8 million (pretax), or \$0.01 per share, in the first quarter primarily related to changes in returns reserve estimates for the withdrawal of Xigris in the fourth quarter of 2011.

Late-Stage Pipeline

Our long-term success depends to a great extent on our ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies. We currently have approximately 60 potential new drugs in human testing or under regulatory review, and a larger number of projects in preclinical research.

The following new molecular entities (NMEs) have been submitted for regulatory review for potential use in the disease described. The quarter the NME initially was submitted for any indication is shown in parentheses: Empagliflozin (Q1 2013)—a sodium glucose co-transporter-2 (SGLT-2) inhibitor for the treatment of type 2 diabetes (in collaboration with Boehringer Ingelheim). Empagliflozin is protected in the U.S. by a compound patent expiring in November 2025, plus any potential patent extension.

Liprotamase (Q1 2010)—a non-porcine pancreatic enzyme replacement therapy for the treatment of exocrine pancreatic insufficiency.

New insulin glargine product (Q2 2013 in Europe only)—a new insulin glargine product for the treatment of type 1 and type 2 diabetes (in collaboration with Boehringer Ingelheim). Lilly's new insulin glargine product has the same amino acid sequence as Sanofi-Aventis' Lantus® and is not covered by any patent protection.

The following NMEs are currently in Phase III clinical trial testing for potential use in the diseases described. The quarter in which the NME initially entered Phase III for any indication is shown in parentheses:

Baricitinib (Q4 2012)—a Janus tyrosine kinase (JAK 1 and JAK 2) inhibitor for the treatment of inflammatory and autoimmune diseases (in collaboration with Incyte Corporation)

Dulaglutide* (Q4 2008)—a long-acting analog of glucagon-like peptide 1 for the treatment of type 2 diabetes

Edivoxetine (Q4 2010)—a norepinephrine reuptake inhibitor for the treatment of major depression

Evacetrapib (Q4 2012)—a cholesteryl ester transfer protein (CETP) inhibitor for the treatment of high-risk vascular disease

Ixekizumab* (Q4 2011)—a neutralizing monoclonal antibody to interleukin-17A (IL-17) for the treatment of psoriasis and psoriatic arthritis

Necitumumab* (Q4 2009)—an anti-epidermal growth factor receptor (EGFR) monoclonal antibody for the treatment of squamous non-small cell lung cancer (NSCLC)

Novel basal insulin analog* (Q4 2011)—a novel basal insulin for the treatment of type 1 and type 2 diabetes

Ramucirumab* (Q4 2009)—an anti-vascular endothelial growth factor receptor-2 (VEGFR-2) monoclonal antibody for the treatment of metastatic breast, gastric, liver, NSCLC, and colorectal cancers

Solanezumab* (Q2 2009)—an anti-amyloid beta (Aβ) monoclonal antibody for the treatment of Alzheimer's disease

Tabalumab* (Q4 2010)—an anti-B-cell activating factor (BAFF) monoclonal antibody for the treatment of systemic lupus erythematosus (lupus).

* Biologic molecule subject to the U.S. Biologics Price Competition and Innovation Act

The following are late-stage pipeline updates since January 1, 2013:

Dulaglutide—In April 2013, we announced that the Phase III AWARD-2 and AWARD-4 trials studying dulaglutide as an investigational once-weekly treatment for type 2 diabetes met the primary endpoints related to reduction in hemoglobin A1c (HbA1c) compared to insulin glargine, and that the 1.5 mg dose demonstrated statistically superior reduction in HbA1c from baseline compared to insulin glargine in both trials. We anticipate filing for regulatory review in the U.S. and Europe in 2013.

Empagliflozin—In January 2013, we announced positive top-line results for four completed Phase III clinical trials studying empagliflozin for treatment of patients with type 2 diabetes. In all four studies, the primary efficacy endpoint, defined as significant change in HbA1c from baseline compared to placebo, was met with empagliflozin (10 and 25 mg) taken once daily. The pivotal studies for empagliflozin completed in 2012. In the first quarter of 2013, we and Boehringer Ingelheim filed for regulatory review in both the United States and Europe. We also anticipate filing for regulatory review in Japan in 2013.

Enzastaurin—In May 2013, we announced the decision to stop development of enzastaurin as a result of negative clinical trial results from the Phase III PRELUDE study, which explored the molecule as a monotherapy in the prevention of relapse for patients with diffuse large B-cell lymphoma.

Ixekizumab—In January 2013, we initiated Phase III clinical trial testing for ixekizumab as a potential treatment for psoriatic arthritis.

New insulin glargine product—In July 2013, we and Boehringer Ingelheim announced that the marketing authorization application for our new insulin glargine product, filed in June 2013 through the biosimilar pathway, was accepted for review by the European Medicines Agency. We anticipate filing for regulatory review in the U.S. in 2013.

Novel basal insulin analog—In January 2013, we announced plans for the 2013 and 2014 initiation of the remainder of the pre-planned clinical trials for the molecule. These studies will be conducted to support regulatory submissions and evaluate safety, efficacy, and differentiation of the molecule. These studies are in addition to the five ongoing IMAGINE clinical trials.

Ramucirumab—In the first quarter of 2013, we initiated a rolling submission to the FDA for ramucirumab as a single-agent biologic therapy in patients with advanced gastric cancer following progression on prior chemotherapy. We anticipate completion of the rolling submission to occur in 2013.

Tabalumab—In February 2013, we announced our decision to discontinue the Phase III rheumatoid arthritis program for tabalumab due to lack of efficacy. The decision was not based on safety concerns. The tabalumab Phase III program for lupus is ongoing and will continue as planned.

There are many difficulties and uncertainties inherent in pharmaceutical research and development (R&D) and the introduction of new products. A high rate of failure is inherent in new drug discovery and development. The process to bring a drug from the discovery phase to regulatory approval can take 12 to 15 years or longer and cost more than \$1 billion. Failure can occur at any point in the process, including late in the process after substantial investment. As a result, most research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success. Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunities. Consequently, it is very difficult to predict which products will ultimately be approved and the sales growth of those products.

We manage R&D spending across our portfolio of molecules, and a delay in, or termination of, any one project will not necessarily cause a significant change in our total R&D spending. Due to the risks and uncertainties involved in the R&D process, we cannot reliably estimate the nature, timing, completion dates, and costs of the efforts necessary to complete the development of our R&D projects, nor can we reliably estimate the future potential revenue that will be generated from a successful R&D project. Each project represents only a portion of the overall pipeline, and none is individually material to our consolidated R&D expense. While we do accumulate certain R&D costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that are neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to report on total R&D costs by project, by preclinical versus clinical spend, or by therapeutic category.

Legal, Regulatory, and Other Matters

We depend on patents or other forms of intellectual-property protection for most of our revenues, cash flows, and earnings. Through 2014, we expect to lose U.S. patent protection for Cymbalta (December 2013) and Evista® (March 2014). The loss of exclusivity for Cymbalta and Evista will likely result in generic competition, generally causing a rapid and severe decline in revenue from the affected product, and having a material adverse effect on our results of operations. The U.S. compound patent for Humalog® expired in May 2013. We do not currently expect the loss of compound patent protection for Humalog to result in a rapid and severe decline in revenue. To date, no biosimilar version of Humalog has been approved in the U.S. or Europe; however, we are aware that other manufacturers have efforts under way to develop biosimilar forms of Humalog, and it is difficult to predict the likelihood, timing, and impact of biosimilars entering the market. Our goal is to mitigate the effect of these exclusivity losses on our operations, liquidity, and financial position through growth in our patent-protected products that do not lose exclusivity during this period, in the emerging markets, in Japan, and in our animal health business. Our expected growth in the emerging markets and Japan is attributable to both the growth of these markets and launches of patent-protected products.

The continuing prominence of U.S. budget deficits as both a policy and political issue increases the risk that taxes, fees, rebates, or other federal measures that would further reduce pharmaceutical companies' revenue or increase expenses may be enacted. Certain federal and state health care proposals, including state price controls, continue to be debated, and could place downward pressure on pharmaceutical industry sales or prices. These federal and

state proposals, or state price pressures, could have a material adverse effect on our consolidated results of operations. International operations also are generally subject to extensive price and market regulations. Proposals for cost-containment measures are pending in a number of countries, including proposals that would directly or indirectly impose additional price controls, limit access to or reimbursement for our products, or reduce the value of our intellectual-property protection. Such proposals are expected to increase in both frequency and impact, given the pressures on national and regional health care budgets as a result of austerity measures being pursued in a number of countries.

The Obama administration has proposed changes to the manner in which the U.S. would tax the international income of U.S.-based companies. There also have been tax proposals under discussion or introduced in the U.S. Congress that could change the manner in which, and the rate at which, income of U.S. companies would be taxed. While it is uncertain how the U.S. Congress may address U.S. tax policy matters in the future, reform of U.S. taxation, including taxation of international income, will continue to be a topic of discussion for Congress and the Obama administration. A significant change to the U.S. tax system, including changes to the taxation of international income, could have a material adverse effect on our consolidated results of operations.

Revenue

Worldwide total revenue increased 6 percent to \$5.93 billion for the second quarter of 2013 and increased 3 percent to \$11.53 billion for the first six months of 2013, compared with the same periods of 2012. For the second quarter, increases of 6 percent and 2 percent due to higher prices and increased volume, respectively, were partially offset by a decrease of 2 percent due to the unfavorable impact of foreign exchange rates. The increase in volume was driven by volume gains for various products, partially offset by continued volume declines of Zyprexa due to the loss of patent exclusivity in most major markets and the transfer of exenatide commercial rights outside of the U.S. to Amylin. For the first six months of 2013, a 5 percent increase due to higher prices was partially offset by decreases of 2 percent and 1 percent due to the unfavorable impact of foreign exchange rates and decreased volume, respectively (numbers do not add due to rounding). Total revenue in the U.S. increased 13 percent to \$3.40 billion for the second quarter of 2013 and increased 7 percent to \$6.53 billion for the first six months of 2013, driven by increased prices, primarily for Cymbalta. Total revenue outside the U.S. decreased 2 percent to \$2.53 billion for the second quarter of 2013 and decreased 2 percent to \$5.00 billion for the first six months of 2013, driven by the unfavorable impact of foreign exchange rates, primarily the Japanese yen, the loss of patent exclusivity for Zyprexa in most markets outside of Japan and, to a lesser extent, decreased prices, partially offset by increased volume.

The following table summarizes our revenue activity:

Product	Three Months Ended June 30, 2013			Three Months Ended June 30, 2012		Percent Change from 2012
	U.S. ⁽¹⁾	Outside U.S.	Total	Total		
	(Dollars in millions)					
Cymbalta	\$1,217.4	\$279.8	\$1,497.2	\$1,223.1	22	%
Alimta	304.9	364.5	669.4	659.5	2	%
Humalog	351.9	276.7	628.6	613.4	2	%
Cialis	214.7	314.7	529.4	469.5	13	%
Humulin®	158.1	169.4	327.5	303.0	8	%
Forteo®	115.8	181.1	296.9	276.4	7	%
Zyprexa	19.5	263.7	283.2	379.5	(25))%
Evista	199.3	79.4	278.7	265.9	5	%
Strattera®	102.6	65.7	168.3	153.0	10	%
Effient	103.8	33.6	137.4	111.0	24	%
Other pharmaceutical products	174.2	225.6	399.8	489.0	(18))%
Animal health products	321.3	222.2	543.5	512.2	6	%
Total net product sales	3,283.5	2,476.4	5,759.9	5,455.5	6	%
Collaboration and other revenue ⁽²⁾	113.8	56.0	169.8	145.2	17	%
Total revenue	\$3,397.3	\$2,532.4	\$5,929.7	\$5,600.7	6	%
	Six Months Ended June 30, 2013			Six Months Ended June 30, 2012		Percent Change from 2012
Product	U.S. ⁽¹⁾	Outside U.S.	Total	Total		
	(Dollars in millions)					
Cymbalta	\$2,274.3	\$551.1	\$2,825.4	\$2,338.0	21	%
Alimta	567.0	719.3	1,286.3	1,266.3	2	%
Humalog	730.1	531.2	1,261.3	1,203.6	5	%
Cialis	428.9	615.5	1,044.4	931.3	12	%
Humulin	321.6	317.8	639.4	610.7	5	%
Forteo	227.3	351.1	578.4	547.7	6	%
Zyprexa	51.5	516.5	568.0	942.1	(40))%
Evista	370.9	148.3	519.2	522.1	(1))%
Strattera	208.2	126.8	335.0	311.9	7	%
Effient	187.5	65.7	253.2	226.9	12	%
Other pharmaceutical products	321.0	534.4	855.4	965.7	(11))%
Animal health products	616.2	426.2	1,042.4	1,003.0	4	%
Total net product sales	6,304.5	4,903.9	11,208.4	10,869.3	3	%
Collaboration and other revenue ⁽²⁾	229.7	93.6	323.3	333.4	(3))%
Total revenue	\$6,534.2	\$4,997.5	\$11,531.7	\$11,202.7	3	%

¹ U.S. revenue includes revenue in Puerto Rico.

Collaboration and other revenue in 2013 consists primarily of royalties for Erbitux and revenue associated with

² Trajenta. Collaboration and other revenue in 2012 also includes revenue associated with exenatide in the United States.

U.S. sales of Cymbalta, a product for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, generalized anxiety disorder, and in the U.S. for the treatment of chronic musculoskeletal pain and the management of fibromyalgia, increased 27 percent and 25 percent during the second quarter and first six months of 2013, respectively, driven by higher prices and, to a lesser extent, increased demand and the favorable impact of wholesaler buying patterns. Sales outside the U.S. increased 4 percent and 5 percent during the second quarter and first six months of 2013, respectively, driven primarily by increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower prices. We will lose effective exclusivity for Cymbalta in the U.S. in December 2013. Several manufacturers have received tentative approvals to market generic duloxetine, and we expect generic duloxetine to be introduced in the market immediately following the loss of exclusivity. While it is difficult to predict the precise impact on Cymbalta sales, we expect the introduction of generics to result in a rapid and severe decline in our Cymbalta sales, which will have a material adverse effect on results of operations and cash flows.

U.S. sales of Alimta, a treatment for various cancers, increased 9 percent and 6 percent during the second quarter and first six months of 2013, respectively, driven by increased demand and higher prices. Sales outside the U.S. decreased 4 percent and 2 percent in the second quarter and first six months of 2013, respectively, due to the unfavorable impact of foreign exchange rates and lower prices, partially offset by increased volume.

U.S. sales of Humalog, our injectable human insulin analog for the treatment of diabetes, remained flat in the second quarter of 2013, driven by lower net effective selling prices, offset by increased volume. For the first six months of 2013, U.S. sales increased 4 percent, driven by the favorable impact of wholesaler buying patterns in the first quarter. Sales outside the U.S. increased 7 percent and 6 percent in the second quarter and first six months of 2013, respectively, due to increased volume, partially offset by the unfavorable impact of foreign exchange rates and lower prices.

U.S. sales of Cialis, a treatment for erectile dysfunction and benign prostatic hyperplasia (BPH), increased 15 percent and 17 percent in the second quarter and first six months of 2013, respectively, driven primarily by higher prices. Sales outside the U.S. increased 11 percent and 9 percent in the second quarter and first six months of 2013, respectively, driven by increased volume and higher prices, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Humulin, an injectable human insulin for the treatment of diabetes, increased 11 percent and 8 percent in the second quarter and first six months of 2013, respectively, driven by higher prices, partially offset by decreased demand. Sales outside the U.S. increased 5 percent and 1 percent in the second quarter and first six months of 2013, respectively, driven by increased volume, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Forteo, an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in postmenopausal women and men, decreased 2 percent in the second quarter due to decreased volume, partially offset by higher prices. For the first six months of 2013, U.S. sales decreased 5 percent, due primarily to decreased volume. Sales outside the U.S. increased 14 percent in both the second quarter and first six months of 2013, due primarily to increased volume in Japan, partially offset by the unfavorable impact of foreign exchange rates.

U.S. sales of Zyprexa, a treatment for schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance, decreased 35 percent and 78 percent in the second quarter and first six months of 2013, respectively. Sales outside the U.S. decreased 25 percent and 27 percent in the second quarter and first six months of 2013, respectively. The decreases were due to the loss of patent exclusivity in 2011 in the U.S. and most major international markets outside of Japan. Zyprexa sales in Japan were approximately \$130 million and \$245 million for the three and six months ended June 30, 2013, respectively, and were negatively affected by the continued weakening of the Japanese yen.

U.S. sales of Evista, a product for the prevention and treatment of osteoporosis in postmenopausal women and for reduction of risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer, increased 9 percent and 5 percent in the second quarter and first six months of 2013, respectively, driven by higher prices, partially offset by decreased demand. Sales outside the U.S. decreased 5 percent in the second quarter driven by the unfavorable impact of foreign exchange rates, partially offset by higher volume. For the first six months of 2013, sales outside the U.S. decreased 12 percent due primarily to the unfavorable

impact of foreign exchange rates. We will lose effective patent exclusivity for Evista in the U.S. in March 2014. We are aware of manufacturers that have received tentative approvals to market generic raloxifene hydrochloride, the active ingredient in Evista, and we expect generic raloxifene hydrochloride to be introduced in the market immediately following the loss of exclusivity. While it is difficult to predict the precise impact on Evista sales,

we expect the introduction of generics to result in a rapid and severe decline in our Evista sales, which will have a material adverse effect on results of operations and cash flows.

U.S. sales of Strattera, a treatment for attention-deficit hyperactivity disorder in children, adolescents, and in the U.S. in adults, increased 10 percent and 5 percent in the second quarter and first six months of 2013, respectively, due to higher prices, partially offset by lower demand. Sales outside the U.S. increased 10 percent and 12 percent in the second quarter and first six months of 2013, respectively, driven by increased volume in Japan, partially offset by lower prices and the unfavorable impact of foreign exchange rates.

U.S. sales of Effient, a product for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are managed with an artery-opening procedure known as percutaneous coronary intervention (PCI), including patients undergoing angioplasty, atherectomy, or stent placement, increased 28 percent and 10 percent in the second quarter and first six months of 2013, respectively, driven by higher prices. Sales outside the U.S. increased 12 percent and 17 percent in the second quarter and first six months of 2013, respectively, driven by increased volume.

Animal health product sales in the U.S. increased 5 percent in the second quarter of 2013, due primarily to increased demand for Trifexis®. For the first six months of 2013, U.S. sales increased 7 percent due to increased demand for Trifexis, partially offset by decreased volume in food animal products. Sales outside the U.S. increased 7 percent in the second quarter, driven primarily by increased sales of companion animal products. For the first six months of 2013, sales outside the U.S. decreased 1 percent as the unfavorable impact of foreign exchange rates was largely offset by increased prices.

Gross Margin, Costs, and Expenses

Gross margin as a percent of total revenue increased 0.8 percentage points, to 80.3 percent, for the second quarter and 0.8 percentage points, to 79.9 percent, for the first six months of 2013. The increase in gross margin percent for the second quarter was primarily due to higher prices and production volumes, partially offset by the impact of foreign exchange rates on international inventories sold. For the first six months of 2013, the increase in gross margin percent was primarily due to higher prices and production volumes, partially offset by the impact of foreign exchange rates on international inventories sold and higher manufacturing expenses.

Marketing, selling, and administrative expenses decreased 3 percent and 7 percent to \$1.87 billion and \$3.52 billion for the second quarter and first six months of 2013, respectively, as ongoing cost-containment efforts and the favorable impact of foreign exchange rates were partially offset by higher litigation expenses in the second quarter.

Research and development expenses increased 1 percent and 8 percent to \$1.33 billion and \$2.68 billion for the second quarter and first six months of 2013, respectively, driven by expenses related to late-stage clinical trials.

During the first quarter of 2013, we made milestone payments of \$92.2 million to Boehringer Ingelheim following the regulatory submissions for empagliflozin and also incurred approximately \$60 million in costs related to the discontinuation of the rheumatoid arthritis program for tabalumab.

We recognized asset impairments, restructuring, and other special charges of \$63.5 million and \$85.2 million for the second quarter and first six months of 2013, respectively, compared with no charges and \$23.8 million for the second quarter and first six months of 2012, respectively. See Note 5 for additional information.

Other—net, (income) expense was income of \$11.9 million and \$541.1 million for the second quarter and first six months of 2013, respectively, compared with expense of \$16.5 million and \$62.5 million for the same respective periods in 2012. The increase for the second quarter was primarily related to a gain on the sale of an investment. The increase for the first six months was primarily driven by the income recognized from the transfer to Amylin of exenatide commercial rights outside the U.S. in the first quarter of 2013. See Notes 4 and 14 for additional information.

The effective tax rate was 20.4 percent and 20.5 percent for the second quarter and first six months of 2013, respectively, compared with an effective tax rate of 22.1 percent and 23.3 percent for the same respective periods in 2012. The decrease in the effective tax rate for both periods reflects the reinstatement of the R&D tax credit in the U.S. effective January 1, 2013. In addition, the decrease in the effective tax rate for the first six months of 2013 reflects the one-time impact of the R&D tax credit for 2012 that was recorded in the first quarter of 2013, partially offset by the tax impact of the transfer to Amylin of exenatide commercial rights outside the U.S. in the first quarter of

2013.

27

Financial Condition

Cash and cash equivalents decreased to \$3.79 billion as of June 30, 2013, compared with \$4.02 billion as of December 31, 2012, as net proceeds from sales and maturities of short-term investments of \$1.47 billion and cash flow from operations of \$2.02 billion were more than offset by share repurchases of \$1.20 billion, dividends paid of \$1.06 billion, and net purchases of noncurrent investments of \$1.01 billion.

Total debt decreased to \$5.31 billion as of June 30, 2013, compared with \$5.53 billion as of December 31, 2012 due to the decrease in fair value of our hedged debt. Our current debt ratings from Standard & Poor's and Moody's are AA- and A2, respectively. Our ratings outlook from both Moody's and Standard & Poor's is stable.

Both domestically and abroad, we continue to monitor the potential impacts of the economic environment; the creditworthiness of our wholesalers and other customers, including foreign government-backed agencies and suppliers; the uncertain impact of recent health care legislation; and various international government funding levels. We continue to focus specifically on the economic health of the European economy, as heightened economic concerns persist. Currently, we believe economic conditions in Europe will not have a material impact on our liquidity. We believe that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund our normal operating needs, including dividends, capital expenditures, and potential business development activity. We believe that amounts accessible through existing commercial paper markets should be adequate to fund short-term borrowings. We currently have \$1.36 billion of unused committed bank credit facilities, \$1.20 billion of which backs our commercial paper program. Various risks and uncertainties, including those discussed in "Forward-Looking Statements", may affect our operating results and cash generated from operations.

We will lose U.S. patent protection for Cymbalta in December 2013 and for Evista in March 2014. See "Executive Overview—Legal, Regulatory, and Other Matters" for additional information.

Legal and Regulatory Matters

Information relating to certain legal proceedings can be found in Note 12 and is incorporated here by reference.

Financial Expectations for 2013

We have revised certain elements of our 2013 financial guidance. For the full year of 2013, we now expect EPS to be in the range of \$4.28 to \$4.38. We still anticipate that total revenue will be between \$22.6 billion and \$23.4 billion. Despite the initial impact of the U.S. Cymbalta patent expiration in the fourth quarter of 2013 and the loss of the anticipated 15 percent revenue-sharing obligation on worldwide exenatide sales, we expect overall revenue growth, driven by a portfolio of products including Humalog, Humulin, Cialis, Strattera, Forteo, Alimta, Cymbalta outside the U.S., Effient, Tradjenta, and Axiron®, as well as animal health products. In addition, significant revenue growth is expected in the emerging markets, particularly China, while a weaker Japanese yen will dampen revenue growth in Japan.

We now anticipate that gross margin as a percent of revenue will be approximately 79 percent. Marketing, selling, and administrative expenses are now expected to be in the range of \$7.0 billion to \$7.2 billion. Research and development expense is now expected to be in the range of \$5.3 billion to \$5.5 billion. Other—net, (income) expense is still expected to be in a range between \$440 million and \$590 million of income. We still anticipate capital expenditures of approximately \$900 million.

Available Information on our Website

We make available through our company website, free of charge, our company filings with the SEC as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The reports we make available include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements, and any amendments to those documents.

The website link to our SEC filings is <http://investor.lilly.com/financials.cfm>.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Under applicable SEC regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically (a) evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be

disclosed by the reporting company in its periodic reports filed with the commission (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of John C. Lechleiter, Ph.D., chairman, president, and chief executive officer, and Derica W. Rice, executive vice president, global services, and chief financial officer, evaluated our disclosure controls and procedures as of June 30, 2013, and concluded that they are effective.

Changes in Internal Controls. During the second quarter of 2013, there were no changes in our internal control over (b) financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

See Note 12: Contingencies to the Consolidated Condensed Financial Statements for information on various legal proceedings, including but not limited to:

- The U.S. patent litigation involving Alimta
- The product liability litigation involving Byetta, diethylstilbestrol, and Prozac
- The employee litigation in Brazil.

That information is incorporated into this Item by reference.

This Item should be read in conjunction with the Legal Proceedings disclosures in our Annual Report on Form 10-K for the year ended December 31, 2012 (Part I, Item 3) and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 (Part II, Item 1).

Other Product Liability Litigation

We are currently a defendant in a variety of other product liability lawsuits in the U.S. involving primarily Darvon[®], Zyprexa, Actos[®], and Cymbalta.

Along with several other manufacturers, we are named as a defendant in approximately 70 active cases in the U.S. involving approximately 1,650 active claimants related to the analgesics Darvon and related formulations of propoxyphene. Additionally, 72 cases involving approximately 215 claimants were recently dismissed and are on appeal to the Sixth Circuit. These cases generally allege various cardiac injuries. Almost all of these cases have been consolidated in a federal multi-district litigation in the Eastern District of Kentucky or are pending in state and federal courts in California. A putative class action has been filed in the U.S. District Court for the Eastern District of Louisiana (Ballard, et al. v. Eli Lilly and Company et al.) against Lilly and other manufacturers seeking to assert product liability claims on behalf of U.S. residents who ingested propoxyphene pain products and allegedly sustained personal injuries. Lilly was dismissed with prejudice following a dispositive motion; however, the case remains open as other defendants have not been dismissed and there is currently no final appealable order. We transferred the U.S. regulatory approvals and all marketing rights to our propoxyphene products in 2002 to NeoSan Pharmaceuticals, Inc. (an affiliate of aaiPharma, Inc.), which subsequently transferred all such approvals and marketing rights to Xanodyne Pharmaceuticals, Inc. We believe these claims are without merit and are prepared to defend against them vigorously.

We have been named along with Takeda Chemical Industries, Ltd., and Takeda affiliates as a defendant in product liability cases in the U.S. related to the diabetes medication Actos, which we co-promoted with Takeda in the U.S. from 1999 until September 2006. In addition, we have been named along with Takeda as a defendant in three purported product liability class actions in Canada related to Actos, including one in Ontario (Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.), one in Quebec (Whyte et al. v. Eli Lilly et al.), and one in Alberta (Epp v. Takeda Canada et al.). We have also been named along with Takeda in an individual action for damages in Ontario, Canada (Antonacci v. Takeda Pharmaceutical Company Ltd, et al.). We promoted Actos in Canada until 2009. In general, plaintiffs in these actions allege that Actos caused or contributed to their bladder cancer. Under our agreement with Takeda, we will be indemnified by Takeda for our losses and expenses with respect to the U.S. litigation and other expenses in accordance with the terms of the indemnification agreement. We believe these claims are without merit and are prepared to defend against them vigorously.

Other Matters

We have been engaged in patent litigation in Canada regarding the validity of our Zyprexa patent. In September 2012, the Canadian Court of Appeals affirmed the lower court's decision that the patent was invalid for lack of utility. We sought leave to file a petition for review of the Court of Appeal's decision before the Supreme Court of Canada. In May of 2013 the Supreme Court of Canada denied our Leave to Appeal. We are exposed to damages from Teva arising from our market exclusivity for Zyprexa. The total amount of damages cannot be determined until after a separate damages trial, which has not yet been scheduled.

We are also a defendant in other litigation and investigations, including product liability, patent, employment, and premises liability litigation, of a character we regard as normal to our business.

Item 1A. Risk Factors

Our material risk factors are disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2012. There have been no material changes from the risk factors previously disclosed in our Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In December 2012, we announced a \$1.50 billion share repurchase program. As of December 31, 2012, there were \$1.10 billion of shares remaining to be purchased. During the first quarter of 2013, we completed this program by purchasing the remaining \$1.10 billion of shares. There was no repurchase activity during the second quarter ended June 30, 2013.

Item 6. Exhibits

The following documents are filed as exhibits to this Report:

- | | |
|--------------|---|
| EXHIBIT 11. | Statement re: Computation of Earnings per Share |
| EXHIBIT 12. | Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges |
| EXHIBIT 31.1 | Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer |
| EXHIBIT 31.2 | Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer |
| EXHIBIT 32. | Section 1350 Certification |
| EXHIBIT 101. | Interactive Data File |

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ELI LILLY AND COMPANY
(Registrant)

Date: July 26, 2013

/s/James B. Lootens
James B. Lootens
Corporate Secretary

Date: July 26, 2013

/s/Donald A. Zakrowski
Donald A. Zakrowski
Vice President, Finance and Chief Accounting Officer

Index to Exhibits

The following documents are filed as a part of this Report:

Exhibit

- | | |
|--------------|---|
| EXHIBIT 11. | Statement re: Computation of Earnings per Share |
| EXHIBIT 12. | Statement re: Computation of Ratio of Earnings (Loss) to Fixed Charges |
| EXHIBIT 31.1 | Rule 13a-14(a) Certification of John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer |
| EXHIBIT 31.2 | Rule 13a-14(a) Certification of Derica W. Rice, Executive Vice President, Global Services and Chief Financial Officer |
| EXHIBIT 32. | Section 1350 Certification |
| EXHIBIT 101. | Interactive Data File |