

BRISTOL MYERS SQUIBB CO

Form 10-Q

October 27, 2011

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**  
**FORM 10-Q**

(Mark One)

- x **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011**
- .. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM            TO**  
**Commission file number:            1-1136**

**BRISTOL-MYERS SQUIBB COMPANY**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**22-0790350**  
(I.R.S. Employer  
Identification No.)

**345 Park Avenue, New York, N.Y. 10154**

(Address of principal executive offices) (Zip Code)

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

(212) 546-4000

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

**APPLICABLE ONLY TO CORPORATE ISSUERS:**

At September 30, 2011, there were 1,694,531,520 shares outstanding of the Registrant's \$0.10 par value common stock.

**Table of Contents**

**BRISTOL-MYERS SQUIBB COMPANY**

**INDEX TO FORM 10-Q**

**SEPTEMBER 30, 2011**

**PART I FINANCIAL INFORMATION**

**Item 1.**

Financial Statements:

<u>Consolidated Statements of Earnings</u>	3
<u>Consolidated Statements of Comprehensive Income</u>	4
<u>Consolidated Balance Sheets</u>	5
<u>Consolidated Statements of Cash Flows</u>	6
<u>Notes to Consolidated Financial Statements</u>	7

**Item 2.**

<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
--	----

**Item 3.**

<u>Quantitative and Qualitative Disclosures About Market Risk</u>	45
---	----

**Item 4.**

<u>Controls and Procedures</u>	45
--------------------------------	----

**PART II OTHER INFORMATION**

**Item 1.**

<u>Legal Proceedings</u>	45
--------------------------	----

**Item 2.**

<u>Issuer Purchases of Equity Securities</u>	45
--	----

**Item 6.**

<u>Exhibits</u>	46
-----------------	----

**Signatures**

47

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS****BRISTOL-MYERS SQUIBB COMPANY****CONSOLIDATED STATEMENTS OF EARNINGS****Dollars and Shares in Millions, Except Per Share Data****(UNAUDITED)**

<b>EARNINGS</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Net Sales	\$ 5,345	\$ 4,798	\$ 15,790	\$ 14,373
Cost of products sold	1,407	1,280	4,231	3,863
Marketing, selling and administrative	1,019	892	2,987	2,686
Advertising and product promotion	205	231	672	706
Research and development	973	824	2,831	2,556
Provision for restructuring	8	15	92	50
Litigation expense, net		22		22
Equity in net income of affiliates	(71)	(70)	(215)	(252)
Other (income)/expense	(26)	(10)	(195)	84
Total Expenses	3,515	3,184	10,403	9,715
Earnings Before Income Taxes	1,830	1,614	5,387	4,658
Provision for income taxes	475	312	1,358	987
Net Earnings	1,355	1,302	4,029	3,671
Net Earnings Attributable to Noncontrolling Interest	386	353	1,172	1,052
Net Earnings Attributable to Bristol-Myers Squibb Company	\$ 969	\$ 949	\$ 2,857	\$ 2,619
Earnings per Common Share Attributable to Bristol-Myers Squibb Company				
Basic	\$ 0.57	\$ 0.55	\$ 1.67	\$ 1.52
Diluted	\$ 0.56	\$ 0.55	\$ 1.66	\$ 1.51
Dividends declared per common share	\$ 0.33	\$ 0.32	\$ 0.99	\$ 0.96

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****BRISTOL-MYERS SQUIBB COMPANY****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME****Dollars in Millions****(UNAUDITED)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
<b>COMPREHENSIVE INCOME</b>				
Net Earnings	\$ 1,355	\$ 1,302	\$ 4,029	\$ 3,671
Other Comprehensive Income/(Loss):				
Foreign currency translation	(40)	82	(12)	42
Foreign currency translation on net investment hedges	44	(79)	(13)	64
Derivatives qualifying as cash flow hedges, net of taxes of \$(23) and \$30 for the three months ended September 30, 2011 and 2010, respectively; and \$3 for the nine months ended September 30, 2011	60	(61)	3	8
Derivatives qualifying as cash flow hedges reclassified to net earnings, net of taxes of \$(9) and \$6 for the three months ended September 30, 2011 and 2010, respectively; and \$(16) and \$3 for the nine months ended September 30, 2011 and 2010, respectively	18	(15)	31	(9)
Pension and postretirement benefits, net of taxes of \$4 for the nine months ended September 30, 2010				(12)
Pension and postretirement benefits reclassified to net earnings, net of taxes of \$(11) and \$(12) for the three months ended September 30, 2011 and 2010, respectively; and \$(30) and \$(35) for the nine months ended September 30, 2011 and 2010, respectively	19	14	56	57
Available for sale securities, net of taxes of \$(3) for the three months ended September 30, 2011; and \$(6) and \$(1) for the nine months ended September 30, 2011 and 2010, respectively	6	25	24	57
<b>Total Other Comprehensive Income/(Loss)</b>	<b>107</b>	<b>(34)</b>	<b>89</b>	<b>207</b>
<b>Comprehensive Income</b>	<b>1,462</b>	<b>1,268</b>	<b>4,118</b>	<b>3,878</b>
<b>Comprehensive Income Attributable to Noncontrolling Interest</b>	<b>386</b>	<b>353</b>	<b>1,172</b>	<b>1,052</b>
<b>Comprehensive Income Attributable to Bristol-Myers Squibb Company</b>	<b>\$ 1,076</b>	<b>\$ 915</b>	<b>\$ 2,946</b>	<b>\$ 2,826</b>

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****BRISTOL-MYERS SQUIBB COMPANY****CONSOLIDATED BALANCE SHEETS****Dollars in Millions, Except Share and Per Share Data****(UNAUDITED)**

	<b>September 30, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 4,471	\$ 5,033
Marketable securities	3,722	2,268
Receivables	3,687	3,480
Inventories	1,357	1,204
Deferred income taxes	1,276	1,036
Prepaid expenses and other	356	252
<b>Total Current Assets</b>	<b>14,869</b>	<b>13,273</b>
Property, plant and equipment	4,492	4,664
Goodwill	5,564	5,233
Other intangible assets	3,196	3,370
Deferred income taxes	333	850
Marketable securities	2,819	2,681
Other assets	741	1,005
<b>Total Assets</b>	<b>\$ 32,014</b>	<b>\$ 31,076</b>
<b>LIABILITIES</b>		
Current Liabilities:		
Short-term borrowings	\$ 182	\$ 117
Accounts payable	2,292	1,983
Accrued expenses	2,699	2,740
Deferred income	321	402
Accrued rebates and returns	1,058	857
U.S. and foreign income taxes payable	183	65
Dividends payable	578	575
<b>Total Current Liabilities</b>	<b>7,313</b>	<b>6,739</b>
Pension, postretirement and postemployment liabilities	811	1,297
Deferred income	860	895
U.S. and foreign income taxes payable	690	755
Other liabilities	467	424
Long-term debt	5,437	5,328
<b>Total Liabilities</b>	<b>15,578</b>	<b>15,438</b>

Commitments and contingencies (Note 16)

**EQUITY**

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Bristol-Myers Squibb Company Shareholders' Equity:		
Preferred stock, \$2 convertible series, par value \$1 per share: Authorized 10 million shares; issued and outstanding 5,268 in 2011 and 5,269 in 2010, liquidation value of \$50 per share		
Common stock, par value of \$0.10 per share: Authorized 4.5 billion shares; 2.2 billion issued in both 2011 and 2010		
	220	220
Capital in excess of par value of stock	3,226	3,682
Accumulated other comprehensive loss	(2,282)	(2,371)
Retained earnings	32,797	31,636
Less cost of treasury stock 511 million common shares in 2011 and 501 million in 2010	(17,389)	(17,454)
Total Bristol-Myers Squibb Company Shareholders' Equity	16,572	15,713
Noncontrolling interest	(136)	(75)
Total Equity	16,436	15,638
Total Liabilities and Equity	\$ 32,014	\$ 31,076

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents**

**BRISTOL-MYERS SQUIBB COMPANY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

Dollars in Millions

(UNAUDITED)

	Nine Months Ended September 30,	
	2011	2010
<b>Cash Flows From Operating Activities:</b>		
Net earnings	\$ 4,029	\$ 3,671
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Net earnings attributable to noncontrolling interest	(1,172)	(1,052)
Depreciation	333	348
Amortization	261	198
Impairment charges	28	207
Deferred income tax expense	273	100
Stock-based compensation expense	120	143
Other	(138)	(34)
Changes in operating assets and liabilities:		
Receivables	(152)	(122)
Inventories	(150)	(37)
Accounts payable	309	77
Deferred income	(119)	1
U.S. and foreign income taxes payable	(20)	(187)
Other	(330)	(417)
<b>Net Cash Provided by Operating Activities</b>	<b>3,272</b>	<b>2,896</b>
<b>Cash Flows From Investing Activities:</b>		
Proceeds from sales and maturities of marketable securities	3,808	2,612
Purchases of marketable securities	(5,344)	(3,703)
Additions to property, plant and equipment and capitalized software	(233)	(299)
Proceeds from sale of businesses and other investing activities	147	57
Purchase of Amira Pharmaceuticals, Inc., net of cash acquired	(310)	
<b>Net Cash Used in Investing Activities</b>	<b>(1,932)</b>	<b>(1,333)</b>
<b>Cash Flows From Financing Activities:</b>		
Short-term borrowings/(repayments)	67	54
Long-term debt borrowings		6
Long-term debt repayments	(78)	(42)
Interest rate swap terminations	296	98
Issuances of common stock	365	211
Common stock repurchases	(859)	(353)
Dividends paid	(1,694)	(1,653)
<b>Net Cash Used in Financing Activities</b>	<b>(1,903)</b>	<b>(1,679)</b>
Effect of Exchange Rates on Cash and Cash Equivalents	1	14
(Decrease)/Increase in Cash and Cash Equivalents	(562)	(102)
Cash and Cash Equivalents at Beginning of Period	5,033	7,683



Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

<b>Cash and Cash Equivalents at End of Period</b>	\$	4,471	\$	7,581
---	----	-------	----	-------

The accompanying notes are an integral part of these consolidated financial statements.

## **Table of Contents**

### **Note 1. BASIS OF PRESENTATION AND NEW ACCOUNTING STANDARDS**

Bristol-Myers Squibb Company (which may be referred to as Bristol-Myers Squibb, BMS or the Company) prepared these unaudited consolidated financial statements following the requirements of the Securities and Exchange Commission and United States (U.S.) generally accepted accounting principles (GAAP) for interim reporting. Under those rules, certain footnotes and other financial information that are normally required for annual financial statements can be condensed or omitted. The Company is responsible for the consolidated financial statements included in this Form 10-Q. These consolidated financial statements include all normal and recurring adjustments necessary for a fair presentation of the financial position at September 30, 2011 and December 31, 2010, the results of operations for the three and nine months ended September 30, 2011 and 2010, and cash flows for the nine months ended September 30, 2011 and 2010. All intercompany balances and transactions have been eliminated. Material subsequent events are evaluated and disclosed through the report issuance date. These unaudited consolidated financial statements and the related notes should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2010 included in the Annual Report on Form 10-K.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Accordingly, the results and trends in these unaudited consolidated financial statements may not be indicative of full year operating results.

The preparation of financial statements requires the use of management estimates and assumptions, based on complex judgments that are considered reasonable, that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and contingent liabilities at the date of the financial statements. The most significant assumptions are employed in estimates used in determining the fair value of intangible assets, restructuring charges and accruals, sales rebate and return accruals including the annual pharmaceutical company fee, legal contingencies, tax assets and tax liabilities, stock-based compensation expense, pension and postretirement benefits, fair value of financial instruments with no direct or observable market quotes, inventory obsolescence, potential impairment of long-lived assets, allowances for bad debt, as well as in estimates used in applying the revenue recognition policy. Actual results may differ from estimated results.

On January 1, 2011, a new revenue recognition standard was adopted for new or materially modified revenue arrangements with upfront licensing fees and contingent milestones relating to research and development deliverables. The guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated and the consideration allocated. The adoption of this standard did not impact the consolidated financial statements.

In June 2011, the Financial Accounting Standard Board (FASB) issued an update to an existing standard for comprehensive income to make the presentation of items within other comprehensive income (OCI) more prominent. This standard is effective for interim and annual periods beginning in 2012. The impact on the presentation of the consolidated financial statements is currently being evaluated.

In September 2011, the FASB amended its guidance for goodwill impairment testing. The amendment allows for entities to first assess qualitative factors in determining whether or not the fair value of a reporting unit exceeds its carrying value. If an entity concludes from this qualitative assessment that it is more likely than not that the fair value of a reporting unit exceeds its carrying value, then performing a two-step impairment test is unnecessary. This standard is effective for fiscal years beginning after December 15, 2011. The adoption of this standard is not expected to have an impact on the consolidated financial statements.

### **Note 2. ALLIANCES AND COLLABORATIONS**

The Company maintains alliances and collaborations with various third parties for the development and commercialization of certain products. See the 2010 Annual Report on Form 10-K for a more complete description of the below agreements, including termination provisions, as well as disclosures of other alliances and collaborations.

#### **Sanofi**

The Company has agreements with Sanofi for the codevelopment and cocommercialization of AVAPRO\*/AVALIDE\* (irbesartan/irbesartan-hydrochlorothiazide) and PLAVIX\* (clopidogrel bisulfate). The worldwide alliance operates under the framework of two geographic territories; one in the Americas (principally the U.S., Canada, Puerto Rico and Latin American countries) and Australia, and the other in Europe and Asia. The agreements expire on the later of (i) with respect to PLAVIX\*, 2013 and, with respect to AVAPRO\*/AVALIDE\*, 2012 in the Americas and Australia and 2013 in Europe and Asia, and (ii) the expiration of all patents and other exclusivity rights in the applicable territory.



## Table of Contents

The Company acts as the operating partner and owns a 50.1% majority controlling interest in the territory covering the Americas and Australia and consolidates all country partnership results for this territory with Sanofi's 49.9% share of the results reflected as a noncontrolling interest. The Company recognizes net sales in this territory and in comarketing countries outside this territory (e.g., Germany, Italy for irbesartan only, Spain and Greece). Discovery royalties owed to Sanofi are included in cost of products sold. Sanofi acts as the operating partner and owns a 50.1% majority controlling interest in the territory covering Europe and Asia. The Company's ownership interest in this territory is 49.9%. The Company does not consolidate the partnership entities in this territory but accounts for them under the equity method and reflects its share of the results recognized in equity in net income of affiliates. Distributions of partnership profits relating to the joint ventures among the Company and Sanofi are recognized in other operating activities in the consolidated statements of cash flows.

The Company and Sanofi have a separate partnership governing the copromotion of irbesartan in the U.S. The Company recognizes other income related to the amortization of deferred income associated with Sanofi's \$350 million payment to the Company for their acquisition of an interest in the irbesartan license for the U.S. upon formation of the alliance. Deferred income will continue to be amortized through 2012, which is the expected expiration of market exclusivity. Certain supply activities and development and opt-out royalties with Sanofi are reflected on a net basis in other (income)/expense.

The Company and Sanofi are currently negotiating certain contractual matters. It is not possible at this time to reasonably assess the outcome of these matters. We do not expect the impact on the Company's results of operations or financial condition to be material.

The following summarized financial information is reflected in the consolidated financial statements:

Dollars in Millions	Three Months Ended September 30, 2011		Nine Months Ended September 30, 2011	
	2011	2010	2011	2010
Territory covering the Americas and Australia:				
Net sales	\$ 1,936	\$ 1,874	\$ 5,959	\$ 5,580
Discovery royalty expense	368	337	1,123	998
Noncontrolling interest pre-tax	590	523	1,764	1,543
Profit distributions to Sanofi	(523)	(545)	(1,824)	(1,598)
Territory covering Europe and Asia:				
Equity in net income of affiliates	(75)	(73)	(226)	(261)
Profit distributions to the Company	97	85	224	239
Other:				
Net sales in Europe comarketing countries and other	68	87	213	295
Amortization (income)/expense irbesartan license fee	(7)	(7)	(23)	(23)
Supply activities and development and opt-out royalty				
(income)/expense	6	3	21	(28)

Dollars in Millions	September 30, 2011		December 31, 2010	
	2011	2010	2011	2010
Investment in affiliates territory covering Europe and Asia	\$ 24	\$ 22		
Deferred income irbesartan license fee	37	60		

The following is summarized financial information for interests in the partnerships with Sanofi for the territory covering Europe and Asia, which are not consolidated but are accounted for using the equity method:

Dollars in Millions	Three Months Ended September 30, 2011		Nine Months Ended September 30, 2011	
	2011	2010	2011	2010
Net sales	\$ 364	\$ 417	\$ 1,125	\$ 1,465
Gross profit	161	174	501	662
Net income	131	141	413	528

**Table of Contents****Otsuka**

The Company has a worldwide commercialization agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka), to codevelop and copromote with Otsuka, ABILIFY\* (aripiprazole), excluding certain Asia Pacific countries. Under the terms of the agreement, the Company purchases the product from Otsuka and performs finish manufacturing for sale to third-party customers by the Company or Otsuka. In the U.S., United Kingdom (UK), Germany, France and Spain, where the product is copromoted and invoiced to third-party customers by the Company on behalf of Otsuka, the Company recognizes alliance revenue for its contractual share of third-party net sales and recognizes this alliance revenue when ABILIFY\* is shipped and all risks and rewards of ownership have transferred to third-party customers. In the U.S. starting January 1, 2011, the Company's contractual share of revenue was reduced from 58% to 53.5% and will be further reduced to 51.5% in 2012. Further reductions in the Company's contractual share of revenue in the U.S. will occur on January 1, 2013 under the terms of the commercialization agreement. Otsuka reimburses the Company 30% of ABILIFY\* related operating expenses in the U.S. Reimbursements are netted principally in advertising and product promotion and marketing, selling and administrative expenses. In France, Germany, Spain and, beginning on January 1, 2011, the UK, the Company receives 65% of third-party net sales with no expense reimbursement. In certain countries where the Company is presently the exclusive distributor for the product or has an exclusive right to sell ABILIFY\*, the Company recognizes all of the net sales and related cost of products sold and expenses.

The Company paid Otsuka \$400 million in April 2009 for extending the term of the U.S. portion of the commercialization and manufacturing agreement through April 2015. This payment is included in other assets and is being amortized as a reduction of net sales through the extension period. Previously capitalized milestone payments totaling \$60 million are included in intangible assets and amortized to cost of products sold over the remaining life of the agreement in the U.S.

The Company and Otsuka also have an oncology collaboration for SPRYCEL (dasatinib) and IXEMPRA (ixabepilone) (the Oncology Products) in the U.S., Japan and the EU (the Oncology Territory). The Company pays a collaboration fee to Otsuka equal to 30% of the first \$400 million annual net sales of the Oncology Products in the Oncology Territory, 5% of annual net sales between \$400 million and \$600 million, and 3% of annual net sales between \$600 million and \$800 million with additional trailing percentages of annual net sales over \$800 million. This fee is included in cost of products sold. Otsuka contributes 20% of the first \$175 million of certain commercial operational expenses relating to the Oncology Products in the Oncology Territory and 1% of such costs in excess of \$175 million. Reimbursements are netted principally in marketing, selling and administrative expense and advertising and product promotion expense.

The following summarized financial information related to this alliance is reflected in the consolidated financial statements:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
ABILIFY* net sales, including amortization of extension payment	\$ 691	\$ 608	\$ 2,021	\$ 1,858
Oncology Products collaboration fee expense	30	30	100	92
Reimbursement of operating expenses to/(from) Otsuka	(23)	(26)	(68)	(74)
Amortization (income)/expense extension payment	16	17	49	49
Amortization (income)/expense upfront, milestone and other licensing payments	1	1	5	5

Dollars in Millions	September 30, 2011	December 31, 2010
Other assets extension payment	\$ 236	\$ 285
Other intangible assets upfront, milestone and other licensing payments	6	11

**Lilly**

The Company has an Epidermal Growth Factor Receptor (EGFR) collaboration agreement with Eli Lilly and Company (Lilly) through Lilly's November 2008 acquisition of ImClone Systems Incorporated (ImClone) for the codevelopment and promotion of ERBITUX\* (cetuximab) and necitumumab (IMC-11F8) in North America and Japan. The EGFR agreement expires as to ERBITUX\* in September 2018 and as to necitumumab when both parties agree to terminate.



**Table of Contents**

Under the EGFR agreement, with respect to ERBITUX\* sales in North America, Lilly receives a distribution fee based on a flat rate of 39% of net sales in North America plus reimbursement of certain royalties paid by Lilly, which is included in cost of products sold. In Japan, the Company shares rights to ERBITUX\* under an agreement with Lilly and Merck KGaA and receives 50% of the pre-tax profit from Merck's net sales of ERBITUX\* in Japan which is further shared equally with Lilly. The Company's share of profits from commercialization in Japan is included in other income. With respect to necitumumab, the companies will share in the cost of developing and potentially commercializing necitumumab in the U.S., Canada and Japan. Lilly maintains exclusive rights to necitumumab in all other markets. The Company will fund 55% of development costs for U.S. studies, 50% for Japan studies, and 27.5% for global studies. All reimbursements to Lilly are recognized in research and development expense.

Previously capitalized milestone payments are being amortized through 2018, the remaining term of the agreement. The amortization is classified in cost of products sold.

The following summarized financial information related to this alliance is reflected in the consolidated financial statements:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net sales	\$ 172	\$ 159	\$ 510	\$ 497
Distribution fees and royalty expense	72	62	212	194
Research and development expense reimbursement				
to Lilly necitumumab	4	4	10	9
Amortization (income)/expense upfront,				
milestone and other licensing payments	9	9	28	28
Japan commercialization fee (income)/expense	(9)	(11)	(24)	(30)

Dollars in Millions	September 30, 2011	December 31, 2010
Other intangible assets upfront, milestone and other licensing payments	\$ 258	\$ 286

**Gilead**

The Company and Gilead Sciences, Inc. (Gilead) have a joint venture to develop and commercialize ATRIPLA\* (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg), a once-daily single tablet three-drug regimen combining the Company's SUSTIVA (efavirenz) and Gilead's TRUVADA\* (emtricitabine and tenofovir disoproxil fumarate), in the U.S., Canada and Europe. The Company accounts for its participation in the U.S. joint venture under the equity method of accounting and recognizes its share of the joint venture results in equity in net income of affiliates in the consolidated statements of earnings.

The Company records revenue for the bulk efavirenz component of ATRIPLA\* upon sales of that product to third-party customers. Revenue for the efavirenz component is determined by applying a percentage to ATRIPLA\* revenue to approximate revenue for the SUSTIVA brand.

The following summarized financial information related to this alliance is reflected in the consolidated financial statements:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net sales	\$ 289	\$ 264	\$ 858	\$ 769
Equity in net loss of affiliates	3	3	11	9

**AstraZeneca**

The Company maintains two worldwide codevelopment and cocommercialization agreements with AstraZeneca PLC (AstraZeneca). The first agreement (Saxagliptin Agreement) is for the worldwide codevelopment and cocommercialization (excluding Japan) of ONGLYZA (saxagliptin). The second agreement (SGLT2 Agreement) is for the worldwide (including Japan) codevelopment and cocommercialization of

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

dapagliflozin. KOMBIGLYZE (saxagliptin and metformin) was codeveloped with AstraZeneca under the Saxagliptin Agreement and is pending regulatory approval in the EU under the tradename KOMBOGLYZE. Under each agreement, the two companies will jointly develop the clinical and marketing strategy and share development expenses, commercialization expenses, and profits and losses equally on a global basis (excluding, in the case of saxagliptin, Japan). The Company will manufacture both products. Under each agreement, the Company has the option to decline involvement in cocommercialization in a given country and instead receive compensation which is tiered based on net sales. Net reimbursements for commercial costs are included principally in advertising and product promotion and selling, general and administrative expenses. AstraZeneca's share of profits is included in cost of products sold.



**Table of Contents**

Upfront, milestone and other licensing payments received for both compounds totaling \$470 million, including \$120 million received during the nine months ended September 30, 2011, are deferred and amortized over the useful life of the products into other income.

The majority of development costs under the initial development plans were paid by AstraZeneca (with AstraZeneca bearing all costs of the initial agreed upon development plan for dapagliflozin in Japan). Additional development costs will be shared equally. The net reimbursements to/(from) AstraZeneca for development costs related to saxagliptin and dapagliflozin are netted in research and development.

The following summarized financial information related to this alliance is reflected in the consolidated financial statements:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net sales	\$ 127	\$ 47	\$ 320	\$ 85
Profit sharing expense	58	21	148	39
Commercialization expense reimbursements				
to/(from) AstraZeneca	(11)	(13)	(30)	(25)
Research and development expense reimbursements				
to/(from) AstraZeneca	4	6	33	9
Amortization (income)/expense   upfront,				
milestone and other licensing payments	(10)	(7)	(28)	(20)

Dollars in Millions	September 30,	December 31,
	2011	2010
Deferred income   upfront, milestone and other		
licensing payments	\$ 382	\$ 290

**Pfizer**

The Company and Pfizer Inc. (Pfizer) maintain a worldwide codevelopment and cocommercialization agreement for ELIQUIS\* (apixaban). Effective January 1, 2007, Pfizer funds 60% of all development costs under the initial development plan and the Company funds 40%. The net reimbursements to the Company for ELIQUIS\* development costs are netted in research and development. The companies will jointly develop the clinical and marketing strategy and will share commercialization expenses and profits and losses equally on a global basis. The Company is responsible for manufacturing the product under this arrangement. In May 2011, ELIQUIS\* was approved in the EU for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. ELIQUIS\* was launched in a limited number of EU countries beginning in July 2011.

Previously received upfront, milestone and other licensing payments totaling \$474 million are deferred and amortized over the useful life of the product into other income.

The following summarized financial information related to this alliance is reflected in the consolidated financial statements:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Commercialization expense reimbursement to/(from) Pfizer	\$ (2)	\$ (2)	\$ (5)	\$ (4)
Research and development reimbursements to/(from) Pfizer	(16)	(39)	(74)	(158)
Amortization (income)/expense   upfront, milestone and other				
licensing payments	(8)	(8)	(24)	(24)

# Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Dollars in Millions		September 30, 2011	December 31, 2010
Deferred income	upfront, milestone and other licensing payments	\$ 358	\$ 382

## Exelixis

In July 2011, the Company notified Exelixis, Inc. (Exelixis) that it is terminating its license for XL-281, a Phase I oral anti-cancer compound with utility in RAS and RAF mutant tumors. Effective October 8, 2011, all rights returned to Exelixis effectively ending the collaboration agreement entered into in December 2008. The Company is no longer obligated for contingent development and regulatory milestones of \$315 million and sales-based milestones of \$150 million. The Company's other collaborations with Exelixis remain unchanged. At September 30, 2011, the Company's equity investment in Exelixis represented less than 1% of their outstanding shares.

**Table of Contents****Note 3. BUSINESS SEGMENT INFORMATION**

The Company operates in a single BioPharmaceuticals segment which is engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale of innovative medicines that help patients prevail over serious diseases. A global research and development organization and a global supply chain organization are utilized and responsible for the development and delivery of products to the market. Products are distributed and sold through regional organizations that serve the United States; Europe; Latin America, Middle East, and Africa; Japan, Asia Pacific and Canada; and Emerging Markets defined as Brazil, Russia, India, China and Turkey. The business is also supported by global corporate staff functions. The segment information presented below is consistent with the financial information regularly reviewed by the chief operating decision maker for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting future periods.

Net sales of key products were as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
PLAVIX*	\$ 1,788	\$ 1,658	\$ 5,415	\$ 4,951
AVAPRO*/AVALIDE*	216	303	757	924
ABILIFY*	691	608	2,021	1,858
REYATAZ	391	375	1,153	1,105
SUSTIVA Franchise	359	342	1,073	1,008
BARACLUDE	311	228	878	667
ERBITUX*	172	159	510	497
SPRYCEL	211	144	576	407
YERVOY	121		216	
ORENCIA	233	184	660	531
NULOJIX			2	
ONGLYZA/KOMBIGLYZE	127	47	320	85
Mature Products and All Other	725	750	2,209	2,340
Net Sales	\$ 5,345	\$ 4,798	\$ 15,790	\$ 14,373

Segment income excludes the impact of significant items not indicative of current operating performance or ongoing results, and earnings attributed to Sanofi and other noncontrolling interest. The reconciliation to earnings before income taxes was as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
BioPharmaceuticals segment income	\$ 1,347	\$ 1,186	\$ 3,934	\$ 3,599
Reconciling items:				
Restructuring and other charges	(20)	(63)	(159)	(395)
Litigation (charges)/recoveries		(22)	102	(22)
Upfront, milestone and other licensing payments	(69)		(207)	(72)
In-process research and development (IPRD) impairment	(13)		(28)	
Product liability charges	(10)	(13)	(36)	(13)
Noncontrolling interest	595	526	1,781	1,561
Earnings before income taxes	\$ 1,830	\$ 1,614	\$ 5,387	\$ 4,658

**Table of Contents****Note 4. RESTRUCTURING**

The following restructuring and other net charges were recognized:

Dollars in Millions	Three Months Ended September 30, 2011		Nine Months Ended September 30, 2010	
	2011	2010	2011	2010
Employee termination benefits	\$ 4	\$ 3	\$ 72	\$ 40
Other exit costs	4	12	20	10
Provision for restructuring	8	15	92	50
Impairment and loss on sale of manufacturing operations		10		225
Accelerated depreciation, asset impairment and other shutdown costs	19	27	64	85
Pension curtailment and settlement charges		3		8
Process standardization implementation costs	5	8	15	27
Gain on sale of product lines, businesses and assets	(12)		(12)	
Total restructuring and other net charges	\$ 20	\$ 63	\$ 159	\$ 395

Restructuring charges were incurred to streamline the organizational structure of the Company. These charges include termination benefits for approximately 50 and 60 manufacturing, selling, administrative, and research and development personnel across all geographic regions for the three months ended September 30, 2011 and 2010, respectively, and approximately 700 and 540 manufacturing, selling, administrative, and research and development personnel across all geographic regions for the nine months ended September 30, 2011 and 2010, respectively.

Most of the accelerated depreciation, asset impairment and other shutdown costs were included in cost of products sold and primarily relate to the rationalization of the manufacturing network. These assets continue to be depreciated until the cease use date of the facility. In connection with the continued optimization of the Company's manufacturing network, the operations in Latina, Italy were sold to International Chemical Investors, SE (ICI) in May 2010 resulting in a \$215 million loss. The loss consisted of a \$200 million impairment charge recorded to other income/(expense) attributed to the write-down of assets to fair value less cost of sale when the assets met the held for sale criteria and \$15 million of other working capital adjustments and transaction related fees recorded upon closing. Process standardization activities are recognized as incurred in marketing, selling and administrative expense.

The following table represents the activity of employee termination and other exit cost liabilities:

Dollars in Millions	Nine Months Ended September 30, 2011		2010	
	2011	2010	2011	2010
Liability at January 1	\$ 126	\$ 173		
Charges	94	55		
Changes in estimates	(2)	(5)		
Provision for restructuring	92	50		
Foreign currency translation	1	(4)		
Spending	(119)	(93)		
Liability at September 30	\$ 100	\$ 126		

**Note 5. AMIRA PHARMACEUTICALS, INC. ACQUISITION**

On September 7, 2011, the Company acquired 100% of the outstanding shares of Amira Pharmaceuticals, Inc. (Amira) for \$325 million in cash plus three separate, contingent \$50 million payments due upon achievement of certain development and sales-based milestones. The fair value of the total contingent consideration was \$58 million, which was recorded in other liabilities.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Amira was a privately-held biotechnology company primarily focused on the discovery and development of therapeutic products for the treatment of cardiovascular and fibrotic inflammatory diseases. The acquisition provides the Company with: 1) full rights to develop and commercialize AM152 which has completed Phase I clinical studies and the remainder of the Amira lysophosphatidic acid 1 receptor antagonist program; 2) researchers with fibrotic expertise; and 3) a pre-clinical autotaxin program. Goodwill generated from the acquisition was primarily attributed to acquired scientific expertise in fibrotic diseases allowing for the expansion of the Company's pipeline into a new therapeutic class.

**Table of Contents**

The purchase price allocation, which is preliminary pending final post-acquisition adjustments, was as follows:

<b>Purchase price:</b>	Dollars in Millions
Cash	\$ 325
Fair value of contingent consideration	58
<b>Total purchase price</b>	<b>383</b>
<b>Identifiable net assets:</b>	
Cash	15
In-process research and development	160
Accrued expenses	(16)
Deferred tax liabilities	(43)
<b>Total identifiable net assets</b>	<b>116</b>
Goodwill	\$ 267

The fair value of the acquired IPRD was estimated utilizing the income method which risk adjusted the expected future net cash flows estimated to be generated from the compound based upon estimated probabilities of technical and regulatory success. The cash flows were then adjusted to present value utilizing a 12.5% discount rate which reflects the risk factors associated with the cash flow streams. The projected cash flows assumed initial positive cash flows to commence shortly after the receipt of expected regulatory approvals, subject to trial results, among other things, which are not estimated to occur for a number of years. Actual cash flows attributed to the acquired IPRD are likely to be different than those assumed.

The contingent liability was estimated utilizing a model that assessed the probability of achieving each milestone and discounted the amount of each potential payment based on the expected timing. Estimates used in evaluating the contingent liability were consistent with those used in evaluating the acquired IPRD. The discount rate for each payment was consistent with market debt yields for the Company's non-callable, publicly-traded bonds with similar maturities to each of the estimated potential payment dates. This fair value measurement was based on significant inputs not observable in the market and therefore represents a Level 3 measurement.

The results of Amira's operations are included in the Company's consolidated financial statements starting on September 7, 2011. Pro forma supplemental financial information is not provided as the impact of the acquisition was not material to operating results. Goodwill, IPRD and all other intangible assets valued in this acquisition are non-deductible for tax purposes. Total acquisition costs approximated \$1 million and were included in other (income)/expense.

**Note 6. EARNINGS PER SHARE**

Amounts in Millions, Except Per Share Data	<b>Three Months Ended September 30, 2011</b>		<b>Three Months Ended September 30, 2010</b>	
Net Earnings Attributable to BMS	\$ 969	\$ 949	\$ 2,857	\$ 2,619
Earnings attributable to unvested restricted shares	(2)	(4)	(6)	(11)
<b>Net Earnings Attributable to BMS common shareholders</b>	<b>\$ 967</b>	<b>\$ 945</b>	<b>\$ 2,851</b>	<b>\$ 2,608</b>
 Earnings per share – basic	 \$ 0.57	 \$ 0.55	 \$ 1.67	 \$ 1.52
 Weighted-average common shares outstanding – basic	 1,698	 1,712	 1,703	 1,715
Contingently convertible debt common stock equivalents	1	1	1	1
Incremental shares attributable to share-based compensation plans	16	13	13	10

# Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Weighted-average common shares outstanding	diluted	1,715	1,726	1,717	1,726
Earnings per share	diluted	\$ 0.56	\$ 0.55	\$ 1.66	\$ 1.51
Anti-dilutive weighted-average equivalent shares	stock incentive plans	11	48	28	64

**Table of Contents**

**Note 7. INCOME TAXES**

The effective income tax rate on earnings was 26.0% for the three months ended September 30, 2011 compared to 19.3% for the three months ended September 30, 2010 and 25.2% for the nine months ended September 30, 2011 compared to 21.2% for the nine months ended September 30, 2010. The effective tax rate is lower than the U.S. statutory rate of 35% primarily attributable to undistributed earnings of certain foreign subsidiaries that have been considered or are expected to be indefinitely reinvested offshore. If, in the future, these earnings are repatriated to the U.S., or if such earnings are determined to be remitted in the foreseeable future, additional tax provisions would be required. Reforms to U.S. tax laws related to foreign earnings have been proposed and if adopted may increase taxes, which could reduce the results of operations and cash flows.

The higher effective income tax rate in the three months ended September 30, 2011 was due to:

An unfavorable earnings mix between high and low tax jurisdictions compared to the prior year;

Lower tax benefits related to the effective settlements and remeasurements of uncertain tax positions (\$5 million in 2011 and \$85 million in 2010); and

The non-tax deductible annual pharmaceutical company fee effective January 1, 2011.

Partially offset by:

Changes in estimates upon finalizing prior period U.S. tax returns resulting in a \$54 million benefit in 2011 and a \$30 million charge in 2010; and

A favorable impact on the current year rate from the research and development tax credit which was not enacted as of September 30, 2010.

The higher effective income tax rate in the nine months ended September 30, 2011 was due to:

An unfavorable earnings mix between high and low tax jurisdictions compared to the prior year;

An out-of-period tax adjustment of \$59 million in 2010 for previously unrecognized net deferred tax assets primarily attributed to deferred profits related to certain alliances as of December 31, 2009;

Lower tax benefits related to the effective settlements and remeasurements of uncertain tax positions (\$121 million in 2011 and \$151 million in 2010); and

The non-tax deductible annual pharmaceutical company fee effective January 1, 2011.

Partially offset by:



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Changes in estimates upon finalizing prior period U.S. tax returns resulting in a \$54 million benefit in 2011 and a \$30 million charge in 2010; and

A favorable impact on the current year rate from the research and development tax credit which was not enacted as of September 30, 2010.

The Company is currently under examination by a number of tax authorities which have proposed adjustments to tax for issues such as transfer pricing, certain tax credits and the deductibility of certain expenses. It is reasonably possible that the total amount of unrecognized tax benefits at September 30, 2011 could decrease in the range of approximately \$190 million to \$220 million in the next twelve months from the settlement of certain tax audits and other events resulting in the payment of additional taxes, the adjustment of certain deferred taxes and/or the recognition of tax benefits. It is also reasonably possible that new issues will be raised by tax authorities which may require adjustments to the amount of unrecognized tax benefits; however, an estimate of such adjustments cannot reasonably be made at this time. The Company believes that it has adequately provided for all open tax years by tax jurisdiction.

### **Note 8. FINANCIAL INSTRUMENTS**

Financial instruments include cash and cash equivalents, marketable securities, accounts receivable and payable, debt instruments and derivatives. Due to their short term maturity, the carrying amount of receivables and accounts payable approximate fair value. Cash equivalents primarily consist of highly liquid investments with original maturities of three months or less at the time of purchase and are recorded at cost, which approximates fair value.

The Company has exposure to market risk due to changes in currency exchange rates and interest rates. As a result, certain derivative financial instruments are used when available on a cost-effective basis to hedge the underlying economic exposure. These instruments qualify as cash flow, net investment and fair value hedges upon meeting certain criteria, including effectiveness of offsetting hedged exposures. Changes in fair value of derivatives that do not qualify for hedge accounting are recognized in earnings as they occur. Derivative financial instruments are not used for trading purposes.

**Table of Contents**

All financial instruments, including derivatives, are subject to counterparty credit risk which is considered as part of the overall fair value measurement. Counterparty credit risk is monitored on an ongoing basis and is mitigated by limiting amounts outstanding with any individual counterparty, utilizing conventional derivative financial instruments and only entering into agreements with counterparties that meet high credit quality standards. The consolidated financial statements would not be materially impacted if any counterparty failed to perform according to the terms of its agreement. Under the terms of the agreements, posting of collateral is not required by any party whether derivatives are in an asset or liability position.

*Fair Value Measurements* The fair values of financial instruments are classified into one of the following categories:

Level 1 inputs utilize quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs. These instruments include U.S. treasury bills and U.S. government agency securities.

Level 2 inputs include observable prices for similar instruments, quoted prices for identical or similar instruments in markets that are not active, and other observable inputs that can be corroborated by market data for substantially the full term of the assets or liabilities. These instruments include corporate debt securities, commercial paper, Federal Deposit Insurance Corporation (FDIC) insured debt securities, certificates of deposit, money market funds, foreign currency forward contracts and interest rate swap contracts. Level 2 derivative instruments are valued using LIBOR and EURIBOR yield curves, less credit valuation adjustments, and observable forward foreign exchange rates at the reporting date. Valuations of derivative contracts may fluctuate considerably from period-to-period due to volatility in underlying foreign currencies and underlying interest rates, which are driven by market conditions and the duration of the contract. Credit adjustment volatility may have a significant impact on the valuation of interest rate swaps due to changes in counterparty credit ratings and credit default swap spreads.

Level 3 unobservable inputs are used when little or no market data is available. Valuation models for the ARS and FRS portfolio are based on expected cash flow streams and collateral values including assessments of counterparty credit quality, default risk underlying the security, discount rates and overall capital market liquidity. The fair value of ARS was determined using internally developed valuations that were based in part on indicative bids received on the underlying assets of the securities and other evidence of fair value. A majority of the ARS, which are private placement securities with long-term nominal maturities, were rated A by Standard and Poor's, and primarily represent interests in insurance securitizations. Due to the current lack of an active market for FRS and the general lack of transparency into their underlying assets, other qualitative analysis is relied upon to value FRS including discussions with brokers and fund managers, default risk underlying the security and overall capital markets liquidity.

The following table summarizes available-for-sale securities at September 30, 2011 and December 31, 2010:

	Amortized Cost	Unrealized Gain in Accumulated OCI	Unrealized Loss in Accumulated OCI	Fair Value	Level 1	Level 2	Level 3
Dollars in Millions							
<b>September 30, 2011</b>							
Marketable Securities:							
Certificates of Deposit	\$ 1,476	\$	\$	\$ 1,476	\$	\$ 1,476	\$
Corporate Debt Securities	2,875	53	(3)	2,925		2,925	
Commercial Paper	1,322			1,322		1,322	
U.S. Treasury Bills	400	3		403	403		
FDIC Insured Debt Securities	302	2		304		304	
Auction Rate Securities (ARS)	80	12		92			92
Floating Rate Securities (FRS)	21		(2)	19			19
Total Marketable Securities	\$ 6,476	\$ 70	\$ (5)	\$ 6,541	\$ 403	\$ 6,027	\$ 111
<b>December 31, 2010</b>							
Marketable Securities:							
Certificates of Deposit	\$ 1,209	\$	\$	\$ 1,209	\$	\$ 1,209	\$
Corporate Debt Securities	1,996	26	(10)	2,012		2,012	
Commercial Paper	482			482		482	

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

FDIC Insured Debt Securities	353	3		356		356	
U.S. Treasury Bills	400	4		404	404		
U.S. Government Agency Securities	375	1		376	376		
Auction Rate Securities (ARS)	80	11		91			91
Floating Rate Securities (FRS)	21		(2)	19			19
Total Marketable Securities	\$ 4,916	\$ 45	\$ (12)	\$ 4,949	\$ 780	\$ 4,059	\$ 110

**Table of Contents**

The following table summarizes the classification of available for sale securities in the consolidated balance sheet:

Dollars in Millions	September 30, 2011	December 31, 2010
Current Marketable Securities	\$ 3,722	\$ 2,268
Non-current Marketable Securities	2,819	2,681
<b>Total Marketable Securities</b>	<b>\$ 6,541</b>	<b>\$ 4,949</b>

Money market funds and other securities aggregating \$4,162 million and \$4,332 million at September 30, 2011 and December 31, 2010, respectively, were included in cash and cash equivalents and valued using Level 2 inputs. At September 30, 2011, \$2,727 million of non-current available for sale corporate debt securities, U.S. treasury bills, FDIC insured debt securities and floating rate securities mature within five years. All auction rate securities mature beyond 10 years.

**Cash Flow Hedges** Foreign currency forward contracts are primarily utilized to hedge forecasted intercompany purchase transactions in certain foreign currencies. These forward contracts are designated as cash flow hedges with the effective portion of changes in fair value being temporarily reported in accumulated OCI and recognized in earnings when the hedged item affects earnings. The primary foreign currency exposures hedged are the Euro, Japanese yen, Canadian dollar, British pound, Australian dollar and Swiss franc. The net deferred gains on foreign currency forward contracts qualifying for cash flow hedge accounting are expected to be reclassified to cost of products sold within the next two years, including \$13 million of pre-tax deferred gains to be reclassified within the next 12 months.

Cash flow hedge accounting is discontinued when the forecasted transaction is no longer probable of occurring on the originally forecasted date, or 60 days thereafter, or when the hedge is no longer effective. Assessments to determine whether derivatives designated as qualifying hedges are highly effective in offsetting changes in the cash flows of hedged items are performed at inception and on a quarterly basis. Any ineffective portion of the change in fair value is included in current period earnings. The earnings impact related to discontinued cash flow hedges and hedge ineffectiveness was not significant during the three and nine months ended September 30, 2011 and 2010.

**Net Investment Hedges** Non-U.S. dollar borrowings of 541 million (\$731 million) are designated to hedge the foreign currency exposures of the net investment in certain foreign affiliates. These borrowings are designated as net investment hedges and recognized in long term debt. The effective portion of foreign exchange gains or losses on the remeasurement of the debt is recognized in the foreign currency translation component of accumulated OCI with the related offset in long term debt.

**Fair Value Hedges** Fixed-to-floating interest rate swap contracts are designated as fair value hedges and are used as part of an interest rate risk management strategy to create an appropriate balance of fixed and floating rate debt. The swaps and underlying debt for the benchmark risk being hedged are recorded at fair value. When the underlying swap is terminated prior to maturity, the fair value basis adjustment to the underlying debt instrument is amortized into earnings as a reduction to interest expense over the remaining life of the debt.

The adjustment to long-term debt from interest rate swaps that qualify as fair value hedges and other items was as follows:

Dollars in Millions	September 30, 2011	December 31, 2010
Principal Value	\$ 4,715	\$ 4,749
Adjustments to Principal Value:		
Fair value of interest rate swaps	131	234
Unamortized basis adjustment from swap terminations	614	369
Unamortized bond discounts	(23)	(24)
<b>Total Long-term debt</b>	<b>\$ 5,437</b>	<b>\$ 5,328</b>

In September 2011, the Company replaced its \$2.0 billion revolving credit facility with a new \$1.5 billion five year revolving credit facility from a syndicate of lenders, which is extendable on any anniversary date with the consent of the lenders. There were no borrowings outstanding under either revolving credit facility at September 30, 2011 or December 31, 2010.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

During the nine months ended September 30, 2011, \$71 million aggregate principal value of the 5.875% Debentures due 2036 was repurchased for \$78 million and \$34 million notional amount of interest rate swaps related to the debt repurchase was terminated resulting in proceeds of \$6 million. The corresponding gain related to these transactions was \$10 million.

During the nine months ended September 30, 2011, fixed-to-floating interest rate swap agreements of \$1.6 billion notional amount and 1.0 billion notional amount were terminated generating total proceeds of \$356 million (including accrued interest of \$66 million).

**Table of Contents**

During the nine months ended September 30, 2010, fixed-to-floating interest rate swap agreements of \$237 million notional amount and 500 million notional amount were terminated generating total proceeds of \$116 million (including accrued interest of \$18 million).

Interest expense was \$40 million and \$38 million for the three months ended September 30, 2011 and 2010, respectively, and \$103 million for both the nine months ended September 30, 2011 and 2010.

**Non-Qualifying Foreign Exchange Contracts** Foreign currency forward contracts are used to offset exposure to foreign currency-denominated monetary assets, liabilities and earnings. The primary objective of these contracts is to protect the U.S. dollar value of foreign currency-denominated monetary assets, liabilities and earnings from the effects of volatility in foreign exchange rates that might occur prior to their receipt or settlement in U.S. dollars. These contracts are not designated as hedges and are adjusted to fair value through other (income)/expense as they occur, and substantially offset the change in fair value of the underlying foreign currency denominated monetary asset, liability or earnings. The effect of non-qualifying hedges on earnings was not significant for the three and nine months ended September 30, 2011 and 2010.

The following table summarizes the fair value of outstanding derivatives:

		September 30, 2011		December 31, 2010	
Dollars in Millions	Balance Sheet Location	Notional	Fair Value (Level 2)	Notional	Fair Value (Level 2)
<i>Derivatives designated as hedging instruments:</i>					
Interest rate contracts	Other assets	\$ 579	\$ 131	\$ 3,526	\$ 234
Foreign currency forward contracts	Other assets	1,579	79	691	26
Foreign currency forward contracts	Accrued expenses	588	(40)	732	(48)
<i>Derivatives not designated as hedging instruments:</i>					
Foreign currency forward contracts	Other assets	25	1		
Foreign currency forward contracts	Accrued expenses	25	(1)		

**Note 9. RECEIVABLES**

Receivables include:

Dollars in Millions	September 30, 2011	December 31, 2010
Trade receivables	\$ 2,305	\$ 2,092
Less allowances	124	107
Net trade receivables	2,181	1,985
Alliance partners receivables	1,075	1,076
Prepaid and refundable income taxes	271	223
Miscellaneous receivables	160	196
Receivables	\$ 3,687	\$ 3,480

Receivables are netted with deferred income related to alliance partners until recognition of income. As a result, alliance partner receivables and deferred income were reduced by \$935 million and \$734 million at September 30, 2011 and December 31, 2010, respectively. For additional information regarding alliance partners, see Note 2. Alliances and Collaborations. Non-U.S. receivables sold on a nonrecourse basis were \$806 million and \$674 million for the nine months ended September 30, 2011 and 2010, respectively. In the aggregate, receivables due from three pharmaceutical wholesalers in the U.S. represented 56% and 51% of total trade receivables at September 30, 2011 and December 31, 2010, respectively.

**Table of Contents****Note 10. INVENTORIES**

Inventories include:

Dollars in Millions	September 30, 2011	December 31, 2010
Finished goods	\$ 443	\$ 397
Work in process	709	608
Raw and packaging materials	205	199
Inventories	\$ 1,357	\$ 1,204

In addition, inventories expected to remain on-hand beyond one year are included in non-current assets and were \$167 million (including \$60 million of capitalized costs which are subject to regulatory approval prior to being sold) at September 30, 2011 and \$297 million at December 31, 2010. The status of the regulatory approval process and the probability of future sales were considered in assessing the recoverability of these costs.

**Note 11. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment includes:

Dollars in Millions	September 30, 2011	December 31, 2010
Land	\$ 137	\$ 133
Buildings	4,536	4,565
Machinery, equipment and fixtures	3,423	3,423
Construction in progress	199	139
Gross property, plant and equipment	8,295	8,260
Less accumulated depreciation	(3,803)	(3,596)
Property, plant and equipment	\$ 4,492	\$ 4,664

**Note 12. GOODWILL**

Changes in the carrying amount of goodwill during the nine months ended September 30, 2011 were as follows:

Dollars in Millions	December	December
Balance at December 31, 2010	\$	5,233
Amira acquisition (Note 5)		267
Other adjustment		64
Balance at September 30, 2011	\$	5,564

During the three months ended September 30, 2011, an out-of-period adjustment was recorded to correct the purchase price allocation for the September 2009 Medarex, Inc. acquisition. The adjustment decreased other intangible assets by \$98 million and increased deferred tax assets by \$34 million and goodwill by \$64 million. The effect of this adjustment was not material for any current or prior period.





**Table of Contents****Note 13. EQUITY**

	Common Stock		Capital in Excess of Par Value of Stock		Retained Earnings	Treasury Stock		Noncontrolling Interest
Dollars and Shares in Millions	Shares	Par Value				Shares	Cost	
Balance at January 1, 2010	2,205	\$ 220	\$	3,768	\$ 30,760	491	\$ (17,364)	\$ (58)
Net earnings attributable to Bristol-Myers Squibb Company					2,619			
Cash dividends declared					(1,658)			
Stock repurchase program						15	(362)	
Employee stock compensation plans				(107)		(12)	428	
Net earnings attributable to noncontrolling interest								1,558
Distributions								(1,613)
Balance at September 30, 2010	2,205	\$ 220	\$	3,661	\$ 31,721	494	\$ (17,298)	\$ (113)
Balance at January 1, 2011	2,205	\$ 220	\$	3,682	\$ 31,636	501	\$ (17,454)	\$ (75)
Net earnings attributable to Bristol-Myers Squibb Company					2,857			
Cash dividends declared					(1,696)			
Stock repurchase program						30	(858)	
Employee stock compensation plans				(456)		(20)	923	
Net earnings attributable to noncontrolling interest								1,781
Distributions								(1,842)
Balance at September 30, 2011	2,205	\$ 220	\$	3,226	\$ 32,797	511	\$ (17,389)	\$ (136)

Treasury stock is recognized at the cost to reacquire the shares. Shares issued from treasury are recognized utilizing the first-in first-out method.

In May 2010, the Board of Directors authorized the repurchase of up to \$3.0 billion of common stock. Repurchases may be made either in the open market or through private transactions, including under repurchase plans established in accordance with Rule 10b5-1 under the Securities Exchange Act of 1934, as amended. The stock repurchase program does not have an expiration date but is expected to take place over a few years. It may be suspended or discontinued at any time.

Noncontrolling interest is primarily related to the partnerships with Sanofi for the territory covering the Americas for net sales of PLAVIX\*. Net earnings attributable to noncontrolling interest are presented net of taxes of \$209 million and \$173 million for the three months ended September 30, 2011 and 2010, respectively, and \$609 million and \$509 million for the nine months ended September 30, 2011 and 2010, respectively, in the consolidated statements of earnings with a corresponding increase to the provision for income taxes. Distribution of the partnership profits to Sanofi and Sanofi's funding of ongoing partnership operations occur on a routine basis and are included within operating activities in the consolidated statements of cash flows. The above activity includes the pre-tax income and distributions related to these partnerships.

The accumulated balances related to each component of other comprehensive income/(loss) (OCI), net of taxes, were as follows:

Dollars in Millions	Foreign Currency Translation	Derivatives Qualifying as Effective Hedges	Pension and Other Postretirement Benefits	Available for Sale Securities	Accumulated Other Comprehensive Income/(Loss)
Balance at January 1, 2010	\$ (343)	\$ (30)	\$ (2,158)	\$ (10)	\$ (2,541)
Other comprehensive income/(loss)	106	(1)	45	57	207

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Balance at September 30, 2010	\$ (237)	\$ (31)	\$ (2,113)	\$ 47	\$ (2,334)
Balance at January 1, 2011	\$ (222)	\$ (20)	\$ (2,163)	\$ 34	\$ (2,371)
Other comprehensive income/(loss)	(25)	34	56	24	89
Balance at September 30, 2011	\$ (247)	\$ 14	\$ (2,107)	\$ 58	\$ (2,282)

**Table of Contents****Note 14. PENSION AND POSTRETIREMENT BENEFIT PLANS**

The net periodic benefit cost of defined benefit pension and postretirement benefit plans includes:

Dollars in Millions	Three Months Ended September 30,				Nine Months Ended September 30,			
	Pension Benefits		Other Benefits		Pension Benefits		Other Benefits	
	2011	2010	2011	2010	2011	2010	2011	2010
Service cost	\$ 11	\$ 10	\$ 2	\$ 1	\$ 32	\$ 32	\$ 6	\$ 5
Interest cost on projected benefit obligation	83	87	7	8	253	260	20	23
Expected return on plan assets	(116)	(112)	(7)	(6)	(349)	(337)	(20)	(18)
Amortization of prior service cost/(benefit)			(1)				(2)	(2)
Amortization of net actuarial loss	28	23	2	1	85	71	5	7
Curtailments					(1)	9		
Settlements	2	2				7		
Total net periodic benefit cost	\$ 8	\$ 10	\$ 3	\$ 4	\$ 20	\$ 42	\$ 9	\$ 15

Contributions to the U.S. pension plans are expected to be approximately \$330 million during 2011, of which \$326 million was contributed in the nine months ended September 30, 2011. Contributions to the international plans are expected to range from \$75 million to \$90 million in 2011, of which \$62 million was contributed in the nine months ended September 30, 2011.

The expense attributed to defined contribution plans in the U.S. was \$47 million and \$44 million for the three months ended September 30, 2011 and 2010, respectively, and \$133 million and \$139 million for the nine months ended September 30, 2011 and 2010, respectively.

**Note 15. EMPLOYEE STOCK BENEFIT PLANS**

Stock-based compensation expense was as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Stock options	\$ 7	\$ 14	\$ 20	\$ 41
Restricted stock	19	21	59	60
Market share units	6	3	17	10
Long-term performance awards	7	9	24	32
Total stock-based compensation expense	\$ 39	\$ 47	\$ 120	\$ 143
Deferred tax benefit related to stock-based compensation expense	\$ 13	\$ 16	\$ 41	\$ 47

In the nine months ended September 30, 2011, 3.2 million restricted stock units, 1.4 million market share units and 1.6 million long-term performance share units were granted. The weighted-average grant date fair value for restricted stock units, market share units and long-term performance share units granted during the nine months ended September 30, 2011 was \$25.83, \$25.83 and \$25.30, respectively.

Substantially all restricted stock units vest ratably over a four year period. Market share units vest ratably over a four year period based on share price performance. The fair value of market share units was estimated on the date of grant using a model applying multiple input variables that determine the probability of satisfying market conditions. Long-term performance share units are determined based on the achievement of annual performance goals, but are not vested until the end of the three year plan period.

Total compensation costs related to nonvested awards not yet recognized and the weighted-average period over which such awards are expected to be recognized at September 30, 2011 were as follows:

Dollars in Millions	Stock Options	Restricted Stock	Market Share Units	Long-Term Performance Awards
Unrecognized compensation cost	\$ 18	\$ 153	\$ 35	\$ 40
Expected weighted-average period in years of compensation cost to be recognized	1.2	2.7	3.1	1.6

## **Table of Contents**

### **Note 16. LEGAL PROCEEDINGS AND CONTINGENCIES**

The Company and certain of its subsidiaries are involved in various lawsuits, claims, government investigations and other legal proceedings that arise in the ordinary course of business. The Company recognizes accruals for such contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. These matters involve patent infringement, antitrust, securities, pricing, sales and marketing practices, environmental, commercial, health and safety matters, consumer fraud, employment matters, product liability and insurance coverage. Legal proceedings that are material or that the Company believes could become material are described below.

Although the Company believes it has substantial defenses in these matters, there can be no assurance that there will not be an increase in the scope of pending matters or that any future lawsuits, claims, government investigations or other legal proceedings will not be material. Unless otherwise noted, the Company is unable to assess the outcome of the respective litigation nor is it able to provide an estimated range of potential loss. Furthermore, failure to enforce our patent rights would likely result in substantial decreases in the respective product sales from generic competition.

### **INTELLECTUAL PROPERTY**

#### **PLAVIX\* Litigation**

PLAVIX\* is currently the Company's largest product ranked by net sales. The PLAVIX\* patents are subject to a number of challenges in the U.S., including the litigation with Apotex Inc. and Apotex Corp. (Apotex) described below, and in other less significant markets for the product. The Company and its product partner, Sanofi, (the Companies) intend to vigorously pursue enforcement of their patent rights in PLAVIX\*.

#### **PLAVIX\* Litigation U.S.**

##### **Patent Infringement Litigation against Apotex and Related Matters**

As previously disclosed, the Company's U.S. territory partnership under its alliance with Sanofi is a plaintiff in a pending patent infringement lawsuit instituted in the United States District Court for the Southern District of New York (District Court) entitled Sanofi-Synthelabo, Sanofi-Synthelabo, Inc. and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership v. Apotex. The suit is based on U.S. Patent No. 4,847,265 (the '265 Patent), a composition of matter patent, which discloses and claims, among other things, the hydrogen sulfate salt of clopidogrel, a medicine made available in the U.S. by the Companies as PLAVIX\*. Also, as previously reported, the District Court upheld the validity and enforceability of the '265 Patent, maintaining the main patent protection for PLAVIX\* in the U.S. through the life of the patent term which now expires on May 17, 2012. The District Court also ruled that Apotex's generic clopidogrel bisulfate product infringed the '265 Patent and permanently enjoined Apotex from engaging in any activity that infringes the '265 Patent, including marketing its generic product in the U.S. until after the patent expires.

Apotex appealed the District Court's decision and on December 12, 2008, the United States Court of Appeals for the Federal Circuit (Circuit Court) affirmed the District Court's ruling sustaining the validity of the '265 Patent. Apotex filed a petition with the Circuit Court for a rehearing en banc, and in March 2009, the Circuit Court denied Apotex's petition. The case was remanded to the District Court for further proceedings relating to damages. In July 2009, Apotex filed a petition for writ of certiorari with the U.S. Supreme Court requesting the Supreme Court to review the Circuit Court's decision. In November 2009, the U.S. Supreme Court denied the petition, declining to review the Circuit Court's decision. In December 2009, the Companies filed a motion in the District Court for summary judgment on damages, and in January 2010, Apotex filed a motion seeking a stay of the ongoing damages proceedings pending the outcome of the reexamination of the PLAVIX\* patent by the U.S. Patent and Trademark Office (PTO) described below. In April 2010, the District Court denied Apotex's motion to stay the proceedings. In October 2010, the District Court granted the Companies' summary judgment motion and awarded \$442 million in damages plus costs and interest. Apotex is appealing the amount of the damages award; however, the validity of the patent claiming clopidogrel bisulfate has been finally judicially determined in favor of the Companies maintaining patent protection for PLAVIX\* in the U.S. until May 17, 2012 (including additional six-month pediatric exclusivity period). In October 2011, the Circuit Court upheld the \$442 million damages award and reversed the District Court's award of prejudgment interest. Either party could appeal this decision.

As previously disclosed, the Company's U.S. territory partnership under its alliance with Sanofi is also a plaintiff in five additional patent infringement lawsuits against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, LTD (Dr. Reddy's), Teva Pharmaceuticals USA, Inc. (Teva), Cobalt Pharmaceuticals Inc. (Cobalt), Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (Watson) and Sun Pharmaceuticals (Sun). The lawsuits against Dr. Reddy's, Teva and Cobalt relate to the '265 Patent. In May 2009, Dr. Reddy's signed a consent judgment in favor of Sanofi and BMS conceding the validity and infringement of the '265 Patent. As previously reported, the patent infringement actions against Teva and Cobalt were stayed pending resolution of the Apotex litigation, and the parties to those actions agreed to be bound by the outcome of

the litigation against Apotex. Consequently, on July 12, 2007,

**Table of Contents**

the District Court entered judgments against Cobalt and Teva and permanently enjoined Cobalt and Teva from engaging in any activity that infringes the '265 Patent until after the Patent expires. Cobalt and Teva each filed an appeal. In July 2009, the Circuit Court issued a mandate in the Teva appeal binding Teva to the decision in the Apotex litigation. In August 2009, Cobalt consented to entry of judgment in its appeal agreeing to be bound by Circuit Court's decision in the Apotex litigation. The lawsuit against Watson, filed in October 2004, was based on U.S. Patent No. 6,429,210 (the '210 Patent), which discloses and claims a particular crystalline or polymorph form of the hydrogen sulfate salt of clopidogrel, which is marketed as PLAVIX\*. In December 2005, the Court permitted Watson to pursue its declaratory judgment counterclaim with respect to U.S. Patent No. 6,504,030. In January 2006, the Court approved the parties' stipulation to stay this case pending the outcome of the trial in the Apotex matter. On May 1, 2009, BMS and Watson entered into a stipulation to dismiss the case. In April 2007, Pharmastar filed a request for inter partes reexamination of the '210 Patent at the PTO. The PTO granted this request in July of 2007 and in July 2009, the PTO vacated the reexamination proceeding. The lawsuit against Sun, filed on July 11, 2008, is based on infringement of the '265 Patent and the '210 Patent. With respect to the '265 Patent, Sun has agreed to be bound by the outcome of the Apotex litigation. Each of Dr. Reddy's, Teva, Cobalt, Watson and Sun have filed an aNDA with the FDA, and, with respect to Dr. Reddy's, Teva, Cobalt and Watson all exclusivity periods and statutory stay periods under the Hatch-Waxman Act have expired. Accordingly, final approval by the FDA would provide each company authorization to distribute a generic clopidogrel bisulfate product in the U.S., subject to various legal remedies for which the Companies may apply including injunctive relief and damages.

On June 1, 2009, Apotex filed a request for ex parte reexamination of the '265 Patent at the PTO and in August 2009, the PTO agreed to reexamine the patent. In December 2009, the PTO issued a non-final office action rejecting several claims covering PLAVIX\* including the claim that was previously upheld in the litigation against Apotex referred to above. The PTO has issued an ex parte Reexamination Certificate withdrawing the rejections in the non-final office action and confirming patentability of all the claims of the '265 Patent. Apotex filed a second request for ex-parte reexamination of the '265 Patent and in June 2010, the PTO denied Apotex's request to reexamine the patent again.

Additionally, on November 13, 2008, Apotex filed a lawsuit in New Jersey Superior Court entitled, Apotex Inc., et al. v. sanofi-aventis, et al., seeking payment of \$60 million, plus interest, related to the break-up of the March 2006 proposed settlement agreement. In April 2011, the New Jersey Superior Court granted the Companies' cross-motion for summary judgment motion and denied Apotex's motion for summary judgment. Apotex has appealed these decisions. It is not possible at this time to determine the outcome of any appeal from the New Jersey Superior Court's decisions.

In January 2011, Apotex filed a lawsuit in Florida State Court, Broward County, alleging breach of contract relating to the parties' May 2006 proposed settlement agreement.

**PLAVIX\* Litigation International****PLAVIX\* Australia**

As previously disclosed, Sanofi was notified that, in August 2007, GenRx Proprietary Limited (GenRx) obtained regulatory approval of an application for clopidogrel bisulfate 75mg tablets in Australia. GenRx, formerly a subsidiary of Apotex, has since changed its name to Apotex. In August 2007, Apotex filed an application in the Federal Court of Australia seeking revocation of Sanofi's Australian Patent No. 597784 (Case No. NSD 1639 of 2007). Sanofi filed counterclaims of infringement and sought an injunction. On September 21, 2007, the Australian court granted Sanofi's injunction. A subsidiary of the Company was subsequently added as a party to the proceedings. In February 2008, a second company, Spirit Pharmaceuticals Pty. Ltd., also filed a revocation suit against the same patent. This case was consolidated with the Apotex case and a trial occurred in April 2008. On August 12, 2008, the Federal Court of Australia held that claims of Patent No. 597784 covering clopidogrel bisulfate, hydrochloride, hydrobromide, and taurocholate salts were valid. The Federal Court also held that the process claims, pharmaceutical composition claims, and claim directed to clopidogrel and its pharmaceutically acceptable salts were invalid. The Company and Sanofi filed notices of appeal in the Full Court of the Federal Court of Australia (Full Court) appealing the holding of invalidity of the claim covering clopidogrel and its pharmaceutically acceptable salts, process claims, and pharmaceutical composition claims which have stayed the Federal Court's ruling. Apotex filed a notice of appeal appealing the holding of validity of the clopidogrel bisulfate, hydrochloride, hydrobromide, and taurocholate claims. A hearing on the appeals occurred in February 2009. On September 29, 2009, the Full Federal Court of Australia held all of the claims of Patent No. 597784 invalid. In November 2009, the Company and Sanofi applied to the High Court of Australia (High Court) for special leave to appeal the judgment of the Full Court. In March 2010, the High Court denied the Company and Sanofi's request to hear the appeal of the Full Court decision. The case has been remanded to the Federal Court for further proceedings related to damages. It is expected the amount of damages will not be material to the Company.

## **Table of Contents**

### **PLAVIX\* EU**

As previously disclosed, in 2007, YES Pharmaceutical Development Services GmbH (YES Pharmaceutical) filed an application for marketing authorization in Germany for an alternate salt form of clopidogrel. This application relied on data from studies that were originally conducted by Sanofi and BMS for PLAVIX\* and were still the subject of data protection in the EU. Sanofi and BMS have filed an action against YES Pharmaceutical and its partners in the administrative court in Cologne objecting to the marketing authorization. This matter is currently pending, although these specific marketing authorizations now have been withdrawn from the market.

### **PLAVIX\* Canada (Apotex, Inc.)**

On April 22, 2009, Apotex filed an impeachment action against Sanofi in the Federal Court of Canada alleging that Sanofi's Canadian Patent No. 1,336,777 (the 777 Patent) is invalid. The 777 Patent covers clopidogrel bisulfate and was the patent at issue in the prohibition action in Canada previously disclosed in which the Canadian Federal Court of Ottawa rejected Apotex's challenge to the 777 Patent, held that the asserted claims are novel, not obvious and infringed, and granted Sanofi's application for an order of prohibition against the Minister of Health and Apotex, precluding approval of Apotex's Abbreviated New Drug Submission until the patent expires in 2012, which decision was affirmed on appeal by both the Federal Court of Appeal and the Supreme Court of Canada. On June 8, 2009, Sanofi filed its defense to the impeachment action and filed a suit against Apotex for infringement of the 777 Patent. The trial was completed in June 2011 and Sanofi is awaiting a decision.

## **OTHER INTELLECTUAL PROPERTY LITIGATION**

### **ABILIFY\***

As previously disclosed, Otsuka has filed patent infringement actions against Teva, Barr Pharmaceuticals, Inc. (Barr), Sandoz Inc. (Sandoz), Synthon Laboratories, Inc (Synthon), Sun Pharmaceuticals (Sun), Zydus Pharmaceuticals USA, Inc. (Zydus), and Apotex relating to U.S. Patent No. 5,006,528, ( 528 Patent) which covers aripiprazole and expires in April 2015 (including the additional six-month pediatric exclusivity period). Aripiprazole is comarketed by the Company and Otsuka in the U.S. as ABILIFY\*. A non-jury trial in the U.S. District Court for the District of New Jersey (NJ District Court) against Teva/Barr and Apotex was completed in August 2010. In November 2010, the NJ District Court upheld the validity and enforceability of the 528 Patent, maintaining the main patent protection for ABILIFY\* in the U.S. until April 2015. The NJ District Court also ruled that the defendants' generic aripiprazole product infringed the 528 Patent and permanently enjoined them from engaging in any activity that infringes the 528 Patent, including marketing their generic product in the U.S. until after the patent (including the six-month pediatric extension) expires. Sandoz, Synthon, Sun and Zydus are also bound by the NJ District Court's decision. In December 2010, Teva/Barr and Apotex appealed this decision to the U.S. Court of Appeals for the Federal Circuit.

It is not possible at this time to determine the outcome of any appeal of the NJ District Court's decision. If Otsuka were not to prevail in an appeal, generic competition would likely result in substantial decreases in the sales of ABILIFY\* in the U.S., which would have a material adverse effect on the results of operations and cash flows and could be material to financial condition.

### **ATRIPLA\***

In April 2009, Teva filed an aNDA to manufacture and market a generic version of ATRIPLA\*. ATRIPLA\* is a single tablet three-drug regimen combining the Company's SUSTIVA and Gilead's TRUVADA\*. As of this time, the Company's U.S. patent rights covering SUSTIVA's composition of matter and method of use have not been challenged. Teva sent Gilead a Paragraph IV certification letter challenging two of the fifteen Orange Book listed patents for ATRIPLA\*. ATRIPLA\* is the product of a joint venture between the Company and Gilead. In May 2009, Gilead filed a patent infringement action against Teva in the U.S. District Court for the Southern District of New York (SDNY). In January 2010, the Company received a notice that Teva has amended its aNDA and is challenging eight additional Orange Book listed patents for ATRIPLA\*. In March 2010, the Company and Merck, Sharp & Dohme Corp. filed a patent infringement action against Teva also in the SDNY relating to two U.S. Patents which claim crystalline or polymorph forms of efavirenz. In March 2010, Gilead filed two patent infringement actions against Teva in the SDNY relating to six Orange Book listed patents for ATRIPLA\*. Discovery in these matters is ongoing. It is not possible at this time to reasonably assess the outcome of these lawsuits or their impact on the Company.

### **REYATAZ**

In December 2009, the Company and Novartis Pharmaceutical Corporation (Novartis) filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Teva (Bristol-Myers Squibb Company et al v. Teva Pharmaceuticals USA Inc., Civ. No.1:09-919-SLR-MPT) for infringement of the two Orange Book listed patents for REYATAZ (U.S. Patent No. 5,849,911 and 6,087,383). The Companies filed two subsequent patent infringement lawsuits against Teva after Teva amended its aNDA to include





## **Table of Contents**

additional dosage strengths of its generic version of REYATAZ. Those subsequent lawsuits were consolidated with Civ. No.1: 09-919-SLR-MPT. In October 2011, the Company, Novartis Corporation and Novartis Pharma AG entered into a settlement agreement with Teva regarding this patent infringement suit. Under the settlement agreement, Teva will have certain rights to launch its aNDA product beginning on July 21, 2017, or December 27, 2017 if REYATAZ is granted 6 months of pediatric market exclusivity, or earlier in certain circumstances. The Company, Novartis and Teva filed a stipulation of dismissal with the U.S. District Court for the District of Delaware asking the court to dismiss the lawsuit.

### **BARACLUDE**

In August 2010, Teva filed an aNDA to manufacture and market generic versions of BARACLUDE. The Company received a Paragraph IV certification letter from Teva challenging the one Orange Book listed patent for BARACLUDE, U.S. Patent No. 5,206,244. In September 2010, the Company filed a patent infringement lawsuit in the Delaware District Court against Teva for infringement of the listed patent covering BARACLUDE, which triggered an automatic 30-month stay of approval of Teva's aNDA. Discovery in this matter is ongoing. It is not possible at this time to reasonably assess the outcome of this lawsuit or its impact on the Company.

### **SPRYCEL**

In September 2010, Apotex filed an aNDA to manufacture and market generic versions of SPRYCEL. The Company received a Paragraph IV certification letter from Apotex challenging the four Orange Book listed patents for SPRYCEL, including the composition of matter patent. In November 2010, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Apotex for infringement of the four Orange Book listed patents covering SPRYCEL which triggered an automatic 30-month stay of approval of Apotex's aNDA. Discovery in this matter is ongoing. It is not possible at this time to reasonably assess the outcome of this lawsuit or its impact on the Company.

## **GENERAL COMMERCIAL LITIGATION**

### **Clayworth Litigation**

As previously disclosed, the Company, together with a number of other pharmaceutical manufacturers, was named as a defendant in an action filed in California State Superior Court in Oakland, James Clayworth et al. v. Bristol-Myers Squibb Company, et al., alleging that the defendants conspired to fix the prices of pharmaceuticals by agreeing to charge more for their drugs in the U.S. than they charge outside the U.S., particularly Canada, and asserting claims under California's Cartwright Act and unfair competition law. The plaintiffs sought trebled monetary damages, injunctive relief and other relief. In December 2006, the Court granted the Company and the other manufacturers' motion for summary judgment based on the pass-on defense, and judgment was then entered in favor of defendants. In July 2008, judgment in favor of defendants was affirmed by the California Court of Appeals. In July 2010, the California Supreme Court reversed the Court of Appeal's judgment and the matter was remanded to the Superior Court for further proceedings. In March 2011, the defendants' motion for summary judgment was granted and judgment was entered in favor of the defendants. Plaintiffs have appealed this decision.

## **PRICING, SALES AND PROMOTIONAL PRACTICES LITIGATION AND INVESTIGATIONS**

### **ABILIFY\* State Attorneys General Investigation**

In March 2009, the Company received a letter from the Delaware Attorney General's Office advising of a multi-state coalition investigating whether certain ABILIFY\* marketing practices violated those respective states' consumer protection statutes. It is not possible at this time to reasonably assess the outcome of this investigation or its potential impact on the Company.

### **AWP Litigation**

As previously disclosed, the Company, together with a number of other pharmaceutical manufacturers, has been a defendant in a number of private class actions as well as suits brought by the attorneys general of various states. In these actions, plaintiffs allege that defendants caused the Average Wholesale Prices (AWPs) of their products to be inflated, thereby injuring government programs, entities and persons who reimbursed prescription drugs based on AWPs. The Company is a defendant in four state attorneys general suits pending in state courts around the country. Beginning in August 2010, the Company was the defendant in a trial in the Commonwealth Court of Pennsylvania (Commonwealth Court), brought by the Commonwealth of Pennsylvania. In September 2010, the jury issued a verdict for the Company, finding that the Company was not liable for fraudulent or negligent misrepresentation; however, the Commonwealth Court Judge issued a decision on a Pennsylvania consumer protection claim that did not go to the jury, finding the Company liable for \$28 million and enjoining the Company from

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

contributing to the provision of inflated AWP's. The Company has moved to vacate the decision and the Commonwealth has moved for a judgment notwithstanding the verdict. In August

---

## **Table of Contents**

2011, the Commonwealth Court issued its decision denying the parties' motions. The Company and the Commonwealth have appealed the decision to the Pennsylvania Supreme Court.

As previously reported, one set of class actions were consolidated in the U.S. District Court for the District of Massachusetts (AWP MDL). In August 2009, the District Court granted preliminary approval of a proposed settlement of the AWP MDL plaintiffs' claims against the Company for \$19 million and in July 2011, the District Court issued a formal, final order and judgment approving the settlement of the AWP MDL.

### **California 340B Litigation**

As previously disclosed, in August 2005, the County of Santa Clara filed a purported class action against the Company and numerous other pharmaceutical manufacturers on behalf of itself and a putative class of other cities and counties in California, as well as the covered entities that purchased drugs pursuant to the 340B drug discount program (340B Entities), alleging that manufacturers did not provide proper discounts to 340B Entities. In May 2009, the U.S. District Court for the Northern District of California (District Court) denied plaintiff's motion, without prejudice, to certify the class. In September 2010, the U.S. Supreme Court granted certiorari on the issue of whether 340B Entities have standing to sue. The District Court had previously dismissed the case after finding that 340B Entities did not have standing, but the U.S. Court of Appeals for the Ninth Circuit reversed the District Court. In March 2011, the U.S. Supreme Court issued a unanimous decision holding that 340B entities do not have standing to sue the defendant manufacturers, effectively ending the litigation.

### **Qui Tam Litigation**

In March 2011, the Company was served with an unsealed qui tam complaint filed by three former sales representatives in California Superior Court, County of Los Angeles. The California Department of Insurance has elected to intervene in the lawsuit. The complaint alleges the Company paid kickbacks to California providers and pharmacies in violation of California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7. It is not possible at this time to reasonably assess the outcome of this lawsuit or its impact on the Company.

## **PRODUCT LIABILITY LITIGATION**

The Company is a party to various product liability lawsuits. As previously disclosed, in addition to lawsuits, the Company also faces unfiled claims involving its products.

### **PLAVIX\***

As previously disclosed, the Company and certain affiliates of Sanofi are defendants in a number of individual lawsuits in various federal and state courts claiming personal injury allegedly sustained after using PLAVIX\*. The defendants have made an application to have all of the federal cases designated as Multi-District Litigation and sent to a single federal court in the District of New Jersey for centralized management and discovery. In the New Jersey Federal Court action, the defendants have executed tolling agreements with respect to unfiled claims by potential additional plaintiffs. It is not possible at this time to reasonably assess the outcome of these lawsuits or the potential impact on the Company.

### **Reglan**

The Company is one of a number of defendants in approximately 200 individual lawsuits claiming personal injury allegedly sustained after using Reglan or another brand of the generic drug metoclopramide, a product indicated for gastroesophageal reflux and certain other gastrointestinal disorders. The Company, through its generic subsidiary, Apothecon, Inc., distributed metoclopramide tablets manufactured by another party between 1996 and 2000. It is not possible at this time to reasonably assess the outcome of these lawsuits or the potential impact on the Company.

### **Hormone Replacement Therapy**

The Company is one of a number of defendants in a mass-tort litigation in which plaintiffs allege, among other things, that various hormone therapy products, including hormone therapy products formerly manufactured by the Company (ESTRACE\*, Estradiol, DELESTROGEN\* and OVCON\*) cause breast cancer, stroke, blood clots, cardiac and other injuries in women, that the defendants were aware of these risks and failed to warn consumers. The Company has agreed to resolve the claims of approximately 400 plaintiffs. As of September 30, 2011, the Company remains a defendant in approximately 35 actively pending lawsuits in federal and state courts throughout the U.S. All of the Company's hormone therapy products were sold to other companies between January 2000 and August 2001.



## **Table of Contents**

### **ENVIRONMENTAL PROCEEDINGS**

As previously reported, the Company is a party to several environmental proceedings and other matters, and is responsible under various state, federal and foreign laws, including the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), for certain costs of investigating and/or remediating contamination resulting from past industrial activity at the Company's current or former sites or at waste disposal or reprocessing facilities operated by third-parties.

#### **CERCLA Matters**

With respect to CERCLA matters for which the Company is responsible under various state, federal and foreign laws, the Company typically estimates potential costs based on information obtained from the U.S. Environmental Protection Agency, or counterpart state or foreign agency and/or studies prepared by independent consultants, including the total estimated costs for the site and the expected cost-sharing, if any, with other potentially responsible parties, and the Company accrues liabilities when they are probable and reasonably estimable. The Company estimated its share of future costs for these sites to be \$69 million at September 30, 2011, which represents the sum of best estimates or, where no best estimate can reasonably be made, estimates of the minimal probable amount among a range of such costs (without taking into account any potential recoveries from other parties).

#### **New Brunswick Facility Environmental & Personal Injury Lawsuits**

Since May 2008, over 250 lawsuits have been filed against the Company in New Jersey Superior Court, by or on behalf of current and former residents of New Brunswick, NJ who live or have lived adjacent to the Company's New Brunswick facility. The complaints either allege various personal injuries damage resulting from alleged soil and groundwater contamination on their property stemming from historical operations at the New Brunswick facility, or are claims for medical monitoring. A portion of these complaints also assert claims for alleged property damage. In October 2008, the New Jersey Supreme Court granted Mass Tort status to these cases and transferred them to the New Jersey Superior Court in Atlantic County for centralized case management purposes. The Company intends to defend itself vigorously in this litigation. Discovery is ongoing. In October 2011, 50 additional cases were filed in New Jersey Superior Court and removed by the Company to federal court in Trenton, NJ. It is not possible at this time to reasonably assess the outcome of these lawsuits or the potential impact on the Company.

#### **North Brunswick Township Board of Education**

As previously disclosed, in October 2003, the Company was contacted by counsel representing the North Brunswick, NJ Board of Education (BOE) regarding a site where waste materials from E.R. Squibb and Sons may have been disposed from the 1940's through the 1960's. Fill material containing industrial waste and heavy metals in excess of residential standards was discovered during an expansion project at the North Brunswick Township High School, as well as at a number of neighboring residential properties and adjacent public park areas. In January 2004, the New Jersey Department of Environmental Protection (NJDEP) sent the Company and others an information request letter about possible waste disposal at the site, to which the Company responded in March 2004. The BOE and the Township, as the current owners of the school property and the park, are conducting and jointly financing soil remediation work and ground water investigation work under a work plan approved by NJDEP, and have asked the Company to contribute to the cost. The Company is actively monitoring the clean-up project, including its costs. To date, neither the school board nor the Township has asserted any claim against the Company. Instead, the Company and the local entities have negotiated an agreement to attempt to resolve the matter by informal means, and avoid litigation. A central component of the agreement is the provision by the Company of interim funding to help defray cleanup costs and assure the work is not interrupted. The Company transmitted interim funding payments in December 2007 and November 2009. The parties commenced mediation in late 2008; however, those efforts were not successful and the parties moved to a binding allocation process. The parties are expected to conduct fact and expert discovery, followed by formal evidentiary hearings and written argument. Hearings likely will be scheduled for mid-to-late 2012. In addition, in September 2009, the Township and BOE filed suits against several other parties alleged to have contributed waste materials to the site. The Company does not currently believe that it is responsible for any additional amounts beyond the two interim payments totaling \$4 million already transmitted. Any additional possible loss is not expected to be material.

### **OTHER PROCEEDINGS**

#### **Italy Investigation**

In July 2011, the Public Prosecutor in Florence, Italy (Italian Prosecutor) initiated a criminal investigation against the Company's subsidiary in Italy (BMS Italy). The allegations against the Company relate to alleged activities of a former employee who left the Company in the 1990s. The Italian Prosecutor has requested as an interim measure that a judicial administrator be appointed to temporarily run the operations of BMS Italy. This request is pending before the Florence Court. It is not possible at this time to assess the outcome of this investigation or its potential impact

on the Company.

## **Table of Contents**

### **SEC Germany Investigation**

As previously disclosed, in October 2004, the SEC notified the Company that it was conducting an informal inquiry into the activities of certain of the Company's German pharmaceutical subsidiaries and its employees and/or agents. In October 2006, the SEC informed the Company that its inquiry had become formal. The SEC's inquiry encompasses matters formerly under investigation by the German prosecutor in Munich, Germany, which have since been resolved. The Company understands the inquiry concerns potential violations of the Foreign Corrupt Practices Act. The Company is cooperating with the SEC.

### **Medarex Shareholder Litigation**

On July 22, 2009, the Company and Medarex announced the signing of a merger agreement providing for the acquisition of Medarex by the Company, through a tender offer, for \$16.00 per share in cash. Following that announcement, certain Medarex shareholders filed similar lawsuits in state and federal court relating to this transaction against Medarex, the members of Medarex's board of directors, and the Company.

Following the consolidation of the state court actions, on August 20, 2009, the parties entered into a memorandum of understanding (MOU), pursuant to which the parties reached an agreement in principle to settle all of the state and federal actions. Pursuant to the agreements in the MOU, among other things, Medarex made certain supplemental disclosures during the tender offer period. The parties also agreed to present to the Superior Court of New Jersey, Mercer County (NJ Superior Court) a Stipulation of Settlement and any other documentation as may be required in order to obtain approval by the court of the settlement and the dismissal of the actions upon the terms set forth in the MOU. In July 2010, the proposed settlement was approved by the NJ Superior Court. The amount of the settlement awarded is not material to the Company. Several objectors to the settlement filed motions for reconsideration asking the Court to reconsider its approval of the settlement which were denied in December 2010. The objectors appealed that decision and in October 2011, the New Jersey Appellate Division dismissed the objectors appeal. The objectors did not appeal the October decision by the Appellate Division, bringing this matter to a final resolution.

### **King Pharmaceuticals, Inc.**

In November 2009, King Pharmaceuticals, Inc. (King) and affiliated entities filed suit against ZymoGenetics, Inc. (ZymoGenetics), now a wholly owned subsidiary of the Company, in the United States District Court for the Eastern District of Tennessee. King alleges that ZymoGenetics engaged in unfair competition, false advertising, trademark infringement, and related claims under federal law and Tennessee state law. King seeks various forms of relief, including damages and injunctive relief precluding the Company from making certain representations regarding King's products and the Company's RECOTHROM product. King also filed motions with the District Court seeking temporary restraining orders and preliminary injunctive relief. In December 2009, the judge denied King's motions for preliminary injunction. The parties have settled this matter for no monetary consideration and this concludes the matter.



**Table of Contents****Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****EXECUTIVE SUMMARY**

Bristol-Myers Squibb Company (which may be referred to as Bristol-Myers Squibb, BMS, the Company, we, our or us) is a global biopharmaceutical company, consisting of global pharmaceutical/biotechnology and international consumer medicines businesses, whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. We license, manufacture, market, distribute and sell pharmaceutical products on a global basis.

In the third quarter of 2011, a subcutaneous formulation of ORENCIA (abatacept) was approved in the United States (U.S.) and we announced the main results of the ARISTOTLE trial of ELIQUIS\* (apixaban) which compared with warfarin significantly reduced the risk for stroke or systematic embolism, major bleeding and mortality.

**Highlights**

The following table is a summary of our operating activity:

Dollars in Millions, except per share data	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net Sales	\$ 5,345	\$ 4,798	\$ 15,790	\$ 14,373
Total Expenses	3,515	3,184	10,403	9,715
Earnings before Income Taxes	1,830	1,614	5,387	4,658
Provision for Income Taxes	475	312	1,358	987
Effective tax rate	26.0%	19.3%	25.2%	21.2%
Net Earnings Attributable to BMS	969	949	2,857	2,619
Net Earnings Attributable to BMS Non-GAAP	1,044	1,017	3,015	2,928
Diluted Earnings Per Share Attributable to BMS	0.56	0.55	1.66	1.51
Diluted Earnings Per Share Attributable to BMS Non-GAAP	0.61	0.59	1.75	1.69

Cash, Cash Equivalents and Marketable Securities

11,012 10,921

Our non-GAAP financial measures, including non-GAAP earnings and related EPS information, are adjusted to exclude specified items which represent certain costs, expenses, gains and losses and other items impacting the comparability of financial results. For a detailed listing of all specified items and further information and reconciliations of non-GAAP financial measures see Specified Items and Non-GAAP Financial Measures below.

**Strategy**

Over the past few years, we have transformed our Company into a focused biopharmaceutical company, a transformation that encompasses all areas of our business and operations. This has not only focused our product portfolio but has yielded and will continue to yield substantial cost savings and cost avoidance. This in turn increases our financial flexibility to take advantage of attractive market opportunities that may arise.

In May 2012, we expect the loss of exclusivity in the U.S. for our largest product, PLAVIX\* (clopidogrel bisulfate), after which time we expect a rapid, precipitous and material decline in PLAVIX\* net sales and a reduction in net income and operating cash flow. We expect a similar decline in AVAPRO\*/AVALIDE\* (irbesartan/irbesartan-hydrochlorothiazide) net sales immediately following the loss of exclusivity in the U.S. in March 2012. Such events are the norm in the industry when a company experiences the loss of exclusivity of a product (particularly a product that is a small molecule). Recognizing this fact, we are, and have been, focused on sustaining our business and building a robust foundation for the future. We plan to achieve this foundation by continuing to support and grow our currently marketed products, advancing our pipeline, and maintaining and improving our financial strength.

We continue to expand our biologics capabilities. We still rely significantly on small molecules as our strongest, most reliable starting point for discovering potential new medicines, but large molecules, or biologics, derived from recombinant DNA technologies, are becoming increasingly important. Currently, greater than one in three of our pipeline compounds are biologics, as are four of our key marketed products, including YERVOY (ipilimumab).



## **Table of Contents**

Our strategy includes a focus on certain emerging markets, our acquisition and licensing strategy known as string-of-pearls, optimizing our mature brands portfolio and managing costs. Our strategy in emerging markets is to develop and commercialize innovative products in key high-growth markets, tailoring the approach to each market. We are continuing to focus on our core biopharmaceuticals and maximizing the value of our mature brands portfolio.

Since June 30, 2011, we completed the following strategic transactions:

We acquired Amira Pharmaceutical, Inc. (Amira), a small-molecule pharmaceutical company focused on fibrotic disease.

We entered into an agreement with Ono Pharmaceuticals Co., Ltd. (Ono) to expand our territorial rights to develop and commercialize the PD-1 antibody and to create a strategic alliance for the codevelopment and cocommercialization of ORENCIA in Japan.

We obtained exclusive worldwide rights from Ambrx Inc. (Ambrx) to research, develop and commercialize novel biologics in diabetes and heart disease.

We obtained exclusive worldwide rights from Innate Pharma S.A. (Innate) to develop and commercialize IPH 2102, a novel immune-oncology biologic in Phase I development.

We announced a licensing agreement with Gilead Sciences, Inc. (Gilead) for the development and commercialization of a new fixed-dose combination containing REYATAZ and Gilead's cobicistat for the treatment of HIV.

### **U.S. Healthcare Reform Legislation**

We have experienced and will continue to experience additional financial costs and certain other changes to our business as the new healthcare law provisions become effective. Two additional provisions that impact our financial results went into effect on January 1, 2011. The first is a 50 percent discount on our brand-name drugs to patients within the Medicare Part D coverage gap, also referred to as the donut hole. The second is an annual non-tax-deductible pharmaceutical company fee payable to the Federal government based on an allocation of our market share of branded prior year sales to certain U.S. government programs including Medicare, Medicaid, Department of Veterans Affairs, Department of Defense and TRICARE.

The annual EPS impact of U.S. healthcare reform is expected to increase from \$0.10 in 2010 to approximately \$0.23 in 2011. In 2011, we expect a reduction of net sales of approximately \$270 million resulting from new discounts associated with the Medicare Part D coverage gap and an increase in marketing, sales and administrative expenses of approximately \$220 million due to the new annual non-tax-deductible pharmaceutical company fee. The incremental impact of the two additional U.S. healthcare reform provisions for new discounts associated with the Medicare Part D coverage gap and the annual pharmaceutical company fee decreased EPS by approximately \$0.04 and \$0.10 for the three and nine months ended September 30, 2011, respectively, on both a GAAP and non-GAAP basis. These new healthcare reform provisions had a greater impact on EPS in the current quarter than in prior quarters this year as more patients moved into the Medicare Part D coverage gap. The new discounts and fee, as well as other aspects of healthcare reform that became effective in 2010, continue to require additional assumptions due to the lack of sufficient historical claims experience and as such are subject to changes in estimates.

### **Product and Pipeline Developments**

We manage our research and development (R&D) programs on a portfolio basis, investing resources in each stage from early discovery through late-stage development. We continually evaluate our portfolio of R&D assets to ensure that there is an appropriate balance of early-stage and late-stage programs to support future growth. We consider our R&D programs that have entered into Phase III development to be significant, as these programs constitute our late-stage development pipeline. These programs include both investigational compounds in Phase III development for initial indications and marketed products that are in Phase III development for additional indications or formulations. Spending on these programs represents approximately 30-40% of our annual R&D expenses. No individual investigational compound or marketed product represented 10% or more of our R&D expenses in any of the last three years. While we do not expect all of our late-stage development programs

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

to make it to market, our late-stage development programs are the R&D programs that could potentially have an impact on our revenue and earnings within the next few years. The following are the recent significant developments in our marketed products and our late-stage pipeline:

**YERVOY** a monoclonal antibody for the treatment of patients with unresectable (inoperable) or metastatic melanoma, which currently is also being studied for other indications including lung cancer as well as adjuvant melanoma and hormone-refractory prostate cancer

In July 2011, the Company announced that the European Commission approved YERVOY for the treatment of adult patients with previously-treated advanced melanoma.

## **Table of Contents**

**ELIQUIS\*** an oral Factor Xa inhibitor for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery and in development for the prevention and treatment of venous thromboembolic disorders and stroke prevention in patients with atrial fibrillation that is part of our strategic alliance with Pfizer, Inc. (Pfizer)

In August 2011 at the European Society of Cardiology Congress, the Company and Pfizer announced the main results of the Phase III ARISTOTLE trial, which evaluated ELIQUIS\* compared to warfarin for the prevention of stroke or systemic embolism in patients with atrial fibrillation and at least one risk factor for stroke. ELIQUIS\* as compared with warfarin significantly reduced the risk of stroke or systematic embolism by 21 percent, major bleeding by 31 percent and mortality by 11 percent. We expect to have a validated application in the EU and an accepted filing in the U.S. for an indication in stroke prevention in atrial fibrillation by the end of 2011.

**NULOJIX (belatacept)** a fusion protein with novel immunosuppressive activity for the prevention of kidney transplant rejection

In September 2011 at the European Society for Organ Transplantation (ESOT) meeting, the Company presented new data on NULOJIX, including donor sub-type analysis of three-year outcomes from a Phase III study of NULOJIX in recipients with extended criteria donor kidneys (BENEFIT-EXT Trial) and three-year outcomes in kidney transplant recipients with pre-transplant diabetes from two Phase III studies.

**Dapagliflozin** an oral SGLT2 inhibitor for the treatment of diabetes that is part of our strategic alliance with AstraZeneca PLC (AstraZeneca)

In July 2011, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee voted nine to six that the efficacy and safety data did not provide substantial evidence to support approval of the New Drug Application (NDA) for dapagliflozin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The FDA is not bound by the Advisory Committee's recommendation but takes its advice into consideration when reviewing New Drug Applications. The Company and AstraZeneca remain committed to dapagliflozin and will continue to work closely with the FDA to support the review of dapagliflozin.

In October 2011, the FDA extended its review timeline of the NDA and has moved the Prescription User Fee Act date, the date by which action from the FDA is expected, to January 28, 2012.

**ORENCIA** a fusion protein indicated for rheumatoid arthritis

In August 2011, the marketing authorization application for the subcutaneous formulation of ORENCIA was validated for review by the European Medicine Agency.

In July 2011, the FDA approved a subcutaneous formulation of ORENCIA for the treatment of adults with moderate to severe rheumatoid arthritis.

**ONGLYZA/KOMBIGLYZE (saxagliptin/saxagliptin and metformin)** a treatment for type 2 diabetes that is part of our strategic alliance with AstraZeneca

In September 2011, the Marketing Authorization Application for KOMBIGLYZE (known in the EU as KOMBOGLYZE) received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP). The CHMP's positive opinion will now be reviewed by the European Commission.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

In September 2011 at the 47<sup>th</sup> European Association for the Study of Diabetes annual meeting, the Company and AstraZeneca announced results from an investigational Phase IIIb clinical study which reported that ONGLYZA 5 mg added to insulin (with or without metformin) maintained glycemic control (glycosylated hemoglobin levels or HbA1c) in adult patients with type 2 diabetes compared to the addition of placebo at 24 to 52 weeks.

SPRYCEL (dasatinib) an oral inhibitor of multiple tyrosine kinases indicated for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy, including GLEEVEC\* (imatinib mesylate) and first-line treatment of adults. SPRYCEL is part of our strategic alliance with Otsuka.

In September 2011, China's State Food and Drug Administration approved SPRYCEL for the treatment of adults with chronic, accelerated or lymphoid or myeloid chronic myeloid leukemia with resistance or intolerance to prior therapy of imatinib.

**Table of Contents****RESULTS OF OPERATIONS****Net Sales**

The composition of the change in net sales was as follows:

	Three Months Ended September 30, 2011 vs. 2010						Nine Months Ended September 30, 2011 vs. 2010					
	Net Sales		Analysis of % Change				Net Sales		Analysis of % Change			
	2011	2010	Total Change	Volume	Price	Foreign Exchange	2011	2010	Total Change	Volume	Price	Foreign Exchange
Dollars in Millions												
United States	\$ 3,477	\$ 3,135	11%	6%	5%		\$ 10,289	\$ 9,329	10%	3%	7%	
Europe	916	804	14%	7%	(4)%	11%	2,738	2,512	9%	6%	(4)%	7%
Japan, Asia Pacific and Canada	464	419	11%	2%	(1)%	10%	1,375	1,193	15%	8%	(2)%	9%
Latin America, the Middle East and Africa	230	207	11%	4%	4%	3%	664	631	5%	2%	1%	2%
Emerging Markets	238	211	13%	10%	(2)%	5%	659	615	7%	6%	(4)%	5%
Other	20	22	(9)%	N/A	N/A		65	93	(30)%	N/A	N/A	1%
<b>Total</b>	<b>\$ 5,345</b>	<b>\$ 4,798</b>	<b>11%</b>	<b>6%</b>	<b>2%</b>	<b>3%</b>	<b>\$ 15,790</b>	<b>\$ 14,373</b>	<b>10%</b>	<b>5%</b>	<b>3%</b>	<b>2%</b>

Our global sales growth in 2011 was attributable to higher volume, higher average net selling prices, favorable foreign exchange and reflects continued growth in most key products offset by declines in sales of AVAPRO\*/AVALIDE\* and mature brands across all regions and international sales of PLAVIX\*.

The change in U.S. net sales attributed to price was a result of higher average net selling prices for PLAVIX\*, partially offset by the reduction in our contractual share of ABILIFY\* (aripiprazole) net sales, the expansion of Medicaid rebates to drugs used in risk-based Medicaid managed care plans, and the impact of the 50% discount on our brand-name drugs to patients within the Medicare Part D coverage gap. The change in U.S. net sales attributed to volume reflects the recent launch of YERVOY and increased demand for ONGLYZA/KOMBIGLYZE, SPRYCEL, ABILIFY\* and other key products partially offset by decreased prescription demand for AVAPRO\*/AVALIDE\* and PLAVIX\*.

Net sales in Europe increased due to sales growth of most key products partially offset by lower sales of certain mature brands from divestitures and generic competition as well as generic competition for PLAVIX\* and AVAPRO\*/AVALIDE\*. The change in net sales was negatively impacted by continuing fiscal challenges in many European countries as healthcare payers, including government agencies, have reduced and are expected to continue to reduce the cost of healthcare through actions that directly or indirectly impose additional price reductions. These measures include, but are not limited to, mandatory discounts, rebates, other price reductions and other restrictive measures.

Net sales in Japan, Asia Pacific and Canada increased primarily due to higher demand for BARACLUDE, SPRYCEL which recently received first line indication in Japan, and ORENCIA which was recently launched in Japan. These impacts were partially offset by generic competition for AVAPRO\* in Canada and lower mature brands sales from generic competition and divestitures.

No single country outside the U.S. contributed more than 10% of total net sales during the three and nine months ended September 30, 2011 and 2010.

In general, our business is not seasonal. For information on U.S. pharmaceutical prescriber demand, reference is made to the table within

Estimated End-User Demand below, which sets forth a comparison of changes in net sales to the estimated total prescription growth (for both retail and mail order customers) for certain of our key products. U.S. and non-U.S. net sales are categorized based upon the location of the customer.

**Table of Contents**

We recognize revenue net of various sales adjustments to arrive at net sales as reported in the consolidated statements of earnings. These adjustments are referred to as gross-to-net sales adjustments. The reconciliation of our gross sales to net sales by each significant category of gross-to-net sales adjustments was as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Gross Sales</b>	\$ 6,081	\$ 5,360	\$ 17,761	\$ 15,932
<b>Gross-to-Net Sales Adjustments</b>				
Charge-Backs Related to Government Programs	(206)	(159)	(571)	(427)
Cash Discounts	(71)	(68)	(210)	(202)
Managed Healthcare Rebates and Other Contract Discounts	(233)	(131)	(514)	(370)
Medicaid Rebates	(137)	(114)	(404)	(328)
Sales Returns	(7)	(4)	(27)	(15)
Other Adjustments	(82)	(86)	(245)	(217)
<b>Total Gross-to-Net Sales Adjustments</b>	(736)	(562)	(1,971)	(1,559)
<b>Net Sales</b>	\$ 5,345	\$ 4,798	\$ 15,790	\$ 14,373

The activities and ending balances of each significant category of gross-to-net sales reserve adjustments were as follows:

Dollars in Millions	Charge-Backs Related to Government Programs	Cash Discounts	Managed Healthcare Rebates and Other Contract Discounts	Medicaid Rebates	Sales Returns	Other Adjustments	Total
Balance at January 1, 2011	\$ 48	\$ 29	\$ 216	\$ 327	\$ 187	\$ 127	\$ 934
Provision related to sales made in current period	571	210	514	404	72	239	2,010
Provision related to sales made in prior periods					(45)	6	(39)
Returns and payments	(570)	(212)	(348)	(346)	(79)	(217)	(1,772)
Impact of foreign currency translation			(1)		(1)	3	1
Balance at September 30, 2011	\$ 49	\$ 27	\$ 381	\$ 385	\$ 134	\$ 158	\$ 1,134

Gross-to-net sales adjustments as a percentage of gross sales were 12% and 10% for the three months ended September 30, 2011 and 2010, respectively, and were 11% and 10% for the nine months ended September 30, 2011 and 2010, respectively, and such changes in rates are primarily a function of changes in sales mix and contractual and legislative discounts and rebates. Gross-to-net sales adjustments increased due to:

Charge-backs related to government programs increased due to U.S. sales growth associated with higher average net selling prices. Managed healthcare rebates and other contract discounts include the impact of the 50% discount on our brand-name drugs to patients within the Medicare Part D coverage gap, which increased during the third quarter of 2011 as more patients entered the coverage gap. Medicaid rebates increased due to the full year impact of the expansion of Medicaid rebates to drugs used in risk-based Medicaid managed care plans and higher average net selling prices for PLAVIX\*, and higher Medicaid channel sales. Sales returns in the nine months ended September 30, 2011 included a \$29 million reduction for previously established U.S. return reserves in connection with a recall of certain lots of AVALIDE\* due to lower returns than expected.





**Table of Contents**

Net sales of key products represented 86% and 84% of total net sales for the three months ended September 30, 2011 and 2010, respectively, and 86% and 84% of total net sales for the nine months ended September 30, 2011 and 2010, respectively. The following table presents U.S. and international net sales by key products, the percentage change from the prior period and the foreign exchange impact when compared to the prior period. Commentary on significant variances for key products is provided below:

Dollars in Millions	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011	2010	% Change	% Change Attributable to Foreign Exchange	2011	2010	% Change	% Change Attributable to Foreign Exchange
<b>Key Products</b>								
PLAVIX* (clopidogrel bisulfate)	\$ 1,788	\$ 1,658	8%	1%	\$ 5,415	\$ 4,951	9%	
U.S.	1,672	1,534	9%		5,060	4,561	11%	
Non-U.S.	116	124	(6)%	7%	355	390	(9)%	4%
<b>AVAPRO*/AVALIDE*</b>								
(irbesartan/irbesartan-hydrochlorothiazide)	216	303	(29)%	2%	757	924	(18)%	2%
U.S.	121	168	(28)%		414	524	(21)%	
Non-U.S.	95	135	(30)%	5%	343	400	(14)%	6%
<b>ABILIFY* (aripiprazole)</b>								
U.S.	691	608	14%	3%	2,021	1,858	9%	2%
Non-U.S.	505	462	9%		1,482	1,423	4%	
Non-U.S.	186	146	27%	10%	539	435	24%	9%
<b>REYATAZ (atazanavir sulfate)</b>								
U.S.	391	375	4%	4%	1,153	1,105	4%	3%
Non-U.S.	184	189	(3)%		554	560	(1)%	
Non-U.S.	207	186	11%	8%	599	545	10%	7%
<b>SUSTIVA (efavirenz) Franchise</b>								
U.S.	359	342	5%	3%	1,073	1,008	6%	2%
Non-U.S.	222	227	(2)%		665	654	2%	
Non-U.S.	137	115	19%	10%	408	354	15%	7%
<b>BARACLUDE (entecavir)</b>								
U.S.	311	228	36%	8%	878	667	32%	7%
Non-U.S.	51	46	11%		150	130	15%	
Non-U.S.	260	182	43%	10%	728	537	36%	9%
<b>ERBITUX* (cetuximab)</b>								
U.S.	172	159	8%		510	497	3%	
Non-U.S.	168	155	8%		497	486	2%	
Non-U.S.	4	4		4%	13	11	18%	4%
<b>SPRYCEL (dasatinib)</b>								
U.S.	211	144	47%	8%	576	407	42%	6%
Non-U.S.	78	47	66%		207	127	63%	
Non-U.S.	133	97	37%	10%	369	280	32%	9%
<b>YERVOY (ipilimumab)</b>								
U.S.	121	N/A	N/A	N/A	216	N/A	N/A	N/A
Non-U.S.	109	N/A	N/A	N/A	204	N/A	N/A	N/A
Non-U.S.	12	N/A	N/A	N/A	12	N/A	N/A	N/A
<b>ORENCIA (abatacept)</b>								
U.S.	233	184	27%	4%	660	531	24%	2%
Non-U.S.	154	138	12%		444	401	11%	
Non-U.S.	79	46	72%	15%	216	130	66%	11%
<b>NULOJIX (belatacept)</b>								
U.S.		N/A	N/A	N/A	2	N/A	N/A	N/A
U.S.		N/A	N/A	N/A	2	N/A	N/A	N/A

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Non-U.S.		N/A	N/A	N/A		N/A	N/A	N/A
ONGLYZA/KOMBIGLYZE								
(saxagliptin/saxagliptin and metformin)	127	47	170%	4%	320	85	**	**
U.S.	91	37	146%		228	66	**	
Non-U.S.	36	10	**	**	92	19	**	**
<b>Mature Products and All Other</b>								
	725	750	(3)%	7%	2,209	2,340	(6)%	5%
U.S.	122	132	(8)%		382	397	(4)%	
Non-U.S.	603	618	(2)%	9%	1,827	1,943	(6)%	6%

\*\* Change in excess of 200%.

## **Table of Contents**

PLAVIX\* a platelet aggregation inhibitor that is part of our alliance with Sanofi

U.S. net sales increased due to higher average net selling prices. Estimated total U.S. prescription demand decreased 6% and 5% for the three and nine months ended September 30, 2011, respectively.

International net sales continue to be negatively impacted by generic clopidogrel products in the EU and Australia. This has a negative impact on both our net sales in EU comarketing countries and Australia and our equity in net income of affiliates from our share of sales from our partnership with Sanofi in Europe and Asia. We expect continued erosion of PLAVIX\* net sales in the EU, which will impact both our international net sales and our equity in net income of affiliates.

See Item 1. Financial Statements Note 16. Legal Proceedings and Contingencies PLAVIX\* Litigation, for further discussion on PLAVIX\* exclusivity litigation in both the U.S. and internationally.

AVAPRO\*/AVALIDE\* (known in the EU as APROVEL\*/KARVEA\*) an angiotensin II receptor blocker for the treatment of hypertension and diabetic nephropathy that is also part of the Sanofi alliance

U.S. net sales decreased due to a loss of customers subsequent to the AVALIDE\* supply shortage in the first quarter of 2011 associated with previously reported recalls. The decrease in U.S. net sales was partially offset by higher average net selling prices and the reduction in 2011 of previously established reserves for estimated returns in connection with the recall of certain lots of AVALIDE\* during 2010 due to lower actual returns than expected. Total estimated U.S. prescription demand decreased 42% and 38% for the three and nine months ended September 30, 2011, respectively, partially offset by higher average net selling prices.

International net sales decreased due to lower demand including generic competition in certain EU markets and Canada.

ELIQUIS\* an oral Factor Xa inhibitor for the prevention of VTE in adult patients who have undergone elective hip or knee replacement surgery and in development for the prevention and treatment of venous thromboembolic disorders and stroke prevention in patients with atrial fibrillation that is part of our strategic alliance with Pfizer

ELIQUIS\* was approved in the EU for VTE prevention in May 2011 and was launched in a limited number of EU countries beginning in May 2011. Net sales were less than \$1 million.

ABILIFY\* an antipsychotic agent for the treatment of schizophrenia, bipolar mania disorder and major depressive disorder that is part of the Company's strategic alliance with Otsuka

U.S. net sales increased due to higher overall demand and average net selling prices partially offset by the reduction in our contractual share of net sales recognized from 58% in 2010 to 53.5% in 2011. Estimated total U.S. prescription demand increased 4% and 5% for the three and nine months ended September 30, 2011, respectively.

International net sales increased primarily due to higher demand.

REYATAZ a protease inhibitor for the treatment of HIV

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

U.S. net sales remained relatively flat. Estimated total U.S. prescription demand increased 1% and 2% for the three and nine months ended September 30, 2011, respectively.

International net sales increased due to higher demand.

SUSTIVA Franchise a non-nucleoside reverse transcriptase inhibitor for the treatment of HIV, which includes SUSTIVA (efavirenz), an antiretroviral drug, and bulk efavirenz, which is also included in the combination therapy, ATRIPLA\* (efavirenz 600mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), a product sold through a joint venture with Gilead Sciences, Inc. (Gilead)

U.S. net sales remained relatively flat as increased demand was offset by wholesaler buying patterns. Estimated total U.S. prescription demand increased 7% and 8% for the three and nine months ended September 30, 2011, respectively.

International net sales increased primarily due to continued demand in the EU.

BARACLUDE an oral antiviral agent for the treatment of chronic hepatitis B

Net sales increased primarily due to continued demand in international markets.

ERBITUX\* a monoclonal antibody designed to exclusively target and block the Epidermal Growth Factor Receptor, which is expressed on the surface of certain cancer cells in multiple tumor types as well as normal cells and is currently indicated for use against colorectal cancer and head and neck cancer. ERBITUX\* is part of our strategic alliance with Lilly.

Net sales increased primarily due to higher demand.

## **Table of Contents**

**SPRYCEL** an oral inhibitor of multiple tyrosine kinases, for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy, including GLEEVEC\* (imatinib mesylate) and first-line treatment of adults. SPRYCEL is part of our strategic alliance with Otsuka.

U.S. net sales increased due to higher demand from the recent approval of SPRYCEL for first-line treatment of adults and higher average net selling prices. Estimated total U.S. demand increased 27% and 19% for the three and nine months ended September 30, 2011, respectively.

International net sales increased due to higher demand including the impact of the European Commission's Marketing Authorization of SPRYCEL in the fourth quarter of 2010 for first-line treatment of adults.

**YERVOY** a monoclonal antibody for the treatment of patients with unresectable (inoperable) or metastatic melanoma

YERVOY was launched in the U.S. in the second quarter of 2011.

YERVOY was approved in the EU and launched in a limited number of EU countries in the third quarter of 2011.

During the third quarter of 2011, \$27 million of net sales were deferred until patient infusion due to a newly established returns policy in the U.S.

**ORENCIA** a fusion protein indicated for adult patients with moderate to severe rheumatoid arthritis who have had an inadequate response to one or more currently available treatments, such as methotrexate or anti-tumor necrosis factor therapy

U.S. net sales increased primarily due to higher demand and higher average net selling prices.

International net sales increased primarily due to higher demand.

**NULOJIX** a fusion protein with novel immunosuppressive activity targeted at prevention of kidney transplant rejection

NULOJIX was approved and launched in the U.S. in June 2011.

NULOJIX was approved in the EU in June 2011 and launched in July 2011.

Net sales were less than \$1 million for the third quarter of 2011.

**ONGLYZA/KOMBIGLYZE** a once-daily oral tablet for the treatment of type 2 diabetes that is part of our strategic alliance with AstraZeneca

ONGLYZA/KOMBIGLYZE increased primarily due to higher overall demand. ONGLYZA/KOMBIGLYZE continues to be launched in various countries.

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Mature Products and All Other includes all other products, including those which have lost exclusivity in major markets and over the counter brands

U.S. net sales decreased in 2011 as the continued generic erosion of certain products was partially offset by sales of RECOTHROM which was acquired as part of our ZymoGenetics, Inc. (ZymoGenetics) acquisition in October 2010.

International net sales decreased due to continued generic erosion of certain brands, lower average net selling prices in Europe, the year over year impact of the rationalization and divestitures of our non-strategic product portfolio and lower demand for certain over the counter products.

The estimated U.S. prescription change data provided throughout this report includes information only from the retail and mail order channels and does not reflect product demand within other channels such as hospitals, home health care, clinics, federal facilities including Veterans Administration hospitals, and long-term care, among others. The data is provided by Wolters Kluwer Health (WK), except for SPRYCEL, and based on the Source Prescription Audit which is a product of WK's own recordkeeping and projection processes. As such, the data is subject to the inherent limitations of estimates based on sampling and may include a margin of error.

The change in SPRYCEL demand is calculated based on tablets sold through retail and mail order channels based upon data obtained from the IMS Health (IMS) National Sales Perspectives Audit, which is a product of IMS's own recordkeeping and projection processes. As such, the data is subject to the inherent limitations of estimates based on sampling and may include a margin of error.

We continuously seek to improve the quality of our estimates of prescription change amounts and ultimate patient/consumer demand by reviewing the calculation methodologies employed and analyzing internal and third-party data. We expect to continue to review and refine our methodologies and processes for calculation of these estimates and will monitor the quality of our own and third parties' data used in such calculations.

## Table of Contents

We calculated the estimated total U.S. prescription change on a weighted-average basis since mail order prescriptions include a higher average volume of product supplied per dispensed prescription, compared to retail prescriptions. Mail order prescriptions typically reflect a 90-day prescription whereas retail prescriptions typically reflect a 30-day prescription. The calculation is derived by multiplying mail order prescription data by a factor that approximates three and adding to this the retail prescriptions. We believe that a calculation of estimated total U.S. prescription change based on this weighted-average approach provides a superior estimate of total prescription demand, with respect to the retail and mail order channels. We use this methodology for our internal demand reporting.

### Estimated End-User Demand

The following table sets forth each of our key products sold in the U.S. for the three and nine months ended September 30, 2011 compared to the same period in the prior year: (i) change in reported U.S. net sales for each period; (ii) estimated total U.S. prescription change for the retail and mail order channels calculated by us based on third-party data on a weighted-average basis and (iii) months of inventory on hand in the wholesale distribution channel.

	Three Months Ended September 30,				Nine Months Ended September 30,				At September 30,	
	% Change in U.S. Net Sales		% Change in U.S. Total Prescriptions		% Change in U.S. Net Sales		% Change in U.S. Total Prescriptions		Months on Hand	
	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010
Dollars in Millions										
PLAVIX*	9%	9%	(6)%	(2)%	11%	11%	(5)%		0.5	0.4
AVAPRO*/AVALIDE*	(28)%	(10)%	(42)%	(19)%	(21)%	(3)%	(38)%	(16)%	0.5	0.4
ABILIFY*	9%	(11)%	4%	3%	4%	(6)%	5%	6%	0.4	0.4
REYATAZ	(3)%	2%	1%	2%	(1)%	5%	2%	5%	0.4	0.4
SUSTIVA Franchise <sup>(a)</sup>	(2)%	16%	7%	6%	2%	13%	8%	9%	0.4	0.5
BARACLUDE	11%	12%	8%	13%	15%	12%	9%	13%	0.5	0.5
ERBITUX <sup>*(b)</sup>	8%	(11)%	N/A	N/A	2%	(4)%	N/A	N/A	0.5	0.4
SPRYCEL	66%	68%	27%	5%	63%	40%	19%	6%	0.6	0.6
YERVOY <sup>(b)(c)</sup>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.6	N/A
ORENCIA <sup>(b)</sup>	12%	10%	N/A	N/A	11%	18%	N/A	N/A	0.4	0.3
NULOJIX <sup>(b)(d)</sup>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	9.8	N/A
ONGLYZA/KOMBIGLYZE <sup>(e)</sup>	146%	85%	138%	N/A	**	**	**	N/A	0.4	0.5

(a) The SUSTIVA Franchise includes sales of SUSTIVA, as well as revenue of bulk efavirenz included in the combination therapy ATRIPLA\*.

(b) ERBITUX\*, YERVOY, ORENCIA and NULOJIX are parenterally administered products and do not have prescription-level data as physicians do not write prescriptions for these products.

(c) YERVOY was launched in the U.S. in the second quarter of 2011.

(d) NULOJIX was launched in the U.S. in the second quarter of 2011.

(e) KOMBIGLYZE was launched in the U.S. in the fourth quarter of 2010.

\*\* Change in excess of 200%.

Pursuant to the U.S. Securities and Exchange Commission (SEC) Consent Order described in our 2010 Annual Report on Form 10-K, we monitor the level of inventory on hand in the U.S. wholesale distribution channel and outside of the U.S. in the direct customer distribution channel. We are obligated to disclose products with levels of inventory in excess of one month on hand or expected demand, subject to a *de minimis* exception. The following are U.S. products that had estimated levels of inventory in the distribution channel in excess of one month on hand at September 30, 2011 and international products that had estimated levels of inventory in the distribution channel in excess of one month on hand at June 30, 2011:

NULOJIX had 9.8 months of inventory on hand in the U.S. to support the initial product launch. The inventory is nominal and is expected to be worked down in less than that amount of time as demand for this new product increases post launch.

DAFALGAN, an analgesic product sold principally in Europe, had approximately 1.4 months of inventory on hand at direct customers compared to approximately 1.4 months of inventory on hand at December 31, 2010. The level of inventory on hand was primarily due to the ordering patterns of private pharmacists in France.



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

EFFERALGAN, an analgesic product sold principally in Europe, had approximately 1.5 months of inventory on hand at direct customers compared to approximately 1.0 months of inventory on hand at December 31, 2010. The increased level of inventory on hand was primarily due to ordering patterns of private pharmacists in France.

**Table of Contents**

FERVEX, a cold and flu product, had approximately 8.8 months of inventory on hand internationally at direct customers compared to approximately 3.4 months of inventory on hand at December 31, 2010. The level of inventory on hand was primarily due to lower than expected demand in Russia and ordering patterns of private pharmacists in France.

LUFTAL, an antacid product, had approximately 1.1 months of inventory on hand internationally at direct customers compared to approximately 1.3 months of inventory on hand at December 31, 2010. The level of inventory on hand was primarily due to a build-up of inventory following a stock-out in the second quarter of 2010.

PICOT, an antacid product, had approximately 1.1 months of inventory on hand internationally at direct customers compared to approximately 1.0 months of inventory on hand at December 31, 2010. The level of inventory on hand was primarily due to lower demand in Mexico.

PENTREXYL, an antibiotic product, had approximately 1.1 months of inventory on hand internationally at direct customers compared to approximately 1.1 months of inventory at December 31, 2010. The level of inventory on hand was primarily due to lower demand in Mexico.

Estimated levels of inventory in the distribution channel in excess of one month on hand for these products were not material as of the dates indicated above.

In the U.S., for all products sold exclusively through wholesalers or distributors, we determined our months on hand estimates using information with respect to inventory levels of product on hand and the amount of out-movement of products provided by our three largest wholesalers and some of our distributors. Our three largest wholesalers accounted for approximately 90% of total gross sales of U.S. products. Factors that may influence our estimates include generic competition, seasonality of products, wholesaler purchases in light of increases in wholesaler list prices, new product launches, new warehouse openings by wholesalers and new customer stockings by wholesalers. In addition, these estimates are calculated using third-party data, which may be impacted by their record keeping processes.

For products in the U.S. that are not sold exclusively through wholesalers or distributors and for our business outside of the U.S., we have significantly more direct customers. Limited information on direct customer product level inventory and corresponding out-movement information and the reliability of third-party demand information, where available, varies widely. In cases where direct customer product level inventory, ultimate patient/consumer demand or out-movement data does not exist or is otherwise not available, we have developed a variety of other methodologies to calculate estimates of such data, including using such factors as historical sales made to direct customers and third-party market research data related to prescription trends and end-user demand. Accordingly, we rely on a variety of methods to estimate direct customer product level inventory and to calculate months on hand for these business units. Factors that may affect our estimates include generic competition, seasonality of products, direct customer purchases in light of price increases, new product or product presentation launches, new warehouse openings by direct customers, new customer stockings by direct customers and expected direct customer purchases for governmental bidding situations. As such, all of the information required to estimate months on hand in the direct customer distribution channel for non-U.S. businesses for the quarter ended September 30, 2011 is not available prior to the filing of this quarterly report on Form 10-Q. We will disclose any product with levels of inventory in excess of one month on hand or expected demand for the current quarter, subject to a *de minimis* exception, in the next annual report on Form 10-K.

**Expenses**

Dollars in Millions	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	% Change	2011	2010	% Change
Cost of products sold	\$ 1,407	\$ 1,280	10%	\$ 4,231	\$ 3,863	10%
Marketing, selling and administrative	1,019	892	14%	2,987	2,686	11%
Advertising and product promotion	205	231	(11)%	672	706	(5)%
Research and development	973	824	18%	2,831	2,556	11%
Provision for restructuring	8	15	(47)%	92	50	84%
Litigation expense		22	(100)%		22	(100)%
Equity in net income of affiliates	(71)	(70)	1%	(215)	(252)	(15)%
Other (income)/expense	(26)	(10)	160%	(195)	84	**
<b>Total Expenses</b>	<b>\$ 3,515</b>	<b>\$ 3,184</b>	<b>10%</b>	<b>\$ 10,403</b>	<b>\$ 9,715</b>	<b>7%</b>

\*\* Change in excess of 200%.

**Table of Contents**

Cost of products sold as a percentage of net sales were 26.3% and 26.7% for the three months ended September 30, 2011 and 2010, respectively, and 26.8% and 26.9% for the nine months ended September 30, 2011 and 2010, respectively.

Marketing, selling and administrative spending increased primarily due to a \$165 million charge during 2011 attributed to the annual pharmaceutical company fee discussed above in Executive Summary U.S. Healthcare Reform Legislation and unfavorable foreign exchange attributed to a weakening U.S. dollar.

Advertising and product promotion spending decreased primarily from lower spending on the promotion of PLAVIX\* and AVAPRO\*/AVALIDE\* to coincide with their product life cycle partially offset by higher spending to support new product launches.

Research and development spending increased primarily due to higher upfront, milestone and other licensing payments compared to the prior year periods, higher clinical grant costs and unfavorable foreign exchange. The upfront charges for 2011 include an \$88 million payment associated with an amendment of an intellectual property license agreement for YERVOY prior to its FDA approval in the first quarter of 2011 and payments to Innate for \$35 million and Ambrx for \$24 million for exclusive licenses to develop and commercialize certain programs and compounds in the third quarter of 2011.

Provision for restructuring resulted primarily from employee termination benefits for certain workforce reductions.

Equity in net income of affiliates continues to be negatively impacted by lower international PLAVIX\* net sales from generic competition and an alternate salt form of clopidogrel. In the third quarter of 2011, this impact was more than offset by favorable foreign exchange.

Other (income)/expense includes:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Interest expense	\$ 40	\$ 38	\$ 103	\$ 103
Interest income	(23)	(23)	(69)	(54)
Impairment and loss on sale of manufacturing operations		10		225
Gain on debt repurchases			(10)	
Foreign exchange transaction losses/(gains)	4	9	15	(23)
Gain on sale of product lines, businesses and assets	(25)	(21)	(36)	(36)
Acquisition related items	1		1	
Other income received from alliance partners	(45)	(28)	(107)	(122)
Pension curtailment and settlement charges	2	2	(1)	16
Litigation charges/(recoveries)	1		(105)	
Product liability charges	10	13	36	13
Other	9	(10)	(22)	(38)
Other (income)/expense	\$ (26)	\$ (10)	\$ (195)	\$ 84

Impairment and loss on sale of manufacturing operations in 2010 is attributed to the write-down of a facility held for sale in Latina, Italy. See Item 1. Financial Statements Note 4. Restructuring.

Other income received from alliance partners includes income earned from the Sanofi partnership and amortization of certain upfront, milestone and other licensing payments related to our alliances. The decrease is attributed to reduced international demand for PLAVIX\* which is manufactured by us and sold to Sanofi for international distribution.

Product liability charges were for additional reserves in connection with the breast implant settlement program and hormone replacement therapy products.



**Table of Contents****Specified Items**

During the three and nine months ended September 30, 2011 and 2010, the following specified items affected the comparability of results of the periods presented herein. Specified items are excluded from segment income.

**Three Months Ended September 30, 2011 and 2010**

	Cost of products sold		Marketing selling and administrative		Research and development		Provision for restructuring		Litigation expense		Other (income)/ expense		Total	
Dollars in Millions	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010
<b>Restructuring and Other Activity:</b>														
Downsizing and streamlining of worldwide operations	\$	\$	\$	\$	\$	\$	\$ 8	\$ 15	\$	\$	\$	\$	\$ 8	\$ 15
Impairment and loss on sale of manufacturing operations												10		10
Accelerated depreciation, asset impairment														
and other shutdown costs	19	27											19	27
Pension curtailment and settlement charges											3		3	
Process standardization implementation costs			5	8									5	8
Gain on sale of product lines, businesses														
and assets											(12)		(12)	
Total Restructuring	19	27	5	8			8	15			(12)	13	20	63
<b>Other Specified Items:</b>														
Litigation charges/(recoveries)										22				22
Upfront, milestone and other licensing														
payments					69								69	
In-process research and development (IPRD)														
impairment					13								13	
Product liability charges											10	13	10	13
Total	\$ 19	\$ 27	\$ 5	\$ 8	\$ 82	\$	\$ 8	\$ 15	\$	\$ 22	\$ (2)	\$ 26	112	98
Income taxes on items above													(37)	(30)
Decrease to Net Earnings													\$ 75	\$ 68

**Nine Months Ended September 30, 2011 and 2010**

	Cost of products sold		Marketing selling and administrative		Research and development		Provision for restructuring		Litigation expense		Other (income)/ expense		Total	
Dollars in Millions	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010
<b>Restructuring and Other Activity:</b>														
Downsizing and streamlining of worldwide operations	\$	\$	\$	\$	\$	\$	\$ 85	\$ 50	\$	\$	\$	\$	\$ 85	\$ 50
Impairment and loss on sale of manufacturing operations											225		225	

# Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

operations															
Accelerated depreciation, asset impairment															
and other shutdown costs	60	85	4			7						71	85		
Pension curtailment and settlement charges											8		8		
Process standardization implementation costs			15	27								15	27		
Gain on sale of product lines, businesses															
and assets											(12)		(12)		
Total Restructuring	60	85	19	27		92	50				(12)	233	159	395	
<b>Other Specified Items:</b>															
Litigation charges/(recoveries)											22	(102)	(102)	22	
Upfront, milestone and other licensing															
payments						207	72						207	72	
In-process research and development (IPRD)															
impairment						28							28		
Product liability charges											36	13	36	13	
Total	\$ 60	\$ 85	\$ 19	\$ 27	\$ 235	\$ 72	\$ 92	\$ 50	\$	\$ 22	\$ (78)	\$ 246	328	502	
Income taxes on items above													(99)	(134)	
Out-of-period tax adjustment														(59)	
Specified tax benefit*													(71)		
Decrease to Net Earnings													\$ 158	\$ 309	

\* Relates to releases of tax reserves that were specified in prior periods.

**Table of Contents****Non-GAAP Financial Measures**

Our non-GAAP financial measures, including non-GAAP earnings and related EPS information, are adjusted to exclude certain costs, expenses, gains and losses and other specified items that due to their substantive and unusual nature are evaluated on an individual basis. Non-GAAP information is intended to portray the results of our baseline performance which include the discovery, development, licensing, manufacturing, marketing, distribution and sale of pharmaceutical products on a global basis and to enhance an investor's overall understanding of our past financial performance and prospects for the future. For example, non-GAAP earnings and EPS information is an indication of our baseline performance before items that are considered by us to not be reflective of our ongoing results. In addition, this information is among the primary indicators we use as a basis for evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods. This information is not intended to be considered in isolation or as a substitute for net earnings or diluted EPS prepared in accordance with GAAP.

Among the items in GAAP measures but excluded for purposes of determining adjusted earnings and other adjusted measures are: restructuring and other exit costs; accelerated depreciation charges; asset and IPRD impairments; charges and recoveries relating to significant legal proceedings; upfront, milestone and other licensing payments for in-licensing of products that have not achieved regulatory approval, which are immediately expensed; and significant tax events. For a detailed listing of items that are excluded from non-GAAP earnings, see Specified Items above. Similar charges or gains for some of these items have been recognized in prior periods and it is reasonably possible that they could reoccur in future periods.

A reconciliation of GAAP to non-GAAP follows:

Dollars in Millions, except per share data	GAAP	2011 Specified Items	Non-GAAP	GAAP	2010 Specified Items	Non-GAAP
<b>Three Months Ended September 30,</b>						
Net Earnings Attributable to BMS	\$ 969	\$ 75	\$ 1,044	\$ 949	\$ 68	\$ 1,017
Earnings attributed to unvested restricted shares	(2)		(2)	(4)		(4)
Net Earnings Attributable to BMS used for Diluted EPS Calculation	\$ 967	\$ 75	\$ 1,042	\$ 945	\$ 68	\$ 1,013
Average Common Shares Outstanding-Diluted	1,715		1,715	1,726		1,726
Diluted EPS Attributable to BMS	\$ 0.56	\$ 0.05	\$ 0.61	\$ 0.55	\$ 0.04	\$ 0.59
<b>Nine Months Ended September 30,</b>						
Net Earnings Attributable to BMS	\$ 2,857	\$ 158	\$ 3,015	\$ 2,619	\$ 309	\$ 2,928
Earnings attributed to unvested restricted shares	(6)		(6)	(11)		(11)
Net Earnings Attributable to BMS used for Diluted EPS Calculation	\$ 2,851	\$ 158	\$ 3,009	\$ 2,608	\$ 309	\$ 2,917
Average Common Shares Outstanding-Diluted	1,717		1,717	1,726		1,726
Diluted EPS Attributable to BMS	\$ 1.66	\$ 0.09	\$ 1.75	\$ 1.51	\$ 0.18	\$ 1.69
<b>Income Taxes</b>						

The effective income tax rate on earnings before income taxes was 26.0% for the three months ended September 30, 2011 compared to 19.3% for the three months ended September 30, 2010 and 25.2% for the nine months ended September 30, 2011 compared to 21.2% for the nine months ended September 30, 2010. See Item 1. Financial Statements Note 7. Income Taxes for a discussion of factors impacting the effective tax rate.

**Noncontrolling Interest**



## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Noncontrolling interest is primarily related to our partnerships with Sanofi for the territory covering the Americas related to PLAVIX\* and AVAPRO\*/AVALIDE\* net sales. See Item 1. Financial Statements Note 2. Alliances and Collaborations for further discussion. The increase in noncontrolling interest corresponds to increased net sales of PLAVIX\* in the U.S. A summary of noncontrolling interest is as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Sanofi partnerships	\$ 590	\$ 523	\$ 1,764	\$ 1,543
Other	5	3	17	18
Noncontrolling interest-pre-tax	595	526	1,781	1,561
Income taxes	209	173	609	509
Net earnings attributable to noncontrolling interest-net of taxes	\$ 386	\$ 353	\$ 1,172	\$ 1,052

**Table of Contents****FINANCIAL POSITION, LIQUIDITY, AND CAPITAL RESOURCES**

Our net cash position was as follows:

Dollars in Millions	September 30, 2011	December 31, 2010
Cash and cash equivalents	\$ 4,471	\$ 5,033
Marketable securities current	3,722	2,268
Marketable securities non-current	2,819	2,681
Total cash, cash equivalents and marketable securities	11,012	9,982
Short-term borrowings, including current portion of long-term debt	(182)	(117)
Long-term debt	(5,437)	(5,328)
Net cash position	\$ 5,393	\$ 4,537

We maintain a significant level of working capital, which was approximately \$7.6 billion and \$6.5 billion at September 30, 2011 and December 31, 2010, respectively. In 2011 and future periods, we expect cash generated by our operations, together with existing cash, cash equivalents, marketable securities and borrowings from the capital markets, to be sufficient to cover cash needs for working capital, capital expenditures, strategic alliances and acquisitions, milestone payments, dividends and common stock repurchases. We do not rely on short-term borrowings to meet our liquidity needs.

Cash, cash equivalents and marketable securities held outside the U.S. were approximately \$3.1 billion at September 30, 2011 and \$1.4 billion at December 31, 2010 which is either utilized to fund non-U.S. operations or repatriated back to the U.S. where taxes have been previously provided. Cash repatriations are subject to restrictions in certain jurisdictions and may be subject to withholding and other taxes.

Our investment portfolio includes non-current marketable securities which are subject to changes in fair value as a result of interest rate fluctuations and other market factors, which may impact our results of operations. Our investment policy places limits on these investments and the amount and time to maturity of investments with any institution. The policy also requires that investments are only entered into with corporate and financial institutions that meet high credit quality standards. See Item 1. Financial Statements Note 8. Financial Instruments.

As discussed in Strategy above, the loss of exclusivity for our largest product, PLAVIX\*, in May 2012 is expected to result in a rapid and material decline in operating cash flow. Additional regulations in the U.S. could be passed in the future which could further reduce our results of operations, operating cash flow, liquidity and financial flexibility. We also continue to monitor the potential impact of the economic conditions in certain European countries and the related impact on prescription trends, pricing discounts, creditworthiness of our customers, and our ability to collect outstanding receivables from our direct customers. Currently, we believe these economic conditions in the EU will not have a material impact on our liquidity, cash flow or financial flexibility.

In September 2011, the Company replaced its \$2.0 billion revolving credit facility with a new \$1.5 billion five year revolving credit facility from a syndicate of lenders, which contains customary terms and conditions and is extendable on any anniversary date with the consent of the lenders. There are no financial covenants under the new facility. There were no borrowings outstanding under either revolving credit facility at September 30, 2011 or December 31, 2010.

As an additional source of liquidity, we sell trade accounts receivables, principally from a few international government-backed entities to third parties. The receivables are sold on a nonrecourse basis and approximated \$806 million and \$674 million during the nine months ended September 30, 2011 and 2010, respectively. Our agreements do not allow for recourse in the event of uncollectibility and we do not retain interest in the underlying asset once sold.

We continue to maximize our operating cash flows with our initiatives designed to improve working capital items that are most directly affected by changes in sales volume, such as receivables, inventories, and accounts payable. The following summarizes these components expressed as a percentage of trailing twelve months net sales:

Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

Dollars in Millions	September 30, 2011	% of Trailing Twelve Month Net Sales	December 31, 2010	% of Trailing Twelve Month Net Sales
Net trade receivables	\$ 2,181	10.5%	\$ 1,985	10.2%
Inventories	1,357	6.5%	1,204	6.2%
Accounts payable	(2,292)	(11.0)%	(1,983)	(10.2)%
Total working capital	\$ 1,246	6.0%	\$ 1,206	6.2%

**Table of Contents***Credit Ratings*

Moody's Investors Service (Moody's) long-term and short-term credit ratings are currently A2 and Prime-1, respectively, and their long-term credit outlook remains on stable outlook. Standard & Poor's (S&P) long-term and short-term credit ratings are currently A+ and A-1, respectively, and their long-term credit rating remains on stable outlook. Fitch Ratings (Fitch) long-term and short-term credit ratings are currently A+ and F1, respectively, and their long-term credit rating remains on a negative outlook. Our credit ratings are considered investment grade. These long-term ratings designate that we have a low default risk but are somewhat susceptible to adverse effects of changes in circumstances and economic conditions. These short-term ratings designate that we have the strongest capacity for timely repayment.

*Cash Flows*

The following is a discussion of cash flow activities:

Dollars in Millions	Nine Months Ended September 30,	
	2011	2010
Cash flow provided by/(used in):		
Operating activities	\$ 3,272	\$ 2,896
Investing activities	(1,932)	(1,333)
Financing activities	(1,903)	(1,679)
<u>Operating Activities</u>		

Cash flow from operating activities represents the cash receipts and cash disbursements from all of our activities other than investing activities and financing activities. Operating cash flow is derived by adjusting net earnings for noncontrolling interest, non-cash operating items, gains and losses attributed to investing and financing activities and changes in operating assets and liabilities resulting from timing differences between the receipts and payments of cash and when the transactions are recognized in our results of operations. As a result, changes in cash from operating activities reflect the timing of cash collections from customers and alliance partners; payments to suppliers, alliance partners and employees; pension contributions and tax payments in the ordinary course of business. For example, most pension contributions and employee bonuses are paid in the first quarter of the year.

Investing Activities

Cash flows used in investing activities during the nine months ended September 30, 2011 and 2010 were primarily attributed to the net purchases of marketable securities of \$1,536 million during 2011 and \$1,091 million during 2010. We have continued to increase investments in time deposits and highly rated corporate debt securities with maturities greater than 90 days in order to manage our return on investment. Other significant 2011 activities included a \$310 million net payment to acquire Amira and a litigation recovery of \$102 million that was included in other investing activities.

Financing Activities

Cash flows used in financing activities during the nine months ended September 30, 2011 and 2010 were primarily attributed to dividend payments of \$1,694 million during 2011 and \$1,653 million during 2010. Dividends declared per common share totaled \$0.99 for the nine months ended September 30, 2011 and \$0.96 for the nine months ended September 30, 2010. Dividend decisions are made on a quarterly basis by our Board of Directors. In addition, a stock repurchase program was authorized in May 2010, resulting in the repurchase of common stock of \$859 million during 2011 and \$353 million during 2010. Net proceeds from the issuances of common stock as a result of stock option exercises were \$365 million during 2011 and \$211 million during 2010 and will vary from period to period based upon fluctuations in the market value of our stock relative to the exercise price of the stock options and other factors. Net proceeds from the termination of interest rate swaps were \$296 million during 2011 and \$98 million in 2010.

## **Table of Contents**

### **CRITICAL ACCOUNTING POLICIES**

For a discussion of our critical accounting policies, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2010 Annual Report on Form 10-K.

### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This quarterly report on Form 10-Q (including documents incorporated by reference) and other written and oral statements we make from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify these forward-looking statements by the fact they use words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. One can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our goals, plans and projections regarding our financial position, results of operations, cash flows, market position, product development, product approvals, sales efforts, expenses, performance or results of current and anticipated products and the outcome of contingencies such as legal proceedings and financial results, which are based on current expectations that involve inherent risks and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years. We have included important factors in the cautionary statements included in our 2010 Annual Report on Form 10-K and our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2011, particularly under Item 1A. Risk Factors, that we believe could cause actual results to differ materially from any forward-looking statement.

Although we believe we have been prudent in our plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved and readers are cautioned not to place undue reliance on such statements, which speak only as of the date made. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

**Table of Contents****Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

For a discussion of our market risk, see Item 7A. Quantitative and Qualitative Disclosures About Market Risk in our 2010 Annual Report on Form 10-K.

**Item 4. CONTROLS AND PROCEDURES**

Management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-Q, the Chief Executive Officer and Chief Financial Officer have concluded that such disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective.

**PART II OTHER INFORMATION****Item 1. LEGAL PROCEEDINGS**

Information pertaining to legal proceedings can be found in Item 1. Financial Statements Note 16. Legal Proceedings and Contingencies, to the interim consolidated financial statements, and is incorporated by reference herein.

**Item 2. ISSUER PURCHASES OF EQUITY SECURITIES**

The following table summarizes the surrenders of our equity securities during the nine months ended September 30, 2011:

Period	Total Number of Shares Purchased <sup>(a)</sup>	Average Price Paid per Share <sup>(a)</sup>	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(b)</sup>	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(b)</sup>
Dollars in Millions, Except Per Share Data				
January 1 to 31, 2011	2,911,859	\$ 25.93	2,897,837	\$ 2,338
February 1 to 28, 2011	2,473,453	\$ 25.53	2,458,416	\$ 2,275
March 1 to 31, 2011	2,064,597	\$ 24.92		\$ 2,275
Three months ended March 31, 2011	7,449,909		5,356,253	
April 1 to 30, 2011	6,971	\$ 26.30		\$ 2,275
May 1 to 31, 2011	4,383,833	\$ 28.54	4,375,600	\$ 2,150
June 1 to 30, 2011	4,401,073	\$ 28.04	4,396,800	\$ 2,027
Three months ended June 30, 2011	8,791,877		8,772,400	
July 1 to 31, 2011	4,195,186	\$ 29.06	4,191,050	\$ 1,905
August 1 to 31, 2011	9,332,353	\$ 27.62	9,324,241	\$ 1,647
September 1 to 30, 2011	3,062,826	\$ 30.08	3,060,000	\$ 1,555
Three months ended September 30, 2011	16,590,365		16,575,291	
Nine months ended September 30, 2011	32,832,151		30,703,944	

(a)

## Edgar Filing: BRISTOL MYERS SQUIBB CO - Form 10-Q

The difference between total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to shares of common stock withheld by us from employee restricted stock awards in order to satisfy our applicable tax withholding obligations.

- (b) In May 2010, we announced that the Board of Directors authorized the purchase of up to \$3.0 billion of our common stock. The repurchase program does not have an expiration date and is expected to take place over a few years.

## **Table of Contents**

### **Item 6. EXHIBITS**

Exhibits (listed by number corresponding to the Exhibit Table of Item 601 in Regulation S-K).

<b>Exhibit No.</b>	<b>Description</b>
10.	\$1,500,000,000 Five Year Competitive Advance and Revolving Credit Facility Agreement dated as of September 29, 2011 among Bristol-Myers Squibb Company, the borrowing subsidiaries, the lenders named in the agreement, BNP Paribas and The Royal Bank of Scotland plc, as documentation agents, Bank of America, N.A., as syndication agent, and JPMorgan Chase Bank, N.A., and Citibank, N.A. as administrative agents (incorporated herein by reference to Exhibit 10.1 to the Form 8-K dated September 29, 2011 and filed on October 4, 2011).
12.	Computation of Earnings to Fixed Charges.
31a.	Section 302 Certification Letter.
31b.	Section 302 Certification Letter.
32a.	Section 906 Certification Letter.
32b.	Section 906 Certification Letter.
101.	The following financial statements from the Bristol-Myers Squibb Company Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) consolidated statements of earnings, (ii) consolidated statements of comprehensive income and retained earnings, (iii) consolidated balance sheets, (iv) consolidated statements of cash flows, and (v) the notes to the consolidated financial statements.

\* Indicates, in this Form 10-Q, brand names of products, which are registered trademarks not owned by the Company or its subsidiaries. ELIQUIS is a trademark of Pfizer, Inc.; ERBITUX is a trademark of Eli Lilly and Company; AVAPRO/AVALIDE (known in the EU as APROVEL/KARVEA) and PLAVIX are trademarks of Sanofi; ABILIFY is a trademark of Otsuka Pharmaceutical Co., Ltd.; TRUVADA is a trademark of Gilead Sciences, Inc.; GLEEVEC is a trademark of Novartis AG; ATRIPLA is a trademark of Bristol-Myers Squibb and Gilead Sciences, LLC; ESTRACE and OVCON are trademarks of Warner-Chilcott Company, LLC; and DELESTROGEN is a trademark of JHP Pharmaceuticals, Inc.



**Table of Contents**

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.

BRISTOL-MYERS SQUIBB COMPANY

(REGISTRANT)

Date: October 27, 2011

By: /s/ Lamberto Andreotti  
Lamberto Andreotti

*Chief Executive Officer*

Date: October 27, 2011

By: /s/ Charles Bancroft  
Charles Bancroft

*Chief Financial Officer*