

BRISTOL MYERS SQUIBB CO

Form 10-Q

October 24, 2012

[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, 2012**
- .. **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)

(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, 2012, there were 1,650,688,859 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, 2012**

**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>	46
---	----

**Item 4.**

<u>Controls and Procedures</u>	46
--------------------------------	----

**PART II OTHER INFORMATION**

**Item 1.**

<u>Legal Proceedings</u>	46
--------------------------	----

**Item 1A.**

<u>Risk Factors</u>	46
---------------------	----

**Item 2.**

<u>Issuer Purchases of Equity Securities</u>	46
--	----

**Item 6.**

<u>Exhibits</u>	47
-----------------	----

<u>Signatures</u>	48
-------------------	----

**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>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net Sales	\$ 3,736	\$ 5,345	\$ 13,430	\$ 15,790
Cost of products sold	987	1,407	3,535	4,231
Marketing, selling and administrative	1,071	1,019	3,077	2,987
Advertising and product promotion	167	205	585	672
Research and development	951	973	2,822	2,831
Impairment charge for BMS-986094 intangible asset	1,830		1,830	
Provision for restructuring	29	8	71	92
Litigation expense/(recoveries)	50		(122)	
Equity in net income of affiliates	(40)	(71)	(150)	(215)
Other (income)/expense	(50)	(26)	(45)	(195)
<b>Total Expenses</b>	<b>4,995</b>	<b>3,515</b>	<b>11,603</b>	<b>10,403</b>
Earnings/(Loss) Before Income Taxes	(1,259)	1,830	1,827	5,387
Provision for/(benefit from) income taxes	(546)	475	250	1,358
Net Earnings/(Loss)	(713)	1,355	1,577	4,029
Net Earnings/(Loss) Attributable to Noncontrolling Interest	(2)	386	542	1,172
Net Earnings/(Loss) Attributable to BMS	\$ (711)	\$ 969	\$ 1,035	\$ 2,857
<b>Earnings/(Loss) per Common Share Attributable to BMS</b>				
Basic	\$ (0.43)	\$ 0.57	\$ 0.62	\$ 1.67
Diluted	\$ (0.43)	\$ 0.56	\$ 0.61	\$ 1.66
Dividends declared per common share	\$ 0.34	\$ 0.33	\$ 1.02	\$ 0.99

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>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
<b>COMPREHENSIVE INCOME</b>				
Net Earnings/(Loss)	\$ (713)	\$ 1,355	\$ 1,577	\$ 4,029
Other Comprehensive Income/(Loss):				
Foreign currency translation	21	(40)	(1)	(12)
Foreign currency translation on net investment hedges	(21)	44	8	(13)
Derivatives qualifying as cash flow hedges, net of taxes of \$9 and \$(23) for the three months ended September 30, 2012 and 2011, respectively; and \$(8) and \$3 for the nine months ended September 30, 2012 and 2011, respectively	(26)	60	1	3
Derivatives qualifying as cash flow hedges reclassified to net earnings, net of taxes of \$9 and \$(9) for the three months ended September 30, 2012 and 2011, respectively; and \$15 and \$(16) for the nine months ended September 30, 2012 and 2011, respectively	(13)	18	(28)	31
Pension and postretirement benefits, net of taxes \$(5) for the nine months ended September 30, 2012			14	
Pension and postretirement benefits reclassified to net earnings, net of taxes of \$(12) and \$(11) for the three months ended September 30, 2012 and 2011, respectively; and \$(35) and \$(30) for the nine months ended September 30, 2012 and 2011, respectively	24	19	70	56
Available for sale securities, net of taxes of \$9 and \$(3) for the three months ended September 30, 2012 and 2011, respectively; and \$8 and \$(6) for the nine months ended September 30, 2012 and 2011, respectively	38	6	45	24
Available for sale securities reclassified to net earnings, net of taxes of \$2 for the nine months ended September 30, 2012			(8)	
<b>Total Other Comprehensive Income/(Loss)</b>	<b>23</b>	<b>107</b>	<b>101</b>	<b>89</b>
 Comprehensive Income/(Loss)	 (690)	 1,462	 1,678	 4,118
<b>Comprehensive Income/(Loss) Attributable to Noncontrolling Interest</b>	<b>(2)</b>	<b>386</b>	<b>542</b>	<b>1,172</b>
 Comprehensive Income/(Loss) Attributable to Bristol-Myers Squibb Company	 \$ (688)	 \$ 1,076	 \$ 1,136	 \$ 2,946

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, 2012</b>	<b>December 31, 2011</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 1,503	\$ 5,776
Marketable securities	1,427	2,957
Receivables	2,889	3,743
Inventories	1,697	1,384
Deferred income taxes	1,339	1,200
Prepaid expenses and other	423	258
Total Current Assets	9,278	15,318
Property, plant and equipment	5,297	4,521
Goodwill	7,498	5,586
Other intangible assets	9,217	3,124
Deferred income taxes	179	688
Marketable securities	3,698	2,909
Other assets	877	824
Total Assets	\$ 36,044	\$ 32,970

**LIABILITIES**

Current Liabilities:		
Short-term borrowings and current portion of long-term debt	\$ 751	\$ 115
Accounts payable	2,085	2,603
Accrued expenses	2,759	2,791
Deferred income	689	337
Accrued rebates and returns	1,122	1,170
U.S. and foreign income taxes payable	193	167
Dividends payable	596	597
Total Current Liabilities	8,195	7,780
Pension, postretirement and postemployment liabilities	1,473	2,017
Deferred income	4,006	866
U.S. and foreign income taxes payable	650	573
Deferred income taxes	748	107
Other liabilities	464	384
Long-term debt	6,608	5,376
Total Liabilities	22,144	17,103

Commitments and contingencies (Note 17)

# **EQUITY**

Bristol-Myers Squibb Company Shareholders' Equity:		
Preferred stock, \$2 convertible series, par value \$1 per share: Authorized 10 million shares; issued and outstanding 5,189 in 2012 and 5,268 in 2011, 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 2012 and 2011	221	220
Capital in excess of par value of stock	2,717	3,114
Accumulated other comprehensive loss	(2,944)	(3,045)
Retained earnings	32,381	33,069
Less cost of treasury stock 558 million shares in 2012 and 515 million in 2011	(18,475)	(17,402)
Total Bristol-Myers Squibb Company Shareholders' Equity	13,900	15,956
Noncontrolling interest		(89)
Total Equity	13,900	15,867
Total Liabilities and Equity	\$ 36,044	\$ 32,970

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,	
	2012	2011
<b>Cash Flows From Operating Activities:</b>		
Net earnings	\$ 1,577	\$ 4,029
Adjustments to reconcile net earnings to net cash provided by operating activities:		
Net earnings attributable to noncontrolling interest	(542)	(1,172)
Depreciation and amortization	482	482
Impairment charges	2,118	28
Deferred income taxes	(737)	273
Stock-based compensation	108	120
Other	21	(138)
Changes in operating assets and liabilities:		
Receivables	643	(152)
Inventories	(135)	(150)
Accounts payable	(321)	309
Deferred income from diabetes collaboration	3,570	
Other deferred income	100	(7)
U.S. and foreign income taxes payable	82	(20)
Other	(861)	(330)
<b>Net Cash Provided by Operating Activities</b>	<b>6,105</b>	<b>3,272</b>
<b>Cash Flows From Investing Activities:</b>		
Sale and maturities of marketable securities	4,384	3,808
Purchases of marketable securities	(3,501)	(5,344)
Additions to property, plant and equipment and capitalized software	(373)	(233)
Sale of businesses and other investing activities	16	147
Purchase of businesses, net of cash acquired	(7,530)	(310)
<b>Net Cash Used in Investing Activities</b>	<b>(7,004)</b>	<b>(1,932)</b>
<b>Cash Flows From Financing Activities:</b>		
Short-term borrowings/(repayments)	20	67
Proceeds from issuance of long-term debt	1,950	
Long-term debt repayments	(2,108)	(78)
Interest rate swap terminations	2	296
Stock option exercises	397	365
Common stock repurchases	(1,911)	(859)
Dividends paid	(1,725)	(1,694)
<b>Net Cash Used in Financing Activities</b>	<b>(3,375)</b>	<b>(1,903)</b>
Effect of Exchange Rates on Cash and Cash Equivalents	1	1
Decrease in Cash and Cash Equivalents	(4,273)	(562)
Cash and Cash Equivalents at Beginning of Period	5,776	5,033



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

<b>Cash and Cash Equivalents at End of Period</b>	\$	1,503	\$	4,471
---	----	-------	----	-------

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

**Table of Contents****Note 1. BASIS OF PRESENTATION**

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 (SEC) 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, 2012 and December 31, 2011, the results of operations for the three and nine months ended September 30, 2012 and 2011 and cash flows for the nine months ended September 30, 2012 and 2011. 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, 2011 included in the Annual Report on Form 10-K.

Certain prior period amounts have been reclassified to conform to the current period presentation. The presentation of depreciation and amortization in the consolidated statements of cash flows includes the depreciation of property, plant and equipment and the amortization of intangible assets and deferred income.

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 and potential impairment of intangible assets; sales rebate and return accruals used in revenue recognition; legal contingencies; income taxes; and pension and postretirement benefits. Actual results may differ from estimated results.

**Note 2. BUSINESS SEGMENT INFORMATION**

BMS operates in a single segment 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. Segment information is consistent with the financial information regularly reviewed by the chief operating decision maker, the chief executive officer, 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,	
	2012	2011	2012	2011
<i>Plavix* (clopidogrel bisulfate)</i>	\$ 64	\$ 1,788	\$ 2,498	\$ 5,415
<i>Avapro*/Avalide* (irbesartan/irbesartan-hydrochlorothiazide)</i>	95	216	419	757
<i>Eliquis (apixaban)</i>			1	
<i>Abilify* (aripiprazole)</i>	676	691	2,008	2,021
<i>Reyataz (atazanavir sulfate)</i>	363	391	1,127	1,153
<i>Sustiva (efavirenz) Franchise</i>	370	359	1,144	1,073
<i>Baraclude (entecavir)</i>	346	311	1,028	878
<i>Erbitux* (cetuximab)</i>	173	172	531	510
<i>Sprycel (dasatinib)</i>	263	211	738	576
<i>Yervoy (ipilimumab)</i>	179	121	495	216
<i>Orencia (abatacept)</i>	307	233	851	660
<i>Nulojix (belatacept)</i>	3		7	2
<i>Onglyza/Kombiglyze (saxagliptin/saxagliptin and metformin)</i>	178	127	511	320

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

<i>Byetta* (exenatide)</i>	55		55	
<i>Bydureon* (exenatide extended-release for injectable suspension)</i>	20		20	
Mature Products and All Other	644	725	1,997	2,209
Net Sales	\$ 3,736	\$ 5,345	\$ 13,430	\$ 15,790

**Table of Contents****Note 3. ALLIANCES AND COLLABORATIONS**

BMS maintains alliances and collaborations with various third parties for the development and commercialization of certain products. Unless otherwise noted, operating results associated with the alliances and collaborations are generally treated as follows: product revenues from BMS sales are included in revenue; royalties, collaboration fees, profit sharing and distribution fees are included in cost of goods sold; post-approval milestone payments to partners are deferred and amortized over the useful life of the related products in cost of products sold; cost sharing reimbursements offset the intended operating expense; payments to BMS attributed to upfront, pre-approval milestone and other licensing payments are deferred and amortized over the estimated useful life of the related products in other income/expense; income and expenses attributed to a collaboration's non-core activities, such as supply and manufacturing arrangements and compensation for opting-out of commercialization in certain countries, are included in other income/expense; partnerships and joint ventures are either consolidated or accounted for under the equity method of accounting and related cash receipts and distributions are treated as operating cash flow.

See the 2011 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**

BMS has agreements with Sanofi for the codevelopment and cocommercialization of *Avapro*\*/*Avalide*\* and *Plavix*\*. 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. Accordingly, two territory partnerships were formed to manage central expenses, such as marketing, research and development and royalties, and to supply finished product to the individual countries. In general, at the country level, agreements either to copromote (whereby a partnership was formed between the parties to sell each brand) or to comarket (whereby the parties operate and sell their brands independently of each other) are in place.

BMS 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 included in net earnings/(loss) attributable to noncontrolling interest. BMS recognizes net sales in this territory and in comarketing countries outside this territory (e.g. Germany, Italy for irbesartan only, Spain and Greece). Sanofi acts as the operating partner and owns a 50.1% majority controlling interest in the territory covering Europe and Asia and BMS has a 49.9% ownership interest in this territory which is included in equity in net income of affiliates.

BMS and Sanofi have a separate partnership governing the copromotion of irbesartan in the U.S. Sanofi paid BMS \$350 million for their acquisition of an interest in the irbesartan license for the U.S. upon formation of the alliance.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Three Months Ended September 30, 2012		Nine Months Ended September 30, 2011	
	2012	2011	2012	2011
<b>Territory covering the Americas and Australia:</b>				
Net sales	\$ 95	\$ 1,936	\$ 2,690	\$ 5,959
Royalty expense	19	430	527	1,229
Noncontrolling interest pre-tax	(7)	590	847	1,764
Distributions to/(from) Sanofi	(290)	523	768	1,824
<b>Territory covering Europe and Asia:</b>				
Equity in net income of affiliates	45	75	163	226
Profit distributions to BMS	54	97	183	224
<b>Other:</b>				
Net sales in Europe comarketing countries and other	64	68	227	213
Amortization (income)/expense irbesartan license fee	(8)	(7)	(24)	(23)
Supply activities and development and opt-out royalty (income)/expense	(53)	6	(98)	21
<b>Investment in affiliates territory covering Europe and Asia</b>				
			<b>September 30, 2012</b>	<b>December 31, 2011</b>
			\$ 17	\$ 37

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

Deferred income    irbesartan license fee

5

29

8

## Table of Contents

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, 2012		Nine Months Ended September 30, 2011	
	2012	2011	2012	2011
Net sales	\$ 248	\$ 364	\$ 886	\$ 1,125
Gross profit	132	161	402	501
Net income	116	131	358	413

In September 2012, BMS and Sanofi restructured the terms of the codevelopment and cocommercialization agreements discussed above. Effective as of January 1, 2013, subject in certain countries to the receipt of regulatory approvals, Sanofi will assume the worldwide operations of the alliance with the exception of *Plavix*\* for the U.S. and Puerto Rico. The alliance for *Plavix*\* in these two markets will continue unchanged through December 2019 under the same terms as in the original alliance arrangements. In exchange for the rights being assumed by Sanofi, BMS will receive quarterly royalties from January 1, 2013 until December 31, 2018 and a terminal payment from Sanofi of \$200 million at the end of 2018. All ongoing disputes between the companies have been resolved, including a one-time payment of \$80 million by BMS to Sanofi related to the *Avalide*\* supply disruption in the U.S. in 2011 (accrued for in 2011).

## Otsuka

BMS has a worldwide commercialization agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka), to codevelop and copromote *Abilify*\*, for the treatment of schizophrenia, bipolar mania disorder and major depressive disorder, excluding certain Asia Pacific countries. The U.S. portion of the amended commercialization and manufacturing agreement expires upon the expected loss of product exclusivity in April 2015. Beginning on January 1, 2012, the contractual share of revenue recognized by BMS in the U.S. was reduced from 53.5% in 2011 to 51.5% and will be further reduced in 2013.

In the UK, Germany, France and Spain, BMS receives 65% of third-party net sales. In these countries and the U.S., third-party customers are invoiced by BMS on behalf of Otsuka and alliance revenue is recognized when *Abilify*\* is shipped and all risks and rewards of ownership have been transferred to third-party customers. In certain countries where BMS is presently the exclusive distributor for the product or has an exclusive right to sell *Abilify*\*, BMS recognizes all of the net sales.

BMS purchases the product from Otsuka and performs finish manufacturing for sale to third-party customers by BMS or Otsuka. Under the terms of the amended agreement, BMS paid Otsuka \$400 million, which is amortized as a reduction of net sales through the expected loss of U.S. exclusivity in April 2015. The unamortized balance is included in other assets. Otsuka receives a royalty based on 1.5% of total U.S. net sales. Otsuka is responsible for 30% of the U.S. expenses related to the commercialization of *Abilify*\* from 2010 through 2012. BMS also reimburses Otsuka for its contractual share of the annual pharmaceutical company fee related to *Abilify*\*.

BMS and Otsuka also have an oncology collaboration for *Sprycel* and *Ixempra* (ixabepilone) (the Oncology Products) in the U.S., Japan and the EU. 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 (U.S., Japan and Europe), 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. Annually, 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. In addition, Otsuka has the right to co-promote *Sprycel* in the U.S., Japan, and the top five markets in the EU.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Three Months Ended September 30, 2012		Nine Months Ended September 30, 2011	
	2012	2011	2012	2011
Abilify* net sales, including amortization of extension payment	\$ 676	\$ 691	\$ 2,008	\$ 2,021
Oncology Products collaboration fee expense	36	30	103	100
Royalty expense	18	18	55	52
Commercialization expense reimbursement to/(from) Otsuka	(2)	(15)	(34)	(37)
Amortization (income)/expense extension payment	16	16	49	49

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

Amortization (income)/expense	upfront, milestone and other licensing payments	1	1	5	5
Dollars in Millions				September 30, 2012	December 31, 2011
Other assets	extension payment			\$ 170	\$ 219
Other intangible assets	upfront, milestone and other licensing payments				5

**Table of Contents****Lilly**

BMS has an Epidermal Growth Factor Receptor (EGFR) commercialization agreement with Lilly through Lilly's November 2008 acquisition of ImClone Systems Incorporated (ImClone) for the codevelopment and promotion of *Erbix*\* and necitumumab (IMC-11F8) in the U.S. which expires as to *Erbix*\* in September 2018. BMS also has codevelopment and copromotion rights to both products in Canada and Japan. *Erbix*\* is indicated for use in the treatment of patients with metastatic colorectal cancer and for use in the treatment of squamous cell carcinoma of the head and neck. Under the EGFR agreement, with respect to *Erbix*\* 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.

In Japan, BMS shares rights to *Erbix*\* under an agreement with Lilly and Merck KGaA and receives 50% of the pre-tax profit from Merck KGaA's net sales of *Erbix*\* in Japan which is further shared equally with Lilly.

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. BMS will fund 55% of development costs for studies that will be used only in the U.S., 50% for Japan studies and 27.5% for global studies.

BMS is amortizing \$500 million of license acquisition costs associated with the EGFR commercialization agreement through 2018.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Three Months Ended		Nine Months Ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Net sales	\$ 173	\$ 172	\$ 531	\$ 510
Distribution fees and royalty expense	71	72	220	212
Research and development expense reimbursement to Lilly necitumumab	5	4	13	10
Amortization (income)/expense upfront, milestone and other licensing payments	9	9	28	28
Commercialization expense reimbursements to/(from) Lilly	(4)	(9)	(14)	(12)
Japan commercialization profit sharing (income)/expense	(9)	(9)	(28)	(24)

Dollars in Millions	September 30, 2012	December 31, 2011
Other intangible assets upfront, milestone and other licensing payments	\$ 221	\$ 249

BMS acquired Amylin Pharmaceuticals, Inc. (Amylin) on August 8, 2012 (see Note 4. Acquisitions for further information). Amylin had previously entered into a settlement and termination agreement with Lilly regarding their collaboration for the global development and commercialization of *Byetta*\* and *Bydureon*\* (exenatide products) under which the parties agreed to transition full responsibility of these products to Amylin. Although the transition of the U.S. operations was completed, Lilly had not yet transitioned the non-U.S. operations to Amylin. In September 2012, BMS provided notification to Lilly that BMS will assume essentially all non-U.S. operations of the exenatide products during the first half of 2013 and therefore terminate Lilly's exclusive right to non-U.S. commercialization of the exenatide products, subject to certain regulatory and other conditions. BMS is responsible for any non-U.S. losses incurred by Lilly during 2012 and 2013 up to a maximum of \$60 million and is entitled to tiered royalties until the transition is complete.

**Gilead**

BMS 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 for the treatment of human immunodeficiency virus (HIV) infection, combining *Sustiva*, a product of BMS, and *Truvada*\* (emtricitabine and tenofovir disoproxil fumarate), a product of Gilead, in the U.S., Canada and Europe.

Net sales of the bulk efavirenz component of *Atripla*\* are deferred until the combined product is sold to third-party customers. Net sales for the efavirenz component are based on the relative ratio of the average respective net selling prices of *Truvada*\* and *Sustiva*.

Summarized financial information related to this alliance is as follows:



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

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net sales	\$ 305	\$ 289	\$ 950	\$ 858
Equity in net loss of affiliates	(6)	(3)	(14)	(11)

**Table of Contents****AstraZeneca**

BMS and AstraZeneca Pharmaceuticals LP, a wholly-owned subsidiary of AstraZeneca, entered into a collaboration regarding the worldwide development and commercialization of Amylin's portfolio of products. The arrangement is based on the framework of the existing diabetes alliance agreements discussed further below, including the equal sharing of profits and losses arising from the collaboration. AstraZeneca has indicated its intent to establish equal governance rights over certain key strategic and financial decisions regarding the collaboration pending required anti-trust approvals in certain international markets.

BMS received preliminary proceeds of \$3.8 billion from AstraZeneca as consideration for entering into the collaboration during the current period, including \$190 million which is included in accrued expenses and expected to be reimbursed back to AstraZeneca. The remaining \$3.6 billion was accounted for as deferred income and is amortized as a reduction to cost of products sold on a pro-rata basis over the estimated useful lives of the related long-lived assets assigned in the purchase price allocation (primarily intangible assets with a weighted-average estimated useful life of 12 years and property, plant and equipment with a weighted-average estimated useful life of 15 years). The net proceeds that BMS will receive from AstraZeneca as consideration for entering into the collaboration are subject to certain other adjustments including the right to receive an additional \$135 million when AstraZeneca exercises its option for equal governance rights.

BMS and AstraZeneca agreed to share in certain tax attributes related to the Amylin collaboration. The preliminary proceeds of \$3.8 billion that BMS received from AstraZeneca included \$207 million related to sharing of certain tax attributes.

In addition, BMS continues to maintain two worldwide codevelopment and cocommercialization agreements with AstraZeneca for *Onglyza*, *Kombiglyze XR* (saxagliptin and metformin hydrochloride extended-release), *Kombiglyze* (saxagliptin and metformin immediate-release marketed in the EU) and *Forxiga* (dapagliflozin). The agreements for saxagliptin exclude Japan which is not covered by the alliance. *Onglyza*, *Kombiglyze* and *Komboglyze* are indicated for use in the treatment of diabetes. In this document unless specifically noted, we refer to both *Kombiglyze* and *Komboglyze* as *Kombiglyze*. *Forxiga* is currently being studied for the treatment of diabetes. *Onglyza* and *Forxiga* were discovered by BMS. *Kombiglyze* was codeveloped with AstraZeneca. Both companies jointly develop the clinical and marketing strategy and share commercialization expenses and profits and losses equally on a global basis and also share in development costs, with the exception of *Forxiga* development costs in Japan, which are borne by AstraZeneca. BMS manufactures both products. BMS has opted to decline involvement in cocommercialization for both products in certain countries not in the BMS global commercialization network and instead receives compensation based on net sales recorded by AstraZeneca in these countries. Opt-out compensation recorded by BMS was not material in the three and nine months ended September 30, 2012.

BMS received \$300 million in upfront, milestone and other licensing payments related to saxagliptin as of September 30, 2012 and \$170 million in upfront, milestone and other licensing payments related to dapagliflozin as of September 30, 2012.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net sales	\$ 266	\$ 127	\$ 599	\$ 320
Profit sharing expense	118	58	268	148
Commercialization expense reimbursements to/(from) AstraZeneca	(43)	(11)	(62)	(30)
Research and development expense reimbursements to/(from) AstraZeneca	(17)	4	(7)	33
Amortization (income)/expense				
Upfront, milestone and other licensing payments recognized in:				
Cost of products sold	(50)		(50)	
Other (income)/expense	(9)	(10)	(30)	(28)
Upfront, milestone and other licensing payments received:				
Amylin-related products	3,570		3,570	
Dapagliflozin				120

Dollars in Millions	September 30, December 31,	
	2012	2011
Deferred income		
Upfront, milestone and other licensing payments:		

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

Amylin-related products	\$ 3,520	\$
Saxagliptin	213	230
Dapagliflozin	129	142

**Table of Contents****Pfizer**

BMS and Pfizer Inc. (Pfizer) maintain a worldwide codevelopment and cocommercialization agreement for *Eliquis*, an anticoagulant discovered by BMS for the prevention and treatment of atrial fibrillation and other arterial thrombotic conditions. Pfizer funds 60% of all development costs under the initial development plan effective January 1, 2007. The companies jointly develop the clinical and marketing strategy and share commercialization expenses and profits equally on a global basis. In certain countries not in the BMS global commercialization network, Pfizer will commercialize *Eliquis* alone and will pay compensation to BMS based on a percentage of net sales. BMS manufactures the product globally.

BMS has received \$559 million in upfront, milestone and other licensing payments for *Eliquis* as of September 30, 2012.

Summarized financial information related to this alliance is as follows:

Dollars in Millions	Three Months Ended September 30,		Three Months Ended September 30,	
	2012	2011	2012	2011
Net sales	\$	\$	\$	\$
Commercialization expense reimbursement to/(from) Pfizer	(6)	(2)	(14)	(5)
Research and development reimbursements to/(from) Pfizer	(1)	(16)	10	(74)
Amortization (income)/expense				
upfront, milestone and other licensing payments	(10)	(8)	(29)	(24)

Dollars in Millions	September 30,		December 31,	
	2012	2011	2012	2011
Deferred income	\$	\$	\$	\$
upfront, milestone and other licensing payments	405	434		

**Note 4. ACQUISITIONS***Amylin Pharmaceuticals, Inc. Acquisition*

On August 8, 2012, BMS completed its acquisition of the outstanding shares of Amylin, a biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines to treat diabetes and other metabolic diseases. Acquisition costs of \$29 million were included in other expenses.

BMS obtained full U.S. commercialization rights to Amylin's two primary commercialized assets, *Bydureon*\*, a once-weekly diabetes treatment and *Byetta*\*, a daily diabetes treatment, both of which are glucagon-like peptide-1 (GLP-1) receptor agonists approved in certain countries to improve glycemic control in adults with type 2 diabetes. BMS also obtained full commercialization rights to *Symlin*\* (pramlintide acetate), an amylinomimetic approved in the U.S. for adjunctive therapy to mealtime insulin to treat diabetes. Goodwill generated from this acquisition was primarily attributed to the expansion of our diabetes franchise.

The fair value of acquired intangible assets, including in-process research and development (IPRD), was estimated utilizing the income method which risk adjusted the expected future net cash flows estimated to be generated from the compounds based upon estimated probabilities of technical and regulatory success (PTRS). All acquired intangible assets were valued utilizing a global view that considered all potential jurisdictions and indications. Actual cash flows are likely to be different than those assumed.

IPRD was attributed to metreleptin, an analog of the human hormone leptine being studied and developed for the treatment of diabetes and/or hypertriglyceridemia in pediatric and adult patients with inherited or acquired lipodystrophy. The estimated useful life and the cash flows utilized to value metreleptin assumed initial positive cash flows to commence shortly after the expected receipt of regulatory approvals, subject to trial results.

The results of Amylin's operations are included in the consolidated financial statements from August 9, 2012.

**Table of Contents***Inhibitex, Inc. Acquisition*

On February 13, 2012, BMS completed its acquisition of the outstanding shares of Inhibitex, Inc. (Inhibitex), a clinical-stage biopharmaceutical company focused on developing products to prevent and treat serious infectious diseases. Acquisition costs of \$12 million were included in other expense. BMS obtained Inhibitex's lead asset, INX-189, an oral nucleotide polymerase (NS5B) inhibitor in Phase II development for the treatment of chronic hepatitis C infections. Goodwill generated from this acquisition was primarily attributed to the potential to offer a full portfolio of therapy choices for hepatitis infections as well as to provide additional levels of sustainability to BMS's virology pipeline.

The fair value of IPRD was estimated utilizing the income method which risk adjusted the expected future net cash flows estimated to be generated from the compounds based upon estimated PTRS and a global view that considered all potential jurisdictions and indications.

IPRD was primarily attributed to INX-189. INX-189 was expected to be most effective when used in combination therapy and it was assumed all market participants would inherently maintain franchise synergies attributed to maximizing the cash flows of their existing virology pipeline assets. The cash flows utilized to value INX-189 included such synergies and also assumed initial positive cash flows to commence shortly after the expected receipt of regulatory approvals, subject to trial results.

In August 2012, the Company discontinued development of INX-189 in the interest of patient safety. As a result, the Company recognized a non-cash, pre-tax impairment charge of \$1.8 billion related to the IPRD intangible asset in the third quarter of 2012. For further information discussion of the impairment charge, see Note 12. Goodwill and Other Intangible Assets.

The results of Inhibitex's operations are included in the consolidated financial statements from February 13, 2012.

Significant estimates utilized at the time of the valuations to support the fair values of the commercial assets and compounds within the acquisitions include:

Dollars in Millions	Fair value	Discount rate utilized	Estimated useful life (in years)	Phase of Development as of acquisition date	PTRS Rate utilized	Year of first projected positive cash flow
<b>Commercialized products:</b>						
<i>Bydureon</i> *	\$ 5,240	11.1%	13	N/A	N/A	N/A
<i>Byetta</i> *	750	10.0%	7	N/A	N/A	N/A
<i>Symlin</i> *	300	10.0%	9	N/A	N/A	N/A
<b>IPRD:</b>						
BMS-986094 (formerly INX-189)	1,830	12.0%	11	Phase II	38%	2017
Metreleptin	370	12.0%	12	Phase III	75%	2014

The components of the cash paid to acquire Amylin and Inhibitex were as follows:

Dollars in Millions	Amylin	Inhibitex
Total consideration transferred	\$ 5,218	\$ 2,539
Stock-based compensation expense	94	
Total cash paid	\$ 5,312	\$ 2,539

The preliminary purchase price allocation for Amylin (pending final valuation of intangible assets and deferred income taxes) and the final purchase price allocation for Inhibitex were as follows:

Dollars in Millions

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

<b>Identifiable net assets:</b>	<b>Amylin</b>	<b>Inhibitex</b>
Cash	\$ 179	\$ 46
Marketable securities	108	17
Inventory	178	
Property, plant and equipment	773	
Developed technology rights	6,290	
IPRD	370	1,875
Other assets	136	
Debt obligations	(2,020)	(23)
Other liabilities	(339)	(10)
Deferred income taxes	(1,156)	(579)
<b>Total identifiable net assets</b>	<b>4,519</b>	<b>1,326</b>
Goodwill	\$ 699	\$ 1,213

**Table of Contents**

Cash paid for the acquisition of Amylin included payments of \$5,093 million to its outstanding common stockholders and \$219 million to holders of its stock options and restricted stock units (including \$94 million attributed to accelerated vesting that was accounted for as stock compensation expense in the third quarter of 2012).

Pro forma supplemental financial information is not provided as the impacts of the acquisitions were not material to operating results in the year of acquisition. Goodwill, IPRD and all intangible assets valued in these acquisitions are non-deductible for tax purposes.

**Note 5. RESTRUCTURING**

The following is the provision for restructuring:

Dollars in Millions	Three Months Ended September 30, Nine Months Ended September 30,			
	2012	2011	2012	2011
Employee termination benefits	\$ 21	\$ 4	\$ 56	\$ 72
Other exit costs	8	4	15	20
Provision for restructuring	\$ 29	\$ 8	\$ 71	\$ 92

Restructuring charges included termination benefits for workforce reductions of manufacturing, selling, administrative, and research and development personnel across all geographic regions of approximately 185 and 50 for the three months ended September 30, 2012 and 2011, respectively, and approximately 480 and 700 for the nine months ended September 30, 2012 and 2011, respectively.

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

Dollars in Millions	Nine Months Ended September 30,	
	2012	2011
Liability at January 1	\$ 77	\$ 126
Charges	77	94
Changes in estimates	(6)	(2)
Provision for restructuring	71	92
Foreign currency translation	(1)	1
Amylin acquisition	26	
Spending	(66)	(119)
Liability at September 30	\$ 107	\$ 100

**Note 6. INCOME TAXES**

The effective tax benefit rate was 43.4% on the pretax loss during the third quarter of 2012 compared to an effective tax rate of 26.0% on pretax earnings during the third quarter of 2011. The effective income tax rates were 13.7% and 25.2% during the nine months ended September 30, 2012 and 2011, respectively. The overall tax benefit rate of 43.4% attributed to the pretax loss in the current quarter was due to the mix of earnings in low tax jurisdictions and pretax loss in the higher U.S. tax jurisdiction resulting from a \$1,830 million intangible asset impairment charge. The impact of the impairment charge reduced the effective tax rate by 11 percentage points during the nine months ended September 30, 2012. The effective tax rate is typically 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 these earnings are repatriated to the U.S. in the future, or if it was determined that such earnings are 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 decrease in the effective tax rate in the nine months ended September 30, 2012 was due to:

Favorable earnings mix between high and low tax jurisdictions primarily attributed to the \$1,830 million IPRD impairment charge in the U.S.

Partially offset by:

Lower tax benefits from contingent tax matters (\$30 million charge in 2012 and \$75 million benefit in 2011);

An unfavorable impact on the current year rate from the research and development tax credit, which was not extended as of September 30, 2012; and

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



**Table of Contents**

BMS 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. BMS estimates that it is reasonably possible that the total amount of unrecognized tax benefits at September 30, 2012 could decrease in the range of approximately \$20 million to \$50 million in the next twelve months as a result of 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. BMS believes that it has adequately provided for all open tax years by tax jurisdiction.

**Note 7. EARNINGS/(LOSS) PER SHARE**

Amounts in Millions, Except Per Share Data	Three Months Ended September 30, 2012		Nine Months Ended September 30, 2012	
	2012	2011	2012	2011
Net Earnings/(Loss) Attributable to BMS	\$ (711)	\$ 969	\$ 1,035	\$ 2,857
Earnings attributable to unvested restricted shares		(2)	(1)	(6)
Net Earnings/(Loss) Attributable to BMS common shareholders	\$ (711)	\$ 967	\$ 1,034	\$ 2,851
Earnings/(Loss) per share basic	\$ (0.43)	\$ 0.57	\$ 0.62	\$ 1.67
Weighted-average common shares outstanding basic	1,666	1,698	1,679	1,703
Contingently convertible debt common stock equivalents		1	1	1
Incremental shares attributable to share-based compensation plans		16	17	13
Weighted-average common shares outstanding diluted	1,666	1,715	1,697	1,717
Earnings/(Loss) per share diluted	\$ (0.43)	\$ 0.56	\$ 0.61	\$ 1.66
Anti-dilutive weighted-average equivalent shares stock incentive plans		11	2	28

Contingently convertible debt common stock equivalents and incremental shares attributable to share-based compensation plans of 17 million were excluded from the per share calculation for the three months ended September 30, 2012 because of the net loss in that period.

**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 account receivables and payables 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.

BMS 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 initial and periodic assessments of the effectiveness in 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.

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

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

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 securities.

**Table of Contents**

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, interest rate swap contracts, equity funds, fixed income funds and long-term debt. Additionally, certain corporate debt securities utilize a third-party matrix-pricing model that uses significant inputs corroborated by market data for substantially the full term of the assets. Equity and fixed income funds are primarily invested in publicly traded securities and are valued at the respective net asset value of the underlying investments. There were no significant unfunded commitments or restrictions on redemptions related to equity and fixed income funds as of September 30, 2012. Level 2 derivative instruments are valued using London Interbank Offered Rate (LIBOR) and Euro Interbank Offered Rate (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 Auction Rate Security (ARS) and Floating Rate Security (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 the ARS was determined using an internally developed valuation which was based in part on indicative bids received on the underlying assets of the security and other evidence of fair value. The ARS is a private placement security rated BBB by Standard and Poor's and represents interests in insurance securitizations. Due to the current lack of an active market for the FRS and the general lack of transparency into its underlying assets, other qualitative analysis is relied upon to value the FRS including discussions with brokers and fund managers, default risk underlying the security and overall capital market liquidity.

*Available-For-Sale Securities and Cash Equivalents*

The following table summarizes available-for-sale securities at September 30, 2012 and December 31, 2011:

Dollars in Millions	Amortized Cost	Gross Unrealized Gain in Accumulated OCI	Gross Unrealized Loss in Accumulated OCI	Gain/(Loss) in Income	Fair Value	Level 1	Fair Value Level 2	Level 3
<b>September 30, 2012</b>								
Marketable Securities								
Certificates of Deposit	\$ 121	\$	\$	\$	\$ 121	\$	\$ 121	\$
Corporate Debt Securities	4,337	94			4,431		4,431	
Commercial Paper	240				240		240	
U.S. Treasury Securities	150	1			151	151		
FDIC Insured Debt Securities	50				50		50	
Equity Funds	51			5	56		56	
Fixed Income Funds	46			1	47		47	
ARS	9	1			10			10
FRS	21		(2)		19			19
Total Marketable Securities	\$ 5,025	\$ 96	\$ (2)	\$ 6	\$ 5,125	\$ 151	\$ 4,945	\$ 29
<b>December 31, 2011</b>								
Marketable Securities								
Certificates of Deposit	\$ 1,051	\$	\$	\$	\$ 1,051	\$	\$ 1,051	\$
Corporate Debt Securities	2,908	60	(3)		2,965		2,965	
Commercial Paper	1,035				1,035		1,035	
U.S. Treasury Securities	400	2			402	402		
FDIC Insured Debt Securities	302	1			303		303	
ARS	80	12			92			92

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

FRS	21	(3)	18	18			
Total Marketable Securities	\$ 5,797	\$ 75	\$ (6)	\$ 5,866	\$ 402	\$ 5,354	\$ 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, 2012	December 31, 2011
Current Marketable Securities	\$ 1,427	\$ 2,957
Non-current Marketable Securities	3,698	2,909
<b>Total Marketable Securities</b>	<b>\$ 5,125</b>	<b>\$ 5,866</b>

Money market funds and other securities aggregating \$1,203 million and \$5,469 million at September 30, 2012 and December 31, 2011, respectively, were included in cash and cash equivalents and valued using Level 2 inputs. At September 30, 2012, \$3,688 million of non-current available for sale corporate debt securities and FRS mature within five years.

The change in fair value for the investments in equity and fixed income funds are recognized in the results of operations and are designed to offset the changes in fair value of certain employee retirement benefits.

The following table summarizes the activity for financial assets utilizing Level 3 fair value measurements:

	2012	2011
Fair value at January 1	\$ 110	\$ 110
Sales	(81)	
<b>Fair value at September 30</b>	<b>\$ 29</b>	<b>\$ 110</b>

**Qualifying Hedges**

The following table summarizes the fair value of outstanding derivatives:

Dollars in Millions	Balance Sheet Location	September 30, 2012 Notional	Fair Value (Level 2)	December 31, 2011 Notional	Fair Value (Level 2)
<i>Derivatives designated as hedging instruments:</i>					
Interest rate swap contracts	Other assets	\$ 573	\$ 154	\$ 579	\$ 135
Foreign currency forward contracts	Other assets	953	47	1,347	88
Foreign currency forward contracts	Accrued expenses	993	(23)	480	(29)

*Cash Flow Hedges* Foreign currency forward contracts are primarily utilized to hedge forecasted intercompany inventory 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 other comprehensive income (OCI) and recognized in earnings when the hedged item affects earnings. As of September 30, 2012, significant outstanding foreign currency forward contracts were primarily attributed to Euro and Japanese yen foreign currency forward contracts in the notional amount of \$1,130 million and \$504 million, respectively.

The net gain on foreign currency forward contracts qualifying for cash flow hedge accounting is expected to be reclassified to cost of products sold within the next two years, including \$33 million of pre-tax 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, 2012 and 2011.

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

*Net Investment Hedges* Non-U.S. dollar borrowings of 541 million (\$698 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 an adjustment to interest expense over the remaining term of the debt.

**Table of Contents**

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). The basis adjustment from the swap terminations is amortized as interest expense over the remaining life of the underlying debt.

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

Dollars in Millions	September 30, 2012	December 31, 2011
Principal Value	\$ 6,601	\$ 4,669
Adjustments to Principal Value:		
Fair value of interest rate swaps	154	135
Unamortized basis adjustment from swap terminations	528	594
Unamortized bond discounts	(56)	(22)
Total	\$ 7,227	\$ 5,376

Current portion of long-term debt	\$ 619	\$
Long-term debt	6,608	5,376

During the three months ended September 30, 2012, \$2.0 billion of senior unsecured notes were issued: \$750 million in aggregate principal amount of 0.875% Notes due 2017, \$750 million in aggregate principal amount of 2.000% Notes due 2022 and \$500 million in aggregate principal amount of 3.250% Notes due 2042 in a registered public offering. Interest on the notes will be paid semi-annually on each February 1 and August 1 beginning February 1, 2013. The notes rank equally in right of payment with all of BMS's existing and future senior unsecured indebtedness. BMS may redeem the notes, in whole or in part, at any time at a predetermined redemption price. The net proceeds of the note issuances were \$1,950 million, which is net of a discount of \$36 million and deferred loan issuance costs of \$14 million.

Commercial paper was issued and matured during the three months ended September 30, 2012 with an average amount outstanding of \$526 million at a weighted-average interest rate of 0.15%. There were no commercial paper borrowings at September 30, 2012.

Substantially all of the \$2.0 billion debt obligations assumed in the acquisition of Amylin were repaid during the three months ended September 30, 2012, including a promissory note with Lilly with respect to a revenue sharing obligation and Amylin senior notes due 2014.

Debt repurchase activity was as follows:

Dollars in Millions	Nine Months Ended September 30,	
	2012	2011
Principal amount	\$ 2,052	\$ 71
Carrying value	2,081	88
Repurchase price	2,108	78
Notional amount of interest rate swaps terminated	6	34
Swap termination proceeds	2	6
Total (gain)/loss	27	(10)

The fair value of debt was \$8,350 million at September 30, 2012 and \$6,406 million at December 31, 2011 and was valued using Level 2 inputs. Interest payments were \$125 million and \$52 million for the nine months ended September 30, 2012 and 2011, respectively, net of amounts related to interest rate swap contracts.

In July 2012, BMS entered into a new \$1.5 billion five year revolving credit facility. There are no financial covenants under the new facility. This revolving credit facility is in addition to the Company's existing \$1.5 billion revolving credit facility which was established in September 2011 with a syndicate of lenders. There were no borrowings under either revolving credit facility at September 30, 2012 and December 31, 2011.





**Table of Contents****Note 9. RECEIVABLES**

Receivables include:

Dollars in Millions	September 30, 2012	December 31, 2011
Trade receivables	\$ 1,844	\$ 2,397
Less allowances	(110)	(147)
Net trade receivables	1,734	2,250
Alliance partners receivables	755	1,081
Prepaid and refundable income taxes	202	256
Miscellaneous receivables	198	156
Receivables	\$ 2,889	\$ 3,743

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 \$1,081 million and \$901 million at September 30, 2012 and December 31, 2011, respectively. For additional information regarding alliance partners, see Note 3. Alliances and Collaborations. Non-U.S. receivables sold on a nonrecourse basis were \$734 million and \$806 million for the nine months ended September 30, 2012 and 2011, respectively. In the aggregate, receivables due from three pharmaceutical wholesalers in the U.S. represented 39% and 55% of total trade receivables at September 30, 2012 and December 31, 2011, respectively.

**Note 10. INVENTORIES**

Inventories include:

Dollars in Millions	September 30, 2012	December 31, 2011
Finished goods	\$ 533	\$ 478
Work in process	868	646
Raw and packaging materials	296	260
Inventories	\$ 1,697	\$ 1,384

Inventories of \$374 million expected to remain on-hand beyond one year were included in non-current assets (including \$29 million of inventories at risk). 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, 2012	December 31, 2011
Land	\$ 114	\$ 137
Buildings	4,897	4,545
Machinery, equipment and fixtures	3,648	3,437
Construction in progress	623	262

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

Gross property, plant and equipment	9,282	8,381
Less accumulated depreciation	(3,985)	(3,860)
Property, plant and equipment	\$ 5,297	\$ 4,521

Depreciation expense was \$274 million and \$333 million for the nine months ended September 30, 2012 and 2011, respectively.

**Table of Contents****Note 12. GOODWILL AND OTHER INTANGIBLE ASSETS**

Changes in the carrying amount of goodwill during the nine months ended September 30, 2012 were as follows:

Dollars in Millions	
Balance at January 1, 2012	\$ 5,586
Inhibitex acquisition	1,213
Amylin acquisition	699
Balance at September 30, 2012	\$ 7,498

Qualitative factors were assessed in the first quarter in determining whether it was more likely than not that the fair value of our aggregated geographic reporting units exceeded its carrying value. Examples of qualitative factors assessed included our share price, our financial performance compared to budgets, long-term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test performed in the prior year. Positive and negative influences of each relevant factor were assessed both individually and in the aggregate and as a result it was concluded that no additional quantitative testing was required.

At September 30, 2012 and December 31, 2011, other intangible assets consisted of the following:

Dollars in Millions	Estimated Useful Lives	September 30, 2012			December 31, 2011		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Licenses	2 15 years	\$ 1,178	\$ 526	\$ 652	\$ 1,218	\$ 443	\$ 775
Developed technology rights	7 15 years	8,777	1,439	7,338	2,608	1,194	1,414
Capitalized software	3 10 years	1,189	919	270	1,147	857	290
Total finite-lived intangible assets		11,144	2,884	8,260	4,973	2,494	2,479
IPRD		957		957	645		645
Total other intangible assets		\$ 12,101	\$ 2,884	\$ 9,217	\$ 5,618	\$ 2,494	\$ 3,124

The changes in the carrying amount of other intangible assets for the nine months ended September 30, 2012 and 2011 were as follows:

Dollars in Millions		
	2012	2011
Other intangible assets carrying amount at January 1	\$ 3,124	\$ 3,370
Capitalized software and other additions	44	54
Acquisitions	8,535	160
Amortization expense	(394)	(261)
Impairment charges	(2,092)	(30)
Other		(97)
Other intangible assets, net carrying amount at September 30	\$ 9,217	\$ 3,196

Annual amortization expense of other intangible assets is expected to be approximately \$650 million in 2012, \$900 million in 2013, \$900 million in 2014, \$800 million in 2015, \$800 million in 2016 and an aggregate \$4.6 billion beyond 2016.

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

On August 23, 2012, BMS announced that it has discontinued development of BMS-986094 (formerly known as INX-189), a nucleotide polymerase (NS5B) inhibitor that was in Phase II development for the treatment of hepatitis C. The decision was made in the interest of patient safety, based on a rapid, thorough and ongoing assessment of patients in a Phase II study that was voluntarily suspended on August 1, 2012. BMS acquired BMS-986094 with its acquisition of Inhibitex in February 2012. As a result of the termination of this development program, BMS recognized a \$1,830 million pre-tax impairment charge related to the IPRD intangible asset.

**Table of Contents****Note 13. DEFERRED INCOME**

Deferred income includes:

Dollars in Millions	September 30, 2012	December 31, 2011
Upfront, milestone and other licensing payments	\$ 4,311	\$ 882
<i>Atripla</i> * deferred revenue	211	113
Gain on sale-leaseback transactions	104	120
Other	69	88
Total deferred income	\$ 4,695	\$ 1,203

Current portion	\$ 689	\$ 337
Non-current portion	4,006	866

For further information pertaining to upfront, milestone and other licensing payments, including \$3.6 billion of proceeds received from AstraZeneca related to the Amylin collaboration during the third quarter of 2012, see Note 3. Alliances and Collaborations.

Amortization of deferred income was \$186 million and \$112 million for the nine months ended September 30, 2012 and 2011.

**Note 14. EQUITY**

	Common Stock		Capital in Excess of Par Value	Retained Earnings	Treasury Stock		Noncontrolling Interest
Dollars and Shares in Millions	Shares	Par Value	of Stock		Shares	Cost	
Balance at January 1, 2011	2,205	\$ 220	\$ 3,682	\$ 31,636	501	\$ (17,454)	\$ (75)
Net earnings attributable to BMS				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)
Balance at January 1, 2012	2,205	\$ 220	\$ 3,114	\$ 33,069	515	\$ (17,402)	\$ (89)
Net earnings attributable to BMS				1,035			
Cash dividends declared				(1,723)			
Stock repurchase program					58	(1,914)	
Employee stock compensation plans	3	1	(397)		(15)	841	
Net earnings attributable to noncontrolling interest							854
Distributions							(765)
Balance at September 30, 2012	2,208	\$ 221	\$ 2,717	\$ 32,381	558	\$ (18,475)	\$

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

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

In June 2012, the Board of Directors increased its authorization for the repurchase of common stock by \$3.0 billion. 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. The stock repurchase program does not have an expiration date and is expected to take place over a couple of 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 a tax benefit of \$2 million and taxes of \$209 million for the three months ended September 30, 2012 and 2011, respectively, and taxes of \$318 million and \$609 million for the nine months ended September 30, 2012 and 2011, respectively, in the consolidated statements of earnings with a corresponding increase or decrease 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. The above activity includes the pre-tax income and distributions related to these partnerships.

**Table of Contents**

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, 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)
Balance at January 1, 2012	\$ (238)	\$ 36	\$ (2,905)	\$ 62	\$ (3,045)
Other comprehensive income/(loss)	7	(27)	84	37	101
Balance at September 30, 2012	\$ (231)	\$ 9	\$ (2,821)	\$ 99	\$ (2,944)

**Note 15. 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	
	2012	2011	2012	2011	2012	2011	2012	2011
Service cost	\$ 7	\$ 11	\$ 1	\$ 2	\$ 24	\$ 32	\$ 5	\$ 6
Interest cost on projected benefit obligation	79	83	5	7	237	253	16	20
Expected return on plan assets	(125)	(116)	(6)	(7)	(377)	(349)	(19)	(20)
Amortization of prior service cost/(benefit)	(1)			(1)	(2)		(1)	(2)
Amortization of net actuarial loss	32	28	2	2	97	85	8	5
Curtailments						(1)		
Settlements	3	2			3			
Total net periodic benefit cost	\$ (5)	\$ 8	\$ 2	\$ 3	\$ (18)	\$ 20	\$ 9	\$ 9

Contributions to the U.S. pension plans are expected to be approximately \$340 million during 2012, of which \$323 million was contributed in the nine months ended September 30, 2012. Contributions to the international plans are expected to range from \$65 million to \$80 million in 2012, of which \$49 million was contributed in the nine months ended September 30, 2012.

The expense attributed to defined contribution plans in the U.S. was \$47 million for both the three months ended September 30, 2012 and 2011, and \$143 million and \$133 million for the nine months ended September 30, 2012 and 2011, respectively.

**Note 16. EMPLOYEE STOCK BENEFIT PLANS**

Stock-based compensation expense was as follows:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Stock options	\$ (1)	\$ 7	\$ 4	\$ 20

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

Restricted stock	9	19	46	59
Market share units	4	6	17	17
Long-term performance awards	14	7	41	24
Amylin stock options and restricted stock units (See Note 4)	94		94	
Total stock-based compensation expense	\$ 120	\$ 39	\$ 202	\$ 120
Income tax benefit	\$ 38	\$ 13	\$ 66	\$ 41

The acceleration of unvested stock options and restricted stock units in connection with the acquisition of Amylin resulted in stock-based compensation expense for the three and nine months ended September 30, 2012.

In the nine months ended September 30, 2012, 3.0 million restricted stock units, 1.1 million market share units and 1.7 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, 2012 was \$32.70, \$31.85 and \$32.33, respectively.



**Table of Contents**

Substantially all restricted stock units vest ratably over a four year period based on share price performance. 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, 2012 were as follows:

Dollars in Millions	Stock Options	Restricted Stock	Market Share Units	Long-Term Performance Awards
Unrecognized compensation cost	\$ 4	\$ 165	\$ 39	\$ 42
Expected weighted-average period in years of compensation cost to be recognized	0.4	2.8	2.9	1.4

**Note 17. 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\** 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 Inc. (Apotex), has since changed its name to Apotex. In August 2007, Apotex filed an application in the Federal Court of Australia (the Federal Court) 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 Federal 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 Court 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.

***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

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

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.

## **Table of Contents**

### ***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. 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 in December 2011, the Federal Court of Canada issued a decision that the 777 Patent is invalid. Sanofi is appealing this decision though generic companies have since entered the market.

## **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 (Federal Circuit). In May 2012, the Federal Circuit affirmed the NJ District Court's decision. In June 2012, Apotex filed a petition for rehearing *en banc* which was denied.

### ***Atripla\****

In April 2009, Teva filed an abbreviated New Drug Application (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. (Merck) 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\**. Trial is expected in 2013. It is not possible at this time to reasonably assess the outcome of these lawsuits or their impact on the Company.

### ***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, which expires in 2015. In September 2010, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Teva for infringement of the listed patent covering *Baraclude*, which triggered an automatic 30-month stay of approval of Teva's aNDA. A trial took place in mid-October 2012 and the Company is currently awaiting a decision. If Teva were to prevail, there could be a significant impact on sales of *Baraclude* in the U.S. In June 2012, the Company filed a patent infringement lawsuit against Sandoz following the receipt of a Paragraph IV certification letter challenging the same Orange-Book listed patent. It is not possible at this time to reasonably assess the outcome of these lawsuits or their 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 NJ District Court 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. In October 2011, the Company received a Paragraph IV notice letter from Apotex informing the Company that it is seeking approval of generic versions of the 80 mg and 140 mg dosage strengths of *Sprycel* and challenging the same four Orange Book listed patents. In November 2011, BMS filed a patent infringement suit against Apotex on the 80 mg and 140 mg dosage strengths in the NJ District Court. This case has been consolidated with the

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

suit filed in November 2010. Trial is currently scheduled for September 2013. 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.

## **Table of Contents**

### ***Sustiva* EU**

In January 2012, Teva obtained a European marketing authorization for Efavirenz Teva 600 mg tablets. In February 2012, the Company and Merck filed lawsuits and requests for injunctions against Teva in the Netherlands, Germany and the U.K. for infringement of Merck's European Patent No. 0582455 and Supplementary Protection Certificates expiring in November 2013. As of September 2012, requests for injunctions have been granted in the U.K. and denied in the Netherlands and Germany. The Company and Merck have are appealing the denial of injunctions in the Netherlands. It is not possible at this time to reasonably assess the outcome of these lawsuits or their 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 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 California Court of Appeal's judgment and the matter was remanded to the California 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. The plaintiffs appealed that decision and the California Court of Appeals affirmed summary judgment for the defendants. In October 2012, the plaintiffs filed a petition seeking review by the California Supreme Court, which is pending. It is not possible at this time to determine the outcome of the appeal.

### **Remaining Apotex Matters Related to *Plavix*\***

As previously disclosed, in November 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 calculated at the rate of 1% per month from the date of the filing of the lawsuit, until paid, related to the break-up of a March 2006 proposed settlement agreement relating to the then pending *Plavix*\* patent litigation against Apotex. In April 2011, the New Jersey Superior Court granted the Company's 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 May 2006 proposed settlement agreement with Apotex relating to the then pending *Plavix*\* patent litigation. Discovery has concluded. The Company and Sanofi have moved for summary judgment.

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

### ***Abilify*\* Federal Subpoena**

In January 2012, the Company received a subpoena from the United States Attorney's Office for the Southern District of New York requesting information related to, among other things, the sales and marketing of *Abilify*\*. It is not possible at this time to assess the outcome of this matter or its potential impact on the Company.

### ***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.

### ***Abilify*\* Co-Pay Assistance Litigation**

In March 2012, the Company and its partner Otsuka were named as co-defendants in a putative class action lawsuit filed by union health and welfare funds in the SDNY. Plaintiffs are challenging the legality of the *Abilify*\* co-pay assistance program under the Federal Antitrust and the

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

Racketeer Influenced and Corrupt Organizations laws, and seeking damages. The Company and Otsuka have filed a motion to dismiss the complaint. It is not possible at this time to reasonably assess the outcome of this litigation or its potential impact on the Company.

## **Table of Contents**

### **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 remains 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 contributing to the provision of inflated AWPs. The Company has moved to vacate the decision and the Commonwealth has moved for a judgment notwithstanding the verdict, which the Commonwealth Court denied. The Company has appealed the decision to the Pennsylvania Supreme Court. The Company has reached agreements in principle to resolve the suits brought by the Mississippi and Louisiana Attorneys General.

### **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. Discovery is ongoing. 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 state and federal courts claiming personal injury damage allegedly sustained after using *Plavix*\*. Currently, more than 2,000 claims are filed in state and federal courts in various states including California, Illinois, New Jersey, New York, Alabama, Iowa and Pennsylvania. The defendants terminated the previously disclosed tolling agreement effective as of September 1, 2012. 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 numerous lawsuits, on behalf of approximately 2,700 plaintiffs, 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. The resolution of these pending lawsuits is not expected to have a material 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 October 2012, 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. The resolution of these remaining lawsuits is not expected to have a material impact on the Company.

## **Table of Contents**

### ***Byetta*\***

Amylin, now a wholly-owned subsidiary of the Company (see Note 4. Acquisitions), and Lilly are co-defendants in product liability litigation related to *Byetta*\*. As of September 30, 2012, there were approximately 100 separate lawsuits pending on behalf of approximately 555 plaintiffs in various courts in the U.S. The vast majority of these cases have been brought by individuals who allege personal injury sustained after using *Byetta*\*, primarily pancreatitis, and, in some cases, claiming alleged wrongful death. Of these, the Company has agreed in principle to resolve the claims of approximately 200 plaintiffs. The vast majority of cases are pending in California state court, where the Judicial Council has granted Amylin's petition for a coordinated proceeding for all California state court cases alleging harm from the alleged use of *Byetta*\*. Amylin and Lilly are currently scheduled for trial in two separate single plaintiff cases for the first half of 2013, the first of which is currently scheduled to begin in February. We cannot reasonably predict the outcome of any lawsuit, claim or proceeding. However, given that Amylin has product liability insurance coverage for existing claims and future related claims, it is expected the amount of damages, if any, will not be material to the Company.

### **BMS-986094**

In August 2012, the Company announced that it had discontinued development of BMS-986094, an investigational compound which was being tested in clinical trials to treat hepatitis C due to the emergence of a serious safety issue. To date, five lawsuits have been filed against the Company in Texas State Court by plaintiffs, which have been removed to Federal Court, alleging that they participated in the Phase II study of BMS-986094 and suffered injuries as a result thereof. In total, slightly fewer than 300 patients were administered the compound at various doses and durations as part of the clinical trials. The resolution of these lawsuits is not expected to have a material impact on the Company.

## **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 \$71 million at September 30, 2012, 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, New Jersey who live or have lived adjacent to the Company's New Brunswick facility. The complaints either allege various personal injuries damages 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. Since October 2011, over 100 additional cases have been filed in New Jersey Superior Court and removed by the Company to United States District Court, District of New Jersey. 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

---

**Table of Contents**

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 late 2012 or early 2013. 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 also had requested interim measures that a judicial administrator be appointed to temporarily run the operations of BMS Italy. In October 2012, the parties reached an agreement to resolve the request for interim measures which resulted in the Italian Prosecutor withdrawing the request and this request was accepted by the Florence Court. It is not possible at this time to assess the outcome of the underlying investigation or its potential impact on the Company.

**SEC Germany Investigation**

In October 2006, the SEC informed the Company that it had begun a formal inquiry into the activities of certain of the Company's German pharmaceutical subsidiaries and its employees and/or agents. 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 (FCPA). The Company is cooperating with the SEC.

**FCPA Investigation**

In March 2012, the Company received a subpoena from the SEC. The subpoena, issued in connection with an investigation under the FCPA, primarily relates to sales and marketing practices in various countries. The Company is cooperating with the government in its investigation of these matters.

**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 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.

The following key events and transactions occurred during the current quarter as discussed in further detail in the Strategy, Product and Pipeline Developments and Results of Operations sections of Management's Discussion and Analysis:

Overall sales continued to decline as a result of the loss of exclusivity of *Plavix*\* (clopidogrel bisulfate) and *Avapro*\*/*Avalide*\* (irbesartan/irbesartan-hydrochlorothiazide).

The development of BMS-986094 (formerly INX-189), a compound which we acquired as part of our acquisition of Inhibitex, Inc. (Inhibitex) to treat hepatitis C, was discontinued in the interest of patient safety resulting in a \$1.8 billion pre-tax impairment charge.

We acquired Amylin Pharmaceuticals, Inc (Amylin) and expanded our existing alliance arrangement with AstraZeneca PLC (AstraZeneca) to include Amylin-related products.

We had regulatory developments pertaining to *Eliquis* (apixaban), *Forxiga* (dapagliflozin) and *Orencia* (abatacept).

The following table is a summary of our financial highlights:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Dollars in Millions, except per share data				
Net Sales	\$ 3,736	\$ 5,345	\$ 13,430	\$ 15,790
Total Expenses	4,995	3,515	11,603	10,403
Earnings/(Loss) before Income Taxes	(1,259)	1,830	1,827	5,387
Provision for/(Benefit from) Income Taxes	(546)	475	250	1,358
Effective tax rate	43.4%	26.0%	13.7%	25.2%
Net Earnings/(Loss) Attributable to BMS				
GAAP	(711)	969	1,035	2,857
Non-GAAP	685	1,044	2,587	3,015
Diluted Earnings/(Loss) Per Share				
GAAP	(0.43)	0.56	0.61	1.66
Non-GAAP	0.41	0.61	1.52	1.75

Cash, Cash Equivalents and Marketable Securities 6,628 11,012

Our non-GAAP financial measures, including non-GAAP earnings and related earnings per share (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 Non-GAAP Financial Measures below.

**Strategy**

Over the past few years, we transformed our Company into a focused biopharmaceutical company. We continue to focus on sustaining our business and building a foundation for the future. We plan to achieve this foundation by growing our newer key marketed products, advancing our pipeline portfolio and managing our costs. We also plan to expand our presence in emerging markets, with a tailored approach to each market. We expect that our portfolio will become increasingly diversified across products and geographies over the next few years.

We experienced substantial exclusivity losses this year for *Plavix*\* and *Avapro*\*/*Avalide*\*, which together had more than \$8 billion of net sales in 2011. We will also face additional exclusivity losses in the coming years. We had been preparing for this for a number of years. As expected, we have experienced a rapid, precipitous, and material decline in *Plavix*\* and *Avapro*\*/*Avalide*\* net sales and a reduction in net income and operating cash flow. Such events are the norm in the industry when companies experience the loss of exclusivity of a significant product. We

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

also face significant challenges with an increasingly complex global and regulatory environment and global economic uncertainty, particularly in the European Union (EU). We believe our strategy to grow our newer marketed products and our robust research and development (R&D) pipeline, particularly within the therapeutic areas of immuno-oncology, cardiovascular/metabolic disease and virology, position us well for the future.

## **Table of Contents**

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, which are derived from recombinant DNA technologies, are becoming increasingly important. Currently, more than one in three of our pipeline compounds are biologics, as are four of our key marketed products, including *Yervoy* (ipilimumab).

We also continue to support our pipeline with our licensing and acquisitions strategy, referred to as our string of pearls. During the third quarter of 2012, we acquired Amylin, a biopharmaceutical company dedicated to the discovery, development and commercialization of innovative medicines for patients with diabetes and other metabolic diseases. Following the completion of our acquisition of Amylin, we entered into a collaboration with AstraZeneca Pharmaceuticals LP, a wholly-owned subsidiary of AstraZeneca, which builds upon our existing alliance, further expanding our collaboration strategy. We are currently integrating the Amylin business into our development, manufacturing and commercial operations. We are also seeking to build relationships with academic organizations that have innovative programs and capabilities that complement our own internal efforts.

## **Product and Pipeline Developments**

We manage our R&D programs on a portfolio basis, investing resources in each stage from early discovery through late-stage development. Our portfolio of R&D assets is evaluated continually 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 Phase III development 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 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:

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

In October 2012, the Company announced in a publication in *The Lancet* that the reductions in stroke or systemic embolism, major bleeding and mortality demonstrated with *Eliquis* compared to warfarin in the ARISTOTLE trial were consistent across a wide range of stroke and bleeding risk scores in patients with nonvalvular atrial fibrillation (NVAf).

In September 2012, the Food and Drug Administration (FDA) acknowledged receipt of the resubmission of the New Drug Application (NDA) for *Eliquis* to reduce the risk of stroke and systemic embolism in patients with NVAf. The FDA deemed the application a complete response to its June 2012 Complete Response Letter that requested additional information on data management and verification from the ARISTOTLE trial. The FDA assigned a new Prescription Drug User Fee Act goal date of March 17, 2013.

In September 2012, the Company and Pfizer received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP). The CHMP recommended that *Eliquis* be granted approval for the prevention of stroke and systemic embolism in adult patients with NVAf and one or more risk factors for stroke. The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines for the EU.

*Forxiga* an oral SGLT2 inhibitor for the treatment of diabetes that is part of our alliance with AstraZeneca

The Company has met with the FDA and now has a path forward for potential approval for *Forxiga* in the U.S. The Company will provide additional data from ongoing studies to the FDA and expects to be able to resubmit the NDA for *Forxiga* in mid-2013. At this time, the Company expects that the FDA will have a six month period in which to review the resubmission and will hold an Advisory Committee meeting.

Brivanib an investigational anti-cancer agent

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

In July 2012, the Company announced that brivanib did not meet its primary overall survival objective based upon a non-inferiority statistical design in the Phase III BRISK-FL clinical trial of brivanib versus sorafenib as first-line treatment in patients with advanced hepatocellular carcinoma.

---

## **Table of Contents**

*Erbitux\** (cetuximab) 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 alliance with Eli Lilly and Company (Lilly).

In July 2012, the FDA granted full approval of *Erbitux\** in combination with the chemotherapy regimen FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for the first-line treatment of patients with KRAS mutation-negative epidermal growth factor receptor-expressing metastatic colorectal cancer as determined by FDA-approved tests for the use.

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

In September 2012, the Company announced at the European Society for Medical Oncology 2012 Congress long-term follow-up data of the 024 study which evaluated newly-diagnosed patients treated with *Yervoy* 10mg/kg in combination with dacarbazine versus dacarbazine alone and five-year follow-up data from the rollover 025 study which evaluated patients with *Yervoy* 0.3 mg/kg or 10 mg/kg. The survival rates observed in study 024 at years three and four were not only stable but higher in patients treated with *Yervoy* plus dacarbazine versus patients who received dacarbazine alone. The estimated survival rates in the 025 study remained unchanged or relatively stable at five years compared to four years in newly-diagnosed patients and previously-diagnosed patients.

*Onglyza/Kombiglyze* (saxagliptin/once daily combination of saxagliptin and metformin hydrochloride extended-release) a treatment for type 2 diabetes that is part of our strategic alliance with AstraZeneca

In July 2012, the Company and AstraZeneca announced at the 17<sup>th</sup> World Congress on Heart Disease the results of analyses showing that *Onglyza* 5mg demonstrated improvements across key measures of blood sugar control (glycosylated hemoglobin levels, or HbA1c; fasting plasma glucose, or FPG and post-prandial glucose, or PPG) compared to placebo in adult patients with type 2 diabetes at high risk for cardiovascular disease.

Marketing authorization for *Komboglyze*, the twice daily, fixed dose combination of saxagliptin and immediate-release metformin, was granted by the European Commission in November 2011. Due to a technical manufacturing issue, launches will begin in the fourth quarter of 2012.

*Orencia* a fusion protein indicated for rheumatoid arthritis (RA)

In October 2012, the European Commission granted marketing authorization for a subcutaneous formulation of *Orencia* in combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adults.

*Baraclude* (entecavir) an oral antiviral agent for the treatment of chronic hepatitis B

In October 2012, a labeling update for *Baraclude* was approved by the FDA to include data on African Americans and liver transplant recipients with chronic hepatitis B infection.

In addition, in August 2012, the Company discontinued development of BMS-986094. This decision was made in the interest of patient safety. See Item 1. Financial Statements Note 12. Goodwill and Other Intangible Assets for further information.

## **RESULTS OF OPERATIONS**

### **Net Sales**

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

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

Dollars in Millions	Three Months Ended September 30, 2012 vs. 2011						Nine Months Ended September 30, 2012 vs. 2011					
	Net Sales		Analysis of % Change				Net Sales		Analysis of % Change			
	2012	2011	Total Change	Volume	Price	Foreign Exchange	2012	2011	Total Change	Volume	Price	Foreign Exchange
United States	\$ 1,985	\$ 3,477	(43)%	(45)%	2%		\$ 8,029	\$ 10,289	(22)%	(28)%	6%	
Europe	800	916	(13)%	2%	(4)%	(11)%	2,548	2,738	(7)%	4%	(3)%	(8)%
Japan, Asia Pacific and Canada	438	464	(6)%		(4)%	(2)%	1,281	1,375	(7)%	(3)%	(3)%	(1)%
Latin America, the Middle East and Africa	208	230	(10)%	(4)%		(6)%	654	664	(2)%	1%	2%	(5)%
Emerging Markets	230	238	(3)%	2%		(5)%	686	659	4%	9%	(1)%	(4)%
Other	75	20	**	N/A	N/A		232	65	**	N/A	N/A	
Total	\$ 3,736	\$ 5,345	(30)%	(28)%	1%	(3)%	\$ 13,430	\$ 15,790	(15)%	(16)%	3%	(2)%

\*\* Change in excess of 100%



**Table of Contents**

Our total net sales decreased in 2012 primarily due to declines in sales of *Plavix*\* and *Avapro*\*/*Avalide*\* following the losses of exclusivity of these products in the U.S. and unfavorable foreign exchange, partially offset by higher average net selling prices, continued growth in most key products and sales of *Byetta*\* (exenatide) and *Bydureon*\* (exenatide extended-release for injectable suspension) from our Amylin acquisition.

The change in U.S. net sales attributed to volume reflects the recent exclusivity losses of *Plavix*\* and *Avapro*\*/*Avalide*\*, partially offset by increased demand for most key products and the addition of *Byetta* and *Bydureon*. The change in U.S. net sales attributed to price was a result of higher average net selling prices for *Abilify*\* (aripiprazole) and *Plavix*\*, partially offset by the reduction in our contractual share of *Abilify*\* net sales. See Key Products for further discussion of sales by key product.

Net sales in Europe decreased primarily due to unfavorable foreign exchange and lower sales of certain mature brands from divestitures and generic competition as well as generic competition for *Plavix*\* and *Avapro*\*/*Avalide*\* partially offset by sales growth of most key products. 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 healthcare costs 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 decreased due to generic competition for *Plavix*\* and *Avapro*\*/*Avalide*\* in Canada as well as lower mature brand sales from generic competition and divestitures partially offset by higher demand for *Baraclude* (entecavir), *Sprycel* (dasatinib), and *Orencia*.

Other increased due to additional sales of bulk active pharmaceutical ingredient to our alliance partner as well as enhanced royalty-related revenue.

No single country outside the U.S. contributed more than 10% of total net sales during the three and nine months ended September 30, 2012 and 2011.

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.

We recognize revenue net of gross-to-net adjustments that are further described in Critical Accounting Policies in the Company's 2011 Annual Report on Form 10-K. Our contractual share of *Abilify*\* and *Atripla*\* sales is reflected net of all gross-to-net sales adjustments in gross sales.

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,			
	2012	2011	2012	2011
<b>Gross Sales</b>	\$ 4,225	\$ 6,081	\$ 15,127	\$ 17,761
<b>Gross-to-Net Sales Adjustments</b>				
Charge-Backs Related to Government Programs	(137)	(206)	(505)	(571)
Cash Discounts	(36)	(71)	(154)	(210)
Managed Healthcare Rebates and Other Contract Discounts	(98)	(233)	(182)	(514)
Medicaid Rebates	(93)	(137)	(296)	(404)
Sales Returns	6	(7)	(228)	(27)
Other Adjustments	(131)	(82)	(332)	(245)
<b>Total Gross-to-Net Sales Adjustments</b>	(489)	(736)	(1,697)	(1,971)
<b>Net Sales</b>	\$ 3,736	\$ 5,345	\$ 13,430	\$ 15,790
<b>Gross-to-Net Adjustments as a Percentage of Gross Sales</b>	12%	12%	11%	11%



**Table of Contents**

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, 2012	\$ (51)	\$ (28)	\$ (417)	\$ (411)	\$ (161)	\$ (181)	\$ (1,249)
Provision related to sales made in current period	(505)	(153)	(249)	(333)	(234)	(338)	(1,812)
Provision related to sales made in prior periods		(1)	67	37	6	6	115
Returns and payments	522	166	422	354	60	323	1,847
Amylin acquisition	(2)	(1)	(34)	(13)	(23)	(3)	(76)
Impact of foreign currency translation					(1)	1	
Balance at September 30, 2012	\$ (36)	\$ (17)	\$ (211)	\$ (366)	\$ (353)	\$ (192)	\$ (1,175)

Changes in the gross-to-net sales adjustment rates are primarily a function of changes in sales mix and contractual and legislative discounts and rebates. Gross-to-net sales adjustments decreased due to:

Managed healthcare rebates and other contract discounts decreased due to a reduction in prior period rebate and discount accruals based upon actual invoices received, the nonrenewal of *Plavix*\* contract discounts in the Medicare Part D program as of January 1, 2012, and the decrease in sales of *Plavix*\* following the loss of exclusivity.

Medicaid rebates decreased primarily due to a reduction in prior period managed Medicaid accruals based upon actual invoices received.

The provision for sales returns increased as a result of the loss of exclusivity in the U.S. of *Plavix*\* in May 2012 and *Avapro*\*/*Avalide*\* in March 2012. The U.S. sales return reserves for these products at September 30, 2012 were \$191 million and were determined after considering several factors including estimated inventory levels in the distribution channels. In accordance with Company policy, these products are eligible to be returned between six months prior to and twelve months after product expiration. Additional adjustments to these reserves might be required in the future for revised estimates to various assumptions including actual returns which are generally not expected to occur until 2014.

**Table of Contents**

Net sales of key products represent 83% and 86% of total net sales for the three months ended September 30, 2012 and 2011, respectively, and 85% and 86% of total net sales for the nine months ended September 30, 2012 and 2011, respectively. The following table presents U.S. and international net sales by key product, the percentage change from the prior period and the foreign exchange impact when compared to the prior period. Commentary detailing the reasons for significant variances for key products is provided below:

Dollars in Millions	Three Months Ended September 30,				Nine Months Ended September 30,			
	2012	2011	% Change	% Change Attributable to Foreign Exchange	2012	2011	% Change	% Change Attributable to Foreign Exchange
<b>Key Products</b>								
<i>Plavix* (clopidogrel bisulfate)</i>	\$ 64	\$ 1,788	(96)%		\$ 2,498	\$ 5,415	(54)%	
U.S.	41	1,672	(98)%		2,372	5,060	(53)%	
Non-U.S.	23	116	(80)%		126	355	(65)%	(2)%
<i>Avapro*/Avalide*</i>								
<i>(irbesartan/irbesartan-hydrochlorothiazide)</i>	95	216	(56)%	(3)%	419	757	(45)%	(2)%
U.S.	7	121	(94)%		127	414	(69)%	
Non-U.S.	88	95	(7)%	(4)%	292	343	(15)%	(3)%
<i>Eliquis (apixaban)</i>								
U.S.			N/A	N/A	1		N/A	N/A
Non-U.S.			N/A	N/A	1		N/A	N/A
<i>Abilify* (aripiprazole)</i>								
	676	691	(2)%	(2)%	2,008	2,021	(1)%	(3)%
U.S.	502	505	(1)%		1,472	1,482	(1)%	
Non-U.S.	174	186	(6)%	(9)%	536	539	(1)%	(9)%
<i>Reyataz (atazanavir sulfate)</i>								
	363	391	(7)%	(4)%	1,127	1,153	(2)%	(3)%
U.S.	194	184	5%		577	554	4%	
Non-U.S.	169	207	(18)%	(7)%	550	599	(8)%	(7)%
<i>Sustiva (efavirenz) Franchise</i>								
	370	359	3%	(3)%	1,144	1,073	7%	(2)%
U.S.	245	222	10%		752	665	13%	
Non-U.S.	125	137	(9)%	(9)%	392	408	(4)%	(7)%
<i>Baraclude (entecavir)</i>								
	346	311	11%	(4)%	1,028	878	17%	(2)%
U.S.	61	51	20%		175	150	17%	
Non-U.S.	285	260	10%	(4)%	853	728	17%	(3)%
<i>Erbitux* (cetuximab)</i>								
	173	172	1%	1%	531	510	4%	
U.S.	166	168	(1)%		512	497	3%	
Non-U.S.	7	4	75%	(2)%	19	13	46%	(2)%
<i>Sprycel (dasatinib)</i>								
	263	211	25%	(6)%	738	576	28%	(5)%
U.S.	107	78	37%		290	207	40%	
Non-U.S.	156	133	17%	(10)%	448	369	21%	(8)%
<i>Yervoy (ipilimumab)</i>								
	179	121	48%	(5)%	495	216	**	(6)%
U.S.	123	109	13%		361	204	77%	
Non-U.S.	56	12	**	**	134	12	**	**

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

<i>Orencia (abatacept)</i>	307	233	32%	(3)%	851	660	29%	(2)%
U.S.	209	154	36%		575	444	30%	
Non-U.S.	98	79	24%	(9)%	276	216	28%	(6)%

<i>Nulojix (belatacept)</i>	3				7	2	**	
U.S.	3				6	2	**	
Non-U.S.			N/A	N/A	1		N/A	N/A

*Onglyza/Kombiglyze (saxagliptin/saxagliptin*

<i>and metformin)</i>	178	127	40%	(3)%	511	320	60%	(3)%
U.S.	127	91	40%		368	228	61%	
Non-U.S.	51	36	42%	(9)%	143	92	55%	(12)%

\*\* Change in excess of 100%.

**Table of Contents**

	Three Months Ended September 30,				Nine Months Ended September 30,			
			%	% Change Attributable to Foreign Exchange			%	% Change Attributable to Foreign Exchange
Dollars in Millions	2012	2011	Change		2012	2011	Change	
<b>Key Products (continued)</b>								
<i>Byetta* (exenatide)</i>	\$ 55	\$	N/A	N/A	\$ 55	\$	N/A	N/A
U.S.	55		N/A		55		N/A	
Non-U.S.								
<i>Bydureon* (exenatide extended-release for injectable suspension)</i>	20		N/A	N/A	20		N/A	N/A
U.S.	20		N/A		20		N/A	
Non-U.S.								
<b>Mature Products and All Other</b>	644	725	(11)%	(6)%	1,997	2,209	(10)%	(5)%
U.S.	125	122	2%		367	382	(4)%	
Non-U.S.	519	603	(14)%	(5)%	1,630	1,827	(11)%	(4)%

\*\* Change in excess of 100%.

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

U.S. net sales decreased due to the loss of exclusivity in May 2012. Estimated total U.S. prescription demand decreased 95% and 48% for the three and nine months ended September 30, 2012, respectively. Net sales included the impact of a \$30 million reduction of inventory in the distribution channel that resulted in a reduction of sales returns reserve during the three months ended September 30, 2012.

International net sales continue to be negatively impacted by generic clopidogrel products in the EU, Canada, and Australia.

*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 the exclusivity loss of *Avapro\*/Avalide\** in March 2012. Total estimated U.S. prescription demand decreased 89% and 65% for the three and nine months ended September 30, 2012, respectively.

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

*Eliquis* an oral 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 AF that is part of our strategic alliance with Pfizer

*Eliquis* is approved in the EU and several other international countries for VTE prevention with launches continuing in many of those countries.

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

U.S. net sales decreased as fluctuations in retail buying patterns and the reduction in our contractual share of net sales recognized from 53.5% in 2011 to 51.5% in 2012 more than offset higher average net selling prices. Estimated total U.S. prescription demand decreased 1% for the three months ended September 30, 2012 and increased 1% for the nine months ended September 30, 2012.

International net sales decreased primarily due unfavorable foreign exchange partially offset by higher prescription demand.

*Reyataz*, a protease inhibitor for the treatment of HIV

U.S. net sales increased due to higher average net selling prices. Estimated total U.S. prescription demand decreased 6% and 3% for the three and nine months ended September 30, 2012, respectively.

International net sales decreased due to lower demand resulting from competing products, the timing of government purchases in certain countries and unfavorable foreign exchange.

## Table of Contents

*Sustiva* Franchise a non-nucleoside reverse transcriptase inhibitor for the treatment of HIV, which includes *Sustiva*, 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 increased due to higher average net selling prices. Estimated total U.S. prescription demand decreased 2% and 1% for the three and nine months ended September 30, 2012.

International net sales decreased due to unfavorable foreign exchange.

*Baraclude* an oral antiviral agent for the treatment of chronic hepatitis B

Worldwide net sales increased primarily due to continued strong demand in international markets.

*Erbix*\* 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. *Erbix*\* is part of our strategic alliance with Lilly.

Sold by us almost exclusively in the U.S., net sales increased primarily due to higher demand.

*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 and higher average net selling prices. Estimated total U.S. demand increased 22% and 33% for the three and nine months ended September 30, 2012, respectively.

International net sales increased due to higher demand partially offset by unfavorable foreign exchange.

*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 and continues to be launched in a number of international countries since the second quarter of 2011.

*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 due to demand for the subcutaneous formulation of *Orencia* launched in the fourth quarter of 2011.

International net sales increased primarily due to increased demand partially offset by unfavorable foreign exchange.

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

*Nulojix* was approved and launched in the U.S. and the EU during 2011.

*Onglyza/Kombiglyze* (known in the EU as *Onglyza/Komboglyze*) a once-daily oral tablet for the treatment of type 2 diabetes that is part of our strategic alliance with AstraZeneca



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

U.S. net sales increased primarily due to higher overall demand.

International net sales increased primarily due to higher overall demand partially offset by unfavorable foreign exchange.

*Byetta*\* a twice daily glucagon-like peptide-1 (GLP-1) receptor agonist for the treatment of type 2 diabetes

*Byetta*\* was acquired from our acquisition of Amylin in August 2012.

*Bydureon*\* a once-weekly GLP-1 receptor agonist for the treatment of type 2 diabetes

*Bydureon*\* was acquired from our acquisition of Amylin in August 2012.

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

U.S. net sales decreased as the continued generic erosion of certain products was partially offset by higher average net selling prices.

International net sales decreased due to continued generic erosion of certain brands and unfavorable foreign exchange.

## Table of Contents

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, except for *Sprycel* and *Orencia* subcutaneous formulation, and is based on the Source Prescription Audit. As of December 31, 2011, *Sprycel* and *Orencia* subcutaneous formulation demand is based upon information from the Next-Generation Prescription Service version 2.0 of the National Prescription Audit provided by IMS Health (IMS). The data is a product of each respective service providers' own recordkeeping and projection processes and therefore subject to the inherent limitations of estimates based on sampling and may include a margin of error.

Prior to December 31, 2011, *Sprycel* demand was calculated based upon data obtained from the IMS National Sales Perspectives Audit. Since management believes information from the IMS National Prescription Audit more accurately reflects subscriber demand trends versus pill data from the IMS National Sales Perspectives Audit, all prior year *Sprycel* data has been restated to reflect information from the IMS National Prescription Audit.

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-party data used in such calculations.

We calculated the estimated total U.S. prescription change on a weighted-average basis to reflect that mail order prescriptions include a greater volume of product supplied, 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 of approximately 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 in 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 by the U.S. for the three and nine months ended September 30, 2012 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	
	2012	2011	2012	2011	2012	2011	2012	2011	2012	2011
Dollars in Millions										
<i>Plavix</i> *	(98)%	9%	(95)%	(6)%	(53)%	11%	(48)%	(5)%	1.6	0.5
<i>Avapro</i> */ <i>Avalide</i> *	(94)%	(28)%	(89)%	(42)%	(69)%	(21)%	(65)%	(38)%	0.9	0.5
<i>Abilify</i> *	(1)%	9%	(1)%	4%	(1)%	4%	1%	5%	0.4	0.4
<i>Reyataz</i>	5%	(3)%	(6)%	1%	4%	(1)%	(3)%	2%	0.5	0.4
<i>Sustiva Franchise</i> <sup>(a)</sup>	10%	(2)%	(2)%	7%	13%	2%	(1)%	8%	0.5	0.4
<i>Baraclude</i>	20%	11%	12%	8%	17%	15%	11%	9%	0.5	0.5
<i>Erbix</i> * <sup>(b)</sup>	(1)%	8%	N/A	N/A	3%	2%	N/A	N/A	0.5	0.5
<i>Sprycel</i>	37%	66%	22%	27%	40%	63%	33%	19%	0.7	0.6
<i>Yervoy</i> <sup>(b)(d)</sup>	13%	N/A	N/A	N/A	77%	N/A	N/A	N/A	0.6	0.6
<i>Orencia</i> <sup>(c)</sup>	36%	12%	N/A	N/A	30%	11%	N/A	N/A	0.5	0.4
<i>Nulojix</i> <sup>(b)(d)</sup>		N/A	N/A	N/A	**	N/A	N/A	N/A	1.0	9.8
<i>Onglyza/Kombiglyze</i>	40%	**	42%	**	61%	**	56%	**	0.4	0.4
<i>Byetta</i> * <sup>(e)</sup>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.8	N/A
<i>Bydureon</i> * <sup>(e)</sup>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.7	N/A

(a) The *Sustiva Franchise* includes sales of *Sustiva*, as well as revenue of bulk efavirenz included in the combination therapy *Atripla*\*. The months on hand relates only to *Sustiva*.

(b)

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

*Erbitux\**, *Yervoy* and *Nulojix* are parenterally administered products and do not have prescription-level data as physicians do not write prescriptions for these products.

- (c) *Orencia* intravenous formulation is a parenterally administered product and does not have prescription-level data as physicians do not write prescriptions for this product. The *Orencia* subcutaneous formulation is not parenterally administered and was launched in the U.S. in the fourth quarter of 2011.
- (d) *Yervoy* and *Nulojix* were launched in the U.S. in the second quarter of 2011.
- (e) *Byetta\** and *Bydureon\** were acquired from our acquisition of Amylin in the third quarter of 2012.

\*\* Change in excess of 100%.

## **Table of Contents**

Pursuant to the Securities and Exchange Commission (SEC) Consent Order described in our 2011 Annual Report on Form 10-K, we monitor the level of inventory on hand in the U.S. wholesaler 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. 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. Below are U.S. products that had estimated levels of inventory in the distribution channel in excess of one month at September 30, 2012, and international products that had estimated levels of inventory in the distribution channel in excess of one month on hand at June 30, 2012:

*Plavix*\* had 1.6 months of inventory on hand in the U.S. compared to 2.2 months of inventory on hand at June 30, 2012 due to the loss of exclusivity in May 2012. We expect a gradual decrease in inventory on hand of *Plavix*\* to occur over the next few years as product in the wholesale distribution channel begins to be worked down or returned following the rapid, precipitous, and material decline in sales of *Plavix*\*. Levels of inventory on hand in the wholesale and retail distribution channels were considered in assessing the sales return reserves established as of September 30, 2012.

*Dafalgan*, an analgesic product sold principally in Europe, had 1.2 months of inventory on hand at direct customers compared to 1.0 month of inventory on hand at December 31, 2011. The level of inventory on hand was due to the ordering patterns of private pharmacists in France.

*Effergan*, an analgesic product sold principally in Europe, had 1.1 months of inventory on hand at direct customers at June 30, 2012 and December 31, 2011. The level of inventory on hand was due to the ordering patterns of private pharmacists in France.

*Luftal*, an antacid product, had 1.1 months of inventory on hand at direct customers compared to 1.9 months of inventory on hand at December 31, 2011. The level of inventory on hand decreased as inventory was worked down following the relaunch of an alternate form.

*Fervex*, a cold and flu product, had 3.8 months of inventory on hand internationally at direct customers compared to 5.3 months of inventory on hand at December 31, 2011. The level of inventory on hand decreased following the peak flu season, but remained above average due to the ordering pattern of pharmacists in France.

In the U.S., for all products sold exclusively through wholesalers or through distributors, we generally determined our months on hand estimates using inventory levels of product on hand and the amount of out-movement provided by our three largest wholesalers and our distributors. Our three largest wholesalers account 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 recordkeeping processes.

For our businesses 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 estimate such data, including using factors such 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. Factors that may affect our estimates include generic competition, seasonality of products, direct customer purchases in light of price increases, new product launches, new warehouse openings by direct customers, new customer stockings by direct customers and expected direct customer purchases for governmental bidding situations. As a result, 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, 2012 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.

**Table of Contents****Expenses**

Dollars in Millions	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	% Change	2012	2011	% Change
Cost of products sold	\$ 987	\$ 1,407	(30)%	\$ 3,535	\$ 4,231	(16)%
Marketing, selling and administrative	1,071	1,019	5%	3,077	2,987	3%
Advertising and product promotion	167	205	(19)%	585	672	(13)%
Research and development	951	973	(2)%	2,822	2,831	
Impairment charge for BMS-986094 intangible asset	1,830		N/A	1,830		N/A
Provision for restructuring	29	8	**	71	92	(23)%
Litigation expense/(recoveries)	50		N/A	(122)		N/A
Equity in net income of affiliates	(40)	(71)	44%	(150)	(215)	30%
Other (income)/expense	(50)	(26)	92%	(45)	(195)	(77)%
Total Expenses	\$ 4,995	\$ 3,515	42%	\$ 11,603	\$ 10,403	12%

\*\* Change in excess of 100%.

Cost of products sold decreased primarily due to lower sales volume following the loss of exclusivity of *Plavix*\* and *Avapro*\*/*Avalide*\* which resulted in lower royalties in connection with our Sanofi alliance and favorable foreign exchange partially offset by impairment charges in the second quarter of 2012 and higher amortization costs resulting from the Amylin acquisition (net of the amortization of Amylin collaboration proceeds). Cost of products sold as a percentage of net sales was 26.4% and 26.3% in the three months ended September 30, 2012 and 2011, respectively, and 26.3% and 26.8% in the nine months ended September 30, 2012 and 2011.

Impairment charges of \$147 million were recognized during the second quarter of 2012, of which \$120 million was related to a partial write-down to fair value of developed technology costs related to a non-key product acquired in the acquisition of ZymoGenetics, Inc. (ZymoGenetics). The developed technology impairment charge resulted from continued competitive pricing pressures and a reduction in the undiscounted projected cash flows to an amount less than the carrying value of the intangible asset at June 30, 2012. The impairment charge was calculated as the difference between the fair value of the asset based on the discounted value of the estimated future cash flows and the carrying value of the intangible asset. The remaining \$27 million impairment charge related to the abandonment of a manufacturing facility resulting from the outsourcing of a manufacturing process.

Marketing, selling and administrative expenses increased in 2012 primarily as a result of the Amylin acquisition (\$86 million, including \$67 million related to the accelerated vesting of stock options and restricted stock units), which was partially offset by a reduction in sales-related activities for *Plavix*\* and *Avapro*\*/*Avalide*\*. Marketing, selling and administrative expenses were also impacted by favorable foreign exchange.

Research and development expenses decreased primarily from the net impact of upfront, milestone, and other licensing payments and IPRD impairment charges. Refer to Specified Items included in Non-GAAP Financial Measures for amounts attributed to each period. Other licensing payments included \$88 million in the first quarter of 2011 associated with the amendment of an intellectual property license agreement for *Yervoy* prior to its approval. IPRD impairment charges relate to projects previously acquired in the Medarex, Inc. (Medarex) acquisition and Inhibitex acquisition (including \$45 million in the second quarter of 2012 related to FV-100, a nucleoside inhibitor for the reduction of shingles-associated pain) resulting from unfavorable clinical trial results and decisions to cease further development. Research and development expenses also included \$59 million of expenses related to the Amylin acquisition (including \$27 million related to the accelerated vesting of Amylin stock options and restricted stock units) and favorable foreign exchange.

A \$1.8 billion impairment charge was recognized when the development of BMS-986094 (formerly INX-189), a compound which we acquired as part of our acquisition of Inhibitex to treat hepatitis C, was discontinued in the interest of patient safety. See Item 1. Financial Statements Note 12. Goodwill and Other Intangible Assets for further information.

Provision for restructuring was primarily attributable to employee termination benefits.

Litigation recoveries, in the nine months ended September 30, 2012, included \$172 million for our share of the Apotex damages award concerning *Plavix*\* partially offset by increases in reserves.

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

Equity in net income of affiliates decreased due to the continued impact of generic competition on international *Plavix*\* net sales, the conversion of certain territories to opt-out markets and unfavorable foreign exchange.

**Table of Contents**

Other (income)/expense includes:

Dollars in Millions	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Interest expense	\$ 48	\$ 40	\$ 131	\$ 103
Investment income	(27)	(23)	(85)	(69)
Out-licensed intangible asset impairment			38	
Gain on sale of product lines, businesses and assets		(25)	(3)	(36)
Other income received from alliance partners, net	(96)	(44)	(225)	(107)
Pension curtailments and settlements	3	2	3	(1)
Litigation charges/(recoveries)		1	22	(105)
Product liability charges		10		36
Other	22	13	74	(16)
Other (income)/expense	\$ (50)	\$ (26)	\$ (45)	\$ (195)

Interest expense increased due to the termination of interest rate swap contracts in 2011 and higher borrowings in 2012.

Investment income included a \$10 million gain from the sale of auction rate securities in the first quarter of 2012.

Out-licensed intangible asset impairment charges are related to assets that were previously acquired in the Medarex and ZymoGenetics acquisitions and resulted from unfavorable clinical trial results and/or the abandonment of the programs. Similar charges of \$15 million were included in research and development in 2011.

Other income from alliance partners, net increased due to lower sales-based development royalties payable to Sanofi, a new supply agreement related to the Sanofi partnership and amortization of certain upfront, milestone and other licensing payments.

Product liability charges in 2011 were for additional reserves in connection with the breast implant settlement program.

Additional pension settlement charges may be recognized in the future, particularly with the U.S. pension plans due to a lower threshold resulting from the elimination of service costs and potentially higher lump sum payments.

Other includes acquisition-related expenses and losses on debt repurchases.

**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 significant and/or unusual nature, are evaluated on an individual basis. 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. 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 not to 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.



**Table of Contents**

Specified items were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Dollars in Millions, except per share data				
Accelerated depreciation, asset impairment and other shutdown costs	\$	\$ 19	\$ 147	\$ 60
Amortization of acquired Amylin intangible assets		91	91	
Amortization of Amylin collaboration proceeds		(46)	(46)	
Amortization of Amylin inventory adjustment		9	9	
<b>Cost of products sold</b>		54	201	60
Stock compensation from accelerated vesting of Amylin awards		67	67	
Process standardization implementation costs		3	16	19
<b>Marketing, selling and administrative</b>		70	83	19
Stock compensation from accelerated vesting of Amylin awards		27	27	
Upfront, milestone and other licensing payments		21	21	207
IPRD impairment			103	28
<b>Research and development</b>		48	151	235
<b>Impairment charge for BMS-986094 intangible asset</b>		1,830	1,830	
<b>Provision for restructuring</b>		29	71	92
<b>Litigation expense/(recoveries)</b>		50	(122)	
Gain on sale of product lines, businesses and assets			(12)	(12)
Acquisition-related expenses		29	42	
Litigation charges/(recoveries)			22	(102)
Product liability charges			10	36
Out-licensed intangible asset impairment			38	
Loss on debt repurchase		8	27	
<b>Other (income)/expense</b>		37	129	(78)
<b>Decrease to pretax income</b>		2,118	2,343	328
Income tax on items above		(722)	(791)	(99)
Specified tax benefit*				(71)
<b>Income taxes</b>		(722)	(791)	(170)
<b>Decrease to net earnings</b>	\$	\$ 1,396	\$ 1,552	\$ 158

\* The 2011 specified tax benefit relates to releases of tax reserves that were specified in prior periods.  
The reconciliations from GAAP to Non-GAAP were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Dollars in Millions, except per share data				
<b>Net Earnings/(Loss) Attributable to BMS GAAP</b>	\$	\$ 969	\$ 1,035	\$ 2,857
Earnings attributable to unvested restricted shares		(2)	(1)	(6)

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

Net Earnings/(Loss) used for Diluted EPS Calculation	GAAP	\$	(711)	\$	967	\$	1,034	\$	2,851
Net Earnings/(Loss)	GAAP	\$	(711)	\$	969	\$	1,035	\$	2,857
Less Specified Items			1,396		75		1,552		158
Net Earnings	Non-GAAP		685		1,044		2,587		3,015
Earnings attributable to unvested restricted shares					(2)		(1)		(6)
Net Earnings used for Diluted EPS Calculation	Non-GAAP	\$	685	\$	1,042	\$	2,586	\$	3,009
Average Common Shares Outstanding	Diluted	GAAP	1,666		1,715		1,697		1,717
Contingently convertible debt common stock equivalents			1						
Incremental shares attributable to share-based compensation plans			16						
Average Common Shares Outstanding	Diluted	Non-GAAP	1,683		1,715		1,697		1,717
Diluted Earnings/(Loss) Per Share	GAAP	\$	(0.43)	\$	0.56	\$	0.61	\$	1.66
Diluted EPS Attributable to Specified Items			0.84		0.05		0.91		0.09
Diluted Earnings/(Loss) Per Share	Non-GAAP	\$	0.41	\$	0.61	\$	1.52	\$	1.75

**Table of Contents**

Common stock equivalents were included in the calculation of GAAP earnings per share for all periods presented above except for the three months ended September 30, 2012, because they were anti-dilutive due to the loss.

**Income Taxes**

The effective tax benefit rate was 43.4% on the pretax loss during the third quarter of 2012 compared to an effective tax rate of 26.0% on pretax earnings during the third quarter of 2011. The effective income tax rates were 13.7% and 25.2% during the nine months ended September 30, 2012 and 2011, respectively. The overall tax benefit rate of 43.4% attributed to the pretax loss in the current quarter was due to the mix of earnings in low tax jurisdictions and pretax loss in the higher U.S. tax jurisdiction resulting from a \$1.8 billion intangible asset impairment charge. The impact of the impairment charge reduced the effective tax rate by 11 percentage points during the nine months ended September 30, 2012. The effective tax rate is typically lower than the U.S. statutory rate of 35% due to our decision to indefinitely reinvest the earnings for certain of our manufacturing operations in Ireland and Puerto Rico. See Item 1. Financial Statements Note 6. Income Taxes for further discussion.

**Noncontrolling Interest**

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 3. Alliances and Collaborations. The decrease in noncontrolling interest resulted from the May 2012 exclusivity loss of *Plavix*\* in the U.S and the March 2012 exclusivity loss of *Avapro*\*/*Avalide*\* 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,	
	2012	2011	2012	2011
Sanofi partnerships	\$ (7)	\$ 590	\$ 847	\$ 1,764
Other	3	5	12	17
Noncontrolling interest-pre-tax	(4)	595	859	1,781
Income taxes	(2)	209	317	609
Net earnings attributable to noncontrolling interest-net of taxes	\$ (2)	\$ 386	\$ 542	\$ 1,172

**FINANCIAL POSITION, LIQUIDITY, AND CAPITAL RESOURCES**

Our net cash position was as follows:

Dollars in Millions	September 30, 2012	December 31, 2011
Cash and cash equivalents	\$ 1,503	\$ 5,776
Marketable securities current	1,427	2,957
Marketable securities non-current	3,698	2,909
Total cash, cash equivalents and marketable securities	6,628	11,642
Short-term borrowings and current portion of long-term debt	(751)	(115)
Long-term debt	(6,608)	(5,376)
Net cash/(debt) position	\$ (731)	\$ 6,151
Working capital	\$ 1,083	\$ 7,538

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

The reduction in net cash and working capital during 2012 resulted primarily from net cash used in connection with the acquisitions of Amylin and Inhibitex. Cash, cash equivalents and marketable securities held in the U.S. were approximately \$2.0 billion at September 30, 2012. Most of the remaining \$4.6 billion is held primarily in low-tax jurisdictions and is attributable to earnings that are expected to be indefinitely reinvested offshore. Cash repatriations are subject to restrictions in certain jurisdictions and may be subject to withholding and additional U.S. income taxes. During the third quarter of 2012, we began to issue commercial paper to meet near-term domestic liquidity requirements following the Amylin acquisition. The average commercial paper outstanding during the three months ended September 30, 2012 was \$526 million with a weighted-average interest rate of 0.15%. There were no month-end commercial paper borrowings outstanding during the third quarter of 2012. We may continue to issue commercial paper to meet domestic liquidity requirements in the future.

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.

**Table of Contents**

In July 2012, BMS entered into 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. This revolving credit facility is in addition to the Company's existing \$1.5 billion five-year revolving credit facility. There are no financial covenants under either facility. There were no borrowings outstanding under either revolving credit facility at September 30, 2012 and December 31, 2011.

In July 2012, in connection with the Amylin acquisition, BMS issued \$2.0 billion of senior unsecured notes in a registered public offering consisting of \$750 million in aggregate principal amount of 0.875% Notes due 2017, \$750 million in aggregate principal amount of 2.000% Notes due 2022 and \$500 million in aggregate principal amount of 3.250% Notes due 2042.

In August 2012, BMS completed its acquisition of Amylin for an aggregate purchase price of \$5.3 billion. BMS also assumed Amylin's net debt and a contractual payment obligation to Eli Lilly & Company, together totaling \$2.0 billion (substantially all of which was repaid during the three months ended September 30, 2012). The acquisition was financed through the use of existing cash balances, the issuance of commercial paper and long-term debt borrowings described above.

BMS received preliminary proceeds of \$3.8 billion from AstraZeneca as consideration for entering into the collaboration during the current period, including \$190 million which is recorded in accrued expenses and expected to be reimbursed back to AstraZeneca during the fourth quarter. The net proceeds that BMS will receive from AstraZeneca as consideration for entering into the collaboration are subject to certain other adjustments including the right to receive an additional \$135 million when AstraZeneca exercises its option for equal governance rights.

As discussed in Strategy above, we lost exclusivity in the U.S. for our largest product, *Plavix*\*, in May 2012 which has resulted in a rapid, precipitous, 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.

Although not material, certain European government-backed entities with a higher risk of default were identified by monitoring economic factors including credit ratings, credit-default swap rates and debt-to-gross domestic product ratios in addition to entity specific factors. Our credit exposure to government-backed trade receivables in Greece, Portugal, Italy and Spain is limited by factoring receivables, deferring revenues until the collection of cash and accruing additional bad debt reserves. Our net receivables in these countries were approximately \$233 million at September 30, 2012, of which approximately 75% was from government-backed entities. During 2012, counterparties in our factoring arrangements suspended factoring of receivables from Spanish and Portuguese government-backed entities and limited factoring of receivables from certain Italian government-backed entities. Sales of trade receivables in Italy, Portugal and Spain were \$250 million in 2012 and \$384 million in 2011. Our credit exposures in Europe may increase in the future due to further reductions in our factoring arrangements and the ongoing sovereign debt crisis. Sales of receivables in Japan were \$484 million in 2012 and \$422 million in 2011. Our sales agreements do not allow for recourse in the event of uncollectibility and we do not retain interest to the underlying assets once sold.

We continue to manage our operating cash flows with initiatives designed to improve working capital items that are most directly affected by changes in sales volume, such as receivables, inventories, and accounts payable. During 2012, the following changes in receivables, inventories and accounts payable resulted primarily from the rapid reduction of *Plavix*\* sales, the acquisition of Amylin and timing of expenditures in the ordinary course of business. The following summarizes these components expressed as a percentage of trailing twelve months' net sales:

Dollars in Millions	September 30, 2012	% of Trailing Twelve Month Net Sales	December 31, 2011	% of Trailing Twelve Month Net Sales
Net trade receivables	\$ 1,734	9.2%	\$ 2,250	10.6%
Inventories	1,697	9.0%	1,384	6.5%
Accounts payable	(2,085)	(11.0)%	(2,603)	(12.2)%
Total	\$ 1,346	7.1%	\$ 1,031	4.9%

**Table of Contents***Credit Ratings*

Moody's Investors Service long-term and short-term credit ratings are currently A2 and Prime-1, respectively, and their long-term credit outlook remains stable. Standard & Poor's (S&P) long-term and short-term credit ratings are currently A+ and A-1+, respectively, and their long-term credit outlook remains stable. S&P upgraded our short-term credit rating from A-1 to A-1+ in May 2012. Fitch Ratings (Fitch) long-term and short-term credit ratings are currently A and F1, respectively, and their long-term credit outlook remains negative. Fitch lowered our long-term credit rating from A+ to A in July 2012. 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,	
	2012	2011
Cash flow provided by/(used in):		
Operating activities	\$ 6,105	\$ 3,272
Investing activities	(7,004)	(1,932)
Financing activities	(3,375)	(1,903)
<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. Preliminary proceeds of \$3.8 billion were received in 2012 from AstraZeneca as consideration for entering into the Amylin collaboration.

Investing Activities

Cash was used to fund the acquisition of Amylin for \$5.0 billion and Inhibitex for \$2.5 billion in 2012.

Net sales and maturities of marketable securities of \$883 million in 2012 were primarily attributed to the Amylin acquisition. Net purchases of marketable securities of \$1.5 billion in 2011 were primarily attributable to the timing of investments in time deposits and highly-rated corporate debt securities with maturities greater than 90 days.

Other investing activities included litigation recoveries of \$102 million in 2011.

Financing Activities

Dividend payments were \$1.7 billion in both 2012 and 2011. Dividends declared per common share totaled \$1.02 for the nine months ended September 30, 2012 and \$0.99 for the nine months ended September 30, 2011. Dividend decisions are made on a quarterly basis by our Board of Directors.

Proceeds of \$2.0 billion were received from the issuance of senior unsecured notes.

Repayments of debt assumed in the Amylin acquisition were \$2.0 billion.

Management periodically evaluates potential opportunities to repurchase certain debt securities and terminate certain interest rate swap contracts prior to their maturity. Cash outflows related to the repurchase of debt were \$109 million in 2012 and \$78 million in 2011.

In June 2012, the Board of Directors increased its authorization for the repurchase of common stock by \$3.0 billion. There is \$2.3 billion of common stock repurchase capacity remaining as of September 30, 2012. Common stock was repurchased in the amount of

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

\$1.9 billion in 2012 and \$859 million in 2011.

Proceeds from stock option exercises were \$397 million in 2012 and \$365 million in 2011 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.

## **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 2011 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 this report and in the 2011 Annual Report on Form 10-K, 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 2011 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.

In August 2012, Bristol-Myers Squibb Company (the Company) completed its acquisition of Amylin Pharmaceuticals, Inc. (Amylin) which represents a material change in the internal control over financial reporting since management's last assessment of effectiveness. Amylin's operations utilize separate information and accounting systems and processes and it was not possible to complete an evaluation and review of the internal controls over financial reporting since the completion of the acquisition. Management intends to complete its assessment of the effectiveness of internal control over financial reporting for Amylin within one year of the acquisition date. Excluding the Amylin acquisition, there were no changes in our internal control over financial reporting that have or are reasonably likely to materially affect the Company's internal control over financial reporting.

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

Information pertaining to legal proceedings can be found in Item 1. Financial Statements Note 17. Legal Proceedings and Contingencies, to the interim consolidated financial statements, and is incorporated by reference herein.

**Item 1A. RISK FACTORS**

There have been no material changes from the risk factors disclosed in the Company's 2011 Annual Report on Form 10-K.

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

The following table summarizes the surrenders of our equity securities during the nine months ended September 30, 2012:

			Total Number of Shares Purchased as	Approximate Dollar Value of Shares that
Period	Total Number of Shares Purchased <sup>(a)</sup>	Average Price Paid per Share <sup>(a)</sup>	Part of Publicly Announced Plans or Programs <sup>(b)</sup>	May Yet Be Purchased Under the Plans or Programs <sup>(b)</sup>
Dollars in Millions, Except Per Share Data				
January 1 to 31, 2012	5,482,912	\$ 33.35	5,477,200	\$ 1,005
February 1 to 29, 2012	4,372,415	\$ 32.22	4,360,900	\$ 864
March 1 to 31, 2012	1,750,695	\$ 32.51		\$ 864
Three months ended March 31, 2012	11,606,022		9,838,100	
April 1 to 30, 2012	5,613,737	\$ 33.42	5,606,834	\$ 677
May 1 to 31, 2012	5,876,829	\$ 33.14	5,858,755	\$ 483
June 1 to 30, 2012	4,912,492	\$ 34.52	4,906,631	\$ 3,313

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

Three months ended June 30, 2012	16,403,058		16,372,220	
July 1 to 31, 2012	6,304,273	\$ 35.30	6,299,644	\$ 3.091
August 1 to 31, 2012	16,960,023	\$ 32.36	16,949,219	\$ 2.543
September 1 to 30, 2012	8,052,099	\$ 33.36	8,045,000	\$ 2.274
Three months ended September 30, 2012	31,316,395		31,293,863	
Nine months ended September 30, 2012	59,325,475		57,504,183	

- (a) 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 June 2012, the Board of Directors increased its authorization for the repurchase of common stock by \$3.0 billion. The repurchase program does not have an expiration date and is expected to take place over a couple of 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>
10a.	Master Restructuring Agreement by and between Bristol-Myers Squibb Company and Sanofi dated as of September 27, 2012.
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, 2012, 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.

Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Commission. The omitted information has been filed separately with the Commission pursuant to the Company's application for confidential treatment.

\* Indicates, in this Form 10-Q, brand names of products, which are registered trademarks not solely owned by the Company or its subsidiaries. *Byetta*, *Bydureon*, and *Symlin* are trademarks of Amylin Pharmaceuticals, LLC and AstraZeneca Pharmaceuticals LP; *Erbix* 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; *Reglan* is a trademark of Alaven Pharmaceutical LLC; *Humira* is a trademark of Abbott Laboratories; 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 24, 2012

By: /s/ Lamberto Andreotti  
Lamberto Andreotti  
*Chief Executive Officer*

Date: October 24, 2012

By: /s/ Charles Bancroft  
Charles Bancroft  
*Executive Vice President and Chief Financial Officer*

48