# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# **FORM 10-Q**

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For the quarterly period ended June 30, 2015

□ 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 001-36782

# Baxalta BAXALTA INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	47-1869689
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
One Baxter Parkway, Deerfield, Illinois	60015
(Address of principal executive offices)	(Zip Code)

224-940-2000 (Registrant's telephone number, including area code)

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 such filing requirements for the past 90 days.

Yes□ No⊠ \*

\* The registrant became subject to such requirements on June 9, 2015 and it has filed all reports so required since that date.

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 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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer 
Accelerated filer 
Non-accelerated filer 
Smaller reporting company 
Cont check if a 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 🗵

The number of shares of the registrant's Common Stock, par value \$0.01 per share, outstanding as of July 31, 2015 was 676,968,543 shares.

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# PART I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# BAXALTA INCORPORATED CONDENSED COMBINED BALANCE SHEETS (UNAUDITED)

	June 30,	December 31,
(in millions)	2015	2014
Assets		
Current Assets:		
Cash and equivalents	\$ 2,091	\$ —
Accounts and other current receivables, net	1,083	960
Inventories	2,114	1,960
Other current assets	381	388
Total current assets	5,669	3,308
Property, Plant and Equipment, Net	4,531	4,192
Other Assets:		
Goodwill	636	565
Other intangible assets, net	608	459
Other	360	260
Total other assets	1,604	1,284
Total assets	\$11,804	\$8,784
Liabilities and Equity		
Current Liabilities:		
Accounts payable	\$ 397	\$ 484
Accrued liabilities	965	1,160
Total current liabilities	1,362	1,644
Long-term debt and capital lease obligations	5,245	275
Other long-term liabilities	1,471	1,118
Commitments and Contingencies		
Equity:		
Net parent company investment	4,474	6,180
Accumulated other comprehensive loss	(748)	(433)
Total equity	3,726	5,747
Total liabilities and equity	\$11,804	\$8,784

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

# BAXALTA INCORPORATED CONDENSED COMBINED STATEMENTS OF INCOME (UNAUDITED)

	Three months ended June 30,		Six mont June	
(in millions, except per share data)	2015	2014	2015	2014
Net sales	\$ 1,429	\$1,452	\$ 2,790	\$ 2,781
Cost of sales	501	599	1,072	1,158
Gross margin	928	853	1,718	1,623
Selling, general and administrative expenses	323	242	606	464
Research and development expenses	240	166	396	329
Net interest expense	3		3	—
Other (income) expense, net	(20)	30	(8)	7
Income from continuing operations before income taxes	382	415	721	823
Income tax expense	98	97	175	196
Net income from continuing operations	284	318	546	627
(Loss) income from discontinued operations, net of tax	(4)	52	6	101
Net income	\$ 280	\$ 370	\$ 552	\$ 728
Income from continuing operations per common share Basic Diluted	\$ 0.42 \$ 0.42	\$ 0.47 \$ 0.47	\$ 0.81 \$ 0.80	\$ 0.93 \$ 0.92
(Loss) income from discontinued operations per common share Basic	\$ (0.01)	\$ 0.08	\$ 0.01	\$ 0.15
Diluted	\$ (0.01)	\$ 0.08	\$ 0.01	\$ 0.15
Net income per common share Basic	\$ 0.41	\$ 0.55	\$ 0.82	\$ 1.08
Diluted Weighted-average number of common shares outstanding Basic	<u>\$ 0.41</u> 676	\$ 0.55 676	<u>\$ 0.81</u> 676	\$ 1.07 676
Diluted	681	681	681	681

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

# BAXALTA INCORPORATED CONDENSED COMBINED STATEMENTS OF COMPREHENSIVE INCOME (UNAUDITED)

	Three months ended June 30,		Six montl June	
(in millions)	2015	2014	2015	2014
Net income	\$ 280	\$ 370	\$ 552	\$ 728
Other comprehensive income (loss), net of tax:				
Currency translation adjustments, net of tax benefit of \$2 and less than \$1 for the three months ended June 30, 2015 and 2014, respectively, and \$5 and \$1 for the six months ended June 30, 2015 and 2014, respectively	125	(12)	(228)	4
Pension and other employee benefits, net of tax benefit (expense) of \$3 and less than (\$1) for the three months ended June 30, 2015 and 2014, respectively, and less than \$1 and (\$1) for the six months ended June 30, 2015 and 2014, respectively	(9)	2	(1)	4
Available-for-sale securities, net of tax (expense) benefit of (\$7) and \$6 for the three months ended June 30, 2015 and 2014, respectively, and (\$11) and less than (\$1) for the six months ended June 30, 2015 and 2014, respectively	10	(13)	15	(9)
Hedging activities, net of tax (expense) of (\$29) and (\$9) for the three and six months ended June 30, 2015, respectively	50		15	_
Total other comprehensive income (loss), net of tax	176	(23)	(199)	(1)
Comprehensive income	\$ 456	\$ 347	\$ 353	\$ 727

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

# BAXALTA INCORPORATED CONDENSED COMBINED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Six montl June	
(in millions)	2015	2014
Cash flows from operations		
Net income	\$ 552	\$ 728
Adjustments		
Depreciation and amortization	116	100
Stock compensation	21	15
Business optimization items	(7)	14
Realized excess tax benefits from stock issued under employee benefit plans	(5)	(6)
Net periodic pension benefit and OPEB cost	33	26
Other	39	25
Changes in balance sheet items		
Accounts and other current receivables, net	(163)	(35)
Inventories	(249)	(204)
Accounts payable	(19)	23
Accrued liabilities	(116)	(410)
Business optimization payments	(8)	(23)
Other	(3)	(39)
Net cash provided from operations	191	214
Cash flows from investing activities		
Capital expenditures	(583)	(439)
Acquisitions, net of cash acquired	(228)	(85)
Other investing activities	(29)	5
Net cash used for investing activities	(840)	(519)
Cash flows from financing activities		
Net proceeds from issuance of long-term debt	4,941	
Net transactions with Baxter	(2,210)	306
Other financing activities	(1)	(1)
Net cash provided from financing activities	2,730	305
Effect of foreign exchange rate changes on cash and equivalents	10	
Change in cash and equivalents	2,091	
Cash and equivalents at beginning of period		
Cash and equivalents at end of period	\$2,091	\$ —

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

# BAXALTA INCORPORATED CONDENSED COMBINED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

		Accu	mulated Other C	omprehensive	Income (Loss)	)	
	Net Parent	Foreign	Pension and Other	Available-			
(in millions)	Company Investment	Currency Translation	Employee Benefits	for-sale Securities	Hedging Activities	Total	Total Equity
Balance as of December 31, 2013	\$ 5,243	\$ —	\$ (51)	\$ (13)	\$ —	\$ (64)	\$5,179
Net income	728	—			_	—	728
Transfers from Baxter, net	308	—				—	308
Foreign currency translation related adjustments		4				4	4
Pension and other employee benefits obligations		—	4			4	4
Available-for-sale securities		—		(9)		(9)	(9)
Hedging activities		—				—	
Balance as of June 30, 2014	\$ 6,279	\$ 4	\$ (47)	\$ (22)	\$ —	\$ (65)	\$6,214
Balance as of December 31, 2014	\$ 6,180	\$ (387)	\$ (52)	\$7	\$(1)	\$(433)	\$5,747
Net income	552	—	—		—	—	552
Transfers to Baxter, net	(2,374)	—				—	(2,374)
Foreign currency translation related adjustments		(228)	—			(228)	(228)
Pension and other employee benefits obligations	144	—	(145)			(145)	(1)
Available-for-sale securities		—	—	15		15	15
Hedging activities	(28)				43	43	15
Balance as of June 30, 2015	\$ 4,474	\$ (615)	\$(197)	\$ 22	\$ 42	\$(748)	\$3,726

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

#### BAXALTA INCORPORATED NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 1 BACKGROUND AND BASIS OF PREPARATION

#### Background

Baxalta Incorporated and its subsidiaries (Baxalta or the company) is a global biopharmaceutical company focused on developing and marketing innovative biopharmaceutical products that seek to address unmet medical needs across many disease areas including hematology, immunology and oncology.

Baxalta was incorporated in Delaware on September 8, 2014. The company separated from Baxter International Inc. (Baxter or Parent) on July 1, 2015, becoming an independent company as a result of a pro rata distribution by Baxter of 80.5% of Baxalta's common stock to Baxter's shareholders. Baxter retained a 19.5% ownership stake in Baxalta immediately following the distribution. Baxter's Board of Directors approved the distribution of its shares of Baxalta on June 5, 2015. Baxalta's Registration Statement was declared effective by the U.S. Securities and Exchange Commission (SEC) on June 9, 2015. On July 1, 2015, Baxter's shareholders of record as of the close of business on June 17, 2015 received one share of Baxalta common stock for every one share of Baxter's common stock held as of the record date. Baxalta common stock began trading "regular way" under the ticker symbol "BXLT" on the New York Stock Exchange on July 1, 2015.

In connection with the separation, the company entered into a manufacturing and supply agreement and a transition services agreement with Baxter. Under the terms of the manufacturing and supply agreement, Baxalta will manufacture certain products and materials and sell them to Baxter at an agreed-upon price reflecting Baxalta's cost plus a mark-up for certain products and materials. As a result, the company will record revenues associated with the manufacturing and supply agreement that were not reported in periods prior to the separation. On a pro forma basis, the manufacturing and supply agreement would have resulted in revenues of \$40 million and \$37 million during the three months ended June 30, 2015 and 2014, respectively, and \$82 million and \$81 million during the six months ended June 30, 2015 and 2014, respectively, had it been in effect beginning January 1, 2014. The company will also purchase products and materials from Baxter at cost plus a mark-up. The costs associated with the manufacturing and supply agreement would not have contributed a significant amount of gross margin or net income to the company's results of operations in the periods presented.

Under the terms of the transition services agreement, Baxalta and Baxter will provide various services to each other on an interim, transitional basis. The services provided by Baxter to Baxalta include certain finance, information technology, human resources, quality, supply chain and other administrative services and functions, and will generally be provided on a cost-plus basis. The services generally extend for approximately 2 years following the separation except for certain information technology services that extend for 3 years following the separation.

The company and Baxter also entered into a separation and distribution agreement, tax matters agreement, an employee matters agreement and a long-term services agreement in connection with the separation.

On July 28, 2015, Baxalta's Board of Directors declared a quarterly cash dividend of \$0.07 per share of common stock. The quarterly dividend will be paid on October 1, 2015, to shareholders of record as of the close of business on September 4, 2015. On July 28, 2015, Baxalta's Board of Directors also approved a share repurchase authorization which will allow the company to purchase up to \$1 billion of its common stock.

#### **Basis of Preparation**

The accompanying condensed combined interim financial statements have been prepared on a standalone basis and are derived from Baxter's consolidated financial statements and accounting records as if the former biopharmaceuticals business of Baxter had been part of Baxalta for all periods presented. The unaudited condensed combined interim financial statements reflect the company's financial position, results of operations and cash flows as the business was operated as part of Baxter prior to the distribution, in conformity with generally accepted accounting principles (GAAP) in the United States.

These unaudited condensed combined interim financial statements include the attribution of certain assets and liabilities that have historically been held at the Baxter corporate level but which are specifically identifiable or attributable to the company. All intercompany transactions and accounts within the company have been eliminated. All transactions between the company and Baxter are considered to be effectively settled in the unaudited condensed combined interim financial statements at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the condensed combined statements of cash flows as a financing activity and in the condensed combined balance sheets as net parent company investment.

These unaudited condensed combined interim financial statements include an allocation of expenses related to certain Baxter corporate functions, including senior management, legal, human resources, finance, treasury, information technology, and quality assurance. These expenses have been allocated to the company based on direct usage or benefit where specifically identifiable, with the remainder allocated primarily on a pro rata basis of revenue, headcount, square footage, or other measures. The company considers the expense methodology and results to be reasonable for all periods presented. However, the allocations may not be indicative of the actual expense that would have been incurred had the company operated as an independent, publicly traded company for the periods presented.

During the periods presented, Baxalta's employees participated in various benefit and share-based compensation plans maintained by Baxter. A portion of the cost of those plans was included in the company's financial statements. However, the condensed combined balance sheets do not include any equity related to share-based compensation plans. Prior to June 30, 2015, the company's condensed combined balance sheets did not include net pension obligations, with the exception of those related to certain plans in Austria. Refer to Note 10 and Note 13 for further description of the accounting for retirement and other benefit programs and share-based compensation, respectively.

The company's equity balance in these unaudited condensed combined interim financial statements represents the excess of total assets over total liabilities, including the due to/from balances between the company and Baxter (net parent company investment) and accumulated other comprehensive income (AOCI). Net parent company investment is primarily impacted by contributions and distributions from or to Baxter, which are the result of treasury activities and net funding provided by or distributed to Baxter, including a \$4 billion cash distribution made by Baxalta to Baxter during the three months ended June 30, 2015.

The unaudited condensed combined interim financial statements of the company have been prepared pursuant to the rules and regulations of the SEC. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. The year-end condensed balance sheet data was derived from the audited combined financial statements, but does not include all disclosures required by GAAP. These unaudited interim condensed combined financial statements should be read in conjunction with the combined financial statements and notes contained in the company's Information Statement included as Exhibit 99.1 to the company's effective Registration Statement on Form 10, as filed with the SEC on June 5, 2015 (Information Statement).

In the opinion of management, the unaudited interim condensed combined financial statements reflect all adjustments necessary for a fair statement of the interim periods. All such adjustments, unless otherwise noted herein, are of a normal, recurring nature. The results of operations for the interim period are not necessarily indicative of the results of operations to be expected for the full year.

### **New Accounting Standards**

In July 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory, which clarifies that inventory should be measured at the lower of cost and net realizable value. ASU 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. ASU 2015-11 will be effective for the company beginning on January 1, 2016, and prospective application is required. Early adoption is permitted. The company is currently evaluating the impact of adopting the standard on its combined financial statements.

In April 2015, the FASB issued ASU No. 2015-05, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement, which provides guidance to customers about how to account for cloud computing arrangements when such arrangements include software licenses. ASU No. 2015-05 will be effective for the company beginning on January 1, 2016. Early adoption is permitted. The standard may be applied retrospectively or prospectively. The company is currently evaluating the impact of adopting the standard on its combined financial statements.

In April 2015, the FASB issued ASU No. 2015-03, Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts. ASU No. 2015-03 will be effective for the company beginning on January 1, 2016, and retrospective application is required. Early adoption is permitted, and the company has adopted Accounting Standard Codifications ASC No. 2015-03 effective June 30, 2015. Refer to Note 7 for additional information.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU 2014-09), which amends the existing accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled to when products are transferred to customers. In July 2015, the FASB voted to approve a one-year deferral on the original effective date of January 1, 2017; therefore ASU No. 2014-09 will be effective for the company beginning on January 1, 2018. Early adoption is permitted as of the original effective date. The new revenue standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. The company is currently evaluating the impact of adopting the new revenue standard on its combined financial statements.

In April 2014, the FASB issued ASU 2014-08, Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity (ASU 2014-08), which amends the definition of a discontinued operation in ASC 205-20 and provides additional requirements for the entities with its disposal transaction to qualify as a discontinued operation. ASU 2014-08 is effective prospectively for all disposals beginning on or after December 15, 2014 (with early adoption permitted). The company did not early adopt the new guidance and it was effective for the company for periods beginning with its first interim period ending March 31, 2015. ASU 2014-08 did not have a material impact on the combined financial statements upon adoption.

#### **Subsequent Events**

The company has evaluated subsequent events and has reflected accounting and disclosure requirements related to material subsequent events in its condensed combined financial statements and related notes.

#### NOTE 2 SUPPLEMENTAL FINANCIAL INFORMATION

#### Inventories

		December 31,
(in millions)	June 30, 2015	2014
Raw material	\$ 498	\$ 524
Work in process	1,045	976
Finished goods	571	460
Total inventories	\$2,114	\$1,960

#### Accrued Liabilities

		December 31,
	June 30,	
(in millions)	2015	2014
Income taxes payable and deferred taxes	\$ 179	\$ 356
Employee compensation and withholdings	184	210
Property, payroll and certain other taxes	62	78
Accrued rebates	245	245
Other	295	271
Total accrued liabilities	\$ 965	\$1,160

#### **Other Long-Term Liabilities**

		December 31,
	June 30,	
(in millions)	2015	2014
Pension and other employee benefits	\$ 504	\$ 177
Contingent payment liabilities	496	518
Long-term deferred income taxes	405	357
Other	66	66
Total other long-term liabilities	\$1,471	\$1,118

#### NOTE 3 EARNINGS PER SHARE

On July 1, 2015, Baxter distributed approximately 544 million shares of Baxalta common stock to its shareholders and retained an additional 132 million shares. The computation of basic earnings per common share (EPS) for all periods disclosed was calculated using the shares distributed and retained by Baxter on July 1, 2015 totaling 676 million. The weighted average number of shares outstanding for diluted EPS for the periods prior to separation also include 5 million of diluted common share equivalents for stock

options, restricted stock units (RSUs), and performance share units (PSUs) as these share-based awards were previously issued by Baxter and outstanding at the time of separation and were assumed by Baxalta following the separation.

The numerator for both basic and diluted EPS is net income, net income from continuing operations, or (loss) income from discontinued operations, net of tax.

The following is a reconciliation of basic shares to diluted shares.

	Three months ended June 30,		Six months ended June 30,	
(in millions)	2015	2014	2015	2014
Basic shares	676	676	676	676
Effect of dilutive shares	5	5	5	5
Diluted shares	681	681	681	681

The computation of diluted EPS excluded 19 million equity awards for the periods presented because their inclusion would have had an antidilutive effect on diluted EPS as of July 1, 2015.

# NOTE 4 ACQUISITIONS AND COLLABORATIONS

#### Acquisitions

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#### SuppreMol Acquisition

In March 2015, the company acquired all of the outstanding shares of SuppreMol GmbH (SuppreMol), a privately held biopharmaceutical company based in Germany. Through the acquisition, the company has acquired SuppreMol's early-stage pipeline of treatment options for autoimmune and allergic diseases, as well as its operations in Munich, Germany. The acquired investigational treatments will complement and build upon the company's immunology portfolio and offer an opportunity to expand into new areas with significant market potential and unmet medical needs in autoimmune diseases.

The following table summarizes the fair value of consideration transferred and the recognized amounts of the assets acquired and liabilities assumed as of the acquisition date.

(in millions)	
Consideration transferred	
Cash, net of cash acquired	\$228
Fair value of consideration transferred	\$228
Assets acquired and liabilities assumed	
Other intangible assets	\$179
Other assets (including deferred tax assets of \$17)	19
Long-term liabilities (including deferred tax liabilities of \$52)	(53)
Total identifiable net assets	145
Goodwill	83
Total assets acquired and liabilities assumed	\$228

While the valuation of the assets acquired and liabilities assumed is substantially complete, measurement period adjustments may be recorded in the future as the company finalizes its fair value estimates. Pro forma financial information has not been included because the acquisition was not material to the company's condensed combined financial statements.

The company allocated \$179 million of the total consideration to acquired-in-process research and development (IPR&D), which is being accounted for as an indefinite-lived intangible asset. The acquired IPR&D primarily relates to SuppreMol's lead candidate SM-101, an investigational immunoregulatory treatment, which had completed Phase IIa studies at the time of the acquisition. This project is expected to be completed in approximately 5 years. The value of the IPR&D was calculated using cash flow projections adjusted for the inherent technical, regulatory, commercial and obsolescence risks in such activities, discounted at a rate of 20%. Additional research and development (R&D) will be required prior to regulatory approval, and as of the acquisition date, incremental R&D costs were projected to be in excess of \$400 million. The goodwill, which is not deductible for tax purposes, includes the value of potential future technologies as well as the overall strategic benefits of the acquisition to the company.

#### **Oncaspar Acquisition**

In July 2015, the company completed its acquisition of the Oncaspar (pegaspargase) product portfolio from Sigma-Tau Finanziaria S.p.A, a privately held biopharmaceutical company based in Italy, for approximately \$900 million before transaction adjustments. Through the acquisition, the company gained the marketed biologic treatment Oncaspar, the investigational biologic calaspargase pegol, and an established oncology infrastructure with clinical and sales resources. Oncaspar is a first-line biologic used as part of a chemotherapy regimen to treat patients with acute lymphoblastic leukemia. It is currently marketed in the United States, Germany, Poland and certain other countries and has approximately \$100 million in annual sales. The acquisition will be accounted for as a business combination in the third quarter of 2015. The initial accounting for the transaction is incomplete, pending completion of valuations for the assets acquired and liabilities assumed.

#### Collaborations

#### CTI BioPharma Corp.

In June 2015, the company entered into an amendment with CTI BioPharma Corp (CTI BioPharma). Pursuant to the amendment, the company paid \$32 million to CTI BioPharma relating to two contingent milestone payments included in the original agreement. The company obtained certain additional rights relating to manufacturing and supply, and CTI BioPharma committed to spend a specified amount on the development of pacritinib through February 2016, with failure to do so resulting in payments to the company equal to the deficiency. Refer to the company's audited combined financial statements contained in its Information Statement for additional information regarding the collaboration agreement with CTI BioPharma.

#### SFJ Pharmaceuticals Group

In June 2015, the company entered into an agreement with SFJ Pharmaceuticals Group (SFJ) relating to adalimumab (BAX 923) (formerly known as M923/BAX 2923), whereby SFJ will fund up to \$200 million of specified development costs related to the company's BAX 923 program, in exchange for payments in the event the product obtains regulatory approval in the United States or Europe. The terms of the agreement include funding limitations of up to \$50 million for incurred costs through Phase I development and cumulative spending caps in six month intervals through December 31, 2017. The contingent success payments total approximately 5.5 times the incurred development costs and are payable in annual installments over an approximate eight-year period following the dates of regulatory approval. The development funding from SFJ is being recognized as an offset to R&D expenses as incurred because there is substantive and genuine transfer of risk to SFJ. The R&D expense offset for the three months ended June 30, 2015 totaled \$9 million.

#### Milestone Payments to Collaboration Partners

Milestone payments to collaboration partners classified as R&D expenses were \$87 million and \$35 million in the three months ended June 30, 2015 and 2014, respectively, and \$87 million and \$60 million in the six months ended June 30, 2015 and 2014, respectively.

## Unfunded Contingent Payments

At June 30, 2015, the company's unfunded contingent milestone payments associated with all of its collaborative arrangements totaled \$2.2 billion. This total excludes contingent royalty and profit-sharing payments. Based on the company's projections, any contingent payments made in the future will be more than offset by the estimated net future cash flows relating to the rights acquired for those payments.

# NOTE 5 GOODWILL AND OTHER INTANGIBLE ASSETS

#### Goodwill

The following is a summary of the activity in goodwill:

(in millions)	
December 31, 2014	\$565
Additions	83
Currency translation adjustment (CTA)	(12)
June 30, 2015	\$636

The additions in the six months ended June 30, 2015 relate to the acquisition of SuppreMol. See Note 4 for further information.

As of June 30, 2015, there were no accumulated goodwill impairment losses.

#### Other intangible assets, net

The following is a summary of the company's other intangible assets:

(in millions)	Developed technology, including patents	Other amortized intangible assets	Indefinite-lived intangible assets	Total
June 30, 2015				
Gross other intangible assets	\$ 426	\$ 26	\$322	\$ 774
Accumulated amortization	(141)	(25)		(166)
Other intangible assets, net	\$ 285	\$ 1	\$322	\$ 608
December 31, 2014				
Gross other intangible assets	\$ 440	\$ 29	\$149	\$ 618
Accumulated amortization	(133)	(26)		(159)
Other intangible assets, net	\$ 307	\$ 3	\$149	\$ 459

Intangible asset amortization expense was \$8 million and \$4 million in the three months ended June 30, 2015 and 2014, respectively, and \$16 million and \$8 million for the six months ended June 30, 2015 and 2014, respectively. The anticipated annual amortization expense for definite-lived intangible assets recorded as of June 30, 2015 is \$29 million in 2015, \$26 million in 2016, \$23 million in 2017, \$22 million in 2018, \$19 million in 2019 and \$19 million in 2020. The increase in other intangible assets, net from the IPR&D acquired in the acquisition of SuppreMol during the first six months of 2015 was partially offset by amortization expense and CTA.

# NOTE 6 BUSINESS OPTIMIZATION CHARGES

The company has historically participated in business optimization plans initiated by Baxter. The company's total charges (benefits) related to these plans are presented below:

		Three months ended June 30,		s ended 30,
(in millions)	2015	2014	2015	2014
Charges	\$ 3	\$ —	\$ 3	\$16
Reserve adjustments	_	(2)	(10)	(2)
Total business optimization expenses (benefits)	3	(2)	(7)	14
Discontinued operations	_	_	_	(8)
Business optimization expenses (benefits) in continuing operations	\$ 3	\$ (2)	\$ (7)	\$6

For the six months ended June 30, 2015, the company adjusted its previously estimated business optimization charges due to changes in assumptions resulting in a \$10 million benefit. The six months ended June 30, 2015 also included charges of \$3 million in selling, general and administrative expenses relating to re-alignment of certain functions. For the six months ended June 30, 2014, the company recorded charges of \$2 million in cost of sales and \$6 million in R&D expenses (with an additional \$8 million recorded in discontinued operations), which primarily related to rationalization of the company's manufacturing facilities and re-alignment of certain R&D activities. The six months ended June 30, 2014 also included adjustments to previously estimated business optimization charges resulting in a \$2 million benefit.

The following table summarizes cash activity in the reserves related to business optimization initiatives:

(in millions)	
Reserves as of December 31, 2014	\$60
Charges	3
Reserve adjustments	(10)
Utilization	(8)
Reserves as of June 30, 2015	\$45

The reserves are expected to be substantially utilized by the end of 2016. Management believes that these reserves are adequate. However, adjustments may be recorded in the future as the programs are completed.

#### NOTE 7 DEBT

As of December 31, 2014 and for the three months ended March 31, 2015, Baxter's third-party debt and the related interest expense were not allocated to the company as the company was not the legal obligor of the debt and Baxter borrowings were not directly attributable to the company's business.

#### **Senior Notes Issuance**

On June 23, 2015, the company issued senior notes with a total aggregate principal amount of \$5 billion. The company used the net proceeds to make a cash distribution of \$4 billion to Baxter as partial consideration for the contribution of net assets to the company in connection with the separation, and intends to use the remainder for general corporate purposes, including to fund acquisitions. The \$4 billion cash distribution to Baxter was made on June 23, 2015. The \$5 billion in senior notes consist of the following tranches;

- \$375 million aggregate principal of senior notes bearing a fixed coupon rate of 2.000% and maturing in June 2018.
- \$375 million aggregate principal of senior notes bearing a floating coupon rate of three-month LIBOR plus 0.780% and maturing in June 2018.
- \$1.0 billion aggregate principal of senior notes bearing a fixed coupon rate of 2.875% and maturing in June 2020.
- \$500 million aggregate principal of senior notes bearing a fixed coupon rate of 3.600% and maturing in June 2022.
- \$1.75 billion aggregate principal of senior notes bearing a fixed coupon rate of 4.000% and maturing in June of 2025.
- \$1.0 billion aggregate principal of senior notes bearing a fixed coupon rate of 5.250% and maturing June 2045.

In connection with this issuance, the company recognized a debt discount of \$51 million and deferred issuance costs totaling \$8 million, which were recorded as a direct deduction from the carrying amount of the debt. Refer to Note 8 for information regarding interest rate derivative contracts the company has entered into related to the senior notes.

#### **Credit Facilities**

Effective July 1, 2015, the company entered into a credit agreement providing for a senior revolving credit facility in an aggregate principal amount of up to \$1.2 billion maturing in 2020. The facility enables the company to borrow funds on an unsecured basis at variable interest rates, and contains various financial and other covenants, including a net leverage ratio covenant and an interest coverage ratio covenant, as well as events of default with respect to the company. The credit facility also provides for the issuance of letters of credit. The company also entered into a Euro-denominated senior revolving credit facility in an aggregate principal amount of up to  $\xi$ 200 million maturing in 2020, with similar terms as the above credit facility. The non-performance of any financial institution supporting either of the credit facilities would reduce the maximum capacity of these facilities by each institution's respective commitment.

#### NOTE 8 DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITY

The company does not hold any instruments for trading purposes and none of the company's outstanding derivative instruments contain creditrisk-related contingent features.

#### **Interest Rate Risk Management**

The company is exposed to the risk that its earnings and cash flows could be adversely impacted by fluctuations in benchmark interest rates relating to its existing debt obligations or anticipated issuances of debt. The company's policy is to manage this risk to an acceptable level.

#### **Foreign Currency Risk Management**

The company is primarily exposed to foreign exchange risk with respect to recognized assets and liabilities, forecasted transactions and net assets denominated in the Euro, Japanese Yen, British Pound, Swiss Franc, Australian Dollar, Turkish Lira, Russian Ruble, Chinese Renminbi and Colombian Peso. The company has historically participated in Baxter's foreign currency risk management program through a central shared entity, which entered into derivative contracts to hedge foreign currency risk associated with forecasted transactions for the entire company, including for Baxalta's operations. Gains and losses on derivative contracts entered into by Baxter were allocated to Baxalta and offset gains and losses on underlying foreign currency exposures. The fair value of outstanding derivative instruments were not allocated to Baxalta's condensed combined balance sheets. During the three months ended June 30, 2015, the company began entering into foreign currency derivative contracts on its own behalf and recorded the related fair value on its condensed combined balance sheets as of June 30, 2015. The contracts are classified as either short-term or long-term based on the scheduled maturity of the instrument.

#### **Cash Flow Hedges**

The company may use options, including collars and purchased options, and forwards to hedge the foreign exchange risk to earnings relating to forecasted transactions and recognized assets and liabilities. In December 2014 and during the three months ended March 31, 2015, the company entered into \$1.8 billion of forward-starting interest rate swaps to hedge the risk to earnings associated with movements in benchmark interest rates relating to an anticipated issuance of debt. The total notional amount of the forward-starting interest rate swaps was \$550 million as of December 31, 2014. During the six months ended June 30, 2015, in conjunction with the debt issuance described in Note 7, the company terminated the swaps, which resulted in a \$37 million net gain that was deferred in AOCI and is being amortized as a decrease to net interest expense over the terms of the underlying debt.

For each derivative instrument that is designated and effective as a cash flow hedge, the gain or loss on the derivative is recorded in AOCI and then recognized in earnings consistent with the underlying hedged item. Option premiums or net premiums paid are initially recorded as assets and reclassified to other comprehensive income (OCI) over the life of the option, and then recognized in earnings consistent with the underlying hedged item. Cash flow hedges are classified in net sales, cost of sales, and net interest expense, and primarily relate to forecasted third-party sales denominated in foreign currencies, forecasted intercompany sales denominated in foreign currencies, and anticipated issuances of debt, respectively. The maximum term over which the company has cash flow hedge contracts in place related to forecasted transactions as of June 30, 2015 was 18 months. The notional amount of foreign exchange contracts were \$651 million as of June 30, 2015.

In certain instances, the company may discontinue cash flow hedge accounting because the forecasted transactions are no longer probable of occurring. As of June 30, 2015, all forecasted transactions were probable of occurring and no gains or losses were reclassified into earnings.

#### **Fair Value Hedges**

The company uses interest rate swaps to convert a portion of its fixed-rate debt into variable-rate debt. These instruments hedge the company's earnings from changes in the fair value of debt due to fluctuations in the designated benchmark interest rate. For each derivative instrument that is designated and effective as a fair value hedge, the gain or loss on the derivative is recognized immediately to earnings, and offsets the loss or gain on the underlying hedged item. Fair value hedges are classified in net interest expense, as they hedge the interest rate risk associated with certain of the company's fixed-rate debt.

The total notional amount of interest rate swaps was \$1.0 billion as of June 30, 2015.

#### **Undesignated Derivative Instruments**

The company uses forward contracts to hedge earnings from the effects of foreign exchange relating to certain of the company's intercompany and third-party receivables and payables denominated in a foreign currency. These derivative instruments generally are not formally designated as hedges and the terms of these instruments generally do not exceed one month.

The total notional amount of undesignated derivative instruments was \$49 million as of June 30, 2015.

#### Gains and Losses on Derivative Instruments

The following tables summarize the income statement locations and gains and losses on the company's derivative instruments for the three months ended June 30, 2015 and 2014.

	Gain (loss) recog	nized in OCI	Location of gain (loss)	Gain (loss) reclas AOCI into i	
(in millions)	2015	2014	in income statement	2015	2014
Cash flow hedges					
Interest rate contracts	\$ 93	\$ —	Net interest expense	\$ —	\$ —
Foreign exchange contracts	_	_	Net sales	_	_
Foreign exchange contracts	1		Cost of sales	15	
Total	\$ 94	\$ —		\$15	\$—
			Location of gain (loss)	Gain (loss) recogniz	zed in income
(in millions)			in income statement	2015	2014
Fair value hedges					
Interest rate contracts			Net interest expense	\$ (12)	\$—
Undesignated derivative instrumen	te				

\$ -

\$

Undesignated derivative instruments Foreign exchange contracts Other (income) expense, net

The following tables summarize the income statement locations and gains and losses on the company's derivative instruments for the six months ended June 30, 2015 and 2014.

	Gain (loss) recogn	ized in OCI	Location of gain (loss)	Gain (loss) recla AOCI into	
(in millions)	2015	2014	in income statement	2015	2014
Cash flow hedges					
Interest rate contracts	\$ 38	\$ —	Net interest expense	\$ —	\$ —
Foreign exchange contracts	_		Net sales	—	
Foreign exchange contracts	1		Cost of sales	15	
Total	\$ 39	\$—		\$ 15	\$—

	Location of gain (loss)	Gain (loss) recognized in income	
(in millions)	in income statement	2015	2014
Fair value hedges			
Interest rate contracts	Net interest expense	\$ (12)	\$ —
Undesignated derivative instruments			
Foreign exchange contracts	Other (income) expense, net	\$ —	\$ —

During the three months ended June 30, 2015, the company assumed pre-tax deferred gains of \$43 million related to certain foreign exchange contracts from Baxter, which were recorded in AOCI.

For the company's fair value hedges, equal and offsetting gains of \$12 million and \$12 million were recognized in net interest expense during the three and six month periods ending June 30, 2015, respectively, as adjustments to the underlying hedged item, fixed-rate debt. Ineffectiveness related to the company's cash flow and fair value hedges for the six months ended June 30, 2015 was not material.

As of June 30, 2015, \$21 million of deferred, net after-tax gains on derivative instruments included in AOCI are expected to be recognized in earnings during the next 12 months, coinciding with when the hedged items are expected to impact earnings. Refer to Note 11 for the balance in AOCI associated with cash flow hedges.

#### Fair Values of Derivative Instruments

The following table presents the classification and estimated fair value of the company's derivative instruments as of June 30, 2015:

	Derivatives in asset pos	itions	Derivatives in liability positions		
(in millions)	Balance sheet location	Fair value	Balance sheet location	Fair value	
Derivative instruments designated as hedges					
Foreign exchange contracts	Other current assets	\$5	Accrued liabilities	\$ 5	
Foreign exchange contracts	Other long-term assets	1	Other long-term liabilities	2	
Interest rate contracts	Other current assets		Other long-term liabilities	12	
Total derivative instruments designated as hedges		\$6		\$ 19	
Undesignated derivative instruments					
Foreign exchange contracts	Other current assets	\$ —	Accrued liabilities	\$ —	
Total derivative instruments		\$6		\$ 19	

The following table presents the classification and estimated fair value of the company's derivative instruments as of December 31, 2014:

	Derivatives in asset pos	itions	Derivatives in liability posit	tions
(in millions)	Balance sheet location	Fair value	Balance sheet location	Fair value
Derivative instruments designated as hedges				
Interest rate contracts	Other current assets	\$ 1	Accrued liabilities	\$ 2

While the company's derivatives are all subject to master netting arrangements, the company presents its assets and liabilities related to derivative instruments on a gross basis within the condensed combined balance sheets. Additionally, the company is not required to post collateral for any of its outstanding derivatives.

The following table provides information on the company's derivative positions as if they were presented on a net basis, allowing for the right of offset by the counterparty:

	June 30, 2015		December 31, 2014	
(in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the combined balance sheet	\$ 6	\$19	\$ 1	\$ 2
Gross amount subject to offset in master netting arrangements not offset				
in the combined balance sheet	(6)	(6)		
Total	\$—	\$13	\$ 1	\$ 2

#### NOTE 9 FINANCIAL INSTRUMENTS AND FAIR VALUE MEASUREMENTS

#### Securitization arrangement

Effective during the three months ended June 30, 2015, the company entered into agreements related to its trade receivables originating in Japan with a financial institution in which the entire interest in and ownership of the receivables are sold. While the company services the receivables in its Japanese securitization arrangement, no servicing asset or liability is recognized because the company receives adequate compensation to service the sold receivables.

During the three months ended June 30, 2015, sold receivables were \$54 million. There were no cash collections remitted to the owners of the receivables. The effect of currency exchange rate changes and net losses relating to the sales of receivables were immaterial.

#### **Concentrations of Credit Risk**

The company engages in business with foreign governments in certain countries that have experienced deterioration in credit and economic conditions, including Greece, Spain, Portugal, Italy and Brazil. As of June 30, 2015, the company's net accounts receivable from the public sector in Greece, Spain, Portugal and Italy totaled \$141 million, of which Greece receivables represented an immaterial balance. The company also has significant accounts receivable related to its Hemobrás partnership in Brazil totaling \$157 million at June 30, 2015.

Global economic conditions and liquidity issues in certain countries have resulted, and may continue to result, in delays in the collection of receivables and credit losses. While the company believes that its allowance for doubtful accounts as of June 30, 2015 is adequate, future governmental actions and customer-specific factors may require the company to re-evaluate the collectability of its receivables and the company could potentially incur additional credit losses that materially impact the company's results of operations.

#### **Fair Value Measurements**

The fair value hierarchy under the accounting standard for fair value measurements consists of the following three levels:

- Level 1—Quoted prices in active markets that the company has the ability to access for identical assets or liabilities;
- Level 2—Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuations in which all significant inputs are observable in the market; and
- Level 3—Valuations using significant inputs that are unobservable in the market and include the use of judgment by the company's management about the assumptions market participants would use in pricing the asset or liability.

The following tables summarize the bases used to measure financial assets and liabilities that are carried at fair value on a recurring basis in the condensed combined balance sheets:

		Basis of fair value measur				
(in millions)	Balance as of June 30, 2015	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)		
Assets						
Foreign currency derivative contracts	\$ 6	\$ —	\$ 6	\$ —		
Available-for-sale securities						
Equity securities	86	86				
Foreign government debt securities	16	_	16			
Total assets	\$108	\$ 86	\$ 22	\$ —		
Liabilities						
Contingent payments related to acquisitions	\$509	\$ —	\$ —	\$509		
Foreign currency derivative contracts	7	_	7			
Interest rate contracts	12	_	12	_		
Total liabilities	\$528	\$ —	\$ 19	\$509		

		Basis of fair value measurement			
(in millions)	Balance as of December 31, 2014	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets					
Available-for-sale securities					
Equity securities	\$ 71	\$ 71	\$ —	\$ —	
Foreign government debt securities	18	—	18	_	
Interest rate contracts	1		1	—	
Total assets	\$ 90	\$ 71	\$ 19	\$ —	
Liabilities					
Contingent payments related to acquisitions	\$518	\$ —	\$ —	\$518	
Interest rate contracts	2	_	2		
Total liabilities	\$520	\$ —	\$ 2	\$518	

For assets that are measured using quoted prices in active markets, the fair value is the published market price per unit multiplied by the number of units held, without consideration of transaction costs. The fair values of foreign government debt securities are obtained from pricing services or broker/dealers who use proprietary pricing applications, which include observable market information for like or same securities.

Contingent payments related to acquisitions consist of development and commercial milestone payments, in addition to sales-based payments, and are valued using discounted cash flow techniques. The fair value of development, regulatory and commercial milestone payments reflects management's expectations of probability of payment, and increases as the probability of payment increases or expectation of timing of payments is accelerated. As of June 30, 2015, management's expected weighted-average probability of payment, regulatory and commercial milestone payments, regulatory and commercial milestone payments was approximately 24%, with individual probabilities

ranging from 10%-95%. The fair value of sales-based payments is based upon probability-weighted future revenue estimates, and increases as revenue estimates increase, probability weighting of higher revenue scenarios increase or expectation of timing of payment is accelerated.

The following table provides information relating to the company's investments in available-for-sale equity securities:

		Unrealized	Unrealized	
(in millions)	Amortized cost	gains	(losses)	Fair value
June 30, 2015				
Available-for-sale equity securities	\$45	\$43	\$(2)	\$86
December 31, 2014				
Available-for-sale equity securities	\$59	\$21	\$(9)	\$71

The company recorded \$9 million in other-than-temporary impairment charges based on the duration of losses related to two of the company's investments during the six months ended June 30, 2015. The company had cumulative unrealized gains on available-for-sale debt securities of \$1 million both as of June 30, 2015 and December 31, 2014.

The following table is a reconciliation of the fair value measurements that use significant unobservable inputs (Level 3), which consists of contingent payments related to acquisitions:

	Contingent
(in millions)	payments
Fair value as of December 31, 2014	\$518
Additions	_
Net losses recognized in earnings	_
СТА	(9)
Fair value as of June 30, 2015	\$509

#### Book Values and Fair Values of Financial Instruments

In addition to the financial instruments that the company is required to recognize at fair value on the condensed combined balance sheets, the company has certain financial instruments that are recognized at historical cost or some basis other than fair value. For these financial instruments, the following table provides the values recognized on the condensed combined balance sheets and the approximate fair values:

	Book values		Approximate fair values		
		December 31,			
	June 30,	0014	June 30,	December 31,	
(in millions)	2015	2014	2015	2014	
Assets					
Investments	\$ 32	\$ 31	\$ 32	\$ 31	
Liabilities					
Capital lease obligations	318	276	318	276	
Long-term debt	\$4,927	\$ —	\$5,100	\$ —	

The estimated fair value of capital lease obligations is based on Level 2 inputs. Investments include certain cost method investments whose fair value is based on Level 3 inputs. The estimated fair values of long-term debt were computed by multiplying price by the notional amount of the respective debt instrument. Price is calculated using the stated terms of the respective debt instrument and yield curves commensurate with the company's credit risk. The discount factors used in the calculations reflect the non-performance risk of the company. The carrying values of the other financial instruments approximate their fair values due to the short-term maturities of most of these assets and liabilities.

In connection with the company's initiative to invest in early-stage products and therapies, the company increased its unfunded commitment as a limited partner in multiple investment companies to \$73 million as of June 30, 2015 from \$32 million as of December 31, 2014.

In the first six months of 2015 and 2014, the company recorded \$10 million and \$34 million of income in other (expense) income, net related to equity method investments, which primarily represented distributions from funds that sold portfolio companies in both periods as well as gains from the sale of certain investments in 2014.

# NOTE 10 RETIREMENT AND OTHER BENEFIT PROGRAMS

# **Shared Baxter Plans**

Prior to the second quarter of 2015 and with the exception of certain Austrian defined benefit pension plans, of which Baxalta was the sole sponsor, the company's employees have participated in certain U.S. and international defined benefit pension and other post-employment benefit (OPEB) plans sponsored by Baxter. These plans included participants of Baxter's other businesses and were accounted for as multiemployer plans in the company's combined financial statements prior to the transfer into newly-created plans sponsored by Baxalta, as discussed below. As a result, no asset or liability was recorded by the company in its combined balance sheets through March 31, 2015 to recognize the funded status of these plans. The costs of these plans were allocated to the company and recorded in cost of sales, selling, general and administrative expenses, and R&D expenses in the condensed combined statements of income. For the Baxter sponsored defined benefit pension and OPEB plans, Baxalta recorded expense of \$4 million and \$9 million for the three months ended June 30, 2015 and 2014, respectively, and \$16 million and \$19 million for the six months ended June 30, 2015 and 2014, respectively, relating to Baxalta employees' participation in Baxter sponsored plans.

#### Transfer of Net Pension and OPEB Obligations to Baxalta Plans

During the three months ended June 30, 2015, Baxalta assumed certain pension and OPEB obligations of \$667 million and related plan assets of \$347 million (which includes a voluntary contribution of \$100 million from Baxter) related to newly-created single employer plans for Baxalta employees and certain other Baxter-sponsored pension plans, as described below. The company also assumed after-tax deferred losses of \$144 million related to these plans, which were recorded in AOCI.

The net benefit plan obligations were re-measured on the date of transfer resulting in an after-tax net loss of \$5 million recognized in AOCI during the three months ended June 30, 2015. The weighted average assumptions used to re-measure the net benefit plan obligations and future net periodic benefit cost for the single and multiple-employer plans as of the transfer date in 2015 are as follows:

	Pension	
	benefits	OPEB
Discount rate		
U.S. plans	4.30%	4.30%
International plans	1.11%	n/a
Expected return on plan assets		
U.S. plans	7.25%	n/a
International plans	5.31%	n/a
Rate of compensation increase		
U.S. plans	3.80%	3.80%
International plans	3.41%	n/a

As noted above, certain pension plans, including those in Switzerland and Japan, continue to be sponsored by Baxter as of June 30, 2015. Based on the terms of the employee matters agreement, the company expects to become the sole sponsor of these pension plans during 2016 and will be responsible for its employees retiring during the interim period, and therefore the company has accounted for these plans as multiple-employer plans beginning with the three months ended June 30, 2015. The funded status of these multiple-employer plans is reflected on the company's condensed combined balance sheet as of June 30, 2015 and totaled \$130 million.

As of June 30, 2015, the net benefit plan obligations related to the company's defined benefit pension and OPEB plans that are accounted for as single and multiple-employer plans totaled \$489 million, with a related pre-tax AOCI balance of \$270 million.

Net periodic benefit cost associated with Baxalta's single and multiple-employer pension and OPEB plans consisted of the following for the three and six months ended June 30, 2015 and 2014:

		onths ended ne 30,		Six months ended June 30,	
(in millions)	2015	2014	2015	2014	
Net periodic benefit cost:					
Service cost	\$ 9	\$ 2	\$10	\$ 3	
Interest cost	4	1	5	2	
Expected return on plan assets	(4)		(4)		
Amortization of actuarial loss	5	1	6	2	
Total net periodic benefit cost	\$14	\$4	\$17	\$ 7	

## NOTE 11 ACCUMULATED OTHER COMPREHENSIVE INCOME

Comprehensive income includes all changes in equity that do not arise from transactions with the Parent and consists of net income, foreign currency translation, pension and other employee benefits, unrealized gains and losses on available-for-sale securities and hedging activities. The following is a net-of-tax summary of the changes in AOCI by component for the six months ended June 30, 2015 and 2014.

(in millions)	Foreign Currency Translation	Pension and Other Employee Benefits	Available- for-sale Securities	Hedging Activities	Total
Gains (losses)					
Balance as of December 31, 2014	\$ (387)	\$ (52)	\$ 7	\$ (1)	\$ (433)
Other comprehensive income before reclassifications	(228)	(5)	8	25	(200)
Amounts reclassified from AOCI (a)		4	7	(10)	1
Net other comprehensive (loss) income	(228)	(1)	15	15	(199)
Assumption from Baxter of deferred (losses) gains on pension and OPEB					
plans and hedging activities		(144)		28	(116)
Balance as of June 30, 2015	\$ (615)	\$ (197)	\$ 22	\$ 42	\$ (748)

(in millions)	Foreign Currency Translation	Pension and Other Employee Benefits	Available- for-sale Securities	Hedging Activities	Total
Gains (losses)					
Balance as of December 31, 2013	\$ —	\$ (51)	\$ (13)	\$ —	\$ (64)
Other comprehensive income before reclassifications	4	3	(9)		(2)
Amounts reclassified from AOCI (a)		1			1
Net other comprehensive income (loss)	4	4	(9)	_	(1)
Balance as of June 30, 2014	\$ 4	\$ (47)	\$ (22)	\$ —	\$ (65)

(a) See table below for details about these reclassifications.

The following is a summary of the amounts reclassified from AOCI to net income during the three months ended June 30, 2015 and 2014.

	Amounts reclassified from AOCI (a)			
(in millions)	Three months ended June 30, 2015	Three months ended June 30, 2014	Location of impact in income statement	
Amortization of pension and other employee benefits				
Actuarial losses and other	\$ (5)(b)	\$ (1)(b)		
	(5)	(1)	Total before tax	
	2	1	Tax benefit	
	\$ (3)	\$ —	Net of tax	
Gains (losses) on hedging activities				
Foreign exchange contracts	\$ 15	\$ —	Cost of sales	
	15	_	Total before tax	
	(5)	—	Tax expense	
	\$ 10	\$ —	Net of tax	
Total reclassification for the period	\$ 7	\$—	Total net of tax	

(a) Amounts in parentheses indicate reductions to net income.

(b) These AOCI components are included in the computation of net periodic benefit cost disclosed in Note 10.

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The following is a summary of the amounts reclassified from AOCI to net income during the six months ended June 30, 2015 and 2014.

	A	mounts reclassified from AOCI (a	a)
(in millions)	Six months ended June 30, 2015	Six months ended June 30, 2014	Location of impact in income statement
Amortization of pension and other employee benefits			
Actuarial losses and other	\$ (6)(b)	\$(2)(b)	
	(6)	(2)	Total before tax
	2	1	Tax benefit
	\$ (4)	\$ (1)	Net of tax
Gains (losses) on hedging activities			
Foreign exchange contracts	\$ 15	\$—	Cost of sales
	15		Total before tax
	(5)		Tax expense
	\$ 10	\$—	Net of tax
Losses on available-for-sale securities			
Other-than-temporary impairment of available-for-sale equity			Other (expense)
securities	\$ (9)	\$—	income, net
	(9)		Total before tax
	2		Tax benefit
	\$ (7)	\$—	Net of tax
Total reclassification for the period	\$ (1)	\$ (1)	Total net of tax

(a) Amounts in parentheses indicate reductions to net income.

(b) These AOCI components are included in the computation of net periodic benefit cost disclosed in Note 10.

#### NOTE 12 INCOME TAXES

#### **Effective Tax Rate**

The company's effective income tax rate from continuing operations was 25.7% and 23.4% during the three months ended June 30, 2015 and 2014, respectively, and 24.3% and 23.8% during the six months ended June 30, 2015 and 2014, respectively. The company's effective income tax rate differs from the U.S. federal statutory rate each year due to certain operations that are subject to tax incentives, state and local taxes, and foreign taxes that are different than the U.S. federal statutory rate. In addition, the effective tax rate can be impacted each period by discrete factors and events.

The effective income tax rate increased during both the three and six months ended June 30, 2015 as compared to the prior year period primarily due to an increase in charges associated with milestone payments made to collaboration partners that were deductible at tax rates lower than the effective tax incurred during the three and six months ended June 30, 2014, partially offset by charges related to the separation incurred during three and six months ended June 30, 2015 that were deductible at tax rates higher than the effective rate.

#### NOTE 13 SHARE-BASED COMPENSATION

Prior to the separation, Baxalta employees participated in Baxter's incentive stock program and Baxalta recorded costs in cost of sales, selling, general and administrative expenses, and R&D expenses for its employees' participation in the program. In connection with the separation, outstanding Baxter equity awards held by Baxter and Baxalta employees were adjusted into both Baxter and Baxalta equity awards, except for awards granted after January 1, 2015 and certain awards granted during 2014 that were adjusted entirely into corresponding awards of either Baxter or Baxalta based on which company would employ the holder following the separation. The value of the combined Baxter and Baxalta stock-based awards after the separation was designed to generally preserve the intrinsic value and the fair value of the award immediately prior to separation.

In connection with the separation, the company adopted the 2015 Baxalta Incorporated Incentive Plan which provides for the assumption of certain awards granted under the Baxter incentive stock programs and provides for additional shares of common stock available for issuance with respect to awards for participants. The 2015 Baxalta Incorporated Incentive Plan provides for 91 million shares of common stock for issuance with respect to awards for participants.

The below disclosures represent the company employees' participation in Baxter's incentive stock program prior to the separation and do not reflect the impact of the separation, including the adjustment of equity awards described above.

The following table provides share-based compensation expense by statement of income line item for the three and six months ended June 30, 2015 and 2014:

	Three months ended June 30,		Six	Six months ended June 30,	
(in millions)	2015	2014	2015	2014	
Cost of sales	\$ 3	\$2	\$5	\$ 4	
Selling, general and administrative expense	6	4	12	8	
Research and development expenses	2	2	4	3	
Total share-based compensation expense	\$11	\$8	\$ 21	\$ 15	

The related tax benefit recognized was \$3 million and \$5 million during the three and six months ended June 30, 2015, respectively, and \$3 million and \$6 million during the three and six month ended June 30, 2014, respectively.

During the six months ended June 30, 2015, Baxter awarded annual stock compensation grants consisting of 2.4 million Baxter stock options and 375,000 Baxter RSUs, with respect to the company's employees.

#### **Stock Options**

The weighted-average Black-Scholes assumptions used in estimating the fair value of stock options granted during the period, along with the weighted-average grant-date fair values, were as follows:

	Six	x months ended June 30,
	2015	2014
Expected volatility	20%	24%
Expected life (in years)	5.5	5.5
Risk-free interest rate	1.7%	1.7%
Dividend yield	3.0%	2.8%
Fair value per stock option	\$ 9	\$ 12

The total intrinsic value of stock options exercised was \$3 million and \$6 million during the three months ended June 30, 2015 and 2014, respectively, and \$7 million and \$17 million during the six months ended June 30, 2015 and 2014, respectively.

As of June 30, 2015, the unrecognized compensation cost related to all unvested stock options of \$28 million is expected to be recognized as expense over a weighted-average period of 2.0 years.

#### RSUs

As of June 30, 2015, the unrecognized compensation cost related to all unvested RSUs of \$38 million is expected to be recognized as expense over a weighted-average period of 2.0 years.

#### **PSUs**

As of June 30, 2015, the unrecognized compensation cost related to all granted unvested PSUs of \$1 million is expected to be recognized as expense over a weighted-average period of 0.9 years.

#### NOTE 14 LEGAL PROCEEDINGS

The company was involved in product liability, patent, commercial, and other legal matters that arise in the normal course of the company's business. The company records a liability when a loss is considered probable and the amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, and no amount within the range is a better estimate, the minimum amount in the range is accrued. If a loss is not probable or a probable loss cannot be reasonably estimated, no liability is recorded. As of June 30, 2015, the company's total recorded reserves with respect to legal matters were \$22 million.

Management is not able to estimate the amount or range of any loss for certain contingencies for which there is no reserve or additional loss for matters already reserved. While the liability of the company in connection with the claims cannot be estimated and although the resolution in any reporting period of one or more of these matters could have a significant impact on the company's results of operations and cash flows for that period, the outcome of these legal proceedings is not expected to have a material adverse effect on the company's combined financial position. While the company believes that it has valid defenses in these matters, litigation is inherently uncertain, excessive verdicts do occur, and the company may incur material judgments or enter into material settlements of claims.

The company remains subject to the risk of future administrative and legal actions. With respect to governmental and regulatory matters, these actions may lead to product recalls, injunctions, and other restrictions on the company's operations and monetary sanctions, including significant civil or criminal penalties. With respect to intellectual property, the company may become exposed to significant litigation concerning the scope of the company's and others' rights. Such litigation could result in a loss of patent protection or the ability to market products, which could lead to a significant loss of sales, or otherwise materially affect future results of operations.

## NOTE 15 RELATED PARTIES

The company has not historically operated as a standalone business and has various relationships with Baxter whereby Baxter provides services to the company.

#### **Corporate Overhead and Other Allocations from Baxter**

During the periods presented, Baxter provided the company certain services, which included, but are not limited to, executive oversight, treasury, finance, legal, human resources, tax planning, internal audit, financial reporting, information technology and investor relations. The financial information in these condensed combined financial statements does not necessarily include all the expenses that would have been incurred had the company been a separate, standalone entity. Baxter charged the company for these services based on direct and indirect costs. When specific identification was not practicable, a proportional cost method was used, primarily based on sales, headcount, or square footage. These allocations were reflected as follows in the unaudited condensed combined financial statements:

	Three months ended June 30,			Six months ended June 30,	
(in millions)	2015	2014	2015	2014	
Cost of sales allocation	\$ 12	\$5	\$ 21	\$ 10	
Selling, general and administrative allocations	136	135	258	257	
Research and development allocations	4	2	5	5	
Total corporate overhead and other allocations from Baxter	\$ 152	\$ 142	\$ 284	\$ 272	

The financial information herein may not necessarily reflect the condensed combined financial position, results of operations and cash flows of the company in the future or what they would have been had the company been a separate, standalone entity during the periods presented. Management believes that the methods used to allocate expenses to the company's historical financial statements are reasonable.

#### **Centralized Cash Management**

Baxter uses a centralized approach to cash management and financing of operations. Prior to the three months ended June 30, 2015, the majority of the company's subsidiaries were party to Baxter's cash pooling arrangements with several financial institutions to maximize the availability of cash for general operating and investing purposes. Under these cash pooling arrangements, cash balances are swept regularly from the company's accounts. Cash transfers to and from Baxter's cash concentration accounts and the resulting

balances at the end of each reporting period were reflected in net parent company investment in the condensed combined balance sheets. Prior to the three months ended June 30, 2015, cash and equivalents were not allocated to the company due to Baxter's centralized approach to cash management. As of June 30, 2015, the company's balance sheet includes the cash and equivalents of the Baxalta legal entities that do not participate in Baxter's centralized cash management program.

#### NOTE 16 DISCONTINUED OPERATIONS

In July 2014, the company entered into an agreement with Pfizer Inc. to sell its commercial vaccines business and committed to a plan to divest the remainder of its vaccines business, which includes certain R&D programs. In December 2014, the company completed the divestiture of the commercial vaccines business. During the six months ended June 30, 2015, the company recorded an after-tax gain of \$9 million as a result of a purchase price adjustment. In December 2014, the company also entered into a separate agreement for the sale of the remainder of the vaccines business. As a result of the divestitures, the operations and cash flows of the vaccines business have been eliminated from the ongoing operations of the company.

Following is a summary of the operating results of the vaccines business, which have been reflected as discontinued operations for the three and six months ended June 30, 2015 and 2014:

	Three mont June		Six months ended June 30,		
(in millions)	2015	2014	2015	2014	
Net sales	\$ —	\$110	\$ 1	\$ 213	
(Loss) income from discontinued operations before income taxes, excluding gain on					
sale	(5)	59	(4)	115	
Gain on sale before income taxes		_	10		
Income tax benefit (expense)	1	(7)		(14)	
(Loss) income from discontinued operations, net of taxes	\$ (4)	\$ 52	\$6	\$ 101	

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

The following is management's discussion and analysis of the financial condition of Baxalta Incorporated (Baxalta or the company) as of June 30, 2015 and December 31, 2014 and the results of operations for the three and six months ended June 30, 2015 and 2014. This commentary should be read in conjunction with the condensed combined financial statements and accompanying notes included in Item 1. Financial Statements. Refer to the company's Information Statement included as Exhibit 99.1 to the company's effective Registration Statement on Form 10, as filed with the Securities and Exchange Commission on June 5, 2015 (Information Statement) for management's discussion and analysis of the financial condition of the company as of March 31, 2015 and December 31, 2014 and 2013, and the results of operations for the three months ended March 31, 2015 and 2014 and the years ended December 31, 2014, 2013 and 2012.

#### **Company Overview**

Baxalta is a global biopharmaceutical leader developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, oncology and immunology. Driven by passion to make a meaningful impact on patients' lives, Baxalta's broad and diverse pipeline includes biologics with novel mechanisms and advanced technology platforms such as gene therapy. The Baxalta Global Innovation and R&D Center is located in Cambridge, Massachusetts. Launched in 2015 following separation from Baxter International Inc., Baxalta's heritage in biopharmaceuticals spans decades. Baxalta's therapies are available in more than 100 countries and it has advanced biological manufacturing operations across 12 facilities, including state-of-the-art recombinant production and plasma fractionation. Headquartered in Northern Illinois, Baxalta employs 16,000 employees worldwide.

#### **Spin-Off Transaction**

On July 1, 2015, Baxalta separated from Baxter International Inc. (Baxter) and became an independent public company. To effect the separation, the two companies undertook a series of transactions to separate entities and net assets. As a result of these transactions, Baxalta Incorporated holds the biopharmaceuticals business that was a part of the combined company prior to the separation. On July 1, 2015, Baxter distributed to its shareholders 80.5% of the common stock of Baxalta Incorporated. Baxter retained a 19.5% ownership stake in Baxalta immediately following the distribution. Baxalta's Registration Statement on Form 10, as amended through the time of its effectiveness, was declared effective by the U.S. Securities and Exchange Commission on June 9, 2015. Baxalta common stock began trading "regular way" under the ticker symbol "BXLT" on the New York Stock Exchange on July 1, 2015.

#### **Oncaspar Acquisition**

In July 2015, the company completed its acquisition of the Oncaspar (pegaspargase) product portfolio from Sigma-Tau Finanziaria S.p.A, a privately held biopharmaceutical company based in Italy, for approximately \$900 million before transaction adjustments. Through the acquisition, the Company gained the marketed biologic treatment Oncaspar, the investigational biologic calaspargase pegol, and an established oncology infrastructure with clinical and sales resources. Oncaspar is a first-line biologic used as part of a chemotherapy regimen to treat patients with acute lymphoblastic leukemia. It is currently marketed in the United States, Germany, Poland and certain other countries and has approximately \$100 million in annual sales.

The company's results of operations discussed below exclude the results of the acquired business because the transaction was not completed until the third quarter of 2015. The company expects to report sales of Oncaspar in a new "Oncology" product category beginning in the third quarter of 2015.

#### **Key Factors Affecting Results of Operations**

For the periods presented, the company did not operate as an independent, standalone company, but rather as a part of a larger group of companies controlled by Baxter. There are limitations inherent in the preparation of all carve-out financial statements due to the fact that the company's business was previously part of a larger organization. The basis of preparation included in the condensed combined interim financial statements provides a detailed description of the treatment of historical transactions. The company's net income has been most notably impacted by the following consequences of carve-out accounting and the separation:

- Baxter utilized a centralized treasury management system and cash or debt was not allocated to Baxalta in the carve-out financial statements. In June 2015, the capital structures of both companies began to be re-aligned, resulting in Baxalta incurring its own debt and having adequate cash to fund its operations. The indebtedness will cause Baxalta to record additional interest expense in future periods. Any additional borrowings entered into in the future will increase interest expense.
- The condensed combined interim statements of income included an allocation to the company from Baxter for the services provided by various Baxter functions including, but not limited to, executive oversight, treasury, finance, legal, human resources, tax planning, internal audit, financial reporting, information technology and investor relations. The

amounts of these allocations may not necessarily be indicative of the similar costs the company will incur as an independent, standalone company. The total amount allocated to Baxalta from Baxter was \$152 million and \$142 million during the three months ended June 30, 2015 and 2014, respectively, and \$284 million and \$272 million during the six months ended June 30, 2015 and 2014, respectively.

- The company has incurred certain one-time separation costs, which are primarily associated with the design and establishment of Baxalta as a standalone public company. Included in results of operations are separation costs of \$40 million and \$83 million during the three and six months ended June 30, 2015, respectively. The company expects to incur additional separation costs in periods following the separation, certain of which may be capitalized in relation to operating infrastructure such as information technology.
- Income tax expense is computed on a separate company basis, as if operated as a standalone entity or a separate entity or a separate consolidated group in each material jurisdiction in which the company operates. As a result of potential changes to the company's business model and potential future tax planning, income tax expense included in the combined financial statements may not be indicative of the company's future expected tax rate.
- Concurrent with the separation, Baxalta has entered into a contract manufacturing agreement with Baxter whereby Baxalta and Baxter will produce certain products for one another at agreed upon terms. As products were historically transferred at cost between Baxter and the businesses that comprise Baxalta, these contract manufacturing agreements will result in changes to both sales and cost of goods sold in future periods.

## **RESULTS OF OPERATIONS**

#### **Special Items**

The following table provides a summary of the company's special items and the related impact by line item on the company's results of operations for the three and six months ended June 30, 2015 and 2014.

		Three mon June		d	Six months ended June 30,				
(in millions)		2015		2014	-	2015		2014	
Gross Margin <sup>1</sup>									
Intangible asset amortization expense	\$	(8)	\$	(4)	\$	(16)	\$	(7)	
Business optimization items		—		2		—		—	
Separation costs		(1)				(1)			
Total Special Items	\$	(9)	\$	(2)	\$	(17)	\$	(7)	
Impact on Gross Margin Ratio	((	).6 pts)	(0	).1 pts)	(0	).6 pts)	((	).3 pts)	
Selling, General and Administrative Expenses <sup>1</sup>									
Plasma related litigation	\$	—	\$		\$		\$	(10)	
Business optimization items <sup>2</sup>		3		(1)		2		(1)	
Separation costs		34		1		70		1	
Total Special Items	\$	37	\$		\$	72	\$	(10)	
Impact on Selling, General and Administrative Expense Ratio	2.6 pts		0 pts		2.6 pts		((	).4 pts)	
Research and Development Expenses <sup>1</sup>									
Business optimization items	\$	—	\$	(2)	\$	(6)	\$	4	
Upfront and milestone payments to collaboration partners		87		35		87		60	
Separation costs		5				12		_	
Total Special Items	\$	92	\$	33	\$	93	\$	64	
Other (Income) Expense, Net <sup>1</sup>									
Change in fair value of contingent payment liability				44				44	
Total Special Items	\$	_	\$	44	\$	_	\$	44	
Income Tax Expense <sup>1</sup>									
Impact of special items	\$	(29)	\$	(16)	\$	(40)	\$	(18)	
Total Special Items	\$	(29)	\$	(16)	\$	(40)	\$	(18)	
Impact on Effective Tax Rate	1	1.3 pts	0.5 pts		0.5 pts		0.7 pts		
Total Special Items, net of tax	\$	109	\$	63	\$	142	\$	87	

For gross margin, a number in parentheses represents an expense to the company, whereas in all other categories a number in parentheses represents a benefit.

<sup>2</sup> Includes a portion allocated from Baxter related to shared activities or functions.

The special items identified in the periods above reflect the portions of special items reported by Baxter that were attributable to Baxalta. Management believes that providing the separate impact of the above items on the company's GAAP (generally accepted accounting principles) results, when used in conjunction with the results presented in accordance with GAAP, may provide a more complete understanding of the company's operations and can facilitate a fuller analysis of the company's results of operations, particularly in evaluating performance from one period to another.

Intangible asset amortization expense is identified as a special item to facilitate an evaluation of current and past operating performance, particularly in terms of cash returns, and is similar to how management internally assesses performance. Upfront and milestone payments related to collaborations that have been expensed as R&D are uncertain and often result in a different payment and expense recognition pattern than internal R&D activities and therefore are typically treated as special items. Refer to the "Research and Development Expenses" caption below for additional information regarding the company's upfront and milestone payments to collaboration partners. Additional special items are identified above because they are highly variable, difficult to predict, and of a size that may substantially impact the company's reported operations for a period.

The company's results for the six months ended June 30, 2015 and 2014 were impacted by costs associated with the execution of certain strategies to optimize its organizational structure, as well as benefits from adjustments to previous business optimization charge estimates. The company recorded a net benefit related to business optimization initiatives of \$4 million during the six months ended June 30, 2015 and a net charge of \$3 million during the six months ended June 30, 2014. The net benefit or charge in each period included a portion allocated from Baxter related to shared functions or activities.

During the three and six months ended June 30, 2015, the company recorded separation costs of \$40 million and \$83 million, respectively, related to expenses incurred to prepare Baxalta to operate as an independent standalone public company.

During the six months ended June 30, 2014, selling, general and administrative expenses included a \$10 million benefit for the reversal of a portion of legal related charges following the settlement of class-action litigation associated with the pricing of plasma-derived therapies. During the three and six months ended June 30, 2014, the company recorded a loss in other (income) expense, net of \$44 million resulting from an increase in fair value of a contingent payment liability associated with the acquisition of OBIZUR and related assets from Inspiration BioPharmaceuticals, Inc. and Ipsen Pharma S.A.S. (Inspiration / Ipsen).

Income tax expense in both periods included the net tax benefit from the special pre-tax items discussed above.

#### **Net Sales**

	Three mor June		Six months ended Percent changeJune 30,			Percent	change	
(in millions)	2015	2014	At actual currency rates	At constant currency rates	2015	2014	At actual currency rates	At constant currency rates
United States	\$ 775	\$ 733	6%	6%	\$1,530	\$1,439	6%	6%
International	654	719	(9%)	9%	1,260	1,342	(6%)	9%
Total net sales	\$1,429	\$1,452	(2%)	7%	\$2,790	\$2,781	0%	8%

Foreign currency unfavorably impacted the net sales growth rate by 9 percentage points and 8 percentage points during the three and six months ended June 30, 2015, respectively, principally due to the strengthening of the U.S. Dollar relative to the Euro.

The comparisons presented at constant currency rates reflect comparative local currency sales at the prior year's foreign exchange rates. This measure provides information on the change in net sales assuming that foreign currency exchange rates had not changed between the prior and the current period. The company believes that the non-GAAP measure of change in net sales at constant currency rates, when used in conjunction with the GAAP measure of change in net sales at actual currency rates, may provide a more complete understanding of the company's operations and can facilitate a fuller analysis of the company's results of operations, particularly in evaluating performance from one period to another.

The table below presents sales results for Baxalta's four product categories. The commentary beneath discusses growth drivers at constant currency rates.

	Three months ended							Six mon	ths er	ded		
	June 30,				Percent	change	June 30,				Percent	change
(in millions)		2015		2014	At actual	At constant currency rates		2015		2014	At actual currency rates	At constant
		2015		2014	currency rates	currency rates		2015		2014	currency rates	currency rates
Hemophilia	<u>ф</u>	222	<u>ф</u>	222	0.00	0.01	φ.	(07	<u>ф</u>	(20)	1.07	1.07
United States	\$	322	\$	323	0%	0%	\$		\$	620	1%	1%
International		350		397	(12%)	7%		686		775	(11%)	4%
Total	\$	672	\$	720	(7%)	4%	\$	1,313	\$	1,395	(6%)	3%
Inhibitor Therapies												
United States	\$	69	\$	52	33%	33%	\$	132	\$	96	38%	38%
International		114		132	(14%)	4%		217		240	(10%)	6%
Total	\$	183	\$	184	(1%)	12%	\$	349	\$	336	4%	15%
Total Hematology	\$	855	\$	904	(5%)	6%	\$	1,662	\$	1,731	(4%)	5%
Immunoglobulin Therapies												
United States	\$	318	\$	294	8%	8%	\$	646	\$	601	7%	7%
International		104		99	5%	27%		196		190	3%	22%
Total	\$	422	\$	393	7%	13%	\$	842	\$	791	6%	11%
BioTherapeutics												
United States	\$	66	\$	64	3%	3%	\$	125	\$	122	2%	2%
International		86		91	(5%)	3%		161		137	18%	28%
Total	\$	152	\$	155	(2%)	3%	\$	286	\$	259	10%	16%
Total Immunology	\$	574	\$	548	5%	10%	\$	1,128	\$	1,050	7%	12%
Total net sales	\$	1,429	\$	1,452	(2%)	7%	\$	2,790	\$	2,781	0%	8%

#### **Hematology**

Hemophilia includes sales of recombinant and plasma-derived hemophilia products (primarily factor VIII and factor IX).

Net sales growth in both the three and six months ended June 30, 2015 was driven primarily by:

- Increased demand for the company's recombinant factor VIII therapies, including ADVATE, due to increased prophylactic use in the United States and increased penetration in certain international markets. Globally, recombinant factor VIII therapies contributed approximately 3 percentage points to the Hemophilia product category's net sales growth rate for both the three and six months ended June 30, 2015.
- Continued growth of RIXUBIS, which the company first launched in the United States in 2013.
- Lower volumes of plasma-derived therapies, driven by timing of certain tenders, negatively impacted the Hemophilia net sales growth rate by 1 percentage point during the six months ended June 30, 2015.

The company expects competition from new entrants; however, long-term growth in the Hemophilia product category is expected to be driven by strong underlying global demand, further penetration in markets outside the United States, new multi-year tenders, and launches of new therapies across a variety of geographies, including BAX 855, the company's own investigational extended half-life factor VIII treatment for hemophilia. The company submitted a Biologics License Application for BAX 855 to FDA in the fourth quarter of 2014 following positive topline results from the phase III clinical trial.

**Inhibitor Therapies** include sales of the company's products to treat patients with congenital hemophilia A or B who have developed inhibitors as well as patients that have developed acquired hemophilia A due to an inhibitor.

Growth in net sales during both the three and six months ended June 30, 2015 was driven by strong global demand for the company's plasmabased inhibitor bypass therapy, FEIBA, and a modest impact from the launch of OBIZUR, a recombinant porcine factor VIII therapy for the treatment of acquired Hemophilia A.

- In the United States, strong growth in both periods was driven by continued increased volume associated with advancement in prophylactic use, and pricing improvements.
- Internationally, FEIBA growth resulted from expanded use in certain markets partially offset by timing of tender sales in emerging markets.
- Globally, FEIBA contributed approximately 8 and 10 percentage points to the Inhibitor Therapies net sales growth rate for the three and six months ended June 30, 2015.

#### <u>Immunology</u>

Immunoglobulin Therapies includes sales of the company's antibody-replacement immunoglobulin therapies.

• Net sales growth during both the three and six months ended June 30, 2015 was driven by increased global demand and improved pricing for immunoglobulin therapies, including GAMMAGARD LIQUID and HYQVIA.

The company launched HYQVIA, a differentiated immunoglobulin therapy, in the United States during the second half of 2014 and in certain European markets beginning in the second half of 2013. The company expects HYQVIA sales to continue to contribute to growth, with global sales expected to approach \$100 million by the end of 2015.

To support expected long-term demand for the company's immunoglobulin therapies and other plasma-based therapies, Baxalta is expanding its capacity through ongoing yield improvements, a contract manufacturing services agreement with Sanquin Blood Supply Foundation of the Netherlands and construction of a new greenfield site in Covington, Georgia.

**BioTherapeutics** includes sales of the company's plasma-based therapies to treat alpha-1 antitrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions.

- During the six months ended June 30, 2015, net sales increased primarily due to benefits from increased volumes and price improvements. Globally, albumin products contributed 9 percentage points to the product category's net sales growth rate during the six months ended June 30, 2015.
- The product category's net sales growth during both periods benefitted from revenues recorded from a contract manufacturing agreement related to the divested commercial vaccines business, which contributed approximately 4 and 6 percentage points to the BioTherapeutics product category growth rate for the three and six months ended June 30, 2015, respectively.

In connection with the separation, Baxalta and Baxter entered into a manufacturing and supply agreement whereby Baxalta will manufacture and sell certain products and materials to Baxter. Baxalta will begin recording revenues associated with the manufacturing and supply agreement with Baxter during the third quarter of 2015 in the BioTherapeutics product category. On a pro forma basis, the manufacturing and supply agreement would have resulted in revenues of \$40 million and \$37 million during the three months ended June 30, 2015 and 2014, respectively, and \$82 million and \$81 million during the six months ended June 30, 2015 and 2014, respectively, had it been in effect beginning January 1, 2014.

#### **Expenses and Expense Ratios**

	Three mon June		Six montl June			
(as a percentage of net sales)	2015	2014	Change	2015	2014	Change
Gross margin	64.9%	58.7%	6.2 pts	61.6%	58.4%	3.2 pts
Selling, general and administrative expenses	22.6%	16.7%	5.9 pts	21.7%	16.7%	5.0 pts

#### Gross Margin

The special items identified above had an unfavorable impact of 0.6 and 0.1 percentage points on the gross margin percentage during the three months ended June 30, 2015 and 2014, respectively, and an unfavorable impact of 0.6 and 0.3 percentage points on the gross margin percentage during the six months ended June 30, 2015 and 2014, respectively. Refer to the "Special Items" caption above for additional details.

Excluding the impact of special items, the gross margin percentage improved during both the three and six months ended June 30, 2015 compared to the prior year periods. The increases in both periods were driven by a favorable impact from foreign currency exchange rate fluctuations (primarily related to the Euro), which contributed approximately 5 and 3 percentage points of improvement during the three and six months ended June 30, 2015, respectively, as compared to the prior year periods. Pricing improvements for certain products, including FEIBA and GAMMAGARD LIQUID, and product mix benefits also contributed to the increase in both periods.

#### Selling, General and Administrative Expenses

The special items identified above had an unfavorable impact of 2.6 percentage points on the selling, general and administrative expense ratio during the three months ended June 30, 2015 and no impact on the ratio during the three months ended June 30, 2014. The special items identified above had an unfavorable impact of 2.6 percentage points for the six months ended June 30, 2015 and a favorable impact of 0.4 percentage points for the six months ended June 30, 2014.

Excluding the impact of the special items, the selling, general and administrative expense ratio increased during both the three and six months ended June 30, 2015 compared to the prior year periods. Leverage from higher sales was more than offset by investments related to new product launches, including for HYQVIA and the anticipated BAX855 launch, costs supporting the company's emerging oncology business and other investments supporting expansion of the company's commercial organization.

Following the separation, the composition of Baxalta's selling, general and administrative expenses will change. The company will no longer receive an allocation of costs from Baxter associated with certain corporate or other functions and will incur costs associated with operating as a standalone public company, including costs associated with certain separation-related agreements entered into with Baxter. Refer to the company's Information Statement for further information regarding the separation-related agreements. As a result, selling, general and administrative expenses included in, and the selling, general and administrative expense ratio calculated from, the company's results of operations prior to the separation may not be indicative of the company's expenses or ratio following the separation.

#### **Business Optimization Items**

The company has implemented certain business optimization initiatives in an effort to streamline its international operations, rationalize its manufacturing facilities, enhance its general and administrative infrastructure and re-align or cancel certain R&D activities and programs.

During the six months ended June 30, 2015, the company recorded a net benefit related to business optimization items of \$4 million, consisting of \$10 million of favorable adjustments to charges recorded in prior periods partially offset by \$6 million of charges, including a portion allocated from Baxter, associated with current period initiatives. The company does not expect a material amount of savings associated with charges recorded during the six months ended June 30, 2015.

During the six months ended June 30, 2015, the company estimates an additional \$9 million of annualized savings was realized associated with business optimization activities initiated from 2012 through 2014.

Refer to Note 6 to the condensed combined interim financial statements for further information regarding business optimization items.

#### **Research and Development Expenses**

	Three mont June	Percent	Six mont June	Percent		
(in millions)	2015	2014	change	2015	2014	change
Discovery, clinical and lifecycle management	\$ 86	\$ 76	13%	\$185	\$157	18%
Upfront and milestone payments to collaboration partners	87	35	149%	87	60	45%
Other research and development expenses	67	55	22%	124	112	11%
Total research and development expenses	\$240	\$166	45%	\$396	\$329	20%

<u>Discovery, clinical and lifecycle management expenses</u> consist of costs supporting specific R&D projects, including those in the exploratory or preclinical phase, those in early-or late-stage clinical trials, as well as those pending regulatory approval or supporting development of products that have already obtained regulatory approval.

The growth in discovery, clinical and lifecycle management R&D expenses was impacted primarily by the following:

- Increased investments in research projects related to development and manufacture of hemophilia treatments, contributing to the increase in both the three and six month periods.
- Development costs supporting oncology programs, including nal-IRI for the treatment of metastatic pancreatic cancer, contributing to the increase in both the three and six month periods.
- Partially offsetting for the three month period was lower costs supporting BAX 855 as the company anticipates regulatory approval in the United States in the second half of 2015.
- Also partially offsetting for the three month period was a \$9 million benefit resulting from an agreement with SFJ Pharmaceuticals Group (SFJ) for the reimbursement for certain biosimilar development costs that the company entered into during the three months ended June 30, 2015. The SFJ agreement is discussed in Note 4 to the condensed combined interim financial statements.

<u>Upfront and milestone payments to collaboration partners</u> during the three and six months ended June 30, 2015 consisted of payments of \$35 million to Coherus BioSciences, Inc. (Coherus) related to the development of a biosimilar to ENBREL <sup>®</sup> (etanercept), of \$32 million to CTI BioPharma Corp. related to the development of pacritinib including for the treatment of myelofibrosis and of \$20 million to Merrimack Pharmaceuticals, Inc. related to the development of nal-IRI. Upfront and milestone payments to collaboration partners during the six months ended June 30, 2014 consisted of payments to Coherus.

<u>Other research and development expenses</u> include costs not directly attributable to individual projects and include depreciation and other facility-based expenses, medical and regulatory affairs functions, pharmacovigilance, other infrastructure and management costs supporting multiple projects, business optimization items and separation costs. Business optimization items reported in R&D expenses included favorable adjustments of \$6 million during the six months ended June 30, 2015, charges of \$4 million during the six months ended June 30, 2014. Separation costs reported in R&D expenses were \$5 million and \$12 million during the three and six months ended June 30, 2015, respectively. Excluding business optimization items and separation costs, other R&D expenses increased during both the three and six month periods primarily due to investments in medical affairs functions and infrastructure to support key projects in the company's R&D pipeline.

#### **Net Interest Expense**

On June 23, 2015, Baxalta issued debt directly attributable to its business and began recording interest expense. Net interest expense during the three and six months ended June 30, 2015 of \$3 million primarily reflects interest expense associated with the June 2015 debt issuance, which is further discussed in the "Liquidity and Capital Resources" section below. Prior to the June 2015 debt issuance, Baxter's third-party debt and the related interest expense were not allocated to the company as the company was not the legal obligor of the debt and Baxter borrowings were not directly attributable to the company's business.

#### Other (Income) Expense, Net

During the three and six months ended June 30, 2015, other (income) expense, net was income of \$20 million and \$8 million, respectively. The three and six month periods included income from equity method investments of \$10 million and gains related to foreign currency of \$7 million. The six month period also included other-than-temporary impairment charges of \$9 million due to the duration of declines in the fair value of two of the company's investments.

During the three and six months ended June 30, 2014, other (income) expense, net was expense of \$30 million and \$7 million, respectively. The three and six month period included a loss of \$44 million resulting from an increase in the fair value of a contingent payment liability associated with the acquisition of OBIZUR and related assets from Inspiration / Ipsen. Partially offsetting was income from equity method investments of \$9 million and \$34 million during the three and six months ended June 30, 2014, respectively, which primarily represented distributions from funds that sold portfolio companies as well as gains from the sale of certain investments.

#### **Income Taxes**

#### Effective Income Tax Rate

The company's effective income tax rate from continuing operations was 25.7% and 23.4% during the three months ended June 30, 2015 and 2014, respectively and 24.3% and 23.8% during the six months ended June 30, 2015 and 2014, respectively. The company's effective income tax rate differs from the U.S. federal statutory rate each year due to certain operations that are subject to tax incentives, state and local taxes, and foreign taxes that are different than the U.S. federal statutory rate. In addition, the effective tax rate can be impacted each period by discrete factors and events.

The effective income tax rate increased during both the three and six months ended June 30, 2015 as compared to the prior year period primarily due to an increase in R&D charges associated with milestone payments made to collaboration partners that were deductible at tax rates lower than the effective tax incurred during the three and six months ended June 30, 2014, partially offset by separation costs incurred during the three and six months ended from the effective rate.

## LIQUIDITY AND CAPITAL RESOURCES

Prior to the three month period ending June 30, 2015, Baxalta participated in Baxter's centralized treasury management including centralized cash pooling and overall financing arrangements. Baxalta did not report cash and equivalents on its balance sheet due to its participation in Baxter's centralized treasury management. No debt was allocated to Baxalta because Baxalta was not the legal obligor of the debt and the borrowings were not directly attributable to Baxalta's business.

During the three months ended June 30, 2015, Baxalta issued approximately \$5 billion of its own debt and began establishing its own centralized treasury management system. The company reported long-term debt and capital lease obligations of \$5.2 billion and cash and equivalents of \$2.1 billion on its condensed combined balance sheet as of June 30, 2015. The debt issuance is further described under the "Financing Arrangements" caption below.

On July 28, 2015, Baxalta's Board of Directors declared a quarterly cash dividend of \$0.07 per share of common stock. The quarterly dividend will be paid on October 1, 2015, to shareholders of record as of the close of business on September 4, 2015. On July 28, 2015, Baxalta's Board of Directors also approved a share repurchase authorization which will allow the company to purchase up to \$1 billion of its common stock.

Baxalta's ability to fund its operations and capital needs will depend on its ongoing ability to generate cash from operations and access to capital markets, and could be adversely affected if there is a material decline in the demand for the company's products or in the solvency of its customers or suppliers, deterioration in the company's key financial ratios or credit ratings or other significant unfavorable changes in conditions. However, Baxalta believes that its future cash from operations, its financing arrangements entered into during the three months ended June 30, 2015 and access to capital markets will provide adequate resources to fund its future cash flow needs. Baxalta's principal uses of cash in the future will be primarily to fund its operations, working capital needs, capital expenditures, repayment of borrowings and strategic investments.

A significant portion of the company's net cash provided from operations is generated within the United States, allowing the company to indefinitely reinvest a portion of its foreign earnings in jurisdictions outside of the United States. The company believes its U.S. cash flows from operations together with repatriations of foreign earnings that are not deemed permanently invested are adequate to meet its ongoing cash flow obligations in the United States.
# **Financing Arrangements**

On June 23, 2015, the company issued senior notes with a total aggregate principal amount of \$5 billion. The company used the net proceeds to make a cash distribution of \$4 billion to Baxter as partial consideration for the contribution of net assets to the company in connection with the separation, and intends to use the remainder for general corporate purposes, including to fund acquisitions. The \$4 billion cash distribution to Baxter was made on June 23, 2015. The \$5 billion in senior notes consist of the following tranches;

- \$375 million aggregate principal of senior notes bearing a fixed coupon rate of 2.000% and maturing in June 2018.
- \$375 million aggregate principal of senior notes bearing a floating coupon rate of three-month LIBOR plus 0.780% and maturing in June 2018.
- \$1.0 billion aggregate principal of senior notes bearing a fixed coupon rate of 2.875% and maturing in June 2020.
- \$500 million aggregate principal of senior notes bearing a fixed coupon rate of 3.600% and maturing in June 2022.
- \$1.75 billion aggregate principal of senior notes bearing a fixed coupon rate of 4.000% and maturing in June of 2025.
- \$1.0 billion aggregate principal of senior notes bearing a fixed coupon rate of 5.250% and maturing June 2045.

In connection with this issuance, the company recognized a debt discount of \$51 million and deferred issuance costs totaling \$8 million, which were recorded as a direct deduction from the carrying amount of the debt. Refer to Note 8 for information regarding interest rate derivative contracts the company has entered into related to the senior notes.

Effective July 1, 2015, the company entered into a credit agreement providing for a senior revolving credit facility in an aggregate principal amount of up to \$1.2 billion maturing in 2020. The facility enables the company to borrow funds on an unsecured basis at variable interest rates, and contains various financial and other covenants, including a net leverage ratio covenant and an interest coverage ratio covenant, as well as events of default with respect to the company. The credit facility also provides for the issuance of letters of credit. The company also entered into a Euro-denominated senior revolving credit facility in an aggregate principal amount of up to  $\xi$ 200 million maturing in 2020, with similar terms as the above credit facility. The non-performance of any financial institution supporting either of the credit facilities would reduce the maximum capacity of these facilities by each institution's respective commitment.

# **Historical Cash Flow Trends**

The company's historical cash flows reflect both continuing and discontinued operations.

	Six months ended June 30,	
(in millions)	2015	2014
Net cash provided from operations	\$ 191	\$ 214
Net cash used for investing activities	(840)	(519)
Net cash provided from financing activities	2,730	305
Effect of foreign exchange rate changes on cash and equivalents	10	
Change in cash and equivalents	\$2,091	\$ _

# Net Cash Provided From Operations

The decrease in net cash provided by operations during the six months ended June 30, 2015 as compared to the prior year period was driven by increases in separation costs, milestone payments made to collaboration partners, and investments in the R&D pipeline. Also contributing was an increase in accounts receivable from Hemobrás in Brazil during the current year period and the impact of an increase in global collections in the prior year period. Partially offsetting were lower cash outflows for tax related items.

The company maintains an income taxes payable to/from account with Baxter, and is deemed to have settled its current income tax payables with Baxter annually on the first day of each year. This results in significant tax related cash outflows during the first six months of each year that are not repeated during the last six months of each year. This annual settlement resulted in cash outflows of \$352 million and \$537 during the six months ended June 30, 2015 and 2014, respectively, which reflected the full prior year's current income tax expense and other current tax balances. Current income tax expense recorded during the first six months of each period does not result in an operating cash outflow, which partially offsets the unfavorable impact of the annual settlement on both periods described above.

#### Net Cash Used For Investing Activities

The company's net cash used for investing activities increased during the six months ended June 30, 2015 as compared to the six months ended June 30, 2014 due to increased cash outflows for acquisitions and an increase in capital expenditures.

Capital expenditures during the six months ended June 30, 2015 and 2014 were \$583 million and \$439 million, respectively. The increase in capital expenditures was driven by several projects aimed at improving manufacturing capacity for the company's products, including increased expenditures associated with the construction of the Covington, Georgia manufacturing facility as the company continues to progress towards completion. A significant portion of the construction is expected to be completed in 2015 and commercial production is expected to begin in 2018.

Cash outflows for acquisitions, net of cash acquired during the six months ended June 30, 2015 and 2014 were \$228 million and \$85 million, respectively. During the first six months of 2015, cash outflows for acquisitions, net of cash acquired included \$228 million for the acquisition of SuppreMol GmbH, a privately held biopharmaceuticals company based in Germany. During the first six months of 2014, cash outflow for acquisitions, net of cash acquired included \$70 million for the acquisition of Chatham Therapeutics, LLC, in which the company acquired Chatham's gene therapy technology for potential treatment of hemophilia.

# Net Cash Provided From Financing Activities

Proceeds from issuance of long-term debt totaled \$4.9 billion during the first six months of 2015 and reflected cash inflows from the debt issuance described under "Financing Arrangements" above, and were net of a debt discount and deferred issuance costs totaling \$59 million.

Other cash provided from or used for financing activities during the six months ended June 30, 2015 and 2014 primarily reflected net cash outflows from transactions with Baxter of \$2.2 billion. The net transactions with Baxter during the six months ended June 30, 2015 included a \$4 billion cash distribution to Baxter as partial consideration for the contribution of assets to Baxalta from Baxter in connection with the separation. The cash distribution was partially offset by cash contributions from Baxter in connection with the formation of Baxalta legal entities and other transactions with Baxter.

### **Credit ratings**

The company's credit ratings are as follows:

	Standard and Poor's	Fitch	Moody's
Ratings			
Senior debt	BBB	BBB+	Baa2
Short-term debt	A-2	F2	P-2
Outlook	Stable	Stable	Stable

### **Concentrations of Credit Risk**

Baxalta engages in business with foreign governments in certain countries that have experienced deterioration in credit and economic conditions, including Greece, Spain, Portugal, Italy and Brazil. As of June 30, 2015, the company's net accounts receivable from the public sector in Greece, Spain, Portugal and Italy totaled \$141 million, of which Greece receivables represented an immaterial balance. The company also has significant accounts receivable related to its Hemobrás partnership in Brazil totaling \$157 million at June 30, 2015.

Global economic conditions and liquidity issues in certain countries have resulted, and may continue to result, in delays in the collection of receivables and credit losses. While the company believes that its allowance for doubtful accounts as of June 30, 2015 is adequate, future governmental actions and customer-specific factors may require the company to re-evaluate the collectability of its receivables and the company could potentially incur additional credit losses that materially impact the company's results of operations.

# **Off-Balance Sheet Arrangements**

Baxalta periodically enters into off-balance sheet arrangements. Certain contingencies arise in the normal course of business, and are not recorded in the combined balance sheet in accordance with GAAP (such as contingent milestone payments associated with the company's collaboration agreements). Also, upon resolution of uncertainties, the company may incur charges in excess of presently

established liabilities for certain matters (such as contractual indemnifications). The company's significant off-balance sheet arrangements and contingencies as of December 31, 2014 are discussed in the combined annual financial statements contained in the company's Information Statement. Refer to Note 4 to the annual combined financial statements for information regarding collaboration agreements, Note 9 to the annual combined financial statements regarding legal contingencies.

Material updates to off-balance sheet arrangements are discussed in the condensed combined interim financial statements contained in this Form 10-Q. Refer to Note 4 to the interim combined financial statements for information regarding collaboration agreements and Note 14 to the interim combined financial statements regarding legal contingencies.

### **Contractual Obligations**

The company's contractual obligations as of December 31, 2014 are disclosed in Management's Discussion and Analysis contained in the company's Information Statement. Below are material updates.

- In June 2015, the company issued senior notes with a total aggregate principal amount of \$5 billion. The maturities and interest rates of the senior notes are discussed under the "Financing Arrangements" caption above.
- As of June 30, 2015 Baxalta increased its unfunded commitments as a limited partner in multiple investment companies to \$73 million from \$32 million as of December 31, 2014, in connection with the company's initiative to invest in early-stage products and therapies.

#### NEW ACCOUNTING STANDARDS

In July 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory, which clarifies that inventory should be measured at the lower of cost and net realizable valued. ASU 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. ASU 2015-11 will be effective for the company beginning on January 1, 2016, and prospective application is required. Early adoption is permitted. The company is currently evaluating the impact of adopting the standard on its combined financial statements.

In April 2015, the FASB issued ASU No. 2015-05, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement, which provides guidance to customers about how to account for cloud computing arrangements when such arrangements include software licenses. ASU No. 2015-05 will be effective for the company beginning on January 1, 2016. Early adoption is permitted. The standard may be applied retrospectively or prospectively. The company is currently evaluating the impact of adopting the standard on its combined financial statements.

In April 2015, the FASB issued ASU No. 2015-03, Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts. ASU No. 2015-03 will be effective for company beginning on January 1, 2016, and retrospective application is required. Early adoption is permitted, and the company has adopted ASC No. 2015-03 effective June 30, 2015. Refer to Note 7 for additional information.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU 2014-09), which amends the existing accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled to when products are transferred to customers. In July 2015, the FASB voted to approve a one-year deferral on the original effective date of January 1, 2017, therefore ASU No. 2014-09 will be effective for the company beginning on January 1, 2018. Early adoption is permitted as of the original effective date. The new revenue standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. The company is currently evaluating the impact of adopting the new revenue standard on its combined financial statements.

In April 2014, the FASB issued ASU 2014-08, Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity (ASU 2014-08) which amends the definition of a discontinued operation in Accounting Standard Codifications (ASC) 205-20 and provides additional requirements for the entities with its disposal transaction to qualify as a discontinued operation. ASU 2014-08 is effective prospectively for all disposals beginning on or after December 15, 2014 (with early adoption permitted). The Company did not early adopt the new guidance and it is effective for the company for periods beginning with its first interim period ended March 31, 2015. ASU 2014-08 did not have a material impact on the company's combined financial statements upon adoption.

# **CRITICAL ACCOUNTING POLICIES**

The preparation of financial statements in accordance with GAAP requires the company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. A summary of the company's significant accounting policies is included in Note 1 to the combined annual financial statements contained in the company's Information Statement. Certain of the company's accounting policies are considered critical because these policies are the most important to the depiction of the company's financial statements and require significant, difficult or complex judgments, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in the Management's Discussion and Analysis section contained in the company's Information Statement. There have been no significant changes in the company's application of its critical accounting policies during the first six months of 2015 other than noted below.

## Pension and Other Postemployment Benefit (OPEB) Plans

Prior to the second quarter of 2015 and with the exception of certain Austrian defined benefit pension plans, of which Baxalta was the sole sponsor, the company's employees have participated in certain U.S. and international defined benefit pension and other post-employment benefit (OPEB) plans sponsored by Baxter. Baxalta accounted for these plans as multiemployer plans prior to the second quarter of 2015, in which case no liabilities or plan assets were included in the company's combined balance sheets.

During the second quarter of 2015, Baxalta assumed certain pension and OPEB obligations and plan assets related to newly-created single employer plans for Baxalta employees and certain other Baxter-sponsored pension plans, as described below.

Certain pension plans, including those in Switzerland and Japan, continue to be sponsored by Baxter as of June 30, 2015. Based on the terms of the separation agreement the company expects to become sole sponsor of these pension plans during 2016, and therefore has accounted for these plans as multiple-employer plans beginning in the second quarter of 2015. As a result, the company recorded a net benefit plan obligation as of June 30, 2015 related to the single and multiple-employer plans described above.

Refer to Note 10 to the condensed combined interim financial statements for further information regarding the company's pension and OPEB plans.

# FORWARD-LOOKING INFORMATION

This quarterly report includes forward-looking statements. Use of the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "seeks," "intends," "evaluates," "pursues," "anticipates," "continues," "designs," "impacts," "affects," "forecasts," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal," or the negative of those words or other similar expressions is intended to identify forward-looking statements that represent our current judgment about possible future events. These forward-looking statements may include statements with respect to accounting estimates and assumptions, the company's expectations regarding the separation, including separation costs, litigation-related matters including outcomes, future regulatory filings and the company's R&D pipeline, strategic objectives, credit exposure to foreign governments, potential developments with respect to credit ratings, investment of foreign earnings, estimates of liabilities including those related to uncertain tax positions, contingent payments, future pension plan contributions, costs, discount rates and rates of return, the company's exposure to financial market volatility and foreign currency and interest rate risks, geographic expansion, the impact of competition, future sales growth, business development activities, business optimization initiatives, future capital and R&D expenditures, future transactions in the company's securities and debt issuances, the impact of healthcare reform, manufacturing expansion, the sufficiency of the company's facilities and financial flexibility, the adequacy of credit facilities, derivative instruments, tax provisions and reserves, the effective tax rate and all other statements that do not relate to historical facts.

These forward-looking statements are based on certain assumptions and analyses made in light of our experience and perception of historical trends, current conditions, and expected future developments as well as other factors that we believe are appropriate in the circumstances. While these statements represent our current judgment on what the future may hold, and we believe these judgments are reasonable, these statements are not guarantees of any events or financial results.

Whether actual future results and developments will conform to expectations and predictions is subject to a number of risks and uncertainties, including the following factors, many of which are beyond our control:

- demand for and market acceptance of risks for and competitive pressures related to new and existing products;
- product development risks, including satisfactory clinical performance, the ability to manufacture at appropriate scale, and the general unpredictability associated with the product development cycle;
- product quality or patient safety issues, leading to product recalls, withdrawals, launch delays, sanctions, seizures, litigation, loss of confidence or declining sales;
- future actions of FDA, EMA or any other regulatory body or government authority that could delay, limit or suspend product development, manufacturing or sale or result in seizures, recalls, injunctions, loss of customer confidence, monetary sanctions or criminal or civil liabilities;

- failures with respect to the company's compliance programs;
- global regulatory, trade and tax policies;
- the impact of competitive products and pricing, including generic competition, drug re-importation and disruptive technologies;
- the company's ability to identify business development and growth opportunities and to successfully execute on its business development strategy;
- the company's ability to realize the anticipated benefits from its joint product development and commercialization arrangements, governmental collaborations and other business development activities or to identify and enter into additional such opportunities in the future;
- future actions of third parties, including third-party payors, as healthcare reform and other similar measures are implemented in the United States and globally;
- the impact of U.S. healthcare reform and other similar actions undertaken by foreign governments with respect to pricing, reimbursement, taxation and rebate policies;
- additional legislation, regulation and other governmental pressures in the United States or globally, which may affect pricing, reimbursement, taxation and rebate policies of government agencies and private payors or other elements of the company's business;
- fluctuations in supply and demand and the pricing of plasma-based therapies;
- the availability and pricing of acceptable raw materials and component supply;
- inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties;
- the ability to protect or enforce the company's owned or in-licensed patent or other proprietary rights (including trademarks, copyrights, trade secrets and know-how) or patents of third parties preventing or restricting the company's manufacture, sale or use of affected products or technology;
- the company's ability to develop and sustain relationships with institutional partners;
- the impact of global economic conditions on the company and its customers and suppliers, including foreign governments in certain countries in which the company operates;
- fluctuations in foreign exchange and interest rates;
- any changes in law concerning the taxation of income, including income earned outside the United States;
- breaches or failures of the company's information technology systems;
- loss of key employees or inability to identify and recruit new employees;
- the outcome of pending or future litigation;
- the adequacy of the company's cash flows from operations to meet its ongoing cash obligations and fund its investment program;
- the company's ability to successfully develop and introduce biosimilar products;
- the company's operations as an independent company;
- the costs and temporary business interruptions related to the separation;
- Baxter's performance under various transaction agreements that will be executed as part of the separation;
- the company's ability to transition away from the services to be provided by Baxter pursuant to the transition services agreement, manufacturing and supply agreement and other agreements with Baxter in a timely manner;
- potential indemnification liabilities owed to Baxter after the separation;
- the tax treatment of the distribution and the limitations imposed on the company under the tax matters agreement that the company entered into Baxalta will enter into with Baxter;



- restrictions on post-separation activities in order to preserve the tax-free treatment of the separation;
- potential conflicts of interest for certain of the company's executive officers and directors because of their previous or continuing positions at Baxter;
- the company's ability to achieve benefits from the separation in a timely manner;
- the incurrence of substantial indebtedness following the separation from Baxter;
- the company's ability to access the capital markets following the separation from Baxter;
- changes to the timing of the subsequent disposal of the equity retained by Baxter;
- the outcome of Shire PLC's unsolicited offer to acquire the company; and
- other factors identified elsewhere in this report and other filings with the Securities and Exchange Commission.

Actual results may differ materially from those projected in the forward-looking statements. The company does not undertake to update its forward-looking statements.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

#### **Currency Risk**

The company is primarily exposed to foreign exchange risk with respect to recognized assets and liabilities, forecasted transactions and net assets denominated in the Euro, Japanese Yen, British Pound, British Pound, Swiss Franc, Australian Dollar, Turkish Lira, Russian Ruble, Chinese Renminbi and Colombian Peso. The company manages its foreign currency exposures on a consolidated basis, which allows the company to net exposures and take advantage of any natural offsets. In addition, the company uses derivative and nonderivative financial instruments to further reduce the net exposure to foreign exchange. Gains and losses on the hedging instruments offset losses and gains on the hedged transactions and reduce the earnings and shareholders' equity volatility relating to foreign exchange. Financial market and currency volatility may limit the company's ability to cost-effectively hedge these exposures.

The company may use options, forwards and cross-currency swaps to hedge the foreign exchange risk to earnings relating to forecasted transactions denominated in foreign currencies and recognized assets and liabilities. The maximum term over which the company has cash flow hedge contracts in place related to forecasted transactions as of June 30, 2015 is 18 months. The company also enters into derivative instruments to hedge certain intercompany and third-party receivables and payables and debt denominated in foreign currencies.

As part of its risk-management program, the company performs a sensitivity analysis to assess potential changes in the fair value of its foreign exchange instruments relating to hypothetical and reasonably possible near-term movements in foreign exchange rates.

A sensitivity analysis of changes in the fair value of foreign exchange option and forward contracts outstanding at June 30, 2015, while not predictive in nature, indicated that if the U.S. Dollar uniformly weakened by 10% against all currencies, on a net-of-tax basis, the net liability balance of \$1 million would increase by \$34 million.

The sensitivity analysis model recalculates the fair value of the foreign exchange option and forward contracts outstanding at June 30, 2015 by replacing the actual exchange rates at June 30, 2015 with exchange rates that are 10% weaker to the actual exchange rates for each applicable currency. All other factors are held constant. The sensitivity analysis disregards the possibility that currency exchange rates can move in opposite directions and that gains from one currency may or may not be offset by losses from another currency. The analysis also disregards the offsetting change in value of the underlying hedged transactions and balances.

## **Interest Rate and Other Risks**

Prior to the three month period ending June 30, 2015, Baxalta participated in Baxter's centralized treasury management including centralized cash pooling and overall financing arrangements. Baxalta did not report cash and equivalents on its balance sheet due to its participation in Baxter's centralized treasury management. No debt or interest expense was allocated to Baxalta because Baxalta was not the legal obligor of the debt and the borrowings were not directly attributable to Baxalta's business.

In June 2015, the company issued senior notes with a total aggregate principal amount of \$5 billion. The \$5 billion of senior notes includes both fixed- and floating interest rates. Additionally, the company has entered into interest rate swaps in which it agrees to exchange, at specified intervals, the difference between fixed and floating interest amounts calculated by reference to an agreed-upon notional amount. Net interest expense associated with the June 2015 debt issuance totaled \$3 million during the three months ended June 30, 2015 and the company's exposure to interest rate risk with respect to its results of operations was not material during the period. The company's exposure to interest rate risk is expected to increase in future periods when its third-party debt is outstanding for a longer period of time. In connection with the June 2015 debt issuance, the company terminated its outstanding forward-starting swaps and no longer bears the related interest rate risk associated with these instruments as of June 30, 2015.

## **Item 4. Controls and Procedures**

## Evaluation of Disclosure Controls and Procedures

Baxalta carried out an evaluation, under the supervision and with the participation of its Disclosure Committee and management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of Baxalta's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of June 30, 2015. Based on that evaluation the Chief Executive Officer and Chief Financial Officer concluded that the company's disclosure controls and procedures were effective as of June 30, 2015.

# Internal Control Over Financial Reporting

Under the rules and regulations of the Securities and Exchange Commission, Baxalta is not required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 until its Annual Report on Form 10-K for the year ending December 31, 2016. In its Annual Report on Form 10-K for the year ending December 31, 2016, management and the company's independent registered public accounting firm will be required to provide an assessment as to the effectiveness of the company's internal control over financial reporting.

# Changes in Internal Control Over Financial Reporting

There have been no changes in the company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, the company's internal control over financial reporting.

# PART II. OTHER INFORMATION

# **Item 1. Legal Proceedings**

On February 25, 2015, the company received a notice of a violation from the Ventura County Air Pollution Control District as a result of it selfreporting certain violations of environmental regulations at its manufacturing facility located in Thousand Oaks, California, to that agency promptly after discovery on October 16, 2014, as required by local regulations. Pursuant to that notice, the company paid penalties in the amount of \$103,000 to the agency, which releases the company of any further claims or liabilities for such violations.

For a description of further legal proceedings, see Note 14 to the interim condensed combined financial statements, which is incorporated herein by reference.

## Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in the company's Information Statement included as Exhibit 99.1 to the company's effective Registration Statement on Form 10, as filed with the SEC on June 5, 2015.

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2.1	Incorporated (incorporated by reference to Exhibit 2.1 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2. 2015, File No. 1-36782). †
3.1	Amended and Restated Certificate of Incorporation of Baxalta Incorporated (incorporated by reference to Exhibit 3.1 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
3.2	Amended and Restated Bylaws of Baxalta Incorporated (incorporated by reference to Exhibit 3.2 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of Baxalta Incorporated (incorporated by reference to Exhibit 3.1 to Baxalta Incorporated's Registration Statement on Form 8-A filed on June 30, 2015, File No. 1-36782).
4.1	Indenture between Baxalta Incorporated and The Bank of New York Mellon Trust Company, N.A., as Trustee, dated as of June 23, 2015 (incorporated by reference to Exhibit 4.1 to Baxalta Incorporated's Current Report on Form 8-K filed on July 23, 2015, File No. 1-36782).
4.2	First Supplemental Indenture, to the Indenture dated as of June 23, 2015, between Baxalta Incorporated and The Bank of New York Mellon Trust Company, N.A., as Trustee, dated as of June 23, 2015 (incorporated by reference to Exhibit 4.2 to Baxalta Incorporated's Current Report on Form 8-K filed on July 23, 2015, File No. 1-36782).
4.3	Registration Rights Agreement, dated as of June 23, 2015, by and among Baxalta Incorporated, Baxter International Inc. and Citigroup Global Markets Inc., Goldman, Sachs & Co., J.P. Morgan Securities LLC and UBS Securities LLC as representatives of the Initial Purchasers (incorporated by reference to Exhibit 4.4 to Baxalta Incorporated's Current Report on Form 8-K filed on July 23, 2015, File No. 1-36782).
4.4	Rights Agreement, dated as of June 30, 2015, by and between Baxalta Incorporated and Computershare Trust Company, N.A. and Computershare Inc. collectively as Rights Agent (incorporated by reference to Exhibit 4.1 to Baxalta Incorporated's Registration Statement on Form 8-A filed on June 30, 2015, File No. 1-36782).
4.5	Shareholder's and Registration Rights Agreement, dated as of June 30, 2015, by and between Baxter International Inc. and Baxalta Incorporated (incorporated by reference to Exhibit 4.2 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
10.1	Transition Services Agreement, dated as of June 30, 2015, by and between Baxter International Inc. and Baxalta Incorporated (incorporated by reference to Exhibit 10.1 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
10.2	Tax Matters Agreement, dated as of June 30, 2015, by and between Baxter International Inc. and Baxalta Incorporated (incorporated by reference to Exhibit 10.2 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
10.3	Manufacturing and Supply Agreement, dated as of June 30, 2015, by and between Baxter International Inc. and Baxalta Incorporated (incorporated by reference to Exhibit 10.3 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
10.4	Employee Matters Agreement, dated as of June 30, 2015, by and between Baxter International Inc. and Baxalta Incorporated (incorporated by reference to Exhibit 10.4 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).

- 10.5 Trademark License Agreement, dated as of June 30, 2015, by and between Baxter International Inc. and Baxalta Incorporated (incorporated by reference to Exhibit 10.5 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.6 International Commercial Operations Agreement, dated as of June 30, 2015, by and among Baxalta World Trade LLC, Baxalta GmbH, Baxalta Holding B.V., Baxter World Trade Corporation, Baxter Healthcare SA and Baxter Holding B.V. (incorporated by reference to Exhibit 10.6 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.7 Long Term Services Agreement, dated as of June 30, 2015, by and between Baxter International Inc. and Baxalta Incorporated (incorporated by reference to Exhibit 10.7 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.8 Galaxy License Agreement, dated as of June 30, 2015, by and among Baxter International Inc., Baxter Healthcare SA and Baxalta Incorporated (incorporated by reference to Exhibit 10.8 to the Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.9 Five-Year Credit Agreement, dated as of July 1, 2015, among Baxalta Incorporated as Borrower, JPMorgan Chase Bank, National Association, as Administrative Agent and certain other financial institutions named therein (incorporated by reference to Exhibit 10.9 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.10 2015 Baxalta Incorporated Non-Employee Director Compensation Plan (incorporated by reference to Exhibit 10.10 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.11 Baxalta Incorporated Directors' Deferred Compensation Plan (incorporated by reference to Exhibit 10.11 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.12 Baxalta Incorporated 2015 Incentive Plan (incorporated by reference to Exhibit 10.12 to Baxalta Incorporated's Registration Statement on Form S-1 filed on June 23, 2015).
- 10.13 Baxalta Incorporated Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to Baxalta Incorporated's Registration Statement on Form S-8, File No. 333-205332 filed on June 29, 2015).
- 10.14 Baxalta Incorporated and Subsidiaries Deferred Compensation Plan (incorporated by reference to Exhibit 4.1 to Baxalta Incorporated's Registration Statement on Form S-8, File No. 333-205330 filed on June 29, 2015).
- 10.15 Baxalta Incorporated and Subsidiaries Supplemental Pension Plan (incorporated by reference to Exhibit 10.15 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.16 Form of Severance Agreement (incorporated by reference to Exhibit 10.1 to Baxalta Incorporated's Amendment No. 2 to the Registration Statement on Form 10 of Baxalta Incorporated, filed on April 10, 2015).
- 10.17 Form of Severance Agreement entered into with executive officers (incorporated by reference to Exhibit 10.16 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.18 Baxalta Incorporated Equity Plan (incorporated by reference to Exhibit 10.17 to Baxalta Incorporated's Current Report on Form 8-K filed on July 2, 2015, File No. 1-36782).
- 10.19 Form of Indemnification Agreement for directors and officers (incorporated by reference to Exhibit 10.10 to Amendment No. 2 to the Registration Statement on Form 10 of Baxalta Incorporated, filed on April 10, 2015).
- 10.20 Office Lease Agreement between Hub Mid-West LLC and Baxter Healthcare Corporation, dated February 20, 2015 (Incorporated by reference to Exhibit 10.11 to Amendment No.4 to the Registration Statement on Form 10 of Baxalta Incorporated filed on May 29, 2015).
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Certifications pursuant to 18 U.S.C. Section 1350.\*
- 101.INS XBRL Instance Document\*

101.SCH XBRL Taxonomy Extension Schema Document\*

- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document\*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document\*
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document\*
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document\*

<sup>\*</sup> Baxalta Incorporated hereby undertakes to furnish supplementally a copy of any omitted schedule or exhibit to such agreement to the U.S. Securities and Exchange Commission upon request.

<sup>\*</sup> Filed herewith.

# Signature

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 hereunto duly authorized.

# BAXALTA INCORPORATED

(Registrant)

Date: August 13, 2015

By: /s/ Robert J. Hombach

Robert J. Hombach Executive Vice President, Chief Financial Officer and Chief Operations Officer (duly authorized officer and principal financial officer)

#### **CERTIFICATION OF CHIEF EXECUTIVE OFFICER Pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as Amended**

I, Ludwig N. Hantson, Ph.D., certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Baxalta Incorporated;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2015

By: /s/ Ludwig N. Hantson, Ph.D.

Ludwig N. Hantson, Ph.D. Chief Executive Officer

## CERTIFICATION OF CHIEF FINANCIAL OFFICER Pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as Amended

I, Robert J. Hombach, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Baxalta Incorporated;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2015

By: /s/ Robert J. Hombach

Robert J. Hombach Chief Financial Officer

# CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the accompanying Quarterly Report of Baxalta Incorporated (the "Company") on Form 10-Q for the quarter ended June 30, 2015 (the "Report"), Ludwig N. Hantson, Ph.D., Chief Executive Officer of the Company, and Robert J. Hombach, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2015

/s/ Ludwig N. Hantson, Ph.D. Ludwig N. Hantson, Ph.D. Chief Executive Officer

Date: August 13, 2015

/s/ Robert J. Hombach Robert J. Hombach Chief Financial Officer