AbbVie Inc. Form 10-Q November 07, 2018

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF $^{\rm x}$ 1934

For the quarterly period ended September 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF $^{\rm 0}1934$

For the transition period from

to

Commission File No. 001-35565

AbbVie Inc.

(Exact name of registrant as specified in its charter)

Delaware 32-0375147

(State or other jurisdiction of incorporation or organization) (I.R.S. employer identification number)

1 North Waukegan Road North Chicago, Illinois 60064

Telephone: (847) 932-7900

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 x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 x Accelerated Filer "

Non-Accelerated Filer " Smaller reporting company "

(Do not check if a smaller reporting company)

Emerging growth company "

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. "

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

As of October 31, 2018, AbbVie Inc. had 1,504,216,327 shares of common stock at \$0.01 par value outstanding.

AbbVie Inc. and Subsidiaries Table of Contents

PART I. FINANCIAL INFORMATION

1 1 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
		Page
Item 1.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	<u>2</u>
Item 2.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	<u>26</u>
Item 3.		<u>36</u>
Item 4.	CONTROLS AND PROCEDURES	<u>37</u>
PART II	LOTHER INFORMATION	
Item 1.	LEGAL PROCEEDINGS	<u>38</u>
Item 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	<u>38</u>
Item 6.	<u>EXHIBITS</u>	<u>39</u>
2018 Fo	orm 10-Q 1	

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

AbbVie Inc. and Subsidiaries

Condensed Consolidated Statements of Earnings (unaudited)

			Nine mo ended	nths
	Septem	ber 30,	Septemb	er 30,
(in millions, except per share data)	2018	2017	2018	2017
Net revenues	\$8,236	\$6,995	\$24,448	\$20,477
Control and doubt and	1 025	1 (1(<i>5.606</i>	4761
Cost of products sold	1,835	1,616	5,696	4,761
Selling, general and administrative	1,919	1,457	5,470	4,339
Research and development	1,268	1,228	3,834	3,599
Acquired in-process research and development	55		124	15
Other expense			500	
Total operating costs and expenses	5,077	4,301	15,624	12,714
Operating earnings	3,159	2,694	8,824	7,763
Latinant	202	252	025	750
Interest expense, net	302	252	825	752
Net foreign exchange loss	2	9	18	28
Other expense, net	94	338	411	449
Earnings before income tax expense	2,761		7,570	6,534
Income tax expense	14	464	57	1,277
Net earnings	\$2,747	\$1,631	\$7,513	\$5,257
Per share data				
Basic earnings per share	\$1.81	\$1.02	\$4.81	\$3.28
Diluted earnings per share	\$1.81	\$1.02	\$4.79	\$3.27
Diace carnings per snare	ψ1.01	ψ1.01	ψ 4. /2	ψ 3.41
Weighted-average basic shares outstanding	1,511	1,597	1,556	1,596
Weighted-average diluted shares outstanding	1,515	1,603	1,561	1,602

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

AbbVie Inc. and Subsidiaries Condensed Consolidated Statements of Comprehensive Income (unaudited)

	Three mended Septemb		Nine mended Septem		
(in millions)	2018	2017	2018	2017	
Net earnings	\$2,747	\$1,631		\$5,257	7
Foreign currency translation adjustments, net of tax expense (benefit) of \$3 for the three months and \$(16) for the nine months ended September 30, 2018 and \$7 for the three months and \$40 for the nine months ended September 30, 2017	30	183	(250	602	
Net investment hedging activities, net of tax expense (benefit) of \$(9) for the three months and \$22 for the nine months ended September 30, 2018 and \$(52) for the three months and \$(174) for the nine months ended September 30, 2017		(90) 73	(307)
Pension and post-employment benefits, net of tax expense (benefit) of \$8 for the three months and \$24 for the nine months ended September 30, 2018 and \$8 for the three months and \$23 for the nine months ended September 30, 2017	28	8	99	21	
Marketable security activities, net of tax expense (benefit) of \$— for the three months and \$— for the nine months ended September 30, 2018 and \$4 for the three months and \$6 for the nine months ended September 30, 2017	e e	(28) (2) (18)
Cash flow hedging activities, net of tax expense (benefit) of \$1 for the three months and \$18 for the nine months ended September 30, 2018 and \$(14) for the three months and \$(29) for the nine months ended September 30, 2017	54	(138) 248	(325)
Other comprehensive income (loss) Comprehensive income	80 \$2,827	(65 \$1,566) 168 \$7,681	(27 \$5,230)

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

AbbVie Inc. and Subsidiaries Condensed Consolidated Balance Sheets

(in millions, except share data)	September 30 2018 (unaudited)), December 2017	31,
Assets			
Current assets			
Cash and equivalents	\$ 8,015	\$ 9,303	
Short-term investments	770	486	
Accounts receivable, net	5,780	5,088	
Inventories	1,786	1,605	
Prepaid expenses and other	2,114	4,741	
Total current assets	18,465	21,223	
Investments	1,463	2,090	
Property and equipment, net	2,950	2,803	
Intangible assets, net	26,625	27,559	
Goodwill	15,718	15,785	
Other assets	943	1,326	
Total assets	\$ 66,164	\$ 70,786	
Liabilities and Equity			
Current liabilities			
Short-term borrowings	\$ 3,002	\$ 400	
Current portion of long-term debt and lease obligations	1,019	6,015	
Accounts payable and accrued liabilities	11,366	10,226	
Total current liabilities	15,387	16,641	
Long-term debt and lease obligations	36,487	30,953	
Deferred income taxes	1,490	2,490	
Other long-term liabilities	15,721	15,605	
	-,-	-,	
Commitments and contingencies			
Stockholders' equity (deficit)			
Common stock, \$0.01 par value, 4,000,000,000 shares authorized, 1,776,109,692 shares issued as of September 30, 2018 and 1,768,738,550 as of December 31, 2017	18	18	
Common stock held in treasury, at cost, 271,949,381 shares as of September 30, 2018 and 176,607,525 as of December 31, 2017	d (21,849)	(11,923)
Additional paid-in capital	14,680	14,270	
Retained earnings	6,789	5,459	
Accumulated other comprehensive loss	•	(2,727)
Total stockholders' equity (deficit)	(2,921)		,
20mi stormistatio equity (activity)	(-,)	5,071	
Total liabilities and equity	\$ 66,164	\$ 70,786	

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

AbbVie Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows (unaudited)

	Nine mo ended Septemb	
(in millions) (brackets denote cash outflows)	2018	2017
Cash flows from operating activities		
Net earnings	\$7,513	\$5,257
Adjustments to reconcile net earnings to net cash from operating activities:		
Depreciation	349	324
Amortization of intangible assets	974	808
Change in fair value of contingent consideration liabilities	432	547
Stock-based compensation	351	288
Upfront costs and milestones related to collaborations	711	85
Other, net	423	(73)
Changes in operating assets and liabilities:		
Accounts receivable	(806)	(163)
Inventories	(367)	(119)
Prepaid expenses and other assets	(426)	(22)
Accounts payable and other liabilities	881	444
Cash flows from operating activities	10,035	7,376
Cash flows from investing activities		
Acquisitions and investments	(541)	(180)
Acquisitions of property and equipment	(515)	(347)
Purchases of investment securities	(1,581)	(1,838)
Sales and maturities of investment securities	1,914	1,890
Cash flows from investing activities	(723)	(475)
Cash flows from financing activities		
Net change in commercial paper borrowings	(400)	423
Proceeds from issuance of other short-term borrowings	3,002	_
Proceeds from issuance of long-term debt	5,963	_
Repayments of long-term debt and lease obligations	(5,021)	(18)
Debt issuance costs	(34)	_
Dividends paid	(4,129)	(3,077)
Purchases of treasury stock	(9,956)	(905)
Proceeds from the exercise of stock options	66	214
Payments of contingent consideration liabilities	(78)	(268)
Other, net	16	47
Cash flows from financing activities		(3,584)
Effect of exchange rate changes on cash and equivalents		29
Net change in cash and equivalents	(1,288)	
Cash and equivalents, beginning of period	9,303	5,100
Cash and equivalents, end of period	\$8,015	\$8,446

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

AbbVie Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 Basis of Presentation

Basis of Historical Presentation

The unaudited interim condensed consolidated financial statements of AbbVie Inc. (AbbVie or the company) have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. Accordingly, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) have been omitted. These unaudited interim condensed consolidated financial statements should be read in conjunction with the company's audited consolidated financial statements and notes included in the company's Annual Report on Form 10-K for the year ended December 31, 2017.

It is management's opinion that these financial statements include all normal and recurring adjustments necessary for a fair presentation of the company's financial position and operating results. Net revenues and net earnings for any interim period are not necessarily indicative of future or annual results. Certain reclassifications were made to conform the prior period interim condensed consolidated financial statements to the current period presentation. Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

ASU No. 2014-09

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs - Contracts with Customers (Subtopic 340-40). The amendments in this standard superseded most existing revenue recognition requirements. The core principle of the new guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. AbbVie adopted the standard in the first quarter of 2018 using the modified retrospective method. Results for reporting periods beginning after December 31, 2017 have been presented in accordance with the standard, while results for prior periods have not been adjusted and continue to be reported in accordance with AbbVie's historical accounting. The cumulative effect of initially applying the new revenue standard was recognized as an adjustment to the opening balance of retained earnings as of January 1, 2018.

There were no significant changes to the amounts or timing of revenue recognition for product sales, the company's primary revenue stream. For certain licensing arrangements where revenue was previously deferred and recognized over time, revenue is now recognized at the point in time when the license is granted. Additionally, for certain contract manufacturing arrangements where revenue was previously recognized at a point in time at the end of the manufacturing process, revenue is now recognized over time throughout the manufacturing process.

Under the new standard, on January 1, 2018, the company recognized a cumulative-effect adjustment to retained earnings primarily related to certain deferred license revenues that were originally expected to be recognized through early 2020. The adjustment to the condensed consolidated balance sheet included: (i) a \$42 million increase to prepaid expenses and other; (ii) a \$39 million decrease to inventories; (iii) a \$57 million decrease to accounts payable and accrued liabilities; (iv) a \$75 million decrease to other long-term liabilities; (v) a \$22 million increase to deferred income taxes; and (vi) a \$124 million increase to retained earnings. Other cumulative-effect adjustments to the condensed consolidated balance sheet were insignificant.

The impact of adoption on the company's condensed consolidated statements of earnings for the three and nine months ended September 30, 2018 was as follows:

	Three months ended			Nine months ended					
	Septem	ber 30, 201	8		September 30, 2018				
	Balances			Balances					
	Without		Effect of			Without	Effect of		
(in millions arount non shore data)	As	Adoption	Effect of		As	Adoption	Effect of		
(in millions, except per share data)	Reportedf		Change Higher/(Lower)		Reported	lof	Change Higher/(Lower)		
	ASU 2014-09					ASU			
						2014-09			
Net revenues	\$8,236	\$ 8,270	\$ (34)	\$24,448	\$ 24,452	\$ (4)	
Cost of products sold	1,835	1,851	(16)	5,696	5,696	_		
Income tax expense	14	16	(2)	57	52	5		
Net earnings	2,747	2,763	(16)	7,513	7,522	(9)	
Diluted earnings per share	\$1.81	\$ 1.82	\$ (0.01)	\$4.79	\$ 4.80	\$ (0.01)	

As of September 30, 2018, due to the impact of the adoption of ASU 2014-09, prepaid expenses and other were \$81 million higher, inventories were \$38 million lower, accounts payable and accrued liabilities were \$47 million lower, other long-term liabilities were \$32 million lower, deferred income taxes were \$14 million higher and retained earnings were \$115 million higher on the company's condensed consolidated balance sheet than they would have been had ASU 2014-09 not been adopted. Other impacts to the condensed consolidated balance sheet were insignificant. ASU No. 2016-01

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The standard requires several targeted changes including that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) be measured at fair value with changes in fair value recognized in net earnings. AbbVie adopted the standard in the first quarter of 2018. The adoption did not impact the accounting for AbbVie's investments in debt securities and did not have a material impact on the company's consolidated financial statements. ASU No. 2016-16

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740). The standard requires entities to recognize the income tax consequences of an intercompany transfer of an asset other than inventory when the transfer occurs. Under previous U.S. GAAP, the income tax consequences of these intercompany asset transfers were deferred until the asset was sold to a third party or otherwise recovered through use. AbbVie adopted the standard in the first quarter of 2018 using the modified retrospective method. As a result, on January 1, 2018, the company recorded a cumulative-effect adjustment to its condensed consolidated balance sheet that included a \$1.9 billion decrease to retained earnings, a \$1.4 billion decrease to prepaid expenses and other and a \$0.5 billion decrease to other assets. ASU No. 2017-07

In March 2017, the FASB issued ASU No. 2017-07, Compensation - Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost. The standard requires that an employer continue to report the service cost component of net periodic benefit cost in the same income statement line item or items as other employee compensation costs arising from services rendered during the period. The other components of net periodic benefit cost are required to be presented separately outside of income from operations and are not eligible for capitalization. AbbVie adopted the standard in the first quarter of 2018 and applied the income statement classification provisions of this standard retrospectively. As a result, the company reclassified income of \$10 million from operating earnings to non-operating income for the three months and \$34 million for the nine months ended September 30, 2017. Additionally, the company recorded approximately \$8 million of non-operating income for the three months and \$26 million for the nine months ended September 30, 2018 which would have been recorded in operating earnings under the previous guidance.

ASU No. 2017-12

In August 2017, the FASB issued ASU No. 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities. The standard simplifies the application of hedge accounting and more closely aligns the accounting with an entity's risk management activities. AbbVie elected to early adopt the standard in the first quarter of 2018. The adoption did not have a material impact on the company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted ASU No. 2016-02

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The standard outlines a comprehensive lease accounting model that supersedes the current lease guidance and requires lessees to recognize lease liabilities and corresponding right-of-use assets for all leases with lease terms greater than 12 months. The guidance also changes the definition of a lease and expands the disclosure requirements of lease arrangements. AbbVie is currently assessing the impact of adopting this guidance on its consolidated financial statements and related disclosures. AbbVie will adopt the standard effective in the first quarter of 2019 and will not restate comparative periods upon adoption. AbbVie will elect a package of practical expedients for leases that commenced prior to January 1, 2019 and will not reassess: (i) whether any expired or existing contracts are or contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs capitalization for any existing leases. AbbVie does not expect the adoption will have a material impact on its consolidated statement of earnings. However, the new standard will require AbbVie to establish liabilities and corresponding right-of-use assets on its consolidated balance sheet for operating leases that exist as of the adoption date.

ASU No. 2016-13

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326). The standard changes how credit losses are measured for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans and other financial instruments, the standard requires the use of a new forward-looking "expected credit loss" model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. Additionally, the standard requires new disclosures and will be effective for AbbVie starting with the first quarter of 2020. Early adoption beginning in the first quarter of 2019 is permitted. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact to retained earnings as of the beginning of the fiscal year of adoption. AbbVie is currently assessing the impact and timing of adopting this guidance on its consolidated financial statements.

ASU No. 2018-02

In February 2018, the FASB issued ASU No. 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, which allows a reclassification from accumulated other comprehensive income (AOCI) to retained earnings for stranded tax effects related to adjustments to deferred taxes resulting from the December 2017 enactment of the Tax Cuts and Jobs Act. The standard will be effective for AbbVie starting with the first quarter of 2019, with early adoption permitted. AbbVie is currently assessing the impact and timing of adopting this guidance on its consolidated financial statements. Note 2 Revenue Recognition

AbbVie recognizes revenue when control of promised goods or services is transferred to the company's customers, in an amount that reflects the consideration AbbVie expects to be entitled to in exchange for those goods or services. Sales, value add and other taxes collected concurrent with revenue-producing activities are excluded from revenue. AbbVie generates revenue primarily from product sales. For the majority of sales, the company transfers control, invoices the customer and recognizes revenue upon shipment to the customer. The company recognizes shipping and handling costs as an expense in cost of products sold when the company transfers control to the customer. Payment terms vary depending on the type and location of the customer, are based on customary commercial terms and are generally less than one year. AbbVie does not adjust revenue for the effects of a significant financing component for contracts where AbbVie expects the period between the transfer of the good or service and collection to be one year or less.

Discounts, rebates, sales incentives to customers, returns and certain other adjustments are accounted for as variable consideration. Provisions for variable consideration are based on current pricing, executed contracts, government pricing legislation and historical data and are provided for in the period the related revenues are recorded. Rebate

amounts are typically based upon the volume of purchases using contractual or statutory prices, which may vary by product and by payer. For each type of rebate, factors used in the calculation of the accrual include the identification of the products subject to the rebate, the applicable price terms and the estimated lag time between sale and payment of the rebate, which can be significant. Sales incentives to customers are insignificant.

In addition to revenue from contracts with customers, the company also recognizes certain collaboration revenues. See Note 6 for additional information related to the collaboration with Janssen Biotech, Inc. Additionally, see Note 14 for disaggregation of revenue by product and geography.

Note 3 Supplemental Financial Information

Interest Expense, Net

	Three mont	hs Nine r	nonths
	ended	ended	
	September	Septer	nber
	30,	30,	
(in millions)	2018 201	7 2018	2017
Interest expense	\$339 \$29	3 \$968	\$851
Interest income	(37) (41) (143)	(99)
Interest expense, net	\$302 \$25	2 \$825	\$752
Inventories			
(in millions) Sept	tember 30, I	ecember	31,
(in millions) 2013	8 2	017	
Finished goods \$ 5	22 \$	610	
Work-in-process 1,05	54 8	22	
Raw materials 210	1	73	
Inventories \$ 1	,786 \$	1,605	
Property and Equipm	ent		
(in m:11i ana)	Se	ptember	30, December 31,
(in millions)	20	18	2017
Property and equipm	ent, gross \$	8,449	\$ 8,071
Accumulated depreci	ation (5	,499) (5,268)

\$ 2,950

Depreciation expense was \$115 million for the three months and \$349 million for the nine months ended September 30, 2018 and \$111 million for the three months and \$324 million for the nine months ended September 30, 2017. Note 4 Earnings Per Share

\$ 2,803

AbbVie grants certain restricted stock awards (RSAs) and restricted stock units (RSUs) that are considered to be participating securities. Due to the presence of participating securities, AbbVie calculates earnings per share (EPS) using the more dilutive of the treasury stock or the two-class method. For all periods presented, the two-class method was more dilutive.

2018 Form 10-Q | 9

Property and equipment, net

The following table summarizes the impact of the two-class method:

	Three months ended		Nine m ended	onths
	Septem	ber 30,	Septem	ber 30,
(in millions, except per share data)	2018	2017	2018	2017
Basic EPS				
Net earnings	\$2,747	\$1,631	\$7,513	\$5,257
Earnings allocated to participating securities	12	8	34	26
Earnings available to common shareholders	\$2,735	\$1,623	\$7,479	\$5,231
Weighted-average basic shares outstanding	1,511	1,597	1,556	1,596
Basic earnings per share	\$1.81	\$1.02	\$4.81	\$3.28
Diluted EPS				
Net earnings	\$2,747	\$1,631	\$7,513	\$5,257
Earnings allocated to participating securities	12	8	34	26
Earnings available to common shareholders	\$2,735	\$1,623	\$7,479	\$5,231
Weighted-average shares of common stock outstanding	1,511	1,597	1,556	1,596
Effect of dilutive securities	4	6	5	6
Weighted-average diluted shares outstanding	1,515	1,603	1,561	1,602
Diluted earnings per share	\$1.81	\$1.01	\$4.79	\$3.27

Certain shares issuable under stock-based compensation plans were excluded from the computation of EPS because the effect would have been antidilutive. The number of common shares excluded was insignificant for all periods presented.

Note 5 Licensing, Acquisitions and Other Arrangements

Cash outflows related to acquisitions and investments totaled \$541 million for the nine months ended September 30, 2018 and \$180 million for the nine months ended September 30, 2017. AbbVie recorded \$55 million acquired in-process research and development (IPR&D) charges for the three months ended September 30, 2018 and \$124 million for the nine months ended September 30, 2018. Abbvie recorded no acquired IPR&D charges for the three months ended September 30, 2017 and recorded acquired IPR&D charges of \$15 million for the nine months ended September 30, 2017.

Calico Life Sciences LLC

In June 2018, AbbVie and Calico Life Sciences LLC (Calico) entered into an extension of a collaboration to discover, develop and bring to market new therapies for patients with age-related diseases, including neurodegeneration and cancer. Under the terms of the agreement, AbbVie and Calico will each contribute an additional \$500 million to the collaboration and the term is extended for an additional 3 years. Calico will be responsible for research and early development until 2022 and will advance collaboration projects through Phase 2a through 2027. Following completion of Phase 2a, AbbVie will have the option to exclusively license collaboration compounds. AbbVie will support Calico in its early research and development efforts and, upon exercise, would be responsible for late-stage development and commercial activities. Collaboration costs and profits will be shared equally by both parties post option exercise. During the nine months ended September 30, 2018, AbbVie recorded \$500 million in other expense in the condensed consolidated statement of earnings related to its commitments under the agreement.

Note 6 Collaboration with Janssen Biotech, Inc.

In December 2011, Pharmacyclics, a wholly-owned subsidiary of AbbVie, entered into a worldwide collaboration and license agreement with Janssen Biotech, Inc. and its affiliates (Janssen), one of the Janssen Pharmaceutical companies of Johnson & Johnson, for the joint development and commercialization of IMBRUVICA, a novel, orally active, selective covalent inhibitor of Bruton's tyrosine kinase (BTK) and certain compounds structurally related to IMBRUVICA, for oncology and other indications, excluding all immune and inflammatory mediated diseases or conditions and all psychiatric or psychological diseases or conditions, in the United States and outside the United States.

The collaboration provides Janssen with an exclusive license to commercialize IMBRUVICA outside of the United States and co-exclusively with AbbVie in the United States. Both parties are responsible for the development, manufacturing and marketing of any products generated as a result of the collaboration. The collaboration has no set duration or specific expiration date and provides for potential future development, regulatory and approval milestone payments of up to \$200 million to AbbVie. The collaboration also includes a cost sharing arrangement for associated collaboration activities. Except in certain cases, Janssen is responsible for approximately 60% of collaboration development costs and AbbVie is responsible for the remaining 40% of collaboration development costs.

In the United States, both parties have co-exclusive rights to commercialize the products; however, AbbVie is the principal in the end-customer product sales. AbbVie and Janssen share pre-tax profits and losses equally from the commercialization of products. Sales of IMBRUVICA are included in AbbVie's net revenues. Janssen's share of profits is included in AbbVie's cost of products sold. Other costs incurred under the collaboration are reported in their respective expense line items, net of Janssen's share.

Outside the United States, Janssen is responsible for and has exclusive rights to commercialize IMBRUVICA. AbbVie and Janssen share pre-tax profits and losses equally from the commercialization of products. AbbVie's share of profits is included in AbbVie's net revenues. Other costs incurred under the collaboration are reported in their respective expense line items, net of Janssen's share.

The following table shows the profit and cost sharing relationship between Janssen and AbbVie:

	Three mo Septembe	nths ended or 30,	Nine month September 3	
(in millions) United States - Janssen's share	2018	2017	2018	2017
of profits (included in cost of products sold) International - AbbVie's share	\$ 377	\$ 268	\$ 978	\$ 727
of profits (included in net revenues)	160	114	455	306
Global - AbbVie's share of other costs	81	75	232	209

(included in respective line items)

AbbVie's receivable from Janssen, included in accounts receivable, net, was \$177 million at September 30, 2018 and \$124 million at December 31, 2017. AbbVie's payable to Janssen, included in accounts payable and accrued liabilities, was \$362 million at September 30, 2018 and \$253 million at December 31, 2017.

Note 7 Goodwill and Intangible Assets

Goodwill

The following table summarizes the changes in the carrying amount of goodwill:

(in millions)

Balance as of December 31, 2017 \$15,785 Foreign currency translation adjustments (67) Balance as of September 30, 2018 \$15,718

The company performs its annual goodwill impairment assessment in the third quarter, or earlier if impairment indicators exist. As of September 30, 2018, there were no accumulated goodwill impairment losses.

Intangible Assets, Net

The following table summarizes intangible assets:

	September 30, 2018			December 31, 2017			
(in millions)	Gross carrying amount	Accumulate amortization		Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Definite-lived intangible assets							
Developed product rights	\$15,877	\$ (5,394)	\$10,483	\$16,138	\$ (4,982)	\$11,156
License agreements	7,865	(1,713)	6,152	7,822	(1,409)	6,413
Total definite-lived intangible assets	23,742	(7,107)	16,635	23,960	(6,391)	17,569
Indefinite-lived research and development	9,990			9,990	9,990	_	9,990
Total intangible assets, net	\$33,732	\$ (7,107)	\$26,625	\$33,950	\$ (6,391)	\$27,559

Amortization expense was \$320 million for the three months and \$974 million for the nine months ended September 30, 2018 and \$268 million for the three months and \$808 million for the nine months ended September 30, 2017. Amortization expense was included in cost of products sold in the condensed consolidated statements of earnings.

Indefinite-lived intangible assets represent acquired IPR&D associated with products that have not yet received regulatory approval. Indefinite-lived intangible assets as of September 30, 2018 and December 31, 2017 relate to the 2016 acquisitions of Stemcentrx and Boehringer Ingelheim compounds. The company performs its annual impairment assessment of indefinite-lived intangible assets in the third quarter, or earlier if impairment indicators exist. No impairment charges were recorded for the nine months ended September 30, 2018 and 2017.

Note 8 Restructuring Plans

AbbVie recorded restructuring charges of \$22 million for the three months and \$45 million for the nine months ended September 30, 2018 and \$7 million for the three months and \$34 million for the nine months ended September 30, 2017.

The following table summarizes the cash activity in the restructuring reserve for the nine months ended September 30, 2018:

(in millions)

Accrued balance as of December 31, 2017 \$86 Restructuring charges 34 Payments and other adjustments (33) Accrued balance as of September 30, 2018 \$87

Note 9 Financial Instruments and Fair Value Measures

Risk Management Policy

See Note 10 to the company's Annual Report on Form 10-K for the year ended December 31, 2017 for a summary of AbbVie's risk management policy and use of derivative instruments.

Financial Instruments

Various AbbVie foreign subsidiaries enter into foreign currency forward exchange contracts to manage exposures to changes in foreign exchange rates for anticipated intercompany transactions denominated in a currency other than the

functional currency of the local entity. These contracts, with notional amounts totaling \$1.9 billion at September 30, 2018 and \$2.2 billion at December 31, 2017, are designated as cash flow hedges and are recorded at fair value. The durations of these forward exchange contracts were

generally less than eighteen months. Accumulated gains and losses as of September 30, 2018 will be reclassified from AOCI and included in cost of products sold at the time the products are sold, generally not exceeding six months from the date of settlement.

The company also enters into foreign currency forward exchange contracts to manage its exposure to foreign currency denominated trade payables and receivables and intercompany loans. These contracts are not designated as hedges and are recorded at fair value. Resulting gains or losses are reflected in net foreign exchange loss in the consolidated statements of earnings and are generally offset by losses or gains on the foreign currency exposure being managed. These contracts had notional amounts totaling \$11.1 billion at September 30, 2018 and \$7.7 billion at December 31, 2017.

The company also uses foreign currency forward exchange contracts or foreign currency denominated debt to hedge its net investments in certain foreign subsidiaries and affiliates. The company designated €3.6 billion aggregate principal amount of senior Euro notes as net investment hedges at September 30, 2018 and December 31, 2017. Realized and unrealized gains and losses from these hedges are included in AOCI.

AbbVie is a party to interest rate hedge contracts designated as fair value hedges with notional amounts totaling \$11.8 billion at September 30, 2018 and December 31, 2017. The effect of the hedge contracts is to change a fixed-rate interest obligation to a floating rate for that portion of the debt. AbbVie records the contracts at fair value and adjusts the carrying amount of the fixed-rate debt by an offsetting amount.

No amounts are excluded from the assessment of effectiveness for cash flow hedges, net investment hedges or fair value hedges.

The following table summarizes the amounts and location of AbbVie's derivative instruments on the condensed consolidated balance sheets:

	Fair value –			Fair value –			
	Derivatives in asset pos	sition		Derivatives in liability position			
		Septem	b D eceml	ber	Septemb Decemb		
(in millions)	Balance sheet caption	30, 2018	31, 2017	Balance sheet caption	30, 2018	31, 2017	
Foreign currency forward exchange contracts							
Designated as cash flow hedges	Prepaid expenses and other	\$ 95	\$ 1	Accounts payable and accrued liabilities	\$ 2	\$ 120	
Designated as cash flow hedges	Other assets	3		Other long-term liabilities		_	
Not designated as hedges	Prepaid expenses and other	17	22	Accounts payable and accrued liabilities	14	29	
Interest rate swaps designated as fair value hedges	Prepaid expenses and other	_	_	Accounts payable and accrued liabilities	7	8	
Interest rate swaps designated as fair value hedges	Other assets	_	_	Other long-term liabilities	700	393	
Total derivatives		\$ 115	\$ 23		\$ 723	\$ 550	

While certain derivatives are subject to netting arrangements with the company's counterparties, the company does not offset derivative assets and liabilities within the condensed consolidated balance sheets.

The following table presents the pre-tax amounts of gains (losses) from derivative instruments recognized in other comprehensive income (loss):

Three months ended September 30,

(in millions) 201**8**017 2018 2017 Foreign currency forward exchange contracts \$1 \$(114) \$122 \$(253)

Assuming market rates remain constant through contract maturities, the company expects to transfer pre-tax gains of \$63 million into cost of products sold for foreign currency cash flow hedges during the next 12 months.

Related to AbbVie's non-derivative, foreign currency denominated debt designated as net investment hedges, the company recognized a pre-tax loss in other comprehensive income (loss) of \$41 million for the three months and a pre-tax gain of \$95 million for the nine months ended September 30, 2018 and recognized pre-tax losses in other comprehensive income (loss) of \$142 million for the three months and \$481 million for the nine months ended September 30, 2017.

The following table summarizes the pre-tax amounts and location of derivative instrument net gains (losses) recognized in the condensed consolidated statements of earnings, including the net gains (losses) reclassified out of AOCI into net earnings. See Note 11 for the amount of net gains (losses) reclassified out of AOCI.

		ended e		Nine mo		;
				r September 3		
		30,				
(in millions)	Statement of earnings caption	2018	2017	2018	2017	7
Foreign currency forward exchange contracts						
Designated as cash flow hedges	Cost of products sold	\$(54)	\$38	\$(144)	\$101	1
Not designated as hedges	Net foreign exchange loss	22	(17)	91	(88))
Interest rate swaps designated as fair value hedges	Interest expense, net	(63)	11	(306)	43	
Debt designated as hedged item in fair value hedges	Interest expense, net	63	(11)	306	(43)

Fair Value Measures

The fair value hierarchy consists of the following three levels:

Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets that the company has the ability to access;

Level 2 – Valuations based on 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 table summarizes the bases used to measure certain assets and liabilities carried at fair value on a recurring basis on the condensed consolidated balance sheet as of September 30, 2018:

		Basis of	fair value me	easurement
(in millions)	Total	markets identical assets	observable inputs inputs	Significant unobservable inputs (Level 3)
Assets				
Cash and equivalents	\$8,015	\$ 653	\$ 7,362	\$ —
Time deposits	559	_	559	_
Debt securities	1,591	_	1,591	_
Equity securities	5	5		
Foreign currency contracts	115	_	115	_
Total assets	\$10,285	\$ 658	\$ 9,627	\$ —

Liabilities

Interest rate hedges	\$707	\$ —	\$ 707	\$ —
Foreign currency contracts	s 16	_	16	
Contingent consideration	4,866			4,866
Total liabilities	\$5,589	\$ —	\$ 723	\$ 4,866

The following table summarizes the bases used to measure certain assets and liabilities carried at fair value on a recurring basis on the condensed consolidated balance sheet as of December 31, 2017:

(in millions)	Total	easurement Significant unobservable inputs (Level 3)		
Assets				
Cash and equivalents	\$9,303	\$ 849	\$ 8,454	\$ —
Debt securities	2,524		2,524	_
Equity securities	4	4		
Foreign currency contracts	23		23	
Total assets	\$11,854	\$ 853	\$ 11,001	\$ —
Liabilities				
Interest rate hedges	\$401	\$ —	\$ 401	\$ —
Foreign currency contracts	149		149	
Contingent consideration	4,534			4,534
Total liabilities	\$5,084	\$ —	\$ 550	\$ 4,534

The fair values of time deposits approximate their amortized cost due to the short maturities of these instruments. The fair values of available-for-sale debt securities were determined based on prices obtained from commercial pricing services. The derivatives entered into by the company were valued using publicized spot curves for interest rate hedges and publicized forward curves for foreign currency contracts. The fair value measurements of the contingent consideration liabilities were determined based on significant unobservable inputs, including the discount rate, estimated probabilities and timing of achieving specified development, regulatory and commercial milestones and the estimated amount of future sales of the acquired products still in development. Changes to the fair value of the contingent consideration liabilities can result from changes to one or a number of inputs, including discount rates, the probabilities of achieving the milestones, the time required to achieve the milestones and estimated future sales. Significant judgment is employed in determining the appropriateness of these inputs. Changes to the inputs described above could have a material impact on the company's financial position and results of operations in any given period. At September 30, 2018, a 50 basis point increase/decrease in the assumed discount rate would have decreased/increased the value of the contingent consideration liabilities by approximately \$170 million. Additionally, at September 30, 2018, a five percentage point increase/decrease in the assumed probability of success across all potential indications would have increased/decreased the value of the contingent consideration liabilities by approximately \$410 million.

There have been no transfers of assets or liabilities between the fair value measurement levels. The following table presents the changes in fair value of contingent consideration liabilities which are measured using Level 3 inputs:

	Nine mo	onths
	ended	
	Septemb	er 30,
(in millions)	2018	2017
Beginning balance	\$4,534	\$4,213
Change in fair value recognized in net earnings	432	547
Milestone payments	(100)	(305)
Ending balance	\$4,866	\$4,455

The change in fair value recognized in net earnings is recorded in other expense, net in the condensed consolidated statements of earnings.

Certain financial instruments are carried at historical cost or some basis other than fair value. The book values, approximate fair values and bases used to measure the approximate fair values of certain financial instruments as of September 30, 2018 are shown in the table below:

(in millions)	Book value		Basis of fair Quoted price in active temarkets for identical assets (Level 1)	value measures Significant other observable inputs (Level 2)	Signific	vable
Liabilities						
Short-term borrowings	\$3,002	\$ 3,002	\$ —	\$ 3,002	\$	_
Current portion of long-term debt and lease obligations, excluding fair value hedges	1,026	1,025	999	26	_	
Long-term debt and lease obligations, excluding fair value hedges	37,187	36,392	36,320	72	_	
Total liabilities	\$41,213	5\$ 40,419	\$ 37,319	\$ 3,100	\$	

AbbVie also holds investments in equity securities that do not have readily determinable fair values. The company records these investments at cost and remeasures them to fair value based on certain observable price changes or impairment events as they occur. The carrying amount of these investments was \$78 million as of September 30, 2018. No significant cumulative upward or downward adjustments have been recorded for these investments as of September 30, 2018. Prior to the adoption of ASU No. 2016-01 discussed in Note 1, these investments were accounted for under the cost method and disclosed in the table below as of December 31, 2017.

The book values, approximate fair values and bases used to measure the approximate fair values of certain financial instruments as of December 31, 2017 are shown in the table below:

(in millions)	Book value	Approxima fair value	Basis of fair Quoted price in active temarkets for identical assets	eSignifican other observable inputs	t Significant
			(Level 1)	(Level 2)	
Assets					
Investments	\$48	\$ 48	\$ —	\$ —	\$ 48
Total assets	\$48	\$ 48	\$ —	\$ —	\$ 48
Liabilities					
Short-term borrowings	\$400	\$ 400	\$ —	\$ 400	\$ —
Current portion of long-term debt and lease obligations, excluding fair value hedges	6,023	6,034	4,004	2,030	_
Long-term debt and lease obligations, excluding fair value hedges	31,346	32,846	32,763	83	_
Total liabilities	\$37,769	9\$ 39,280	\$ 36,767	\$ 2,513	\$ —

Available-for-sale Securities

Substantially all of the company's investments in debt securities were classified as available-for-sale with changes in fair value recognized in other comprehensive income. Debt securities classified as short-term were \$210 million as of September 30, 2018 and \$482 million as of December 31, 2017. Long-term debt securities mature primarily within five years. Estimated fair values of available-for-sale debt securities were generally determined based on prices obtained from commercial pricing services.

The following table is a summary of available-for-sale securities by type as of September 30, 2018:

(in millions)	Amortized cost	unre	ss alized Losse		Fair value
Asset backed securities	\$ 447	\$ —	\$ (2)	\$445
Corporate debt securities	1,050	3	(3)	1,050
Other debt securities	97		(1)	96
Total	\$ 1,594	\$ 3	\$ (6)	\$1,591

The following table is a summary of available-for-sale securities by type as of December 31, 2017:

(in millions)	Amortized cost		ss alized Losse		Fair value
Asset backed securities	\$ 930	\$ 1	\$ (3)	\$928
Corporate debt securities	1,451	4	(2)	1,453
Other debt securities	144	—	(1)	143
Equity securities	4	2	(2)	4
Total	\$ 2,529	\$ 7	\$ (8)	\$2,528

AbbVie had no other-than-temporary impairments as of September 30, 2018. Net realized gains (losses) were insignificant for both the three and nine months ended September 30, 2018 and 2017.

Concentrations of Risk

AbbVie continues to do business with foreign governments in certain countries, including Greece, Portugal, Italy and Spain, which have historically experienced challenges in credit and economic conditions. Substantially all of AbbVie's trade receivables in Greece, Portugal, Italy and Spain are with government health systems. Outstanding governmental receivables in these countries, net of allowances for doubtful accounts, totaled \$270 million as of September 30, 2018 and \$255 million as of December 31, 2017. The company also continues to do business with foreign governments in certain oil-exporting countries that have experienced a deterioration in economic conditions, including Saudi Arabia and Russia, which may result in delays in the collection of receivables. Outstanding governmental receivables related to Saudi Arabia, net of allowances for doubtful accounts, were \$147 million as of September 30, 2018 and \$149 million as of December 31, 2017. Outstanding governmental receivables related to Russia, net of allowances for doubtful accounts, were \$104 million as of September 30, 2018 and \$152 million as of December 31, 2017. Global economic conditions and customer-specific factors may require the company to periodically re-evaluate the collectability of its receivables and the company could potentially incur credit losses.

Of total net accounts receivable, three U.S. wholesalers accounted for 61% as of September 30, 2018 and 56% as of December 31, 2017, and substantially all of AbbVie's net revenues in the United States were to these three wholesalers.

HUMIRA (adalimumab) is AbbVie's single largest product and accounted for approximately 61% of AbbVie's total net revenues for the nine months ended September 30, 2018 and 66% for the nine months ended September 30, 2017.

Debt and Credit Facilities

In September 2018, the company issued \$6.0 billion aggregate principal amount of unsecured senior notes, consisting of \$1.25 billion aggregate principal amount of 3.375% senior notes due 2021, \$1.25 billion aggregate principal amount of 3.75% senior notes due 2023, \$1.75 billion aggregate principal amount of 4.25% senior notes due 2028 and \$1.75 billion aggregate principal amount of

4.875% senior notes due 2048. These senior notes rank equally with all other unsecured and unsubordinated indebtedness of the company. AbbVie may redeem the senior notes prior to maturity at a redemption price equal to the principal amount of the senior notes redeemed plus a make-whole premium and, except for the 3.375% notes due 2021, AbbVie may redeem the senior notes at par between one and six months prior to maturity. In connection with the offering, debt issuance costs incurred totaled \$37 million and debt discounts totaled \$37 million and are being amortized over the respective terms of the senior notes to interest expense, net in the condensed consolidated statements of earnings. Of the \$5.9 billion net proceeds, \$2.0 billion was used to repay the company's outstanding term loan that was due to mature in November 2018. The company intends to use the remaining proceeds to repay senior note obligations in 2018 and term loan obligations in 2019 as they become due.

In May 2018, the company also repaid \$3.0 billion aggregate principal amount of 1.80% senior notes at maturity. Short-Term Borrowings

Short-term borrowings included commercial paper borrowings of \$400 million as of December 31, 2017. There were no commercial paper borrowings outstanding as of September 30, 2018. The weighted-average interest rate on commercial paper borrowings was 1.9% for the nine months ended September 30, 2018 and 1.2% for the nine months ended September 30, 2017.

In August 2018, AbbVie replaced its existing revolving credit facility with a new \$3.0 billion five-year revolving credit facility that matures in August 2023. The new facility enables the company to borrow funds on an unsecured basis at variable interest rates and contains various covenants, all of which the company was in compliance with as of September 30, 2018.

In May 2018, AbbVie entered into a \$3.0 billion 364-day term loan credit agreement (term loan). In June 2018, the company drew on this term loan and as of September 30, 2018, \$3.0 billion was outstanding and was included in short-term borrowings on the condensed consolidated balance sheet. Borrowings under the term loan bear interest at one month LIBOR plus applicable margin. The term loan may be prepaid without penalty upon prior notice and contains customary covenants, all of which the company was in compliance with as of September 30, 2018. Note 10 Post-Employment Benefits

The following is a summary of net periodic benefit cost relating to the company's defined benefit and other post-employment plans:

	Defined				Other post-				
	benef	it plan	ıs		emp	loyme	nt pla	nt plans	
	Three	2	Ninan	aontha	Thre	ee	Nine		
	mont	months Nine month				ths	mont	hs	
	ended	1	ended	ahan	ende	ed	ended	d	
	Septe	September September			Sept	embei	Septe	ember	
	30,		30,		30,		30,		
(in millions)	2018	2017	2018	2017	2018	32017	2018	2017	
Service cost	\$70	\$59	\$214	\$176	\$7	\$6	\$ 20	\$ 19	
Interest cost	57	52	171	153	6	6	18	18	
Expected return on plan assets	(109)	(96)	(330)	(286)	_		_		
Amortization of actuarial losses and prior service costs	38	27	114	80	_	1	1	1	
Net periodic benefit cost	\$56	\$42	\$169	\$123	\$13	\$ 13	\$ 39	\$ 38	

The components of net periodic benefit cost other than service cost are included in other expense, net in the condensed consolidated statements of earnings.

Note 11 Equity

Stock-Based Compensation

Stock-based compensation expense is principally related to awards issued pursuant to the AbbVie 2013 Incentive Stock Program and is summarized as follows:

	Three	2	Nine			
	months					
	ended	i	ended			
	September					
	30,		30,			
(in millions)	2018	2017	2018	2017		
Cost of products sold	\$7	\$ 7	\$23	\$20		
Research and development	32	30	139	127		
Selling, general and administrative	36	34	189	141		
Pre-tax compensation expense	75	71	351	288		
Tax benefit	13	20	61	85		
After-tax compensation expense	\$62	\$ 51	\$290	\$203		

Stock Options

During the nine months ended September 30, 2018, primarily in connection with the company's annual grant, AbbVie granted 0.6 million stock options with a weighted-average grant-date fair value of \$21.63. As of September 30, 2018, \$8 million of unrecognized compensation cost related to stock options is expected to be recognized as expense over approximately the next two years.

RSAs, RSUs and Performance Shares

During the nine months ended September 30, 2018, primarily in connection with the company's annual grant, AbbVie granted 3.9 million RSUs and performance shares with a weighted-average grant-date fair value of \$114.37. As of September 30, 2018, \$331 million of unrecognized compensation cost related to RSAs, RSUs and performance shares is expected to be recognized as expense over approximately the next two years.

Cash Dividends

The following table summarizes quarterly cash dividends declared during 2018 and 2017: 2018

2010			-017		
		Dividend			Dividend
Date Declared	Payment Date	Per	Date Declared	Payment Date	Per
		Share			Share
11/02/18	02/15/19	\$ 1.07	10/27/17	02/15/18	\$ 0.71
09/07/18	11/15/18	\$ 0.96	09/08/17	11/15/17	\$ 0.64
06/14/18	08/15/18	\$ 0.96	06/22/17	08/15/17	\$ 0.64
02/15/18	05/15/18	\$ 0.96	02/16/17	05/15/17	\$ 0.64

Stock Repurchase Program

On February 15, 2018, AbbVie's board of directors authorized a new \$10.0 billion stock repurchase program, which superseded AbbVie's previous stock repurchase program. The new stock repurchase program permits purchases of AbbVie shares from time to time in open-market or private transactions, including accelerated share repurchases, at management's discretion. The program has no time limit and can be discontinued at any time. Shares repurchased under this program are recorded at acquisition cost, including related expenses, and are available for general corporate purposes.

Under the new authorization, AbbVie repurchased 83.2 million shares for \$8.5 billion during the nine months ended September 30, 2018. AbbVie's remaining stock repurchase authorization was \$1.5 billion as of September 30, 2018.

Prior to the new \$10.0 billion authorization, AbbVie repurchased 10.9 million shares in the open market for \$1.3 billion during the nine months ended September 30, 2018.

Accumulated Other Comprehensive Loss

The following table summarizes the changes in each component of accumulated other comprehensive loss, net of tax, for the nine months ended September 30, 2018:

(in millions)		on	Net investme hedging sactivitie		Pension t and post- employmer benefits	٦t	Marke securit activit	.y	Cash flow hedging activities	Total
Balance as of December 31, 2017	\$ (439)	\$ (203)	\$ (1,919)	\$ —		\$ (166)	\$(2,727)
Other comprehensive income (loss) before reclassifications	(250)	73		7		(6)	110	(66)
Net losses reclassified from accumulated other comprehensive loss					92		4		138	234
Net current-period other comprehensive income (loss)	(250)	73		99		(2)	248	168
Balance as of September 30, 2018	\$ (689)	\$ (130)	\$ (1,820)	\$ (2)	\$ 82	\$(2,559)

Other comprehensive income for the nine months ended September 30, 2018 included foreign currency translation adjustments totaling a loss of \$250 million, which was principally due to the weakening of the Euro in the nine months ended September 30, 2018 on the translation of the company's assets denominated in the Euro.

The following table summarizes the changes in each component of accumulated other comprehensive loss, net of tax, for the nine months ended September 30, 2017:

(in millions)	Foreign currency translation adjustments	hedging	Pension at and post- employmen benefits	Marketab security activities	Cash flow hedging activities	Total
Balance as of December 31, 2016	\$ (1,435)	\$ 140	\$ (1,513)	\$ 46	\$ 176	\$(2,586)
Other comprehensive income (loss) before reclassifications	602	(307)	(37)	31	(229)	60
Net losses (gains) reclassified from accumulated other comprehensive loss	_		58	(49)	(96)	(87)
Net current-period other comprehensive income (loss)	602	(307)	21	(18)	(325)	(27)
Balance as of September 30, 2017	\$ (833)	\$ (167)	\$ (1,492)	\$ 28	\$ (149)	\$(2,613)

Other comprehensive loss for the nine months ended September 30, 2017 included foreign currency translation adjustments totaling a gain of \$602 million, which was principally due to the impact of the improvement in the Euro in the nine months ended September 30, 2017 on the translation of the company's assets denominated in the Euro.

The table below presents the impact on AbbVie's condensed consolidated statements of earnings for significant amounts reclassified out of each component of accumulated other comprehensive loss:

	Three				
	months ended September 30,		Nine months		
			ended		
			September 30,		
(in millions) (brackets denote gains)	2018	2017	2018	2017	
Pension and post-employment benefits					
Amortization of actuarial losses and other ^(a)	\$38	\$28	\$115	\$81	
Tax benefit	(8)	(8)	(23)	(23)	
Total reclassifications, net of tax	\$30	\$20	\$92	\$58	
Cash flow hedging activities					
Losses (gains) on designated cash flow hedges ^(b)	\$54	\$(38)	\$144	\$(101)	
Tax expense (benefit)			(6)	5	
Total reclassifications, net of tax	\$54	\$(38)	\$138	\$(96)	

- (a) Amounts are included in the computation of net periodic benefit cost (see Note 10).
- (b) Amounts are included in cost of products sold (see Note 9). Note 12 Income Taxes

The effective tax rate was 1% for the three and nine months ended September 30, 2018 and 22% for the three months and 20% for the nine months ended September 30, 2017. The effective tax rate in each period differed from the U.S. statutory tax rates of 21% in 2018 and 35% in 2017, principally due to the benefit from foreign operations which reflects the impact of lower income tax rates in locations outside the United States, tax exemptions and incentives in Puerto Rico and other foreign tax jurisdictions and business development activities.

The change in the effective tax rate for both the three and nine months ended September 30, 2018 over the prior year was principally due to the effects of the enactment of the Tax Cuts and Jobs Act (the "Act") in December 2017. The Act significantly changes the U.S. corporate tax system, reducing the U.S. federal corporate tax rate from 35% to 21%, requiring companies to pay a one-time transition tax on a mandatory deemed repatriation of earnings of certain foreign subsidiaries that were previously untaxed and creating new taxes on certain foreign sourced earnings. The Act also creates a territorial tax system that generally excludes dividends from foreign subsidiaries from U.S. taxation. Specific to 2018, there is a beneficial impact due to timing of provisions related to the earnings from certain foreign subsidiaries.

Given the complexity of the Act and anticipated guidance from the U.S. Treasury about implementing the Act, the company's analysis and accounting for the tax effects of the enactment of the Act is preliminary. In the fourth quarter of 2017, the company recorded, as a direct result of the Act, \$4.5 billion of transition tax expense, as well as \$4.1 billion of net tax benefit for deferred tax remeasurement. Both of these amounts are provisional estimates, as the company has not fully completed its analysis and calculation of foreign earnings subject to the transition tax or its analysis of certain other aspects of the Act that could result in adjustments to the remeasurement of deferred tax balances. Upon completion of the analysis in 2018, these estimates may be adjusted through income tax expense in the consolidated statement of earnings. No adjustments to these provisional estimates were made during the three and nine months ended September 30, 2018. The Act also created a minimum tax on certain foreign sourced earnings. The taxability of the foreign sourced earnings and the applicable tax rates are dependent on future events. While the company is still evaluating its accounting policy for the minimum tax on foreign sourced earnings, the provisional

estimates of the tax effects of the Act were reported on the basis that the minimum tax will be recognized in tax expense in the year it is incurred as a period expense.

Due to the potential for resolution of federal, state and foreign examinations and the expiration of various statutes of limitations, it is reasonably possible that the company's gross unrecognized tax benefits balance may change within the next twelve months by up to \$550 million. At the time of separation, AbbVie and Abbott Laboratories (Abbott) entered into a tax sharing agreement which provides that Abbott is liable for and has indemnified AbbVie against all income tax liabilities for periods prior to the separation. Accordingly, Abbott will indemnify and hold AbbVie harmless if the tax positions are settled for amounts in excess of recorded liabilities, and AbbVie will not benefit if prior tax positions are resolved more favorably than recorded amounts.

Note 13 Legal Proceedings and Contingencies

AbbVie is subject to contingencies, such as various claims, legal proceedings and investigations regarding product liability, intellectual property, commercial, securities and other matters that arise in the normal course of business. Loss contingency provisions are recorded for probable losses at management's best estimate of a loss, or when a best estimate cannot be made, a minimum loss contingency amount within a probable range is recorded. The recorded accrual balance for litigation was approximately \$770 million as of September 30, 2018 and \$445 million as of December 31, 2017. Initiation of new legal proceedings or a change in the status of existing proceedings may result in a change in the estimated loss accrued by AbbVie. While it is not feasible to predict the outcome of all proceedings and exposures with certainty, management believes that their ultimate disposition should not have a material adverse effect on AbbVie's consolidated financial position, results of operations or cash flows.

Subject to certain exceptions specified in the separation agreement by and between Abbott and AbbVie, AbbVie assumed the liability for, and control of, all pending and threatened legal matters related to its business, including liabilities for any claims or legal proceedings related to products that had been part of its business, but were discontinued prior to the distribution, as well as assumed or retained liabilities, and will indemnify Abbott for any liability arising out of or resulting from such assumed legal matters.

Several pending lawsuits filed against Unimed Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc. (a company Abbott acquired in February 2010 and now known as AbbVie Products LLC) and others are consolidated for pre-trial purposes in the United States District Court for the Northern District of Georgia under the Multi-District Litigation (MDL) Rules as In re: AndroGel Antitrust Litigation, MDL No. 2084. These cases, brought by private plaintiffs and the Federal Trade Commission (FTC), generally allege Solvay's patent litigation involving AndroGel was sham litigation and the 2006 patent litigation settlement agreements and related agreements with three generic companies violate federal antitrust laws. Plaintiffs generally seek monetary damages and/or injunctive relief and attorneys' fees. These cases include: (a) four individual plaintiff lawsuits; (b) three purported class actions; and (c) Federal Trade Commission v. Actavis, Inc. et al. Following the district court's dismissal of all plaintiffs' claims, appellate proceedings led to the reinstatement of the claims regarding the patent litigation settlements, which are proceeding in the district court. In July 2018, the court denied the plaintiffs' motion for class certification.

Lawsuits are pending against AbbVie and others generally alleging that the 2005 patent litigation settlement involving Niaspan entered into between Kos Pharmaceuticals, Inc. (a company acquired by Abbott in 2006 and presently a subsidiary of AbbVie) and a generic company violates federal and state antitrust laws and state unfair and deceptive trade practices and unjust enrichment laws. Plaintiffs generally seek monetary damages and/or injunctive relief and attorneys' fees. The lawsuits consist of four individual plaintiff lawsuits and two consolidated purported class actions: one brought by three named direct purchasers of Niaspan and the other brought by ten named end-payer purchasers of Niaspan. The cases are consolidated for pre-trial proceedings in the United States District Court for the Eastern District of Pennsylvania under the MDL Rules as In re: Niaspan Antitrust Litigation, MDL No. 2460. In October 2016, the Orange County, California District Attorney's Office filed a lawsuit on behalf of the State of California regarding the Niaspan patent litigation settlement in Orange County Superior Court, asserting a claim under the unfair competition provision of the California Business and Professions Code seeking injunctive relief, restitution, civil penalties and attorneys' fees. In May 2018, the California Court of Appeals ruled that the District Attorney's Office may not bring monetary claims beyond the scope of Orange County.

In September 2014, the FTC filed a lawsuit against AbbVie and others in the United States District Court for the Eastern District of Pennsylvania, alleging that the 2011 patent litigation with two generic companies regarding AndroGel was sham litigation and the settlements of that litigation violated federal antitrust law. In May 2015, the court dismissed the FTC's settlement-related claim. In June 2018, following a bench trial, the court found for the FTC

on its sham litigation claim and ordered a disgorgement remedy of \$448 million, plus prejudgment interest. The court denied the FTC's request for injunctive relief. AbbVie is appealing the court's liability and disgorgement rulings and, based on an assessment of the merits of that appeal, no liability has been accrued for this matter. The FTC is also appealing aspects of the court's trial ruling and the dismissal of its settlement-related claim. In July and August 2018, several direct AndroGel purchasers brought two individual and one class action cases in the United States District Court for the Eastern District of Pennsylvania alleging sham litigation based on the court's trial ruling in the FTC's case.

In March 2015, the State of Louisiana filed a lawsuit, State of Louisiana v. Fournier Industrie et Sante, et al., against AbbVie, Abbott and affiliated Abbott entities in Louisiana state court. Plaintiff alleges that patent applications and patent litigation filed and other alleged conduct from the early 2000's and before related to the drug TriCor violated Louisiana State antitrust and unfair trade practices laws. The lawsuit seeks monetary damages and attorneys' fees.

In November 2014, a putative class action lawsuit, Medical Mutual of Ohio v. AbbVie Inc., et al., was filed against several manufacturers of testosterone replacement therapies (TRTs), including AbbVie, in the United States District Court for the Northern District of Illinois on behalf of all insurance companies, health benefit providers, and other third party payers who paid for TRTs, including AndroGel. The claims asserted include violations of the federal RICO Act and state consumer fraud and deceptive trade practices laws. The complaint seeks monetary damages and injunctive relief. In July 2018, the court denied the plaintiff's motion for class certification.

Product liability cases are pending in which plaintiffs generally allege that AbbVie and other manufacturers of TRTs did not adequately warn about risks of certain injuries, primarily heart attacks, strokes and blood clots. Approximately 4,067 claims are consolidated for pre-trial purposes in the United States District Court for the Northern District of Illinois under the MDL Rules as In re: Testosterone Replacement Therapy Products Liability Litigation, MDL No. 2545. Approximately 205 claims against AbbVie are pending in various state courts. Plaintiffs generally seek compensatory and punitive damages. Six cases have gone to trial. Four of those have resulted in complete verdicts for AbbVie: three by juries in the United States District Court for the Northern District of Illinois in January, May, and June 2018, and one by a jury in the Cook County, Illinois Circuit Court in August 2017. Another case in the United States District Court for the Northern District of Illinois resulted in a jury verdict for AbbVie on two claims and for the plaintiff on one claim and an award of \$150 million in punitive damages with no compensatory damages in July 2017. In orders from December 2017 and February 2018, the court vacated that verdict and ordered a new trial. In the March 2018 retrial, the jury reached a verdict for AbbVie on strict liability and fraud and for the plaintiff on negligence and awarded \$200,000 in compensatory damages and \$3 million in punitive damages, which is the subject of post-trial proceedings. Another case in the United States District Court for the Northern District of Illinois resulted in a jury verdict for AbbVie on strict liability and for the plaintiff on remaining claims and an award of \$140,000 in compensatory damages and \$140 million in punitive damages in August 2017. In July 2018, the court vacated that verdict and ordered a new trial. In September 2018, AbbVie entered into a confidential term sheet with representatives of the Plaintiffs' Steering Committee in the MDL proceeding for the settlement of existing claims in all courts. That settlement is subject to the execution of a definitive settlement agreement and other contingencies.

Product liability cases are pending in which plaintiffs generally allege that AbbVie did not adequately warn about risk of certain injuries, primarily various birth defects, arising from use of Depakote. Over ninety percent of the approximately 595 claims are pending in the United States District Court for the Southern District of Illinois, and the rest are pending in various other federal and state courts. Plaintiffs generally seek compensatory and punitive damages. Over ninety percent of the claims pending in all courts, plus other unfiled claims, are subject to confidential settlement agreements and are expected to be dismissed with prejudice.

In November 2014, five individuals filed a putative class action lawsuit, Rubinstein, et al. v Gonzalez, et al., on behalf of purchasers and sellers of certain Shire plc (Shire) securities between June 20 and October 14, 2014, against AbbVie and its chief executive officer in the United States District Court for the Northern District of Illinois alleging that the defendants made and/or are responsible for material misstatements in violation of federal securities laws in connection with AbbVie's proposed transaction with Shire.

In June 2016, a lawsuit, Elliott Associates, L.P., et al. v. AbbVie Inc., was filed by five investment funds against AbbVie in the Cook County, Illinois Circuit Court alleging that AbbVie made misrepresentations and omissions in connection with its proposed transaction with Shire. Similar lawsuits were filed between July 2017 and October 2018 against AbbVie and in some instances its chief executive officer in the same court by additional investment funds. Plaintiffs seek compensatory and punitive damages.

In May 2017, a shareholder derivative lawsuit, Ellis v. Gonzalez, et al., was filed in Delaware Chancery Court, alleging that AbbVie's directors breached their fiduciary duties in connection with statements made regarding the

Shire transaction. The lawsuit sought unspecified compensatory damages for AbbVie, among other relief. In July 2018, the court dismissed this case with prejudice. In August 2018, plaintiff appealed that dismissal to the Delaware Supreme Court.

In September 2018, the Commissioner of the California Department of Insurance intervened in a qui tam lawsuit, State of California and Lazaro Suarez v. AbbVie Inc., et al., brought under the California Insurance Frauds Prevention Act, in California Superior Court for Alameda County. The Department of Insurance's complaint alleges that, through patient and reimbursement support services and other services and items of value provided in connection with HUMIRA, AbbVie caused the submission of fraudulent commercial insurance claims for HUMIRA in violation of the California statute. The complaint seeks injunctive relief, an assessment of up to three times the amount of the claims at issue, and civil penalties. In addition, two federal securities lawsuits were filed in September (Pippins v. AbbVie Inc., et al., in the United States District Court for the Central District of California) and October (Holwill v. AbbVie Inc., et al., in the United States District Court for the Northern District of Illinois) against AbbVie, its chief executive officer and then-chief financial officer, alleging that reasons stated for HUMIRA sales growth in financial filings between 2013 and 2017 were misleading because they omitted the conduct alleged in the Department of Insurance's complaint.

Beginning in May 2016, the Patent Trial & Appeal Board of the U.S. Patent & Trademark Office (PTO) instituted five inter partes review proceedings brought by Coherus Biosciences and Boehringer Ingelheim related to three AbbVie patents covering methods of treatment of rheumatoid arthritis using adalimumab. In these proceedings, the PTO reviewed the validity of the patents and issued decisions of invalidity in May, June and July of 2017. AbbVie's appeal of the decisions is pending in the Court of Appeals for the Federal Circuit.

In March 2017, AbbVie filed a lawsuit, AbbVie Inc. v. Novartis Vaccines and Diagnostics, Inc. and Grifols Worldwide Operations Ltd., in the United States District Court for the Northern District of California against Novartis Vaccines and Grifols Worldwide seeking a declaratory judgment that eleven HCV-related patents licensed to AbbVie in 2002 are invalid.

AbbVie is seeking to enforce certain patent rights related to adalimumab (a drug AbbVie sells under the trademark HUMIRA®). In a case filed in United States District Court for the District of Delaware in August 2017, AbbVie alleges that Boehringer Ingelheim International GmbH's, Boehringer Ingelheim Pharmaceutical, Inc.'s, and Boehringer Ingelheim Fremont, Inc.'s proposed biosimilar adalimumab product infringes certain AbbVie patents. AbbVie seeks declaratory and injunctive relief.

Pharmacyclics LLC, a wholly owned subsidiary of AbbVie, is seeking to enforce its patent rights relating to ibrutinib capsules (a drug Pharmacyclics sells under the trademark IMBRUVICA®). In February 2018, four separate cases were filed in the United States District Court for the District of Delaware against the following defendants: Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited; Shilpa Medicare Limited, Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd.; Cipla Limited and Cipla USA Inc.; and Zydus Worldwide DMCC, Cadila Healthcare Limited, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Sandoz Inc., and Lek Pharmaceuticals D.D. In each case, Pharmacyclics alleges the defendant's proposed generic ibrutinib product infringes certain Pharmacyclics patents and seeks declaratory and injunctive relief. Janssen Biotech, Inc. which is in a global collaboration with Pharmacyclics concerning the development and marketing of IMBRUVICA, is the co-plaintiff in these suits.

Note 14 Segment Information

AbbVie operates in one business segment—pharmaceutical products. The following table details AbbVie's worldwide net revenues:

net revenues.				
	ended	ended		nths er 30,
(in millions)	2018	2017	2018	2017
Immunology				
HUMIRA				
United States	\$3,546	\$3,151	\$10,070	\$9.048
International	1,578	-	-	•
Total	-		\$15,018	•
Hematologic Oncology IMBRUVICA	. ,	,		
United States	\$812	\$574	\$2,129	\$1,559
Collaboration revenues	160	114	455	306
Total	\$972	\$688	\$2,584	\$1,865
VENCLEXTA				,
United States	\$69	\$25	\$157	\$60
International	27	8	63	18
Total	\$96	\$33	\$220	\$78
HCV				
MAVYRET				
United States	\$444	\$60	\$1,206	\$60
International	395	35	1,413	35
Total	\$839	\$95	\$2,619	\$95
VIEKIRA				
United States	\$—	\$ —	\$3	\$64
International	23	181	132	605
Total	\$23	\$181	\$135	\$669
Other Key Products				
Creon				
United States	\$239	\$215	\$667	\$596
Lupron				
United States	\$173	\$161	\$530	\$488
International	41	40	126	117
Total	\$214	\$201	\$656	\$605
Synthroid				
United States	\$192	\$191	\$567	\$576
Synagis				
International	\$97	\$116	\$462	\$456
AndroGel				
United States	\$135	\$147	\$393	\$437
Duodopa				
United States	\$19	\$16	\$57	\$44
International	87	78	260	211
Total	\$106	\$94	\$317	\$255

Edgar Filing: AbbVie Inc. - Form 10-Q

Sevoflurane				
United States	\$18	\$19	\$54	\$56
International	68	81	251	255
Total	\$86	\$100	\$305	\$311
Kaletra				
United States	\$16	\$16	\$42	\$54
International	72	69	210	256
Total	\$88	\$85	\$252	\$310
All other	\$25	\$148	\$253	\$689
Total net revenues	\$8,236	\$6,995	\$24,448	\$20,477

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following is a discussion and analysis of the financial condition of AbbVie Inc. (AbbVie or the company) as of September 30, 2018 and December 31, 2017 and the results of operations for the three and nine months ended September 30, 2018 and 2017. This commentary should be read in conjunction with the condensed consolidated financial statements and accompanying notes appearing in Item 1, "Financial Statements and Supplementary Data." EXECUTIVE OVERVIEW

Company Overview

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories (Abbott). AbbVie uses its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. AbbVie's products are focused on treating conditions such as chronic autoimmune diseases in rheumatology, gastroenterology and dermatology; oncology, including blood cancers; virology, including hepatitis C (HCV) and human immunodeficiency virus (HIV); neurological disorders, such as Parkinson's disease; metabolic diseases, including thyroid disease and complications associated with cystic fibrosis; as well as other serious health conditions. AbbVie also has a pipeline of promising new medicines across such important medical specialties as immunology, oncology and neuroscience, with additional targeted investment in cystic fibrosis and women's health. AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies and independent retailers from AbbVie-owned distribution centers and public warehouses. In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies and patients, Outside the United States, sales are made either directly to customers or through distributors, depending on the market served. Certain products are co-marketed or co-promoted with other companies. AbbVie has approximately 30,000 employees. AbbVie operates in one business segment—pharmaceutical products.

2018 Strategic Objectives

AbbVie's mission is to be an innovation-driven, patient-focused specialty biopharmaceutical company capable of achieving top-tier financial performance through outstanding execution and a consistent stream of innovative new medicines. AbbVie intends to continue to advance its mission in a number of ways, including: (i) growing revenues by diversifying revenue streams, driving late-stage pipeline assets to the market and ensuring strong commercial execution of new product launches; (ii) continued investment and expansion in its pipeline in support of opportunities in immunology, oncology and neurology as well as continued investment in key on-market products; (iii) expanding operating margins; and (iv) returning cash to shareholders via dividends and share repurchases. In addition, AbbVie anticipates several regulatory submissions and key data readouts from key clinical trials in the next twelve months. Financial Results

The company's financial performance for the nine months ended September 30, 2018 included delivering worldwide net revenues of \$24.4 billion, operating earnings of \$8.8 billion, diluted earnings per share of \$4.79 and cash flows from operations of \$10.0 billion. Worldwide net revenues grew by 18% on a constant currency basis, driven primarily by the continued strength of HUMIRA and revenue growth related to IMBRUVICA and HCV product MAVYRET. Diluted earnings per share was \$4.79 for the nine months ended September 30, 2018 and included the following after-tax costs: (i) \$801 million related to the amortization of intangible assets; (ii) \$500 million as a result of a collaboration agreement extension with Calico Life Sciences LLC (Calico); (iii) \$432 million for the change in fair value of contingent consideration liabilities; (iv) litigation reserve charges of \$276 million; (v) charitable contributions of \$182 million as part of AbbVie's previously announced plan to make contributions to U.S. not-for-profit organizations in 2018; (vi) \$124 million for acquired in-process research and development (IPR&D); and (vii) milestone payments of \$87 million. Financial results for the nine months ended September 30, 2018 were also impacted by U.S. tax reform and the timing of the new legislation's phase in on certain subsidiaries. Additionally, financial results reflected continued added funding to support all stages of AbbVie's emerging pipeline assets and

continued investment in AbbVie's growth brands.

In November 2018, the company announced that its board of directors declared an increase in the company's quarterly cash dividend from \$0.96 per share to \$1.07 per share beginning with the dividend payable in February 2019. This reflects an increase of approximately 11.5% over the previous quarterly rate.

In addition to these financial results, AbbVie continued to advance and augment its pipeline as further described below under the heading "Research and Development."

Research and Development

Research and innovation are the cornerstones of AbbVie's business as a global biopharmaceutical company. AbbVie's long-term success depends to a great extent on its ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies.

AbbVie's pipeline currently includes more than 60 compounds or indications in clinical development individually or under collaboration or license agreements and is focused on such important medical specialties as immunology, oncology and neurology along with targeted investments in cystic fibrosis and women's health. Of these programs, more than 30 are in mid- and late-stage development.

The following sections summarize transitions of significant programs from Phase 2 development to Phase 3 development as well as developments in significant Phase 3 and registration programs. AbbVie expects multiple Phase 2 programs to transition into Phase 3 programs in the next twelve months.

Significant Programs and Developments

Immunology

Upadacitinib

In January 2018, the U.S. Food and Drug Administration (FDA) granted breakthrough therapy designation for upadacitinib, an investigational oral JAK1-selective inhibitor, in adult patients with moderate to severe atopic dermatitis who are candidates for systemic therapy.

In April 2018, AbbVie announced that top-line results from the Phase 3 SELECT-COMPARE clinical trial evaluating upadacitinib met all primary and ranked secondary endpoints in patients with moderate to severe rheumatoid arthritis (RA) who are on a stable background of methotrexate and who have an inadequate response. The safety profile of upadacitinib was consistent with previously reported clinical trials and no new safety signals were detected. In June 2018, AbbVie announced that top-line results from the Phase 3 SELECT-EARLY clinical trial evaluating upadacitinib versus methotrexate in adult patients with moderate to severe RA who were methotrexate-naïve met all primary and ranked secondary endpoints. The safety profile of upadacitinib was consistent with previously reported clinical trials and no new safety signals were detected.

In July 2018, AbbVie initiated two Phase 3 clinical trials to evaluate the efficacy and safety of upadacitinib in subjects with moderate to severe atopic dermatitis.

In September 2018, AbbVie initiated a Phase 3 clinical trial to evaluate the efficacy and safety of upadacitinib in subjects with moderate to severe ulcerative colitis.

Risankizumab

In January 2018, AbbVie initiated two Phase 3 clinical trials to evaluate the efficacy and safety of risankizumab, an investigational interleukin-23 (IL-23) inhibitor, versus placebo during induction therapy in subjects with moderately to severely active Crohn's disease.

In February 2018, AbbVie announced that top-line results from two Phase 3 clinical trials evaluating risankizumab with 12-week dosing compared to ustekinumab met ranked additional secondary endpoints for the treatment of patients with moderate to severe chronic plaque psoriasis. The initial results from these clinical trials were previously announced in October 2017. The safety profile was consistent with all previously reported studies, and there were no new safety signals detected across the two studies.

In April 2018, AbbVie submitted a Biologics License Application (BLA) to the FDA and a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for risankizumab for the treatment of plaque psoriasis in adults.

In May 2018, AbbVie initiated a Phase 2b/3 clinical trial to evaluate the efficacy and safety of risankizumab versus placebo in subjects with moderately to severely active ulcerative colitis.

Oncology

IMBRUVICA

In April 2018, AbbVie initiated a Phase 3 clinical trial to evaluate the safety and efficacy of IMBRUVICA in combination with VENCLEXTA versus chlorambucil plus GAZYVA (obinutuzumab) for the first-line treatment of subjects with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).

In May 2018, AbbVie announced that results from the Phase 3 iLLUMINATE study evaluating IMBRUVICA in combination with GAZYVA in previously untreated CLL/SLL met its primary endpoint.

In June 2018, AbbVie announced that results from an interim analysis of the Phase 3 iNNOVATE study evaluating ¶MBRUVICA plus Rituxan (rituximab) in previously untreated and relapsed/refractory (R/R) patients with Waldenström's macroglobulinemia (WM) met its primary endpoint.

In July 2018, AbbVie announced that results from a Phase 3 study evaluating the addition of IMBRUVICA to a chemotherapy regimen consisting of five different agents used in combination did not meet its primary endpoint in a subset of untreated diffuse large B-cell lymphoma patients identified to have the non-germinal center B-cell or activated B-cell subtypes of this disease.

In August 2018, the FDA approved IMBRUVICA, in combination with Rituxan, for the treatment of adult patients with WM.

In October 2018, the FDA accepted for priority review AbbVie's supplemental New Drug Application (sNDA) for IMBRUVICA in combination with GAZYVA in patients with previously untreated CLL/SLL.

VENCLEXTA

In January 2018, AbbVie submitted an sNDA to the FDA for VENCLEXTA monotherapy in patients with CLL who are refractory to or have relapsed B-cell receptor pathway inhibitors.

In June 2018, the FDA approved VENCLEXTA in combination with Rituxan for the treatment of patients with CLL/SLL, with or without 17p deletion, who have received at least one prior therapy. VENCLEXTA plus Rituxan is the first oral-based, chemotherapy-free combination in CLL that allows patients an option for fixed treatment duration.

In July 2018, AbbVie submitted an sNDA to the FDA for VENCLEXTA in combination with a hypomethylating agent or in combination with low dose cytarabine for treatment of newly diagnosed patients with acute myeloid leukemia who are ineligible for intensive chemotherapy. In August, AbbVie was granted priority review for VENCLEXTA by the FDA.

In September 2018, the FDA expanded the label for VENCLEXTA in combination with Rituxan to include information about patients with previously-treated CLL who achieved minimal residual disease (MRD)-negativity in the Phase 3 MURANO trial.

In October 2018, the European Commission approved the type-II variation application for VENCLYXTO in combination with Rituxan for the treatment of patients with R/R CLL who have received at least one prior therapy. In October 2018, AbbVie announced that the results from the Phase 3 CLL14 study comparing the efficacy and safety of VENCLEXTA plus obinutuzumab versus obinutuzumab plus chlorambucil in previously untreated patients with CLL and coexisting medical conditions met its primary endpoint.

Rova-T

In March 2018, AbbVie announced top-line results from the Phase 2 TRINITY study evaluating rovalpituzumab tesirine (Rova-T) for third-line R/R small cell lung cancer (SCLC). Although Rova-T demonstrated single agent responses in advanced SCLC patients, after consulting with the FDA, based on the magnitude of effect across multiple parameters in this single-arm study, the company will not seek accelerated approval for Rova-T in third-line R/R SCLC. Ongoing Phase 3 studies will continue to investigate Rova-T in first- and second-line SCLC. Other

In August 2018, Bristol-Myers Squibb Company (BMS) announced that the FDA accepted for priority review its supplemental Biologics License Application (sBLA) for Empliciti (elotuzumab) in combination with pomalidomide and low-dose dexamethasone for the treatment of patients with relapsed/refractory multiple myeloma (RRMM) who have received at least two prior therapies. This submission followed the BMS announcement in June 2018 that results from the Phase 2 ELOQUENT-3 study evaluating the combination of Empliciti with pomalidomide/dexamethasone in RRMM patients met its primary endpoint. BMS and AbbVie are co-developing Empliciti, with BMS solely responsible for commercial activities.

Neurology

In March 2018, Biogen and AbbVie announced the voluntary worldwide withdrawal of marketing authorizations for ZINBRYTA, a prescription medicine used to treat adults with relapsing forms of multiple sclerosis.

Other

In February 2018, AbbVie announced that top-line results from the Phase 3 ELARIS UF-I study evaluating elagolix, an investigational, orally administered gonadotropin-releasing hormone (GnRH) antagonist, being investigated in combination with low-dose hormone (add-back) therapy for uterine fibroids met its primary efficacy endpoint and all ranked secondary endpoints.

In March 2018, AbbVie announced that top-line results from the Phase 3 ELARIS UF-II study evaluating elagolix in combination with low-dose hormone (add-back) therapy for uterine fibroids met its primary efficacy endpoint and all ranked secondary endpoints.

In July 2018, the FDA approved ORILISSA (elagolix) for the management of moderate to severe pain associated with endometriosis.

In August 2018, AbbVie announced that top-line results from the Phase 3 ELARIS UF-EXTEND study evaluating elagolix in combination with low-dose hormone therapy for uterine fibroids were consistent with findings observed in the ELARIS UF-I and ELARIS UF-II Phase 3 studies.

In October 2018, AbbVie announced that it will assume full development and commercial responsibility for its collaboration with Galapagos to discover and develop new therapies to treat cystic fibrosis (CF). Under a revised agreement, AbbVie will assume full development and commercial responsibility over the investigational program comprising several clinical and pre-clinical compounds originally discovered and developed jointly by AbbVie and Galapagos. Galapagos will not pursue further research and development in CF, but is eligible for future milestones and royalties on commercialized programs.

For a more comprehensive discussion of AbbVie's products and pipeline, see the company's Annual Report on Form 10-K for the year ended December 31, 2017.

RESULTS OF OPERATIONS

Net Revenues

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

	Three n	nonths	Percent change		Nine mo	nths	Percent change			
	ended		currency rates		ended		At actual At constant			
	Septem	ber 30,			September 30,		currency			
(dollars in millions)	2018	2017				2018	2017	currency rates rates		
United States	\$5,597	\$4,586	22.0%	22.0	%	\$15,836	\$13,284	19.2 %	19.2	%
International	2,639	2,409	9.6 %	11.7	%	8,612	7,193	19.7 %	15.3	%
Net revenues	\$8,236	\$6,995	17.8 %	18.5	%	\$24,448	\$20,477	19.4 %	17.8	%

The following table details AbbVie's worldwide net revenues: Three months Percent change Nine months Percent change												
	ended		At actual	[At consta		ended		At actua	[At const	
(dollars in millions)	2018	ber 30, 2017	currency	rate	currency es rates		Septemb 2018	2017	currency	rate	currency es rates	/
Immunology	2010	2017			races		2010	2017			races	
HUMIRA												
United States	\$3 546	\$3,151	12.5	%	12.5	%	\$10,070	\$9 048	11.3	%	11.3	%
International		1,550	1.8		4.2		4,948	4,487	10.3		5.9	%
Total		\$4,701			9.8		\$15,018	-			9.5	%
Hematologic Oncology	, - ,	, ,, ,					, -,-	, - ,				
IMBRUVICA												
United States	\$812	\$574	41.5	%	41.5	%	\$2,129	\$1,559	36.6	%	36.6	%
Collaboration revenues	160	114	40.1	%	40.1	%	455	306	48.5	%	48.5	%
Total	\$972	\$688	41.3	%	41.3	%	\$2,584	\$1,865	38.5	%	38.5	%
VENCLEXTA												
United States	\$69	\$25	>100.0%)	>100.0%)	\$157	\$60	>100.0%)	>100.0%	6
International	27	8	>100.0%)	>100.0%)	63	18	>100.0%)	>100.0%	6
Total	\$96	\$33	>100.0%)	>100.0%)	\$220	\$78	>100.0%)	>100.0%	6
HCV												
MAVYRET												
United States	\$444	\$60	>100.0%		>100.0%		\$1,206	\$60	>100.0%		>100.0%	
International	395	35	>100.0%		>100.0%		1,413	35	>100.0%		>100.0%	
Total	\$839	\$95	>100.0%)	>100.0%)	\$2,619	\$95	>100.0%)	>100.0%	6
VIEKIRA												
United States	\$—	\$ <u></u>	n/m		n/m		\$3	\$64	(96.3		(96.3)%
International	23	181	(87.0	-	(86.1	-	132	605	(78.1	-	(78.9)%
Total	\$23	\$181	(87.1)%	(86.2)%	\$135	\$669	(79.8)%	(80.6)%
Other Key Products												
Creon United States	\$239	\$215	11.3	07	11.3	01	\$667	\$596	11.8	07	11.8	%
	\$239	\$213	11.3	%	11.3	%	\$007	\$390	11.8	%	11.0	%
Lupron United States	\$173	\$161	7.6	0%	7.6	0%	\$530	\$488	8.7	0%	8.7	%
International	41	40	1.5		7.0		126	117	7.4		6.9	%
Total	\$214	\$201	6.4		7.5		\$656	\$605	8.4		8.3	%
Synthroid	Ψ217	Ψ201	0.1	70	7.5	70	φοσο	ΨΟΟΣ	0.4	70	0.5	70
United States	\$192	\$191	0.7	%	0.7	%	\$567	\$576	(1.5)%	(1.5)%
Synagis	Ψ172	ΨΙΊΙ	0.7	,0	0.7	,,	φυση	Ψυνο	(1.5	,,,	(1.5	,,,
International	\$97	\$116	(16.2)%	(14.1)%	\$462	\$456	1.3	%	(2.2)%
AndroGel	,	,		,		, .	, -	,				, .
United States	\$135	\$147	(8.3)%	(8.3)%	\$393	\$437	(10.1)%	(10.1)%
Duodopa					•				•		`	
United States	\$19	\$16	18.7	%	18.7	%	\$57	\$44	30.0	%	30.0	%
International	87	78	10.8	%	12.2	%	260	211	22.8	%	15.6	%
Total	\$106	\$94	12.1	%	13.3	%	\$317	\$255	24.0	%	18.1	%
Sevoflurane												
United States	\$18	\$19	(2.8		(2.8		\$54	\$56	(2.8		(2.8)%
International	68	81	(15.7)		(12.2		251	255	(1.5		(2.8)%
Total	\$86	\$100	(13.2)%	(10.4)%	\$305	\$311	(1.7)%	(2.7)%

Edgar Filing: AbbVie Inc. - Form 10-Q

Kaletra											
United States	\$16	\$16	(2.9)%	(2.9)%	\$42	\$54	(21.4)% (21.4)%
International	72	69	5.3	%	8.2	%	210	256	(18.1)% (19.0)%
Total	\$88	\$85	3.7	%	6.0	%	\$252	\$310	(18.7))% (19.5)%
All other	\$25	\$148	(82.7)%	(82.0)%	\$253	\$689	(63.1)% (73.8)%
Total net revenues	\$8 236	\$6 995	17.8	%	18.5	%	\$24 448	\$20 477	194	% 178	%

n/m – Not meaningful

The following discussion and analysis of AbbVie's net revenues by product is presented on a constant currency basis.

Global HUMIRA sales increased 10% for the three months and 9% for the nine months ended September 30, 2018 primarily as a result of market growth across therapeutic categories and geographies as well as favorable pricing in certain geographies. In the United States, HUMIRA sales increased 13% for the three months and 11% for the nine months ended September 30, 2018 driven by market growth across all indications and favorable pricing. Internationally, HUMIRA sales increased 4% for the three months and 6% for the nine months ended September 30, 2018 driven primarily by market growth across indications. In October 2018, the European Union composition of matter patent for adalimumab expired and biosimilars of HUMIRA launched in Europe. Biosimilar competition is not expected in the United States until 2023. AbbVie continues to pursue strategies intended to further differentiate HUMIRA from competing products and add to the sustainability and future growth of HUMIRA.

Net revenues for IMBRUVICA represent product sales in the United States and collaboration revenues outside of the United States related to AbbVie's 50% share of IMBRUVICA profit. AbbVie's global IMBRUVICA revenues increased 41% for the three months and 39% for the nine months ended September 30, 2018 as a result of continued penetration of IMBRUVICA for patients with chronic lymphocytic leukemia (CLL) as well as favorable pricing.

Global HCV sales increased by more than 100% for both the three and nine months ended September 30, 2018 as a result of the launch of MAVYRET in certain geographies beginning in the second half of 2017 partially offset by a decrease in revenues of VIEKIRA.

Net revenues for Creon increased 11% for the three months and 12% for the nine months ended September 30, 2018 driven primarily by continued market growth and higher market share. Creon maintains market leadership in the pancreatic enzyme market.

Net revenues for Duodopa increased 13% for the three months and 18% for the nine months ended September 30, 2018 primarily as a result of increased market penetration.

Gross Margin

				Nine months ended				
				September				
(dollars in millions)	2018	2017	% change	2018	2017	% change		
Gross margin	\$6,401	\$5,379	19 %	\$18,752	\$15,716	19 %		
as a % of net revenues	78 %	77 %		77 %	77 %			

Gross margin as a percentage of net revenues increased for the three months and was flat for the nine months ended September 30, 2018 compared to the prior year. Gross margin percentage for the three months ended September 30, 2018 was favorably impacted by the reduction of HUMIRA royalty expense and foreign exchange partially offset by the IMBRUVICA profit sharing arrangement. Gross margin percentage for the nine months ended September 30, 2018 was favorably impacted by the reduction of HUMIRA royalty expense offset by the IMBRUVICA profit sharing arrangement and foreign exchange.

Selling, General and Administrative

	Three months	s ended	Nine months ended		
	September 30,			per 30,	
(dollars in millions)	2018 20	17	2018	2017	

Edgar Filing: AbbVie Inc. - Form 10-Q

			%			%
			change			change
Selling, general and administrative	\$1,919	\$1,457	32 %	\$5,470	\$4,339	26 %
as a % of net revenues	23 %	21 %		22 %	21 %	

Selling, general and administrative (SG&A) expenses as a percentage of net revenues increased for both the three and nine months ended September 30, 2018 compared to the prior year. SG&A expense percentage was unfavorably impacted by litigation reserves charges that increased by \$224 million for the three months and \$249 million for the nine months ended September 30, 2018 compared to the prior year and charitable contributions of \$115 million for the three months and \$235 million for the nine months ended September 30, 2018 to select organizations as part of AbbVie's previously announced plan to make \$350 million in contributions to U.S. not-for-profit organizations in 2018. Additionally, new product launch expenses unfavorably impacted SG&A expense percentage for both the three and nine months ended September 30, 2018.

Research and Development and Acquired In-Process Research and Development

	Three months ended September 30,			Nine mor Septembe		
(dollars in millions)	2018	2017	% change	2018	2017	% change
Research and development	\$1,268	\$1,228	3 %	\$3,834	\$3,599	7 %
as a % of net revenues	15 %	18 %		16 %	18 %	
Acquired in-process research and development	\$55	\$ —	n/m	\$124	\$15	>100%

Research and Development (R&D) expenses for both the three and nine months ended September 30, 2018 increased compared to the prior year principally due to increased funding to support all stages of the company's pipeline assets.

Acquired in-process research and development (IPR&D) expenses reflect upfront payments related to various collaborations. There were no individually significant transactions during both the three and nine months ended September 30, 2018 and 2017.

Other Operating Expenses

Other operating expenses for the nine months ended September 30, 2018 included a \$500 million charge related to the extension of the previously announced Calico collaboration to discover, develop and bring to market new therapies for patients with age-related diseases, including neurodegeneration and cancer.

Other Non-Operating Expenses

	Three i	months	Nine months ended		
	Septen	nber	September		
	30,		30,		
(in millions)	2018	2017	2018	2017	
Interest expense	\$339	\$293	\$968	\$851	
Interest income	(37)	(41)	(143)	(99)	
Interest expense, net	\$302	\$252	\$825	\$752	
Net foreign exchange loss	\$2	\$9	\$18	\$28	
Other expense, net	94	338	411	449	

Interest expense, net increased for both the three and nine months ended September 30, 2018 compared to the prior year primarily due to the unfavorable impact of higher interest rates on the company's debt obligations.

Other expense, net included charges related to changes in fair value of the Boehringer Ingelheim and Stemcentrx contingent consideration liabilities of \$95 million for the three months and \$432 million for the nine months ended September 30, 2018 compared to charges of \$401 million for the three months and \$547 million for the nine months ended September 30, 2017. The fair value of contingent consideration liabilities is impacted by the passage of time and multiple other inputs, including the probability of success of achieving regulatory/commercial milestones, discount rates and other market-based factors. For the three months ended September 30, 2018, the change in fair value primarily represented the passage of time. For the nine months ended September 30, 2018, the change in fair value represented higher estimated future sales and the passage of time partially offset by the effect of rising interest rates. For the three and nine months ended September 30, 2017, the change in fair value represented mainly higher probabilities of success and the passage of time.

Income Tax Expense

The effective tax rate was 1% for the three and nine months ended September 30, 2018 and 22% for the three months and 20% for the nine months ended September 30, 2017. The effective tax rate in each period differed from the U.S. statutory tax rates of 21% in 2018 and 35% in 2017, principally due to the benefit from foreign operations which reflects the impact of lower income tax rates in locations outside the United States, tax exemptions and incentives in Puerto Rico and other foreign tax jurisdictions and business development activities.

The change in the effective tax rate for both the three and nine months ended September 30, 2018 over the prior year was principally due to the effects of the enactment of the Tax Cuts and Jobs Act (the "Act") in December 2017. The Act significantly changes the U.S. corporate tax system, reducing the U.S. federal corporate tax rate from 35% to 21%, requiring companies to pay a one-time transition tax on a mandatory deemed repatriation of earnings of certain foreign subsidiaries that were previously untaxed and creating new taxes on certain foreign sourced earnings. The Act also creates a territorial tax system that generally excludes dividends from foreign subsidiaries from U.S. taxation. Specific to 2018, there is a beneficial impact due to timing of provisions related to the earnings from certain foreign subsidiaries.

FINANCIAL POSITION, LIQUIDITY AND CAPITAL RESOURCES

Nine months

ended

September 30,

(in millions) 2018 2017

Cash flows provided by (used in):

Operating activities \$10,035 \$7,376 Investing activities (723) (475) Financing activities (10,571) (3,584)

Operating cash flows for the nine months ended September 30, 2018 increased from the prior year due to improved results of operations resulting from revenue growth and an improvement in operating earnings. Operating cash flows also reflected AbbVie's voluntary contributions to its principal domestic defined benefit plan of \$150 million for both the nine months ended September 30, 2018 and 2017. The company also made an additional voluntary contribution of \$600 million to various other defined benefit plans in 2018.

Investing cash flows for the nine months ended September 30, 2018 included payments made for acquisitions and investments of \$541 million, capital expenditures of \$515 million and net sales and maturities of investment securities totaling \$333 million. Investing cash flows for the nine months ended September 30, 2017 included capital expenditures of \$347 million, payments made for acquisitions and investments of \$180 million and net sales and maturities of investment securities totaling \$52 million.

Financing cash flows for the nine months ended September 30, 2018 included proceeds from the issuance of a \$3.0 billion 364-day term loan credit agreement (term loan) entered into in May 2018. In June 2018, the company drew on this term loan and as of September 30, 2018, \$3.0 billion was outstanding and was included in short-term borrowings on the condensed consolidated balance sheet. Borrowings under the term loan bear interest at one month LIBOR plus applicable margin. The term loan may be prepaid without penalty upon prior notice and contains customary covenants, all of which the company was in compliance with as of September 30, 2018. In September 2018, the company issued \$6.0 billion aggregate principal amount of unsecured senior notes. The company used a portion of the proceeds to repay the company's outstanding \$2.0 billion term loan that was due to mature in November 2018. Financing cash flows for the nine months ended September 30, 2018 also included the May 2018 repayment of \$3.0 billion aggregate principal amount of the company's 1.80% senior notes at maturity.

The company made cash dividend payments of \$4.1 billion for the nine months ended September 30, 2018 and \$3.1 billion for the nine months ended September 30, 2017. The increase in cash dividend payments was driven by an increase in the quarterly dividend rate. On September 7, 2018, the board of directors declared a quarterly cash dividend of \$0.96 per share for stockholders of record at the close of business on October 15, 2018, payable on November 15, 2018. On November 2, 2018, the company announced that its board of directors declared an increase in the company's quarterly cash dividend from \$0.96 per share to \$1.07 per share beginning with the dividend payable on February 15, 2019 to stockholders of record as of January 15, 2019. This reflects an increase of approximately 11.5% over the previous quarterly rate. The timing, declaration, amount of and payment of any dividends by AbbVie in the

future is within the discretion of its board of directors and will depend upon many factors, including AbbVie's financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of AbbVie's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets and other factors deemed relevant by its board of directors.

On February 15, 2018, AbbVie's board of directors authorized a new \$10.0 billion stock repurchase program, which superseded AbbVie's previous stock repurchase program. The new stock repurchase program permits purchases of AbbVie shares from time to time in open-market or private transactions, including accelerated share repurchases, at management's discretion. The program has

no time limit and can be discontinued at any time. Under the new authorization, AbbVie repurchased 83.2 million shares for \$8.5 billion during the nine months ended September 30, 2018.

Prior to the new \$10.0 billion authorization, AbbVie repurchased 10.9 million shares in the open market for \$1.3 billion during the nine months ended September 30, 2018.

During the nine months ended September 30, 2018, AbbVie paid \$100 million of contingent consideration to Boehringer Ingelheim related to BLA and MAA acceptance milestones. \$78 million of these payments were included in financing cash flows and \$22 million of the payments were included in operating cash flows. During the nine months ended September 30, 2017, AbbVie paid \$305 million of contingent consideration to BI related to a Phase 3 enrollment milestone. \$268 million of this milestone was included in financing cash flows and \$37 million was included in operating cash flows.

During the nine months ended September 30, 2018 and 2017, the company issued and redeemed commercial paper. The balance of commercial paper outstanding was \$400 million as of December 31, 2017. There were no commercial paper borrowings outstanding as of September 30, 2018. AbbVie may issue additional commercial paper or retire commercial paper to meet liquidity requirements as needed.

Credit Risk

AbbVie monitors economic conditions, the creditworthiness of customers and government regulations and funding, both domestically and abroad. AbbVie regularly communicates with its customers regarding the status of receivable balances, including their payment plans and obtains positive confirmation of the validity of the receivables. AbbVie establishes an allowance against accounts receivable when it is probable they will not be collected. AbbVie may also utilize factoring arrangements to mitigate credit risk, although the receivables included in such arrangements have historically not been a significant amount of total outstanding receivables.

AbbVie continues to do business with foreign governments in certain countries, including Greece, Portugal, Italy and Spain, which have historically experienced challenges in credit and economic conditions. Substantially all of AbbVie's trade receivables in Greece, Portugal, Italy and Spain are with government health systems. Outstanding governmental receivables in these countries, net of allowances for doubtful accounts, totaled \$270 million as of September 30, 2018 and \$255 million as of December 31, 2017. The company also continues to do business with foreign governments in certain oil-exporting countries that have experienced a deterioration in economic conditions, including Saudi Arabia and Russia, which may result in delays in the collection of receivables. Outstanding governmental receivables related to Saudi Arabia, net of allowances for doubtful accounts, were \$147 million as of September 30, 2018 and \$149 million as of December 31, 2017. Outstanding governmental receivables related to Russia, net of allowances for doubtful accounts, were \$104 million as of September 30, 2018 and \$152 million as of December 31, 2017. Global economic conditions and customer-specific factors may require the company to periodically re-evaluate the collectability of its receivables and the company could potentially incur credit losses.

Currently, AbbVie does not believe the economic conditions in oil-exporting countries will have a significant impact on the company's liquidity, cash flow or financial flexibility. However, if government funding were to become unavailable in these countries or if significant adverse changes in their reimbursement practices were to occur, AbbVie may not be able to collect the entire balance outstanding as of September 30, 2018.

Credit Facility, Access to Capital and Credit Ratings

Credit Facility

In September 2018, AbbVie replaced its existing revolving credit facility with a new \$3.0 billion five-year revolving credit facility. The new facility enables the company to borrow funds on an unsecured basis at variable interest rates and contains various covenants. At September 30, 2018, the company was in compliance with all its credit facility covenants. Commitment fees under the credit facility were insignificant. There were no amounts outstanding under the company's credit facilities as of September 30, 2018 and December 31, 2017.

Access to Capital

The company intends to fund short-term and long-term financial obligations as they mature through cash on hand, future cash flows from operations, or by issuing additional debt. The company's ability to generate cash flows from operations, issue debt or enter into financing arrangements on acceptable terms 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 material unfavorable changes in business conditions. At the current time, the company believes it has sufficient financial flexibility to issue debt, enter into other financing arrangements and attract long-term capital on acceptable terms to support the company's growth objectives.

Credit Ratings

There were no changes in the company's credit ratings during the nine months ended September 30, 2018. Unfavorable changes to the ratings may have an adverse impact on future financing arrangements; however, they would not affect the company's ability to draw on its credit facility and would not result in an acceleration of scheduled maturities of any of the company's outstanding debt.

CRITICAL ACCOUNTING POLICIES

A summary of the company's significant accounting policies is included in Note 2, "Summary of Significant Accounting Policies" in AbbVie's Annual Report on Form 10-K for the year ended December 31, 2017. Significant changes in the company's application of its critical accounting policies include the adoption of a new accounting standard that establishes a new revenue recognition framework. See Notes 1 and 2 to the condensed consolidated financial statements for additional information.

FORWARD-LOOKING STATEMENTS

Some statements in this quarterly report on Form 10-Q may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project," and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in AbbVie's Annual Report on Form 10-K for the year ended December 31, 2017, which has been filed with the Securities and Exchange Commission. AbbVie notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of the company's market risk, see Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" in AbbVie's Annual Report on Form 10-K for the year ended December 31, 2017.

ITEM 4. CONTROLS AND PROCEDURES

DISCLOSURE CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. The Chief Executive Officer, Richard A. Gonzalez, and the Chief Financial Officer, Robert A. Michael, evaluated the effectiveness of AbbVie's disclosure controls and procedures as of the end of the period covered by this report, and concluded that AbbVie's disclosure controls and procedures were effective to ensure that information AbbVie is required to disclose in the reports that it files or submits with the Securities and Exchange Commission under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and to ensure that information required to be disclosed by AbbVie in the reports that it files or submits under the Exchange Act is accumulated and communicated to AbbVie's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

INTERNAL CONTROL OVER FINANCIAL REPORTING

Changes in internal control over financial reporting. There were no changes in AbbVie's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, AbbVie's internal control over financial reporting during the quarter ended September 30, 2018.

Inherent Limitations on Effectiveness of Controls. AbbVie's management, including its Chief Executive Officer and its Chief Financial Officer, do not expect that AbbVie's disclosure controls or internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

PART II. OTHER INFORMATION ITEM 1. LEGAL PROCEEDINGS

Information pertaining to legal proceedings is provided in Note 13 to the condensed consolidated financial statements and is incorporated by reference herein.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(c) Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares (or Units) Purchased	(b) Averag Price Paid per Share (or Unit)	e	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
July 1, 2018 – July 31, 2018	1,157	\$96.23	(1)	_	\$2,500,000,000
August 1, 2018 – August 31, 2018	10,392,841 (1	\$96.23	(1)	10,391,816	\$1,500,000,050
September 1, 2018 – September 30, 2018	81,145	\$93.73	(1)	_	\$1,500,000,050
Total	10,395,143 (1	\$96.23	(1)	10,391,816	\$1,500,000,050

In addition to AbbVie shares repurchased on the open market under a publicly announced program, if any, these 1. shares also included the shares purchased on the open market for the benefit of participants in the AbbVie Employee Stock Purchase Plan – 1,157 in July; 1,025 in August; and 1,145 in September.

These shares do not include the shares surrendered to AbbVie to satisfy minimum tax withholding obligations in connection with the vesting or exercise of stock-based awards.

ITEM 6. EXHIBITS

Exhibits 32.1 and 32.2 are furnished herewith and should not be deemed to be "filed" under the Securities Exchange Act of 1934.

Exhibit No. Exhibit Description

- *Underwriting Agreement, dated September 13, 2018, by and among AbbVie Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC and BNP Paribas Securities Corp. (acting for themselves and as representatives of the several underwriters named therein) (incorporated by reference to Exhibit 1.1 of the company's Current Report on Form 8-K filed on September 18, 2018).
- *Supplemental Indenture No. 5, dated September 18, 2018, between AbbVie Inc. and U.S. Bank National

 Association, as trustee (incorporated by reference to Exhibit 4.2 of the company's Current Report on Form

 8-K filed on September 18, 2018).
- *Revolving Credit Agreement, dated as of August 31, 2018, among AbbVie, the lenders and other parties party thereto, and JPMorgan Chase Bank, N.A., as administrative agent (incorporated by reference to Exhibit 10.1 of the company's Current Report on Form 8-K filed on September 6, 2018).
- *First Amendment to 364-Day Term Loan Credit Agreement, dated as of August 31, 2018, among

 AbbVie, the lenders and other parties party thereto, and Bank of America, N.A., as administrative agent (incorporated by reference to Exhibit 10.2 of the company's Current Report on Form 8-K filed on September 6, 2018).
- 31.1 Certification of Chief Executive Officer Required by Rule 13a-14(a) (17 CFR 240.13a-14(a)).
- 31.2 Certification of Chief Financial Officer Required by Rule 13a-14(a) (17 CFR 240.13a-14(a)).
- <u>32.1</u> <u>Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
- 32.2 Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- The following financial statements and notes from the AbbVie Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed on November 7, 2018, formatted in XBRL: (i) Condensed Consolidated Statements of Earnings; (ii) Condensed Consolidated Statements of Comprehensive Income; (iii) Condensed Consolidated Balance Sheets; (iv) Condensed Consolidated Statements of Cash Flows; and (v) the Notes to Condensed Consolidated Financial Statements.

^{*} Incorporated herein by reference. Commission file number 001-35565.

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 thereunto duly authorized.

ABBVIE INC.

By:/s/ Robert A. Michael Robert A. Michael Senior Vice President, Chief Financial Officer

Date: November 7, 2018