Alexion Reports Third Quarter 2019 Results

October 23, 2019

- 3Q19 total revenues of $1,263.1 million, a 23 percent increase over 3Q18 and a 23 percent volume increase
- 3Q19 GAAP diluted EPS of $2.08; non-GAAP diluted EPS of $2.79
- Received 2 recent regulatory approvals - ULTOMIRIS® (ravulizumab-cwvz) for atypical hemolytic uremic syndrome (aHUS) in the U.S. and SOLIRIS® (eculizumab) for adults with neuromyelitis optica spectrum disorder (NMOSD) in the EU
- Announced agreement to acquire Achillion Pharmaceuticals
- Continued disciplined business development execution with Eidos and Stealth BioTherapeutics collaborations
- Increased revenues and EPS guidance to reflect strong business and continued growth

BOSTON--(BUSINESS WIRE)--Oct. 23, 2019-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the third quarter of 2019. Total revenues in the third quarter were $1,263.1 million, a 23 percent increase compared to the same period in 2018. The negative impact of foreign currency on total revenues year-over-year was less than 1 percent, or $2.5 million, inclusive of hedging activities. On a GAAP basis, diluted EPS in the quarter was $2.08, a 41 percent increase versus the prior year. Non-GAAP diluted EPS for the third quarter of 2019 was $2.79, a 38 percent increase versus the third quarter of 2018.

"With consistent and strong execution, we have delivered another record performance in the third quarter, building on our momentum from the first half of 2019. Our teams continued to demonstrate launch excellence across the globe, with very rapid starts to the German and Japanese ULTOMIRIS PNH launches, where conversion is progressing ahead of the best-in-class U.S. launch at the same time points, as well as a strong start to the SOLIRIS NMOSD launch in the U.S.," said Ludwig Hantson, Ph.D., Chief Executive Officer of Alexion. "We also continued to expand our portfolio with two additional approvals - ULTOMIRIS for atypical HUS in the U.S. and SOLIRIS for NMOSD in the EU - and three new business development transactions that further diversify our pipeline, including an agreement to acquire Achillion. By continuing to deliver on the ambitious transformation plan we laid out two-and-a-half years ago, we have successfully established a strong foundation for the future and look forward to building on this progress as we advance our mission of delivering life-changing therapies to people with rare diseases."

Third Quarter 2019 Financial Highlights

- Total net product sales were $1,263.1 million in the third quarter of 2019, compared to $1,026.5 million in the third quarter of 2018.
- SOLIRIS® (eculizumab) net product sales were $990.5 million, compared to $888.0 million in the third quarter of 2018, representing a 12 percent increase. SOLIRIS volume increased 11 percent year-over-year.
- ULTOMIRIS® (ravulizumab-cwvz) net product sales were $89.9 million in the third quarter of 2019.
- STRENSIQ® (asfotase alfa) net product sales were $154.3 million, compared to $113.2 million in the third quarter of 2018, representing a 36 percent increase. STRENSIQ volume increased 36 percent year-over-year.
- KANUMA® (sebelipase alfa) net product sales were $28.4 million, compared to $25.3 million in the third quarter of 2018, representing a 12 percent increase. KANUMA volume increased 16 percent year-over-year.
- GAAP cost of sales was $95.2 million, compared to $90.6 million in the third quarter of 2018. Non-GAAP cost of sales was $91.8 million, compared to $87.3 million in the third quarter of 2018.
- GAAP R&D expense was $232.9 million, compared to $174.8 million in the third quarter of 2018. Non-GAAP R&D expense was $186.1 million, compared to $162.3 million in the third quarter of 2018.
- GAAP SG&A expense was $299.3 million, compared to $258.7 million in the third quarter of 2018. Non-GAAP SG&A expense was $260.4 million, compared to $224.5 million in the third quarter of 2018.
- GAAP income tax expense was $67.9 million, compared to $11.2 million in the third quarter of 2018. Non-GAAP income tax expense was $82.5 million, compared to $75.8 million in the third quarter of 2018.
- GAAP diluted EPS was $2.08, compared to $1.47 in the third quarter of 2018. Non-GAAP diluted EPS was $2.79,

compared to $2.02 in the third quarter of 2018.

Research and Development

PHASE 3

- **SOLIRIS - Neuromyelitis Optica Spectrum Disorder (NMOSD):** In August 2019, the European Commission approved SOLIRIS for adults with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD. An application for approval in Japan is under review. Alexion plans to initiate a Phase 3 study in children and adolescents with NMOSD by the end of 2019.

- **SOLIRIS - Generalized Myasthenia Gravis (gMG):** A Phase 3 study of SOLIRIS in children and adolescents with gMG is underway.

- **ULTOMIRIS - Paroxysmal Nocturnal Hemoglobinuria (PNH):** A Phase 3 study of ULTOMIRIS in children and adolescents with PNH is underway.

- **ULTOMIRIS - Atypical Hemolytic Uremic Syndrome (aHUS):** In October 2019, the U.S. Food and Drug Administration (FDA) approved ULTOMIRIS for the treatment of aHUS to inhibit complement-mediated thrombotic microangiopathy (TMA) for adults and children one month and older. Applications for approval in the EU and Japan are under review. A Phase 3 study of ULTOMIRIS in children and adolescents with aHUS is underway.

- **ULTOMIRIS - Subcutaneous:** A single, PK-based Phase 3 study of ULTOMIRIS delivered subcutaneously once per week is underway to support registration in PNH and aHUS. Data are expected in the first half of 2020.

- **ULTOMIRIS - gMG:** A Phase 3 study of ULTOMIRIS in adults with gMG is underway.

- **ULTOMIRIS - NMOSD:** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in NMOSD by the end of 2019.

- **ULTOMIRIS - Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy (HSCT-TMA):** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in HSCT-TMA in the first half of 2020, pending regulatory feedback.

- **ULTOMIRIS - Amyotrophic Lateral Sclerosis (ALS):** Alexion plans to initiate a Phase 2/3 study for ULTOMIRIS in ALS in early 2020, pending regulatory feedback.

- **ALXN1840 (WTX101) - Wilson Disease:** A Phase 3 study of ALXN1840 (WTX101) in Wilson disease is underway. Enrollment is expected to complete in early 2020.

- **CAEL-101 - Caelum Biosciences:** Alexion is collaborating with Caelum Biosciences to develop CAEL-101 for light chain (AL) amyloidosis, a rare systemic disorder that causes misfolded immunoglobulin light chain protein to build up in and around tissues, resulting in progressive and widespread organ damage. A pivotal Phase 2/3 study investigating CAEL-101 as an add-on to current standard-of-care therapy is planned to begin in the first half of 2020. In October 2019, the European Commission granted orphan drug designation to CAEL-101 for the treatment of AL amyloidosis.

- **AG10 - Eidos:** In September 2019, Alexion announced an agreement with Eidos for an exclusive license to develop and commercialize AG10 in Japan. AG10 is a small molecule designed to treat the root cause of transthyretin amyloidosis (ATTR) – destabilized and misfolded transthyretin (TTR) protein – by binding and stabilizing TTR in the blood. Eidos is currently evaluating AG10 in a Phase 3 study in the U.S. and Europe for ATTR cardiomyopathy (ATTR-CM) – a progressive, fatal disease caused by the accumulation of misfolded TTR amyloid in the heart – and plans to begin a Phase 3 study in ATTR polyneuropathy (ATTR-PN) – a progressive, fatal disease caused by the accumulation of misfolded TTR amyloid in the peripheral nervous system. Alexion plans to expand the AG10 program into Japan in 2020, pending regulatory feedback.

- **Elamipretide - Stealth:** In October 2019, Alexion announced an agreement with Stealth BioTherapeutics for an option to co-develop and commercialize elamipretide for mitochondrial diseases. Currently being evaluated in a Phase 3 study in people with primary mitochondrial myopathy (PMM) - a genetic mitochondrial disease - elamipretide is a novel, potential first-in-class therapy that targets mitochondrial dysfunction. Alexion will have the opportunity to exercise the option following the delivery of results from the Phase 3 PMM study, which are expected in the first quarter of 2020. If exercised, the option also provides for co-development and commercialization of elamipretide in Barth syndrome, Leber's hereditary optic neuropathy (LHON) and geographic atrophy associated with dry age-related macular degeneration (GA).

PHASE 1/2

- **ALXN1830 (SYNT001):** Alexion plans to initiate a Phase 2 study of ALXN1830 (SYNT001) in warm autoimmune hemolytic anemia (WAIHA) in early 2020. In addition, Alexion plans to initiate a Phase 1 study of a subcutaneous formulation of

ALXN1830 in healthy volunteers in early 2020. Pending results from the Phase 1 study, Alexion plans to initiate a Phase 2 study of subcutaneous ALXN1830 in gMG in the second half of 2020.

- **Danicopan (ACH-4471) & ACH-5228 - Achillion:** In October 2019, Alexion announced an agreement to acquire Achillion. Pending approval of Achillion shareholders, satisfaction of customary closing conditions and approval from relevant regulatory agencies, including clearance under the HSR Act, the acquisition is expected to close in the first half of 2020. The acquisition will add two oral Factor D inhibitors to treat rare diseases associated with the complement alternative pathway to Alexion's clinical-stage pipeline - danicopan (ACH-4471) and ACH-5228. Danicopan is currently in Phase 2 development as an add-on therapy to eculizumab for PNH in patients with clinical extravascular hemolysis (EVH) and for C3 glomerulopathy, and ACH-5228 is currently in Phase 1 development.

- **ULTOMIRIS - Primary Progressive Multiple Sclerosis (PPMS):** Alexion plans to initiate an exploratory clinical study of ULTOMIRIS in PPMS.

- **ALXN1810 - Subcutaneous:** Alexion has completed a Phase 1 study of subcutaneous ALXN1210 co-administered with Halozyme's ENHANZE® drug-delivery technology, recombinant human hyaluronidase enzyme (rHuPH20), a next-generation subcutaneous formulation called ALXN1810. Strategic planning for the best development path for ALXN1810 is ongoing.

- **Affibody AB - ABY-039:** Alexion is partnering with Affibody AB to co-develop ABY-039 for rare Immunoglobulin G (IgG)-mediated autoimmune diseases. Currently in Phase 1 development, ABY-039 is a bivalent antibody-mimetic that targets the neonatal Fc receptor (FcRn).

- **ALXN1720:** In September 2019, Alexion began a Phase 1 study of ALXN1720, a novel anti-C5 albumin-binding bi-specific mini-body that binds and prevents activation of human C5, in healthy volunteers.

PRE-CLINICAL

- **Zealand Pharma A/S:** Alexion is collaborating with Zealand Pharma A/S to discover and develop novel peptide therapies for up to four targets in the complement pathway. Peptides offer a number of advantages, including being highly selective and potent, allowing low dosage volumes for ease of administration, and having the potential to treat a broad range of complement-mediated diseases.

- **Dicerna - GalXC™:** Alexion is collaborating with Dicerna Pharmaceuticals to jointly discover and develop up to four subcutaneously delivered GalXC™ RNA interference (RNAi) candidates, currently in pre-clinical development, for the treatment of complement-mediated diseases.

- **Complement Pharma - CP010:** Alexion is collaborating with Complement Pharma to co-develop CP010, a pre-clinical C6 inhibitor that has the potential to treat multiple neurological disorders.

- **Immune Pharma - anti-eotaxin-1 antibody:** Alexion has entered into an asset purchase agreement with Immune Pharma to acquire an anti-eotaxin-1 antibody for potential development in inflammatory diseases. The agreement is pending completion of bankruptcy proceedings, which are expected to conclude by the first quarter of 2020.

Share Repurchase Authorization

In October 2019, the Board of Directors approved a new share repurchase authorization of $1 billion. The repurchase program does not have an expiration date and we are not obligated to acquire a particular number of shares of common stock.

2019 Financial Guidance

Alexion is increasing revenues and EPS guidance. Full guidance updates are outlined below.

	Previous (as of July 24, 2019)	Updated (as of October 23, 2019)
Total revenues	$4,750 to $4,800 million	$4,860 to $4,890 million
SOLIRIS/ULTOMIRIS revenues	$4,095 to $4,130 million	$4,180 to $4,200 million
Metabolic revenues	$655 to $670 million	$680 to $690 million
R&D (% total revenues)		
GAAP	17% to 19%	17% to 18%
Non-GAAP	14% to 16%	14% to 15%
SG&A (% total revenues)		
GAAP	23% to 24%	24% to 25%
Non-GAAP	20% to 21%	21% to 22%
Operating margin		
GAAP	42% to 43%	41% to 42%

Non-GAAP	55% to 56%	55% to 56%
Earnings per share		
GAAP	$8.13 to $8.41	$8.58 to $8.78
Non-GAAP	$9.65 to $9.85	$10.25 to $10.40

Updated 2019 financial guidance assumes a GAAP effective tax rate of 5 to 6 percent and a non-GAAP effective tax rate of 13 to 14 percent for the year.

Updated guidance excludes the financial impact of the recently announced agreement to acquire Achillion as it is anticipated to close in the first half of 2020.

Alexion's financial guidance is based on current foreign exchange rates net of hedging activities and does not include the effect of acquisitions, license and collaboration agreements, intangible asset impairments, litigation charges, changes in fair value of contingent consideration or restructuring and related activity outside of the previously announced activities that may occur after the issuance of this press release.

Conference Call/Webcast Information:

Alexion will host a conference call/audio webcast to discuss the third quarter 2019 results today at 8:00 a.m. Eastern Time. To participate in the call, dial 866-762-3111 (USA) or 210-874-7712 (International), conference ID 6281803 shortly before 8:00 a.m. Eastern Time. A replay of the call will be available for a limited period following the call. The audio webcast can be accessed on the Investor page of Alexion's website at: http://ir.alexion.com.

About Alexion

Alexion is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the discovery, development and commercialization of life-changing therapies. As the global leader in complement biology and inhibition for more than 20 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first and only approved complement inhibitor to treat anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD). Alexion also has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). In addition, the company is developing several mid-to-late-stage therapies, including a second complement inhibitor, a copper-binding agent for Wilson disease and an anti-neonatal Fc receptor (FcRn) antibody for rare Immunoglobulin G (IgG)-mediated diseases as well as several early-stage therapies, including one for light chain (AL) amyloidosis and a second anti-FcRn therapy. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and its development efforts on the core therapeutic areas of hematology, nephrology, neurology and metabolic disorders. Alexion has been named to the *Forbes'* list of the World's Most Innovative Companies seven years in a row and is headquartered in Boston, Massachusetts' Innovation District. The company also has offices around the globe and serves patients in more than 50 countries. This press release and further information about Alexion can be found at: www.alexion.com.

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Forward-Looking Statement

This press release contains forward-looking statements, including statements related to: guidance regarding anticipated financial results for 2019 (and the assumptions related to such guidance); the strength of our business and continued growth; plans to expand the Company's pipeline; Company's goal of continuing to build on momentum as the year progresses; future plans for, and the timing for, the commencement of future clinical trials and the expected timing of the receipt of results of certain clinical trials and studies, including clinical programs for ULTOMIRIS in aHUS, NMOSD, HSCT-TMA, ALS, PPMS and a subcutaneous administration in PNH and aHUS and for ALXN1830 in WAIHA and gMG; potential benefits of current products and products under development and in clinical trials; plans for development programs with third parties including, Eidos, Affibody, Dicerna, Zealand, Stealth and Complement Pharma; the potential to treat a broad range of complement mediated diseases with the product to be developed with Zealand; the anticipated closings of the Achillion acquisition and the Immune Pharma asset acquisition; and Alexion's future clinical, regulatory, and commercial plans for ULTOMIRIS and other products and product candidates. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ materially from those forward-looking statements, including for example: our dependence on sales from our principal product (SOLIRIS); our ability to facilitate the timely conversion from SOLIRIS to ULTOMIRIS; payer, physician and patient acceptance of ULTOMIRIS as an alternative to SOLIRIS; appropriate pricing for ULTOMIRIS; future competition from biosimilars and novel products; decisions of regulatory authorities regarding the adequacy of our research, marketing approval or material limitations on the marketing of our products; delays or failure of product candidates to obtain regulatory approval; delays or the inability to launch product candidates due to regulatory restrictions, anticipated expense or other matters; interruptions or failures in the manufacture and supply of our products and our product candidates; failure to satisfactorily address matters raised by the FDA and other regulatory agencies; results in early stage clinical trials may not be indicative of full results or results from later stage or larger clinical trials (or broader patient populations) and do not ensure regulatory approval; the possibility that results of clinical trials are not predictive of safety and efficacy and potency of our products (or we fail to adequately operate or manage our clinical trials) which could cause us to halt trials, delay or prevent us from making regulatory approval filings or result in denial of approval of our product candidates; unexpected delays in clinical trials; unexpected concerns that may arise from additional data or analysis obtained during clinical trials; future product improvements may not be realized due to expense or feasibility or other factors; uncertainty of long-term success in developing, licensing or acquiring other product candidates or additional indications for existing products; inability to complete planned acquisitions due to failure of regulatory approval or material changes in target or otherwise; inability to complete acquisitions and investments due to increased competition for technology; the possibility that current rates of adoption of our products are not sustained; the adequacy of our pharmacovigilance and drug safety reporting processes; failure to protect and enforce our data, intellectual property and proprietary rights and the risks and uncertainties relating to intellectual property claims, lawsuits and challenges against us (including intellectual property lawsuits relating to ULTOMIRIS brought by third parties against Alexion and inter partes review petitions submitted by third parties); the risk that third party payors (including governmental agencies) will not reimburse or continue to reimburse for the use of our products at acceptable rates or at all; failure to realize the benefits and potential of investments, collaborations, licenses and acquisitions; the possibility that expected tax benefits will not be realized; assessment of impact of recent accounting pronouncements; potential declines in sovereign credit ratings or sovereign defaults in countries where we sell our products; delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement; uncertainties surrounding legal proceedings, company investigations and government investigations, including investigations of

Alexion by the U.S. Securities and Exchange Commission (SEC) and U.S. Department of Justice; the risk that estimates regarding the number of patients with PNH, aHUS, gMG, NMOSD, HPP and LAL-D and other future indications we are pursuing are inaccurate; the risks of changing foreign exchange rates; risks relating to the potential effects of the Company's restructuring; risks related to the acquisition of companies and co-development and collaboration efforts; and a variety of other risks set forth from time to time in Alexion's filings with the SEC, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the period ended June 30, 2019 and in our other filings with the SEC. Alexion disclaims any obligation to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

In addition to financial information prepared in accordance with GAAP, this press release also contains non-GAAP financial measures that Alexion believes, when considered together with the GAAP information, provide investors and management with supplemental information relating to performance, trends and prospects that promote a more complete understanding of our operating results and financial position during different periods. The non-GAAP results exclude the impact of the following GAAP items (see reconciliation tables below for additional information): share-based compensation expense, fair value adjustment of inventory acquired, amortization of purchased intangible assets, changes in fair value of contingent consideration, restructuring and related expenses, upfront payments related to licenses and collaborations, acquired in-process research and development assets, impairment of intangible assets, change in value of strategic equity investments, litigation charges, gain or loss on sale of a business or asset and certain adjustments to income tax expense. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP, and should be reviewed in conjunction with the relevant GAAP financial measures. Please refer to the attached Reconciliations of GAAP to non-GAAP Financial Results and GAAP to non-GAAP 2019 Financial Guidance for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three and nine month periods ended September 30, 2019 and 2018 and projected twelve months ending December 31, 2019.

(Tables Follow)

ALEXION PHARMACEUTICALS, INC.
TABLE 1: CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions, except per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Net product sales	$ 1,263.1	$ 1,026.5	$3,605.8	$3,001.6
Other revenue	—	—	1.0	0.8
Total revenues	1,263.1	1,026.5	3,606.8	3,002.4
Cost of sales	95.2	90.6	280.2	277.5
Operating expenses:				
Research and development	232.9	174.8	616.4	524.8
Selling, general and administrative	299.3	258.7	880.1	793.1
Acquired in-process research and development	—	—	(4.1)	803.7
Amortization of purchased intangible assets	75.6	80.0	235.7	240.1
Change in fair value of contingent consideration	29.8	53.5	7.2	110.9
Restructuring expenses	0.3	10.3	11.9	26.4
Total operating expenses	637.9	577.3	1,747.2	2,499.0
Operating income	530.0	358.6	1,579.4	225.9
Other income and expense:				
Investment income	23.0	5.9	50.6	119.4
Interest expense	(17.9)	(24.6)	(56.1)	(73.7)
Other income and (expense)	0.4	2.2	2.9	3.5
Income before income taxes	535.5	342.1	1,576.8	275.1
Income tax expense	67.9	11.2	61.5	152.5
Net income	$ 467.6	$ 330.9	$1,515.3	$ 122.6
Earnings per common share				
Basic	$ 2.09	$ 1.48	$ 6.77	$ 0.55
Diluted	$ 2.08	$ 1.47	$ 6.72	$ 0.55
Shares used in computing earnings per common share				
Basic	223.3	222.9	223.8	222.5
Diluted	224.5	224.6	225.4	224.2

ALEXION PHARMACEUTICALS, INC.
TABLE 2: RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(in millions, except per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
GAAP net income	$ 467.6	$ 330.9	$1,515.3	$ 122.6

Before tax adjustments:				
Cost of sales:				
Share-based compensation	3.4	3.3	10.7	12.2
Restructuring related expenses [1]	—	—	—	5.8
Research and development expense:				
Share-based compensation	16.7	12.5	45.9	42.5
Upfront payments related to licenses and collaborations [2]	30.1	—	76.3	—
Restructuring related expenses [1]	—	—	—	0.1
Selling, general and administrative expense:				
Share-based compensation	38.9	29.8	120.1	96.2
Restructuring related expenses [1]	—	7.9	—	18.0
Litigation charges	—	—	0.1	7.1
Gain on sale of asset	—	(3.5)	—	(3.5)
Acquired in-process research and development [3]	—	—	(4.1)	803.7
Amortization of purchased intangible assets	75.6	80.0	235.7	240.1
Change in fair value of contingent consideration [4]	29.8	53.5	7.2	110.9
Restructuring expenses [1]	0.3	10.3	11.9	26.4
Investment income:				
Change in value of strategic equity investments [5]	(12.0)	—	(20.6)	(100.8)
Other income:				
Restructuring related expenses [1]	—	—	—	(0.1)
Adjustments to income tax expense [6]	(14.6)	(64.6)	(212.1)	(68.9)
Non-GAAP net income	$ 635.8	$ 460.1	$ 1,786.4	$ 1,312.3
GAAP earnings per common share - diluted	$ 2.08	$ 1.47	$ 6.72	$ 0.55
Non-GAAP earnings per common share - diluted	$ 2.79	$ 2.02	$ 7.83	$ 5.78
Shares used in computing diluted earnings per common share (GAAP)	224.5	224.6	225.4	224.2
Shares used in computing diluted earnings per common share (non-GAAP)	227.7	227.4	228.2	227.0

(1) The following table summarizes the total restructuring and related expenses recorded by type of activity and the classification within the Reconciliation of GAAP to non-GAAP Financial Results:

	Three months ended September 30, 2019				Three months ended September 30, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Research and development	—	—	—	—	—	—	—	—
Selling, general and administrative	—	—	—	—	—	7.9	—	7.9
Restructuring expense	(2.8)	—	3.1	0.3	2.8	—	7.5	10.3
Other (income) expense	—	—	—	—	—	—	—	—
	$ (2.8)	$ —	$ 3.1	$ 0.3	$ 2.8	$ 7.9	$ 7.5	$ 18.2

	Nine months ended September 30, 2019				Nine months ended September 30, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ 5.8	$ —	$ 5.8
Research and development	—	—	—	—	—	0.1	—	0.1
Selling, general and administrative	—	—	—	—	—	18.0	—	18.0
Restructuring expense	8.7	—	3.2	11.9	6.9	—	19.5	26.4
Other (income) expense	—	—	—	—	—	—	(0.1)	(0.1)
	$ 8.7	$ —	$ 3.2	$ 11.9	$ 6.9	$ 23.9	$ 19.4	$ 50.2

(2) During the three months ended September 30, 2019, we recorded an upfront license payment of $30.1 million in connection with an agreement that we entered into with Eidos Therapeutics, Inc. (Eidos). During the nine months ended September 30, 2019, we recorded upfront license payments of

$76.3 million in connection with agreements that we entered into with Eidos, Affibody AB and Zealand Pharma A/S.

(3) In connection with the agreement of the final working capital adjustment for the Syntimmune acquisition, we recognized a benefit of $4.1 million associated with previously acquired in-process research and development in the second quarter of 2019.

(4) Changes in the fair value of contingent consideration expense for the three and nine months ended September 30, 2019 include the impact of changes in the expected timing of achieving contingent milestones, in addition to the interest component related to the passage of time. For the three and nine months ended September 30, 2018, changes in the fair value of contingent consideration expense was primarily due to amending certain contingent milestone payments due under our prior merger agreement with Enobia Pharma Corp. in September 2018 as well as due to increases in the likelihood and anticipated timing of payments for contingent consideration.

(5) During the three and nine months ended September 30, 2019, we recognized an unrealized gain of $12.0 million and $20.6 million, respectively, in investment income to adjust our strategic equity investments to fair value. The nine months ended September 30, 2018 included the recognition of an unrealized gain of $100.8 million on our investment in Moderna Therapeutics, Inc. following the completion of a new round of equity financing in the first quarter 2018.

(6) Alexion's non-GAAP income tax expense for the three and nine months ended September 30, 2019 and 2018 excludes the tax effect of pre-tax adjustments to GAAP profit. Non-GAAP income tax expense for the three and nine months ended September 30, 2019 excludes a one-time tax expense of $10.2 million related to the July 1, 2019 integration of Wilson Therapeutics intellectual property into the Alexion corporate structure. Non-GAAP income tax expense for the nine months ended September 30, 2019 also excludes certain one-time tax benefits of $95.7 million and $30.3 million associated with a tax election made with respect to intellectual property of Wilson Therapeutics and a release of an existing valuation allowance, respectively. Non-GAAP income tax expense for the three and nine months ended September 30, 2018 excludes adjustments to provisional estimates of the impact of Tax Cuts and Jobs Act we recorded in fourth quarter 2017.

ALEXION PHARMACEUTICALS, INC.
TABLE 3: RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL GUIDANCE
(in millions, except per share amounts and percentages)
(unaudited)

	Twelve months ending December 31, 2019	
	Low	**High**
GAAP net income	$ 1,926	$ 1,970
Before tax adjustments:		
Share-based compensation	251	234
Upfront payments related to licenses and collaborations	96	96
Acquired in-process research and development	(4)	(4)
Amortization of purchased intangible assets	309	309
Change in fair value of contingent consideration	12	12
Restructuring expenses	20	20
Change in value of strategic equity investments	(21)	(21)
Adjustments to income tax expense	(257)	(250)
Non-GAAP net income	$ 2,332	$ 2,366
Diluted GAAP earnings per common share	$ 8.58	$ 8.78
Diluted non-GAAP earnings per common share	$ 10.25	$ 10.4
Operating expense and margin (% total revenues)		
GAAP research and development expense	18%	17%
Share-based compensation	1%	1%
Upfront payments related to licenses and collaborations	2%	2%
Non-GAAP research and development expense	15%	14%
GAAP selling, general and administrative expense	25%	24%
Share-based compensation	3%	3%
Non-GAAP selling, general and administrative expense	22%	21%
GAAP operating margin	41%	42%
Share-based compensation	5%	5%
Upfront payments related to licenses and collaborations	2%	2%
Acquired in-process research and development	0%	0%
Amortization of purchased intangible assets	6%	6%
Change in fair value of contingent consideration	0%	0%
Restructuring expenses	0%	0%

Non-GAAP operating margin	55%	56%

Income tax expense (% of income before income taxes)

GAAP income tax expense	6%	5%
Tax effect of pre-tax adjustments to GAAP net income and other one-time items associated with intellectual property	8%	8%
Non-GAAP income tax expense	14%	13%

Amounts may not foot due to rounding.

ALEXION PHARMACEUTICALS, INC.
TABLE 4: NET PRODUCT SALES BY GEOGRAPHY
(in millions)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
SOLIRIS				
United States	$ 496.8	$ 404.5	$ 1,456.8	$ 1,136.3
Europe	255.5	262.1	800.2	766.3
Asia Pacific	118.0	98.2	329.2	277.3
Rest of World	120.2	123.2	347.1	406.4
Total Soliris	$ 990.5	$ 888.0	$ 2,933.3	$ 2,586.3
ULTOMIRIS				
United States	$ 65.1	$ —	$ 143.9	$ —
Europe	21.1	—	21.1	—
Asia Pacific	3.7	—	3.7	—
Rest of World	—	—	—	—
Total Ultomiris	$ 89.9	$ —	$ 168.7	$ —
STRENSIQ				
United States	$ 118.0	$ 86.6	$ 323.7	$ 275.7
Europe	19.0	16.6	56.0	47.0
Asia Pacific	14.0	7.2	36.0	19.2
Rest of World	3.3	2.8	10.0	7.1
Total Strensiq	$ 154.3	$ 113.2	$ 425.7	$ 349.0
KANUMA				
United States	$ 16.0	$ 13.7	$ 45.1	$ 38.6
Europe	6.3	4.7	19.4	16.4
Asia Pacific	1.3	0.8	3.4	2.9
Rest of World	4.8	6.1	10.2	8.4
Total Kanuma	$ 28.4	$ 25.3	$ 78.1	$ 66.3
Net Product Sales				
United States	$ 695.9	$ 504.8	$ 1,969.5	$ 1,450.6
Europe	301.9	283.4	896.7	829.7
Asia Pacific	137.0	106.2	372.3	299.4
Rest of World	128.3	132.1	367.3	421.9
Total Net Product Sales	$ 1,263.1	$ 1,026.5	$ 3,605.8	$ 3,001.6

ALEXION PHARMACEUTICALS, INC.
TABLE 5: CONDENSED CONSOLIDATED BALANCE SHEETS
(in millions)
(unaudited)

	September 30, 2019	December 31 2018
Cash and cash equivalents	$ 2,171.3	$ 1,365.5
Marketable securities	44.4	198.3
Trade accounts receivable, net	1,116.3	922.3
Inventories	576.7	472.5
Prepaid expenses and other current assets [(1)]	432.5	426.4
Property, plant and equipment, net [(1)]	1,148.0	1,471.5

Intangible assets, net	3,410.1	3,641.3
Goodwill	5,037.4	5,037.4
Right of use operating assets [(1)]	206.9	—
Other assets	671.4	396.7
Total assets	$ 14,815.0	$ 13,931.9
Accounts payable and accrued expenses	$ 868.2	$ 698.2
Revolving credit facility	—	250.0
Current portion of long-term debt	126.6	93.8
Current portion of contingent consideration	—	97.6
Other current liabilities [(1)]	96.4	34.4
Long-term debt, less current portion	2,406.7	2,501.7
Contingent consideration	188.0	183.2
Facility lease obligations [(1)]	—	361.0
Deferred tax liabilities	314.7	391.1
Noncurrent operating lease liabilities [(1)]	166.8	—
Other liabilities [(1)]	280.4	155.6
Total liabilities	4,447.8	4,766.6
Total stockholders' equity [(1)]	10,367.2	9,165.3
Total liabilities and stockholders' equity	$ 14,815.0	$ 13,931.9

(1) In February 2016, the Financial Accounting Standards Board issued a new standard that requires lessees to recognize leases on-balance sheet. We adopted the new standard on January 1, 2019 using the modified retrospective approach. The September 30, 2019 condensed consolidated balance sheet is presented under the new standard, while the December 31, 2018 condensed consolidated balance sheet is not adjusted and continues to be reported under the accounting standards in effect for that period. Upon adoption of the new lease standard, we derecognized $472.8 million of property, plant and equipment and other assets and $372.2 million of facility lease obligations associated with previously existing build-to-suit arrangements which resulted in a decrease of $90.3 million to retained earnings, net of tax. In addition, we capitalized $326.1 million and $255.3 million of right of use assets and lease liabilities, respectively, within our condensed consolidated balance sheet upon adoption.

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