Alexion Reports Second Quarter 2019 Results

July 24, 2019

- 2Q19 total revenues of $1,203.3 million, a 15 percent increase over 2Q18 and a 23 percent volume increase
- 2Q19 GAAP diluted EPS of $2.04; non-GAAP diluted EPS of $2.64
- Received 3 regulatory approvals - SOLIRIS® (eculizumab) for adults with neuromyelitis optica spectrum disorder (NMOSD) in the U.S., and ULTOMIRIS® (ravulizumab-cwvz) for adults with paroxysmal nocturnal hemoglobinuria (PNH) in Japan and the EU
- ULTOMIRIS for atypical hemolytic uremic syndrome (aHUS) under priority review with U.S. FDA
- Total revenues and EPS guidance increased to reflect strength of the business and continued growth

BOSTON--(BUSINESS WIRE)--Jul. 24, 2019-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the second quarter of 2019. Total revenues in the second quarter were $1,203.3 million, a 15 percent increase compared to the same period in 2018. The negative impact of foreign currency on total revenues year-over-year was 1 percent, or $15.1 million, inclusive of hedging activities. On a GAAP basis, diluted EPS in the quarter was $2.04, a 200 percent increase versus the prior year. The second quarter of 2018 included $803.7 million of expense related to the value of the in-process research and development asset acquired in connection with our acquisition of Wilson Therapeutics AB. Non-GAAP diluted EPS for the second quarter of 2019 was $2.64, a 28 percent increase versus the second quarter of 2018.

"We delivered another strong quarter, with continued growth driven by the successful U.S. launches of ULTOMIRIS in PNH and SOLIRIS in gMG. We received three regulatory approvals over the last month, including SOLIRIS for NMOSD in the U.S., and ULTOMIRIS for PNH in Japan and the EU. In addition, the FDA granted priority review for ULTOMIRIS in atypical HUS," said Ludwig Hantson, Ph.D., Chief Executive Officer of Alexion. "We are well positioned to continue our momentum in the second half of 2019, strengthening our four durable franchises in hematology and nephrology, neurology, metabolics and FcRn, advancing and expanding our pipeline, and serving more people living with rare diseases than ever before."

Second Quarter 2019 Financial Highlights

- Total net product sales were $1,202.5 million in the second quarter of 2019, compared to $1,044.7 million in the second quarter of 2018.
- SOLIRIS® (eculizumab) net product sales were $980.8 million, compared to $898.2 million in the second quarter of 2018, representing a 9 percent increase. SOLIRIS volume increased 17 percent year-over-year. SOLIRIS net product sales for the second quarter 2019 included a $31.6 million reduction to revenue related to a recent judicial order on SOLIRIS pricing in Canada. The reduction in revenue includes the impact for the period from September 2017 to June 2019.
- ULTOMIRIS® (ravulizumab-cwvz) net product sales were $54.2 million in the second quarter of 2019.
- STRENSIQ® (asfotase alfa) net product sales were $141.3 million, compared to $125.1 million in the second quarter of 2018, representing a 13 percent increase. STRENSIQ volume increased 21 percent year-over-year.
- KANUMA® (sebelipase alfa) net product sales were $26.2 million, compared to $21.4 million in the second quarter of 2018, representing a 22 percent increase. KANUMA volume increased 33 percent year-over-year.
- GAAP cost of sales was $99.2 million, compared to $95.3 million in the second quarter of 2018. Non-GAAP cost of sales was $95.7 million, compared to $89.3 million in the second quarter of 2018.
- GAAP R&D expense was $187.6 million, compared to $173.4 million in the second quarter of 2018. Non-GAAP R&D expense was $148.7 million, compared to $158.3 million in the second quarter of 2018.
- GAAP SG&A expense was $299.3 million, compared to $277.3 million in the second quarter of 2018. Non-GAAP SG&A expense was $255.8 million, compared to $230.4 million in the second quarter of 2018.
- GAAP acquired in-process research and development expense (benefit) was $(4.1) million related to the agreement of the final working capital adjustment for the Syntimmune, Inc. acquisition, compared to $803.7 million in the second quarter of 2018, related to the in-process research and development asset acquired in connection with the 2018 acquisition of Wilson Therapeutics AB.
- GAAP income tax expense was $39.7 million, compared to income tax expense of $38.8 million in the second quarter of 2018. Non-GAAP income tax expense was $90.2 million, compared to $77.1 million in the second quarter of 2018.
- GAAP diluted EPS was $2.04, compared to $(2.05) in the second quarter of 2018. The second quarter of 2018 included $803.7 million of expense related to the value of the in-process research and development asset acquired in connection with the Wilson Therapeutics AB acquisition. Non-GAAP diluted EPS was $2.64, compared to $2.07 in the second quarter of 2018.

Research and Development

PHASE 3

- **SOLIRIS - Neuromyelitis Optica Spectrum Disorder (NMOSD):** In June 2019, the U.S. Food and Drug Administration (FDA) approved SOLIRIS for adults with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD. Applications for approval in the European Union (EU) and Japan are 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):** Dosing is underway in a Phase 3 study of SOLIRIS in children and adolescents with gMG.
- **ULTOMIRIS - Paroxysmal Nocturnal Hemoglobinuria (PNH):** ULTOMIRIS was approved for adults with PNH in Japan in June 2019 and in the EU in July 2019. A Phase 3 study of ULTOMIRIS in children and adolescents with PNH is underway.
- **ULTOMIRIS- Atypical Hemolytic Uremic Syndrome (aHUS):** In June 2019, Alexion announced that the FDA granted priority review for ULTOMIRIS in aHUS and set a Prescription Drug User Fee Act (PDUFA) target action date of October 19, 2019. The filing was based on previously announced positive topline results from a Phase 3 study of ULTOMIRIS in complement inhibitor-naïve patients with aHUS. Alexion plans to file for regulatory approvals in the EU and Japan in the second half of 2019. In addition, a Phase 3 study of ULTOMIRIS in children and adolescents with aHUS is underway.
- **ULTOMIRIS- Subcutaneous:** Dosing is underway in a single, PK-based Phase 3 study of ULTOMIRIS delivered subcutaneously once per week to support registration in PNH and aHUS. Data are expected in early 2020.
- **ULTOMIRIS- gMG:** Dosing is underway in a Phase 3 study of ULTOMIRIS in gMG.
- **ULTOMIRIS- NMOSD:** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in NMOSD by the end of 2019, pending regulatory feedback.
- **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.
- **ALXN1840 (WTX101) - Wilson Disease:** Dosing is underway in a Phase 3 study of ALXN1840 (WTX101) in Wilson disease, a rare genetic disorder with devastating hepatic and neurological consequences. ALXN1840 is a first-in-class oral copper-binding agent with a unique mechanism of action to bind serum copper and promote its removal from the liver. Enrollment is expected to complete in early 2020.

PHASE 1/2

- **ALXN1830 (SYNT001):** Alexion plans to initiate a Phase 2/3 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 2/3 study of subcutaneous ALXN1830 in gMG in 2020.
- **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.
- **ULTOMIRIS- Amyotrophic Lateral Sclerosis(ALS):** Alexion plans to initiate a proof-of-concept study for ULTOMIRIS in ALS in early 2020, pending regulatory feedback.
- **ULTOMIRIS- Primary Progressive Multiple Sclerosis(PPMS):** Alexion plans to initiate an exploratory clinical study of ULTOMIRIS in PPMS.
- **Caelum Biosciences - CAEL-101- Light Chain (AL) Amyloidosis:** Alexion is collaborating with Caelum Biosciences to develop CAEL-101 for 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. CAEL-101 is a first-in-class amyloid fibril targeted therapy designed to improve organ function by reducing or eliminating amyloid deposits in patients with AL amyloidosis. In a Phase 1a/1b study, CAEL-101 demonstrated improved organ function, including cardiac and renal function, in patients with relapsed and refractory AL amyloidosis. Pending regulatory feedback, a Phase 2/3 study investigating CAEL-101 as an add-on to current standard-of-care therapy is planned to begin in 2020.
- **Affibody AB - ABY-039:** In April 2019, Alexion entered into a partnership with Affibody AB, following approval from the relevant regulatory authorities, 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). ABY-039 has been specifically designed to combine Affibody's protein therapeutics platform (Affibody® molecules) and Albumod™ technology to achieve a long half-life, which, along with its small size provides the potential for less frequent, convenient, at-home subcutaneous administration.

PRE-CLINICAL

- **ALXN1720:** In June 2019, Alexion submitted the initial Clinical Trial Authorization (CTA) application to the Medicines and Healthcare Products Regulatory Agency (MHRA) for the initiation of a Phase 1 study of ALXN1720, a novel anti-C5 albumin-binding bi-specific mini-body that binds and prevents activation of human C5. Alexion plans to initiate this first-

in-human study in late 2019.

- **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.

2019 Financial Guidance

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

	Previous (as of April 25, 2019)	Updated (as of July 24, 2019)
Total revenues	$4,675 to $4,750 million	$4,750 to $4,800 million
SOLIRIS/ULTOMIRIS revenues	$4,020 to $4,070 million	$4,095 to $4,130 million
Metabolic revenues	$655 to $680 million	$655 to $670 million
R&D (% total revenues)		
GAAP	19% to 20%	17% to 19%
Non-GAAP	16% to 17%	14% to 16%
SG&A (% total revenues)		
GAAP	23% to 24%	23% to 24%
Non-GAAP	20% to 21%	20% to 21%
Operating margin		
GAAP	35% to 42%	42% to 43%
Non-GAAP	54% to 55%	55% to 56%
Earnings per share		
GAAP	$6.76 to $7.96	$8.13 to $8.41
Non-GAAP	$9.25 to $9.45	$9.65 to $9.85

Updated 2019 financial guidance assumes a GAAP effective tax rate of 6 to 7 percent and a non-GAAP effective tax rate of 14 to 15 percent.

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 second 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 5564357 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), as well as the first and only approved complement inhibitor to treat atypical hemolytic uremic syndrome (aHUS), 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; further future growth in the Company's four durable franchises (hematology/nephrology, metabolics, neurology and FcRn); plans to make future regulatory submissions/filings for approval of certain of our products and product candidates, including SOLIRIS (eculizumab) and ULTOMIRIS (ALXN1210/ravulizumab-cwvz), and the expected timing related thereto, (as well as the expected timing of the receipt of certain regulatory approvals to market a product); 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; potential benefits of current products and products under development and in clinical trials (including further extended dosing intervals); Company's plans to initiate proof-of-concept studies for ULTOMIRIS in ALS and exploratory clinical study for ULTOMIRIS in PPMS; the potential to treat a broad range of complement mediated diseases with the product to be developed with Zealand Pharma A/S; and Alexion's future clinical, regulatory, and commercial plans for ULTOMIRIS and other 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 of PNH patients (and any future indications) 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 March 31, 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 six month periods ended June 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 June 30		Six months ended June 30	
	2019	**2018**	**2019**	**2018**
Net product sales	$ 1,202.5	$ 1,044.7	$ 2,342.7	$ 1,975.1
Other revenue	0.8	0.3	1.0	0.8
Total revenues	1,203.3	1,045.0	2,343.7	1,975.9
Cost of sales	99.2	95.3	185.0	186.9
Operating expenses:				
Research and development	187.6	173.4	383.5	350.0
Selling, general and administrative	299.3	277.3	580.8	534.4
Acquired in-process research and development	(4.1)	803.7	(4.1)	803.7

Amortization of purchased intangible assets	80.1	80.1	160.1	160.1
Change in fair value of contingent consideration	6.1	4.7	(22.6)	57.4
Restructuring expenses	2.5	10.6	11.6	16.1
Total operating expenses	571.5	1,349.8	1,109.3	1,921.7
Operating income (loss)	532.6	(400.1)	1,049.4	(132.7)
Other income and expense:				
Investment (expense) income	(14.9)	7.7	27.6	113.5
Interest expense	(18.3)	(25.0)	(38.2)	(49.1)
Other income and (expense)	0.1	(1.2)	2.5	1.3
Income (loss) before income taxes	499.5	(418.6)	1,041.3	(67.0)
Income tax (benefit) expense	39.7	38.8	(6.4)	141.3
Net income (loss)	$ 459.8	$ (457.4)	$ 1,047.7	$ (208.3)
Earnings (loss) per common share				
Basic	$ 2.05	$ (2.05)	$ 4.68	$ (0.94)
Diluted	$ 2.04	$ (2.05)	$ 4.64	$ (0.94)
Shares used in computing earnings (loss) per common share				
Basic	224.2	222.6	224.0	222.3
Diluted	225.6	222.6	225.7	222.3

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

	Three months ended June 30		Six months ended June 30	
	2019	2018	2019	2018
GAAP net income (loss)	$ 459.8	$ (457.4)	$ 1,047.7	$ (208.3)
Before tax adjustments:				
Cost of sales:				
Share-based compensation	3.5	5.5	7.3	8.8
Restructuring related expenses (1)	—	0.5	—	5.8
Research and development expense:				
Share-based compensation	13.9	15.1	29.2	30.0
Upfront payments related to licenses and collaborations (2)	25.0	—	46.2	—
Restructuring related expenses (1)	—	—	—	0.1
Selling, general and administrative expense:				
Share-based compensation	43.5	33.3	81.2	66.4
Restructuring related expenses (1)	—	6.5	—	10.1
Litigation charges(3)	—	7.1	0.1	7.1
Acquired in-process research and development (4)	(4.1)	803.7	(4.1)	803.7
Amortization of purchased intangible assets	80.1	80.1	160.1	160.1
Change in fair value of contingent consideration (5)	6.1	4.7	(22.6)	57.4
Restructuring expenses (1)	2.5	10.6	11.6	16.1
Investment income:				
Change in value of strategic equity investments (6)	25.2	—	(8.6)	(100.8)
Other income:				
Restructuring related expenses (1)	—	—	—	(0.1)
Adjustments to income tax (benefit) expense (7)	(50.5)	(38.3)	(197.5)	(4.4)
Non-GAAP net income	$ 605.0	$ 471.4	$ 1,150.6	$ 852.0
GAAP earnings (loss) per common share - diluted	$ 2.04	$ (2.05)	$ 4.64	$ (0.94)

Non-GAAP earnings per common share - diluted	$ 2.64	$ 2.07	$ 5.04	$ 3.76
Shares used in computing diluted earnings (loss) per common share (GAAP)	225.6	222.6	225.7	222.3
Shares used in computing diluted earnings per common share (non-GAAP)	228.9	227.2	228.5	226.8

(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 June 30, 2019				Three months ended June 30, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ 0.5	$ —	$ 0.5
Research and development	—	—	—	—	—	—	—	—
Selling, general and administrative	—	—	—	—	—	6.5	—	6.5
Restructuring expense	2.4	—	0.1	2.5	3.1	—	7.5	10.6
Other (income) expense	—	—	—	—	—	—	—	—
	$ 2.4	$ —	$ 0.1	$ 2.5	$ 3.1	$ 7.0	$ 7.5	$17.6

	Six months ended June 30, 2019				Six months ended June 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	—	—	—	—	—	10.1	—	10.1
Restructuring expense	11.5	—	0.1	11.6	4.1	—	12.0	16.1
Other (income) expense	—	—	—	—	—	—	(0.1)	(0.1)
	$ 11.5	$ —	$ 0.1	$11.6	$ 4.1	$ 16.0	$11.9	$32.0

(2) During the three months ended June 30, 2019, we recorded an upfront license payment of $25.0 million in connection with an agreement that we entered into with Affibody AB (Affibody). During the six months ended June 30, 2019, we recorded upfront license payments of $25.0 million and $21.2 million in connection with agreements that we entered into with Affibody and Zealand Pharma A/S, respectively.

(3) During the second quarter of 2018, we recorded $7.1 million in litigation charges in connection with ongoing investigations.

(4) 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. During the second quarter of 2018, we completed the acquisition of Wilson Therapeutics AB. The acquisition was accounted for as an asset acquisition, as substantially all of the fair value of the gross assets acquired is concentrated in a single asset, WTX101, an early Phase III development asset. The value of the acquired in-process research and development asset related to WTX101 was expensed during the three and six months ended June 30, 2018 due to the stage of development of this asset.

(5) For the three months ended June 30, 2019 and 2018, changes in the fair value of contingent consideration expense reflect the interest component of contingent consideration related to the passage of time. Changes in the fair value of contingent consideration expense for the six months ended June 30, 2019 and 2018 include the impact of changes in the expected timing and probability of achieving contingent milestones, in addition to the interest component related to the passage of time.

(6) During the three and six months ended June 30, 2019, we recognized an unrealized (loss) gain of $(25.2) million and $8.6 million, respectively, in investment income to adjust our strategic equity investments to fair value. The six months ended June 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.

(7) Alexion's non-GAAP income tax expense for the three and six months ended June 30, 2019 and 2018 excludes the tax effect of pre-tax adjustments to GAAP profit. Non-GAAP income tax expense for the six months ended June 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 AB and a release of an existing valuation allowance, respectively. Non-GAAP income tax expense for the six months ended June 30, 2018 also 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	$1,842	$1,904
Before tax adjustments:		
Share-based compensation	256	239
Upfront payments related to licenses and collaborations	46	46
Acquired in-process research and development	(4)	(4)
Amortization of purchased intangible assets	320	320
Change in fair value of contingent consideration	(15)	(15)
Restructuring expenses	25	20
Change in value of strategic equity investments	(9)	(9)
Adjustments to income tax expense	(252)	(246)
Non-GAAP net income	$2,210	$2,256
Diluted GAAP earnings per common share	$ 8.13	$ 8.41
Diluted non-GAAP earnings per common share	$ 9.65	$ 9.85
Operating expense and margin (% total revenues)		
GAAP research and development expense	19%	17%
Share-based compensation	2%	2%
Upfront payments related to licenses and collaborations	1%	1%
Non-GAAP research and development expense	16%	14%
GAAP selling, general and administrative expense	24%	23%
Share-based compensation	3%	3%
Non-GAAP selling, general and administrative expense	21%	20%
GAAP operating margin	42%	43%
Share-based compensation	5%	5%
Upfront payments related to licenses and collaborations	1%	1%
Acquired in-process research and development	0%	0%
Amortization of purchased intangible assets	7%	7%
Change in fair value of contingent consideration	0%	0%
Restructuring expenses	1%	0%
Non-GAAP operating margin	55%	56%
Income tax expense (% of income before income taxes)		
GAAP income tax expense	7%	6%
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	15%	14%

Amounts may not foot due to rounding.

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

	Three months ended June 30		Six months ended June 30	
	2019	2018	2019	2018
SOLIRIS				
United States	$ 496.3	$ 395.8	$ 960.0	$ 731.8
Europe	280.2	253.4	544.7	504.2
Asia Pacific	110.3	93.6	211.2	179.1
Rest of World	94.0	155.4	226.9	283.2
Total Soliris	$ 980.8	$ 898.2	$1,942.8	$1,698.3
ULTOMIRIS				
United States	$ 54.2	$ —	$ 78.8	$ —
Europe	—	—	—	—
Asia Pacific	—	—	—	—
Rest of World	—	—	—	—
Total Ultomiris	$ 54.2	$ —	$ 78.8	$ —
STRENSIQ				
United States	$ 106.2	$ 99.9	$ 205.7	$ 189.1
Europe	19.5	16.4	37.0	30.4
Asia Pacific	12.1	6.3	22.0	12.0
Rest of World	3.5	2.5	6.7	4.3
Total Strensiq	$ 141.3	$ 125.1	$ 271.4	$ 235.8
KANUMA				
United States	$ 15.3	$ 13.0	$ 29.1	$ 24.9
Europe	6.8	5.8	13.1	11.7
Asia Pacific	1.3	1.1	2.1	2.1
Rest of World	2.8	1.5	5.4	2.3
Total Kanuma	$ 26.2	$ 21.4	$ 49.7	$ 41.0
Net Product Sales				
United States	$ 672.0	$ 508.7	$1,273.6	$ 945.8
Europe	306.5	275.6	594.8	546.3
Asia Pacific	123.7	101.0	235.3	193.2
Rest of World	100.3	159.4	239.0	289.8
Total Net Product Sales	$ 1,202.5	$ 1,044.7	$2,342.7	$1,975.1

ALEXION PHARMACEUTICALS, INC.

TABLE 5: CONDENSED CONSOLIDATED BALANCE SHEETS

(in millions)

(unaudited)

	June 30 2019	December 31 2018
Cash and cash equivalents	$ 1,984.2	$ 1,365.5
Marketable securities	105.4	198.3
Trade accounts receivable, net	1,123.6	922.3
Inventories	494.6	472.5
Prepaid expenses and other current assets [(1)]	460.7	426.4
Property, plant and equipment, net [(1)]	1,123.5	1,471.5
Intangible assets, net	3,487.6	3,641.3
Goodwill	5,037.4	5,037.4
Right of use operating assets [(1)]	209.5	—
Other assets	541.2	396.7
Total assets	$ 14,567.7	$ 13,931.9
Accounts payable and accrued expenses	$ 728.7	$ 698.2
Revolving credit facility	—	250.0
Current portion of long-term debt	126.6	93.8
Current portion of contingent consideration	100.0	97.6

Other current liabilities [(1)]	76.2	34.4
Long-term debt, less current portion	2,438.3	2,501.7
Contingent consideration	158.2	183.2
Facility lease obligations [(1)]	—	361.0
Deferred tax liabilities	341.2	391.1
Noncurrent operating lease liabilities [(1)]	165.5	—
Other liabilities [(1)]	269.5	155.6
Total liabilities	4,404.2	4,766.6
Total stockholders' equity [(1)]	10,163.5	9,165.3
Total liabilities and stockholders' equity	$ 14,567.7	$ 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 June 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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