Alexion Reports First Quarter 2019 Results

April 25, 2019

- 1Q19 total revenues of $1,140.4 million, a 23 percent increase over 1Q18 and a 26 percent volume increase
- 1Q19 GAAP diluted EPS of $2.61; non-GAAP diluted EPS of $2.39
- Strong U.S. launch underway for ULTOMIRIS® (ravulizumab-cwvz) in adults with paroxysmal noctural hemoglobinuria (PNH); PNH applications under review in EU and Japan; U.S. filing submitted for atypical hemolytic uremic syndrome (aHUS)
- SOLIRIS® (eculizumab) for neuromyelitis optica spectrum disorder (NMOSD) granted Priority Review by U.S. FDA with action date of June 28, 2019; EU and Japanese applications under review
- Announced collaborations with Caelum Biosciences, Affibody and Zealand Pharma
- Total Revenues and EPS guidance increased to reflect strength of the business and continued growth

BOSTON--(BUSINESS WIRE)--Apr. 25, 2019-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the first quarter of 2019. Total revenues in the first quarter were $1,140.4 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 1 percent, or $12.3 million, inclusive of hedging activities. On a GAAP basis, diluted EPS in the quarter was $2.61, a 135 percent increase versus the prior year. Non-GAAP diluted EPS for the first quarter of 2019 was $2.39, a 42 percent increase versus the first quarter of 2018.

"We had a great start to 2019, with a strong launch in ULTOMIRIS' first full quarter since FDA approval. We've also made significant progress executing and expanding our pipeline. This progress includes three business development deals, multiple filings under regulatory review and having begun dosing patients in two new ULTOMIRIS Phase 3 programs," said Ludwig Hantson, Ph.D., Chief Executive Officer of Alexion. "We look forward to continuing to build on our momentum as the year progresses, further growing our four durable franchises in hematology/nephrology, neurology, metabolics and FcRn."

First Quarter 2019 Financial Highlights

- Total net product sales were $1,140.2 million in the first quarter of 2019, compared to $930.4 million in the first quarter of 2018.
- SOLIRIS® (eculizumab) net product sales were $962.0 million, compared to $800.1 million in the first quarter of 2018, representing a 20 percent increase. SOLIRIS volume increased 23 percent year-over-year.
- ULTOMIRIS® (ravulizumab-cwvz) net product sales were $24.6 million in its first full quarter since FDA approval.
- STRENSIQ® (asfotase alfa) net product sales were $130.1 million, compared to $110.7 million in the first quarter of 2018, representing an 18 percent increase. STRENSIQ volume increased 26 percent year-over-year.
- KANUMA® (sebelipase alfa) net product sales were $23.5 million, compared to $19.6 million in the first quarter of 2018, representing a 20 percent increase. KANUMA volume increased 28 percent year-over-year.
- GAAP cost of sales was $85.8 million, compared to $91.6 million in the first quarter of 2018. Non-GAAP cost of sales was $82.1 million, compared to $83.0 million in the first quarter of 2018.
- GAAP R&D expense was $195.9 million, compared to $176.6 million in the first quarter of 2018. Non-GAAP R&D expense was $159.4 million, compared to $161.6 million in the first quarter of 2018.
- GAAP SG&A expense was $281.5 million, compared to $257.1 million in the first quarter of 2018. Non-GAAP SG&A expense was $243.7 million, compared to $220.4 million in the first quarter of 2018.
- GAAP income tax benefit was $46.1 million, compared to income tax expense of $102.5 million in the first quarter of 2018. GAAP income tax benefit for the first quarter 2019 includes deferred tax benefits of $95.7 million and $30.3 million associated with a tax election related to intellectual property and release of an existing valuation allowance, respectively. Non-GAAP income tax expense was $100.9 million, compared to $68.6 million in the first quarter of 2018.

- GAAP diluted EPS was $2.61, compared to $1.11 in the first quarter of 2018. GAAP diluted EPS for the first quarter 2019 includes deferred tax benefits of $95.7 million and $30.3 million associated with a tax election related to intellectual property and release of an existing valuation allowance, respectively. Non-GAAP diluted EPS was $2.39, compared to $1.68 in the first quarter of 2018.

Research and Development

PHASE 3

- **SOLIRIS - Neuromyelitis Optica Spectrum Disorder (NMOSD):** In February 2019, Alexion announced that the U.S. Food and Drug Administration (FDA) granted Priority Review for SOLIRIS in NMOSD and set a Prescription Drug User Fee Act (PDUFA) action date of June 28, 2019. Alexion has filed for regulatory approval in the European Union (EU) and Japan, and orphan drug priority review has been granted in Japan. These filings are based on previously announced results from the Phase 3 PREVENT study, in which 97.9 percent of patients with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD who received SOLIRIS on top of stable standard-of-care therapy were relapse free at 48 weeks compared to 63.2 percent of patients who received placebo.
- **ULTOMIRIS - Paroxysmal Nocturnal Hemoglobinuria (PNH):** Applications for approval in the EU and Japan are currently under review. In addition, a Phase 3 study of ULTOMIRIS in children and adolescents with PNH is underway.
- **ULTOMIRIS- Atypical Hemolytic Uremic Syndrome (aHUS):** In April 2019, Alexion submitted an application in the U.S. for the approval of ULTOMIRIS in patients with aHUS. 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 approval in the EU and Japan in 2019. In addition, a Phase 3 study of ULTOMIRIS in adolescents and children with aHUS is underway.
- **ULTOMIRIS- Subcutaneous:** Enrollment and dosing are 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- Generalized Myasthenia Gravis (gMG):** In the first quarter of 2019, Alexion initiateda Phase 3 study of ULTOMIRIS in gMG.
- **ULTOMIRIS- Neuromyelitis Optica Spectrum Disorder (NMOSD):** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in NMOSD by the end of 2019.
- **ALXN1840 (WTX101) - Wilson Disease:** Enrollment and dosing are underway in a Phase 3 study of ALXN1840 (WTX101) in Wilson disease, a rare genetic disorder with devastating hepatic and neurological consequences. The study is now powered for superiority versus standard-of-care therapy. 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.

PHASE 1/2

- **ALXN1830 (SYNT001):** Alexion plans to initiate two Phase 2/3 trials of ALXN1830 (SYNT001) in late 2019 or early 2020 - one in warm autoimmune hemolytic anemia (WAIHA) and one in gMG.
- **ALXN1810 - Subcutaneous:** In the first quarter of 2019,Alexion completed dosing in 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.
- **ULTOMIRIS- Amyotrophic Lateral Sclerosis(ALS):** Alexion plans to initiate a proof-of-concept study for ULTOMIRIS in ALS.
- **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:** In January 2019, Alexion entered into a collaboration 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 early 2020.

- **Affibody AB - ABY-039:** In March 2019, Alexion announced a partnership with Affibody AB to co-develop ABY-039 for rare Immunoglobulin G (IgG)-mediated autoimmune diseases. Pending relevant regulatory approvals, the transaction is expected to close in the second quarter of 2019. 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 March 2019, Alexion announced the development of ALXN1720, a novel anti-C5 albumin-binding bi-specific mini-body that binds and prevents activation of human C5. Alexion plans to initiate a first-in-human study of ALXN1720 in late 2019.
- **Zealand Pharma A/S:** In March 2019, Alexion began a collaboration 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	Updated
Total revenues	$4,625 to $4,700 million	$4,675 to $4,750 million
SOLIRIS/ULTOMIRIS revenues	$3,970 to $4,020 million	$4,020 to $4,070 million
Metabolic revenues	$655 to $680 million	$655 to $680 million
R&D (% total revenues)		
GAAP	17% to 18%	19% to 20%
Non-GAAP	16% to 17%	16% to 17%
SG&A (% total revenues)		
GAAP	23% to 24%	23% to 24%
Non-GAAP	20% to 21%	20% to 21%
Operating margin		
GAAP	36% to 43%	35% to 42%
Non-GAAP	54% to 55%	54% to 55%
Earnings per share		
GAAP	$6.14 to $7.26	$6.76 to $7.96
Non-GAAP	$9.10 to $9.30	$9.25 to $9.45

Updated 2019 financial guidance assumes the following:

- GAAP guidance reflects the financial impact of the announced collaboration with Affibody.
- GAAP effective tax rate of 7 to 9 percent; non-GAAP effective tax rate of 14 to 16 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 first 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 1692605 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) and anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG), and is also developing it for patients with 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 expected timing of the closing of the Affibody AB transaction; 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, 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 Syntimmune and other 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 Annual Report on Form 10-K for the period ended December 31, 2018 and in our other filings with the SEC. Alexion disclaims any obligation to update any of these forward-looking statementsto 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 month periods ended March 31, 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 March 31	
	2019	**2018**
Net product sales	$ 1,140.2	$ 930.4
Other revenue	0.2	0.5
Total revenues	1,140.4	930.9
Cost of sales	85.8	91.6
Operating expenses:		
Research and development	195.9	176.6
Selling, general and administrative	281.5	257.1
Amortization of purchased intangible assets	80.0	80.0
Change in fair value of contingent consideration	(28.7)	52.7
Restructuring expenses	9.1	5.5
Total operating expenses	537.8	571.9
Operating income	516.8	267.4
Other income and expense:		
Investment income	42.5	105.8
Interest expense	(19.9)	(24.1)
Other income and (expense)	2.4	2.5
Income before income taxes	541.8	351.6
Income tax (benefit) expense	(46.1)	102.5
Net income	$ 587.9	$ 249.1
Earnings per common share		
Basic	$ 2.63	$ 1.12
Diluted	$ 2.61	$ 1.11
Shares used in computing earnings per common share		
Basic	223.8	222.1
Diluted	225.5	223.7

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

	Three months ended March 31	
	2019	**2018**
GAAP net income	$ 587.9	$ 249.1
Before tax adjustments:		
Cost of sales:		
Share-based compensation	3.7	3.3

Restructuring related expenses [1]	—	5.3
Research and development expense:		
Share-based compensation	15.3	14.9
Upfront payments related to licenses and collaborations [2]	21.2	—
Restructuring related expenses [1]	—	0.1
Selling, general and administrative expense:		
Share-based compensation	37.7	33.1
Restructuring related expenses [1]	—	3.6
Litigation charges	0.1	—
Amortization of purchased intangible assets	80.0	80.0
Change in fair value of contingent consideration [3]	(28.7)	52.7
Restructuring expenses [1]	9.1	5.5
Investment income:		
Change in value of strategic equity investments [4]	(33.8)	(100.8)
Other income:		
Restructuring related expenses [1]	—	(0.1)
Adjustments to income tax expense [5]	(147.0)	33.9
Non-GAAP net income	$ 545.5	$ 380.6
GAAP earnings per common share - diluted	$ 2.61	$ 1.11
Non-GAAP earnings per common share - diluted	$ 2.39	$ 1.68
Shares used in computing diluted earnings per common share (GAAP)	225.5	223.7
Shares used in computing diluted earnings per common share (non-GAAP)	228.1	226.4

(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 March 31, 2019				Three months ended March 31, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ 5.3	$ —	$ 5.3
Research and development	—	—	—	—	—	0.1	—	0.1
Selling, general and administrative	—	—	—	—	—	3.6	—	3.6
Restructuring expense	9.1	—	—	9.1	1.0	—	4.5	5.5
Other (income) expense	—	—	—	—	—	—	(0.1)	(0.1)
	$ 9.1	$ —	$ —	$9.1	$ 1.0	$ 9.0	$ 4.4	$14.4

(2) We recorded an upfront license payment of $21.2 million in connection with an agreement that we entered into with Zealand Pharma A/S in March 2019.

(3) For the three months ended March 31, 2019 and 2018, changes in the fair value of contingent consideration reflect the impact of changes in the expected timing of payments of contingent consideration. Changes in the fair value of contingent consideration for the three months ended March 31, 2018 also included the impact of changes in the probability of achieving the contingent milestones.

(4) Our investments include strategic equity investments in Moderna Therapeutics, Inc., Dicerna Pharmaceuticals, Inc. and Zealand Pharma A/S which are recorded at fair value. During the three months ended March 31, 2019, we recognized an unrealized gain of $33.8 million in investment income to adjust our strategic equity investments to fair value. During the three months ended March 31, 2018, we recognized an unrealized gain of $100.8 million to adjust our investment in Moderna Therapeutics, Inc. to fair value.

(5) Alexion's non-GAAP income tax expense for the three months ended March 31, 2019 and 2018 excludes the tax effect of pre-tax adjustments to GAAP profit. Non-GAAP income tax expense for the three months ended March 31, 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 three months ended March 31, 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	$ 1,532	$ 1,804
Before tax adjustments:		
Share-based compensation	256	239
Upfront payments related to licenses and collaborations	46	46
Acquired in-process research and development	240	—
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	(34)	(34)
Adjustments to income tax expense	(252)	(216)
Non-GAAP net income	$ 2,118	$ 2,164
Diluted GAAP earnings per common share	$ 6.76	$ 7.96
Diluted non-GAAP earnings per common share	$ 9.25	$ 9.45
Operating expense and margin (% total revenues)		
GAAP research and development expense	20%	19%
Share-based compensation	2%	2%
Upfront payments related to licenses and collaborations	1%	1%
Non-GAAP research and development expense	17%	16%
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	35%	42%
Share-based compensation	5%	5%
Upfront payments related to licenses and collaborations	1%	1%
Acquired in-process research and development	5%	—%
Amortization of purchased intangible assets	7%	7%
Change in fair value of contingent consideration	0%	0%
Restructuring expenses	1%	0%
Non-GAAP operating margin	54%	55%
Income tax expense (% of income before income taxes)		
GAAP income tax expense	9%	7%
Tax effect of pre-tax adjustments to GAAP net income and other one-time items associated with intellectual property	7%	7%
Non-GAAP income tax expense	16%	14%

Amounts may not foot due to rounding.

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

	Three months ended March 31	
	2019	2018
SOLIRIS		
United States	$ 463.7	$ 336.0
Europe	264.5	250.8
Asia Pacific	100.9	85.5
Rest of World	132.9	127.8
Total Soliris	$ 962.0	$ 800.1
ULTOMIRIS		
United States	$ 24.6	$ —
Europe	—	—
Asia Pacific	—	—
Rest of World	—	—
Total Ultomiris	$ 24.6	$ —
STRENSIQ		
United States	$ 99.5	$ 89.2
Europe	17.5	14.0
Asia Pacific	9.9	5.7
Rest of World	3.2	1.8
Total Strensiq	$ 130.1	$ 110.7
KANUMA		
United States	$ 13.8	$ 11.9
Europe	6.3	5.9
Asia Pacific	0.8	1.0
Rest of World	2.6	0.8
Total Kanuma	$ 23.5	$ 19.6
Net Product Sales		
United States	$ 601.6	$ 437.1
Europe	288.3	270.7
Asia Pacific	111.6	92.2
Rest of World	138.7	130.4
Total Net Product Sales	$1,140.2	$ 930.4

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

	March 31 2019	December 31 2018
Cash and cash equivalents	$ 1,544.8	$ 1,365.5
Marketable securities	110.3	198.3
Trade accounts receivable, net	1,016.3	922.3
Inventories	482.2	472.5
Prepaid expenses and other current assets (1)	497.0	426.4
Property, plant and equipment, net (1)	1,095.7	1,471.5
Intangible assets, net	3,560.8	3,641.3
Goodwill	5,037.4	5,037.4
Right of use operating assets (1)	192.8	—
Other assets	462.3	396.7
Total assets	$ 13,999.6	$ 13,931.9
Accounts payable and accrued expenses	$ 669.8	$ 698.2
Revolving credit facility	—	250.0
Current portion of long-term debt	126.5	93.8

Current portion of contingent consideration	97.6	97.6
Other current liabilities [1]	49.9	34.4
Long-term debt, less current portion	2,470.0	2,501.7
Contingent consideration	154.5	183.2
Facility lease obligations [1]	—	361.0
Deferred tax liabilities	306.1	391.1
Noncurrent operating lease liabilities [1]	150.8	—
Other liabilities [1]	267.8	155.6
Total liabilities	4,293.0	4,766.6
Total stockholders' equity [1]	9,706.6	9,165.3
Total liabilities and stockholders' equity	$ 13,999.6	$ 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 March 31, 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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Source: Alexion Pharmaceuticals, Inc.

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