Alexion Reports Third Quarter 2020 Results

October 29, 2020

- 3Q20 total revenues of $1,588.7 million, a 26% increase over 3Q19
- 3Q20 GAAP diluted EPS of $2.62; non-GAAP diluted EPS of $3.24
- Received Japanese approval for ULTOMIRIS® (ravulizumab) in atypical hemolytic uremic syndrome (aHUS)
- Received U.S. approval & positive CHMP opinion for ULTOMIRIS 100 mg/mL higher concentration formulation in paroxysmal nocturnal hemoglobinuria (PNH) & aHUS
- Established ULTOMIRIS as new standard of care in PNH ahead of set goal, with more than 70% patient conversion from SOLIRIS® (eculizumab) in 3 largest markets - U.S., Germany & Japan
- Initiated Phase 3 program for CAEL-101 in AL amyloidosis in collaboration with Caelum Biosciences
- Raised full year guidance, driven by increased revenue guidance of $350 million

BOSTON--(BUSINESS WIRE)--Oct. 29, 2020-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the third quarter of 2020. Total revenues in the third quarter were $1,588.7 million, a 26 percent increase compared to the same period in 2019. The negative impact of foreign currency on total revenues year-over-year was 2 percent, or $25.5 million, inclusive of hedging activities. On a GAAP basis, diluted EPS in the quarter was $2.62, compared to $2.08 in the prior year. Non-GAAP diluted EPS for the third quarter of 2020 was $3.24, a 16 percent increase versus the third quarter of 2019.

"We have continued to build on our momentum from the first half of the year, delivering another strong quarter despite the ongoing challenges and uncertainty surrounding COVID-19. In the third quarter, we further progressed our LEAD-EXPAND-DIVERSIFY strategy with multiple regulatory approvals, the initiation of new Phase 3 trials and the integration of the Portola team," said Ludwig Hantson, Ph.D., Chief Executive Officer of Alexion. "Our foundation for the future is stronger than ever, and by maintaining our focus on serving patients and delivering for shareholders, I am confident that we will continue to build on our success to date and further advance our mission of delivering life-changing therapies to people with rare diseases and devastating conditions."

Third Quarter 2020 Financial Highlights

- Net product sales were $1,588.3 million in the third quarter of 2020, compared to $1,263.1 million in the third quarter of 2019.
- SOLIRIS net product sales were $1,042.3 million, compared to $990.5 million in the third quarter of 2019, representing a 5 percent increase.
- ULTOMIRIS net product sales were $289.3 million, compared to $89.9 million in the third quarter of 2019, representing a 222 percent increase.
- STRENSIQ net product sales were $189.4 million, compared to $154.3 million in the third quarter of 2019, representing a 23 percent increase.
- KANUMA net product sales were $28.4 million in both of the third quarters of 2020 and 2019.
- ANDEXXA/ONDEXXYA net product sales were $38.9 million in the third quarter of 2020.
- GAAP cost of sales was $144.7 million, compared to $95.2 million in the third quarter of 2019. Non-GAAP cost of sales was $129.8 million, compared to $91.8 million in the third quarter of 2019.
- GAAP R&D expense was $285.9 million, compared to $232.9 million in the third quarter of 2019. Non-GAAP R&D expense was $269.3 million, compared to $186.1 million in the third quarter of 2019.
- GAAP SG&A expense was $334.2 million, compared to $299.3 million in the third quarter of 2019. Non-GAAP SG&A expense was $301.3 million, compared to $260.4 million in the third quarter of 2019.
- GAAP income tax expense was $88.8 million, compared to $67.9 million in the third quarter of 2019. Non-GAAP income

tax expense was $135.1 million, compared to $82.5 million in the third quarter of 2019.

- GAAP diluted EPS was $2.62, compared to $2.08 in the third quarter of 2019. Non-GAAP diluted EPS was $3.24, compared to $2.79 in the third quarter of 2019.

COVID-19

We continue to take steps to proactively respond to the evolving COVID-19 pandemic and to plan for related uncertainties. We remain focused on continuing to serve patients, protecting the health and safety of our employees and the communities in which we live and work, and supporting patients in clinical trials. We are also focused on minimizing potential interactions that could contribute to the spread of the virus and put additional strain on healthcare systems through the use of innovative virtual means where possible.

- **Clinical Trials:** We have implemented a pandemic response business continuity plan designed to protect patients and site staff safety while continuing our clinical trials with limited interruption to the extent we are able. The COVID-19 impact has varied by study and program, but there has been little timing impact on fully-enrolled trials. We have successfully re-initiated the majority of studies that had been temporarily paused. There has been, and may continue to be, an impact to the timing of trials that are enrolling patients and activating sites, or have not yet started to do so, based on local dynamics where these studies are being conducted.

- **Business Impact:** We continue to take proactive measures designed to mitigate the risk of potential interruptions in supply and/or access to patients' customary site-of-care locations. Treatment compliance rates across all our medicines have remained strong and continue to be slightly above expectations. We have also seen the predicted slowing of new patient initiations and delays in treatment starts, and we are continuing to closely monitor this environment as the pandemic continues.

Research and Development

PHASE 3/4

- **SOLIRIS - Neuromyelitis Optica Spectrum Disorder (NMOSD):** A Phase 2/3 study of SOLIRIS in children and adolescents with NMOSD is underway.

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

- **SOLIRIS - Guillain-Barre Syndrome (GBS):** SOLIRIS in GBS has been granted SAKIGAKE designation by Japan's Ministry of Health, Labour and Welfare (MHLW). Alexion plans to initiate a Phase 3 study of SOLIRIS in GBS in Japan in 2021, pending regulatory feedback.

- **ULTOMIRIS - Severe COVID-19:** A Phase 3 randomized controlled trial of ULTOMIRIS in adults with COVID-19 who are hospitalized with severe pneumonia or acute respiratory distress syndrome 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 September 2020, Japan’s MHLW approved ULTOMIRIS for adults and children with aHUS. A global Phase 3 study of ULTOMIRIS in children and adolescents with aHUS is underway.

- **ULTOMIRIS - 100 mg/mL:** In October 2020, the U.S. FDA approved the ULTOMIRIS 100 mg/mL formulation for PNH and aHUS. In September 2020, Alexion announced a positive opinion for the ULTOMIRIS 100 mg/mL formulation from the European Medicines Agency Committee for Medicinal Products for Human Use. An application for approval is under review in Japan. This higher concentration formulation is designed to reduce infusion time by more than 60 percent to approximately 45 minutes.

- **ULTOMIRIS - Subcutaneous:** The Phase 3 study of weekly subcutaneous (SC) ULTOMIRIS demonstrated PK-based non-inferiority versus intravenous ULTOMIRIS. Pending collection of 12-month safety and drug-device combination data, Alexion plans to file for approval in the U.S. and EU for the ULTOMIRIS SC formulation and device combination in PNH and aHUS in the third quarter of 2021.

- **ULTOMIRIS - gMG:** As completion of full enrollment nears, screening of new patients has closed for the Phase 3 study of ULTOMIRIS in adults with gMG.

- **ULTOMIRIS - NMOSD:** A Phase 3 study of ULTOMIRIS in NMOSD is underway.

- **ULTOMIRIS - Amyotrophic Lateral Sclerosis (ALS):** A Phase 3 study of ULTOMIRIS in ALS is underway.
- **ULTOMIRIS - Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy (HSCT-TMA):** Alexion has initiated a Phase 3 study of ULTOMIRIS in adults with HSCT-TMA and plans to initiate a Phase 3 study in children with HSCT-TMA by the end of 2020.
- **ULTOMIRIS - Complement Mediated Thrombotic Microangiopathy (CM-TMA):** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in CM-TMA in the first half of 2021, pending regulatory feedback.
- **ALXN1840 - Wilson Disease:** Enrollment is complete in a Phase 3 study of ALXN1840 in Wilson disease. Study results are expected in the first half of 2021.
- **CAEL-101 - Caelum Biosciences:** In September 2020, Alexion and Caelum Biosciences announced the initiation of the Cardiac Amyloid Reaching for Extended Survival (CARES) Phase 3 clinical program to evaluate CAEL-101, a first-in-class amyloid fibril targeted therapy, in combination with standard-of-care therapy in AL amyloidosis. Enrollment is underway in two parallel Phase 3 studies – one in patients with Mayo stage IIIa disease and one in patients with Mayo stage IIIb disease.
- **ALXN2060 (AG10) - Eidos:** Alexion holds an exclusive license to develop and commercialize ALXN2060 (AG10) in Japan. Eidos is currently evaluating AG10 in a Phase 3 study in the U.S. and Europe for ATTR cardiomyopathy (ATTR-CM) and plans to begin a Phase 3 study in ATTR polyneuropathy (ATTR-PN) in the second half of 2020. Alexion plans to initiate a Phase 3 bridging study of ALXN2060 for patients with ATTR-CM in Japan by the end of 2020.
- **ALXN2040 (Danicopan) - PNH with Extravascular Hemolysis (EVH):** Alexion plans to initiate a Phase 3 study of ALXN2040 as an add-on therapy for PNH patients with EVH by the end of 2020.
- **ANDEXXA - Acute Intracranial Hemorrhage (ICH):** The Phase 4 ANNEXA-I study - designed to provide clinical data supporting full approval - is underway to assess ANDEXXA compared to usual standard of care in patients presenting with acute intracranial hemorrhage while taking an oral Factor Xa inhibitor.

PHASE 1/2

- **ULTOMIRIS - Renal Diseases:** Alexion plans to initiate a proof-of-concept trial of ULTOMIRIS in patients with IgA nephropathy and lupus nephritis in 2020.
- **ALXN1830:** Due to COVID-19, Alexion discontinued the Phase 2 study of ALXN1830, administered intravenously, in warm autoimmune hemolytic anemia (WAIHA) and paused the Phase 1 study of a subcutaneous formulation of ALXN1830 in healthy volunteers. The paused Phase 1 study and new Phase 2 studies of subcutaneous ALXN1830 in gMG and WAIHA are planned to begin in 2021.
- **ALXN2040 - Geographic Atrophy (GA):** Alexion plans to initiate a Phase 2 study of ALXN2040 in GA in the second half of 2021.
- **ALXN2050 - PNH:** A Phase 2 study of ALXN2050 monotherapy in PNH is underway.
- **ALXN2050 - Renal Diseases:** Alexion plans to initiate a proof-of-concept trial of ALXN2050 in patients with various renal diseases in 2021, pending regulatory feedback.
- **ALXN1720:** Seven of nine cohorts are complete in a Phase 1 healthy volunteer study of ALXN1720, a novel anti-C5 albumin-binding bi-specific mini-body that is designed to bind and prevent activation of human C5. Remaining cohorts of the study, which had previously been paused due to COVID-19, have been restarted. Data are expected in the first half of 2021. Following successful completion of the Phase 1 study, Alexion plans to initiate Phase 2 studies of ALXN1720 in gMG and dermatomyositis (DM), pending regulatory feedback.
- **ANDEXXA - Urgent Surgery:** ANDEXXA is currently being evaluated in a single-arm, open-label study in patients taking apixaban, rivaroxaban, edoxaban, or enoxaparin who require urgent surgery. The results of this study will inform the design of a randomized controlled clinical trial to expand the label in this population.
- **Cerdulatinib:** Acquired as part of the Portola acquisition, cerdulatinib is a dual spleen tyrosine kinase and janus kinase (SYK/JAK) inhibitor being evaluated in a Phase 1/2a study in patients with relapsed/refractory chronic lymphocytic leukemia or B-cell or T-cell non-Hodgkin lymphoma.

2020 Financial Guidance

Alexion is increasing full year 2020 financial guidance. Full guidance updates are outlined below.

	Previous	Updated
Total revenues	$5,550 to $5,600 million	$5,900 to $5,950 million
SOLIRIS/ULTOMIRIS revenues	$4,725 to $4,755 million	$5,000 to $5,035 million
Metabolic revenues	$785 to $800 million	$835 to $845 million
ANDEXXA revenues	$40 to $45 million	$65 to $70 million
R&D (% total revenues)		
GAAP	18.1% to 19.2%	17.2% to 18.3%
Non-GAAP	16.5% to 17.5%	16.0% to 17.0%
SG&A (% total revenues)		
GAAP	24.5% to 25.7%	22.6% to 23.8%
Non-GAAP	21.0% to 22.0%	19.5% to 20.5%
Operating margin		
GAAP	3.8% to 5.4%	7.2% to 8.8%
Non-GAAP	53.0% to 54.0%	54.5% to 55.5%
Earnings per share		
GAAP	$0.96 to $1.30	$1.78 to $2.13
Non-GAAP	$10.65 to $10.95	$11.70 to $12.00

Updated 2020 financial guidance assumes a GAAP effective tax rate of (5.0) to (4.5) percent and a non-GAAP effective tax rate of 15.5 to 16.0 percent. The 2020 GAAP and non-GAAP tax rates do not benefit from one-time events that benefited the tax rates in 2019.

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 other strategic agreements, intangible asset impairments, litigation charges, changes in fair value of contingent consideration, gains or losses related to strategic equity investments 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 2020 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 6582445 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 and devastating conditions through the discovery, development and commercialization of life-changing medicines. As a leader in rare diseases for more than 25 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) as well as the first and only approved Factor Xa inhibitor reversal agent. In addition, the company is developing several mid-to-late-stage therapies, including a copper-binding agent for Wilson disease, an anti-neonatal Fc receptor (FcRn) antibody for rare Immunoglobulin G (IgG)-mediated diseases and an oral Factor D inhibitor as well as several early-stage therapies, including one for light chain (AL) amyloidosis, a second oral Factor D inhibitor and a third complement inhibitor. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and its development efforts on hematology, nephrology, neurology, metabolic disorders, cardiology, ophthalmology and acute care. Headquartered in Boston, Massachusetts, Alexion 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 2020 (and the assumptions related to such guidance); our expectations regarding the affects COVID-19 will have on our business and operations, including clinical trials and product supply; the strength of our business and continued growth; the Company's capital allocation strategy; plans to expand the Company's pipeline; 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, a higher concentration formulation of ULTOMIRIS, a subcutaneous administration of ULTOMIRIS, SOLIRIS, ALXN1840, CAEL-101, ALXN2060, ALXN2040, ALXN2050, ALXN1720, ALXN1830, ANDEXXA and CERDULATINIB; potential benefits of current products and products under development and in clinical trials; plans for development programs with third parties; 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; the impact of the COVID-19 pandemic on Alexion's business, including its sales, clinical trials, operations and supply chain; 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, including the acquisition of Portola Pharmaceuticals, Inc.; the possibility that expected tax benefits will not be realized or that potential tax liabilities exceed current expectations; 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; the risk that estimates regarding the number of patients with PNH, aHUS, gMG, NMOSD, HPP and LAL-D and other 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, 2020 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. Alexion also uses these non-GAAP financial measures to establish budgets, set operational goals and to evaluate the performance of the business. The non-GAAP results, determined in accordance with our internal policies, 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 other strategic agreements, acquired in-process research and development, impairment of purchased intangible assets, gains and losses related to strategic equity investments, litigation charges, gain or loss on sale of a business or asset, gain or loss related to purchase options, contingent milestone payments associated with acquisitions of legal entities accounted for as asset acquisitions, acquisition-related costs 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 2020 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, 2020 and 2019 and projected twelve months ending December 31, 2020.

(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,	
	2020	**2019**	**2020**	**2019**
Net product sales	$ 1,588.3	$ 1,263.1	$ 4,477.4	$ 3,605.8
Other revenue	0.4	—	0.7	1.0
Total revenues	1,588.7	1,263.1	4,478.1	3,606.8
Costs and expenses:				
Cost of sales (exclusive of amortization of purchased intangible assets)	144.7	95.2	401.3	280.2
Research and development	285.9	232.9	707.9	616.4
Selling, general and administrative	334.2	299.3	955.5	880.1
Acquired in-process research and development	—	—	—	(4.1)
Acquisition-related costs	63.0	—	105.7	—
Restructuring expenses	14.3	0.3	13.5	11.9
Change in fair value of contingent consideration	23.4	29.8	45.0	7.2
Amortization of purchased intangible assets	53.1	75.6	200.5	235.7
Impairment of intangible assets	—	—	2,053.3	—
Gain on sale of asset	(14.8)	—	(14.8)	—
Total costs and expenses	903.8	733.1	4,467.9	2,027.4
Operating income	684.9	530.0	10.2	1,579.4
Other income and expense:				
Investment income, net	11.5	23.0	47.8	50.6
Interest expense	(27.6)	(17.9)	(77.0)	(56.1)

Other income and (expense)	(1.9)	0.4	(2.6)	2.9
Income (loss) before income taxes	666.9	535.5	(21.6)	1,576.8
Income tax expense (benefit)	88.8	67.9	(89.2)	61.5
Net income	$ 578.1	$ 467.6	$ 67.6	$ 1,515.3
Earnings per common share				
Basic	$ 2.64	$ 2.09	$ 0.31	$ 6.77
Diluted	$ 2.62	$ 2.08	$ 0.30	$ 6.72
Shares used in computing earnings per common share				
Basic	219.1	223.3	220.4	223.8
Diluted	220.6	224.5	221.9	225.4

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,	
	2020	2019	2020	2019
GAAP net income	$ 578.1	$ 467.6	$ 67.6	$ 1,515.3
Before tax adjustments:				
Cost of sales:				
Share-based compensation	3.1	3.4	9.3	10.7
Fair value adjustment in inventory acquired (1)	11.8	—	11.8	—
Research and development expense:				
Share-based compensation	15.9	16.7	47.6	45.9
Upfront payments related to licenses and other strategic agreements (2)	—	30.1	—	76.3
Fair value adjustment in inventory acquired (1)	0.7	—	0.7	—
Selling, general and administrative expense:				
Share-based compensation	32.8	38.9	119.9	120.1
Litigation charges (3)	0.1	—	21.6	0.1
Acquired in-process research and development	—	—	—	(4.1)
Amortization of purchased intangible assets	53.1	75.6	200.5	235.7
Change in fair value of contingent consideration (4)	23.4	29.8	45.0	7.2
Acquisition-related costs (5)	63.0	—	105.7	—
Restructuring expenses (6)	14.3	0.3	13.5	11.9
Impairment of intangible assets (7)	—	—	2,053.3	—
Gain on sale of asset (8)	(14.8)	—	(14.8)	—
Investment income (expense):				
(Gains) and losses related to strategic equity investments	(8.4)	(12.0)	(34.2)	(20.6)
Adjustments to income tax expense (9)	(46.3)	(14.6)	(491.0)	(212.1)
Non-GAAP net income	$ 726.8	$ 635.8	$ 2,156.5	$ 1,786.4
GAAP earnings per common share - diluted	$ 2.62	$ 2.08	$ 0.30	$ 6.72
Non-GAAP earnings per common share - diluted	$ 3.24	$ 2.79	$ 9.56	$ 7.83
Shares used in computing diluted earnings per common share (GAAP)	220.6	224.5	221.9	225.4
Shares used in computing diluted earnings per common share (non-GAAP)	224.5	227.7	225.5	228.2

(1) During the three and nine months ended September 30, 2020, we recorded $11.8 million and $0.7 million within cost of sales and research and development expense, respectively, related to the amortization of the excess fair value of ANDEXXA inventory over the estimated historical cost basis of the inventory, recognized in connection with the acquisition of Portola Pharmaceuticals, Inc.

(2) During the three months ended September 30, 2019, we recorded expense of $30.1 million in connection with an upfront payment on a strategic agreement that we entered into with Eidos Therapeutics, Inc. (Eidos). During the nine months ended September 30, 2019, we recorded expense of $76.3 million in connection with upfront payments on strategic agreements that we entered into with Eidos, Affibody AB and Zealand Pharma A/S.

(3) During the nine months ended September 30, 2020, we recorded $21.6 million in litigation charges in connection with legal proceedings.

(4) Changes in the fair value of contingent consideration expense for the three and nine months ended September 30, 2020 reflect changes in the expected timing and probability of achieving contingent milestone payments, and the interest component of contingent consideration related to the passage of time. Changes in fair value of contingent consideration expense for the three and nine months ended September 30, 2019 reflect changes in the expected timing of achieving contingent milestone payments and the interest component of contingent consideration related to the passage of time.

(5) For the three and nine months ended September 30, 2020, we recorded $63.0 million and $105.7 million, respectively, of acquisition-related costs in connection with the Achillion Pharmaceuticals, Inc. and Portola Pharmaceuticals, Inc. acquisitions. Acquisition-related costs primarily consist of transaction costs, costs associated with the accelerated vesting of equity awards previously granted to employees and employee separation costs.

(6) During the three and nine months ended September 30, 2020, we recorded $14.3 million of restructuring expenses relating to restructuring activities initiated during the third quarter 2020 primarily within our commercial organization.

(7) In the second quarter 2020, we recognized impairment charges of $2,053.3 million, primarily related to our KANUMA intangible asset.

(8) In July 2020, we sold certain intellectual property rights and assets to Inozyme Pharma in exchange for $14.8 million of Inozyme common stock. As a result, we recognized a gain on the sale during the three and nine months ended September 30, 2020.

(9) Alexion's non-GAAP income tax expense for the three and nine months ended September 30, 2020 and 2019 excludes the tax effect of pre-tax adjustments to GAAP profit. 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 and a release of an existing valuation allowance, respectively.

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, 2020	
	Low	**High**
GAAP net income	$ 395	$ 473
Before tax adjustments:		
Share-based compensation	258	244
Fair value adjustment of inventory acquired	23	25
Impairment of intangible assets	2,053	2,053
Amortization of purchased intangible assets	254	254
Acquisition-related costs	120	120
Change in fair value of contingent consideration	51	51
Restructuring expenses	25	25
(Gains) and losses related to strategic equity investments	(34)	(34)
Litigation charges	22	22
Gain on sale of asset	(15)	(15)
Adjustments to income tax expense	(519)	(518)
Non-GAAP net income	$ 2,633	$ 2,700
Diluted GAAP earnings per common share	$ 1.78	$ 2.13
Diluted non-GAAP earnings per common share	$ 11.70	$ 12.00
Costs and expenses and margin (% total revenues)		
GAAP research and development expense	18.3%	17.2%
Share-based compensation	1.3%	1.2%
Fair value adjustment in inventory acquired	0.0%	0.0%
Non-GAAP research and development expense	17.0%	16.0%
GAAP selling, general and administrative expense	23.8%	22.6%
Share-based compensation	2.9%	2.7%
Litigation charges	0.4%	0.4%
Non-GAAP selling, general and administrative expense	20.5%	19.5%
GAAP operating margin	7.2%	8.8%

Share-based compensation	4.4%	4.1%
Fair value adjustment in inventory acquired	0.4%	0.4%
Litigation charges	0.4%	0.4%
Gain on sale of asset	(0.3)%	(0.3)%
Impairment of intangible assets	34.8%	34.5%
Amortization of purchased intangible assets	4.3%	4.3%
Acquisition-related costs	2.0%	2.0%
Change in fair value of contingent consideration	0.9%	0.9%
Restructuring expenses	0.4%	0.4%
Non-GAAP operating margin	54.5%	55.5%

Income tax expense (% of income before income taxes)

GAAP income tax expense (benefit)	(4.5)%	(5.0)%
Tax effect of pre-tax adjustments to GAAP net income	20.5%	20.5%
Non-GAAP income tax expense	16.0%	15.5%

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,	
	2020	**2019**	**2020**	**2019**
SOLIRIS				
United States	$ 562.8	$ 496.8	$ 1,672.3	$ 1,456.8
Europe	254.3	255.5	765.7	800.2
Asia Pacific	86.0	118.0	255.5	329.2
Rest of World	139.2	120.2	347.2	347.1
Total SOLIRIS	$ 1,042.3	$ 990.5	$ 3,040.7	$ 2,933.3
ULTOMIRIS				
United States	$ 170.7	$ 65.1	$ 460.3	$ 143.9
Europe	46.6	21.1	112.4	21.1
Asia Pacific	69.6	3.7	186.3	3.7
Rest of World	2.4	—	4.2	—
Total ULTOMIRIS	$ 289.3	$ 89.9	$ 763.2	$ 168.7
STRENSIQ				
United States	$ 149.3	$ 118.0	$ 418.1	$ 323.7
Europe	19.3	19.0	61.6	56.0
Asia Pacific	16.1	14.0	44.7	36.0
Rest of World	4.7	3.3	21.5	10.0
Total STRENSIQ	$ 189.4	$ 154.3	$ 545.9	$ 425.7
KANUMA				
United States	$ 15.8	$ 16.0	$ 47.6	$ 45.1
Europe	9.5	6.3	25.4	19.4
Asia Pacific	1.1	1.3	2.9	3.4
Rest of World	2.0	4.8	12.8	10.2
Total KANUMA	$ 28.4	$ 28.4	$ 88.7	$ 78.1
ANDEXXA				
United States	$ 36.2	$ —	$ 36.2	$ —
Europe	2.7	—	2.7	—
Asia Pacific	—	—	—	—
Rest of World	—	—	—	—
Total ANDEXXA	$ 38.9	$ —	$ 38.9	$ —
Net Product Sales				
United States	$ 934.8	$ 695.9	$ 2,634.5	$ 1,969.5

Europe	332.4	301.9	967.8	896.7
Asia Pacific	172.8	137.0	489.4	372.3
Rest of World	148.3	128.3	385.7	367.3
Total Net Product Sales	$ 1,588.3	$ 1,263.1	$ 4,477.4	$ 3,605.8

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

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 2,268.0	$ 2,685.5
Marketable securities	28.9	64.0
Trade accounts receivable, net	1,437.1	1,243.2
Inventories	729.0	627.6
Prepaid expenses and other current assets	604.8	456.1
Property, plant and equipment, net	1,214.5	1,163.3
Intangible assets, net	3,056.6	3,344.3
Goodwill	5,100.7	5,037.4
Right of use operating assets	220.1	204.0
Deferred tax assets	2,270.5	2,290.2
Other assets	618.2	429.0
Total assets	$ 17,548.4	$ 17,544.6
Accounts payable and accrued expenses	$ 1,067.6	$ 966.7
Current portion of long-term debt	138.6	126.7
Other current liabilities	124.8	100.9
Total current liabilities	1,331.0	1,194.3
Long-term debt, less current portion	2,453.3	2,375.0
Contingent consideration	398.1	192.4
Deferred tax liabilities	1,818.2	2,081.4
Noncurrent operating lease liabilities	175.8	164.1
Other liabilities	297.1	265.6
Total liabilities	6,473.5	6,272.8
Total stockholders' equity	11,074.9	11,271.8
Total liabilities and stockholders' equity	$ 17,548.4	$ 17,544.6

ALEXION PHARMACEUTICALS, INC.
TABLE 6: CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(in millions)
(unaudited)

	Nine months ended September 30, 2020	2019
Cash flows from operating activities:		
Net income	$ 67.6	$ 1,515.3
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	254.3	286.2
Change in fair value of contingent consideration	45.0	7.2
Payments of contingent consideration	—	(100.0)
Share-based compensation expense	195.6	176.8
Deferred taxes (benefit)	(174.2)	(136.1)
Unrealized foreign currency loss (gain)	0.9	(3.3)
Unrealized gain on forward contracts	(3.9)	(15.3)
Unrealized gain on strategic equity investments	(4.6)	(20.6)
Gain on sale of asset	(14.8)	—
Gain on derecognition of Portola strategic equity investment	(29.7)	—
Inventory obsolescence charge	24.6	—
Impairment of intangible assets	2,053.3	—
Other	10.7	(2.3)
Changes in operating assets and liabilities, excluding the effect of acquisitions:		

Accounts receivable	(183.5)	(199.1)
Inventories	(10.3)	(105.9)
Prepaid expenses, right of use operating assets and other assets	(92.3)	(42.2)
Accounts payable, accrued expenses, lease liabilities and other liabilities	23.7	207.1
Net cash provided by operating activities	2,162.4	1,567.8
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(19.4)	(51.2)
Proceeds from maturity or sale of available-for-sale debt securities	184.2	211.0
Purchases of mutual funds related to nonqualified deferred compensation plan	(14.1)	(13.4)
Proceeds from sale of mutual funds related to nonqualified deferred compensation plan	9.6	11.4
Purchases of strategic equity investments and options	(38.1)	(63.7)
Purchase of intangible assets	—	(16.0)
Purchases of property, plant and equipment	(29.2)	(124.7)
Payment for acquisition of businesses, net of cash and restricted cash acquired	(2,111.9)	—
Net cash used in investing activities	(2,018.9)	(46.6)
Cash flows from financing activities:		
Payments on revolving credit facility	—	(250.0)
Payments on term loan	(97.9)	(65.4)
Repurchases of common stock	(434.3)	(383.5)
Net proceeds from issuance of common stock under share-based compensation arrangements	22.1	23.2
Other	(28.0)	(3.7)
Net cash used in financing activities	(538.1)	(679.4)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(0.5)	(6.1)
Net change in cash and cash equivalents and restricted cash	(395.1)	835.7
Cash and cash equivalents and restricted cash at beginning of period	2,723.6	1,367.4
Cash and cash equivalents and restricted cash at end of period	$ 2,328.5	$ 2,203.1

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