Alexion Reports First Quarter 2021 Results

April 30, 2021

- 1Q21 total revenues of $1,636.5 million, a 13% increase over 1Q20
- 1Q21 GAAP diluted EPS of $2.86; non-GAAP diluted EPS of $3.52
- Completed enrollment in Phase 3 studies of ULTOMIRIS® (ravulizumab) in NMOSD and ALS
- Filed for regulatory approval of ONDEXXYA® [coagulation factor Xa (recombinant), inactivated-zhzo] in Japan
- Secured UK reimbursement for ULTOMIRIS in PNH and ONDEXXYA for GI bleeds
- Received U.S. Federal Trade Commission clearance for proposed acquisition by AstraZeneca; transaction expected to close in 3Q21

BOSTON--(BUSINESS WIRE)--Apr. 30, 2021-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the first quarter of 2021. Total revenues in the first quarter were $1,636.5 million, a 13 percent increase compared to the same period in 2020. The positive impact of foreign currency on total revenues year-over-year was less than 1 percent inclusive of hedging activities. On a GAAP basis, diluted EPS attributable to Alexion in the first quarter of 2021 was $2.86, a 14 percent increase versus the first quarter of 2020. Non-GAAP diluted EPS attributable to Alexion for the first quarter of 2021 was $3.52, a 9 percent increase versus the first quarter of 2020.

"We are off to a strong start in 2021, with continued advancement of our LEAD-EXPAND-DIVERSIFY strategy to progress our commercial portfolio as well as our many development programs," said Ludwig Hantson, Ph.D., Chief Executive Officer of Alexion. "I am so proud of our teams' ongoing dedication and execution, which are further advancing our mission of delivering life-changing medicines to people with rare diseases and devastating conditions. We are well positioned to build on our success and momentum as the year progresses and once we become part of AstraZeneca."

First Quarter 2021 Financial Highlights

- Net product sales were $1,635.7 million in the first quarter of 2021, compared to $1,444.6 million in the first quarter of 2020.
- SOLIRIS net product sales were $1,027.6 million, compared to $1,022.9 million in the first quarter of 2020, representing a 0.5 percent increase.
- ULTOMIRIS net product sales were $346.9 million, compared to $222.8 million in the first quarter of 2020, representing a 56 percent increase.
- STRENSIQ net product sales were $197.5 million, compared to $172.2 million in the first quarter of 2020, representing a 15 percent increase.
- KANUMA net product sales were $34.8 million, compared to $26.7 million in the first quarter of 2020, representing a 30 percent increase.
- ANDEXXA/ONDEXXYA net product sales were $28.9 million in the first quarter of 2021.
- GAAP cost of sales was $125.4 million, compared to $111.7 million in the first quarter of 2020. Non-GAAP cost of sales was $113.8 million, compared to $108.6 million in the first quarter of 2020.
- GAAP R&D expense was $289.1 million, compared to $200.9 million in the first quarter of 2020. Non-GAAP R&D expense was $267.0 million, compared to $185.7 million in the first quarter of 2020.
- GAAP SG&A expense was $342.9 million, compared to $319.9 million in the first quarter of 2020. Non-GAAP SG&A expense was $292.2 million, compared to $259.1 million in the first quarter of 2020.
- GAAP income tax expense was $113.4 million, compared to income tax expense of $106.0 million in the first quarter of 2020. Non-GAAP income tax expense was $145.7 million, compared to income tax expense of $141.2 million in the first quarter of 2020.
- GAAP diluted EPS attributable to Alexion was $2.86, compared to $2.50 in the first quarter of 2020. Non-GAAP diluted

EPS attributable to Alexion was $3.52, compared to $3.22 in the first quarter of 2020.

Research and Development

PHASE 3/4

- **SOLIRIS - Guillain-Barre Syndrome (GBS):** SOLIRIS in GBS has been granted SAKIGAKE designation by Japan's Ministry of Health, Labour and Welfare (MHLW). In February 2021, Alexion initiated a Phase 3 study of SOLIRIS in GBS in Japan and dosing is underway.
- **ULTOMIRIS - 100 mg/mL:** An application for approval of the ULTOMIRIS 100 mg/mL formulation for PNH and aHUS 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. for the ULTOMIRIS SC formulation and device combination in PNH and aHUS in the third quarter of 2021, and in the EU in the first quarter of 2022.
- **ULTOMIRIS - Paroxysmal Nocturnal Hemoglobinuria (PNH):** The U.S. FDA granted priority review for ULTOMIRIS in children and adolescents with PNH and has set a Prescription Drug User Fee Act (PDUFA) target action date of June 7, 2021.
- **ULTOMIRIS - gMG:** Enrollment is complete in the Phase 3 study of ULTOMIRIS in adults with gMG. Study results are expected in the second half of 2021.
- **ULTOMIRIS - NMOSD:** In March 2021, Alexion completed enrollment in the Phase 3 study of ULTOMIRIS in NMOSD.
- **ULTOMIRIS - Amyotrophic Lateral Sclerosis (ALS):** In March 2021, Alexion completed enrollment in the Phase 3 study of ULTOMIRIS in ALS. Study results are expected in the first half of 2022.
- **ULTOMIRIS - Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy (HSCT-TMA):** Phase 3 studies of ULTOMIRIS in adults and children with HSCT-TMA are underway.
- **ULTOMIRIS - Complement Mediated Thrombotic Microangiopathy (CM-TMA):** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in CM-TMA in the second quarter of 2021.
- **ULTOMIRIS - Severe COVID-19:** Further enrollment in a Phase 3 trial of ULTOMIRIS in adults hospitalized with severe COVID-19 requiring mechanical ventilation is paused, due to lack of efficacy, pending further analysis of the data. Alexion continues to provide ULTOMIRIS for the ongoing TACTIC-R platform study led by Cambridge University Hospitals NHS Foundation Trust, which is evaluating the potential of earlier immune modulatory treatment (hospitalized patients not requiring mechanical ventilation) in preventing progression of the virus.
- **ULTOMIRIS - Dermatomyositis (DM):** Alexion plans to initiate a Phase 2/3 study of ULTOMIRIS in DM in the second half of 2021, pending regulatory feedback.
- **ALXN1840 - Wilson Disease:** Enrollment and dosing are complete in a Phase 3 study of ALXN1840 in Wilson disease. Study results are expected in the third quarter of 2021.
- **CAEL-101 - Caelum Biosciences:** Alexion and Caelum Biosciences are conducting 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. Two parallel Phase 3 studies – one in patients with Mayo stage IIIa disease and one in patients with Mayo stage IIIb disease – are underway.
- **ALXN2060 (AG10):** Alexion holds an exclusive license to develop and commercialize ALXN2060 (AG10) in Japan. Eidos is currently evaluating AG10 in two Phase 3 studies in the U.S. and Europe – one for ATTR cardiomyopathy (ATTR-CM) and one for ATTR polyneuropathy (ATTR-PN). Alexion is conducting a Phase 3 bridging study of ALXN2060 for patients with ATTR-CM in Japan.
- **ALXN2040 (Danicopan) - PNH with Extravascular Hemolysis (EVH):** A Phase 3 study of ALXN2040 as an add-on therapy for PNH patients with EVH is underway.
- **ANDEXXA/ONDEXXYA - 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. In addition, a supplemental Biologics License Application (sBLA) is under review by the U.S. FDA to enable the addition of edoxaban and enoxaparin to the U.S. label. In February 2021, Alexion filed for regulatory approval of ONDEXXYA in Japan.

PHASE 1/2

- **ULTOMIRIS - Renal Diseases:** A proof-of-concept study of ULTOMIRIS in patients with IgA nephropathy and lupus nephritis is underway.
- **ALXN1830:** Due to COVID-19, Alexion discontinued the Phase 2 study of ALXN1830, administered intravenously, in warm autoimmune hemolytic anemia (WAIHA) and the Phase 1 study of a subcutaneous formulation of ALXN1830 in healthy volunteers. In March 2021, Alexion initiated a new Phase 1 study of subcutaneous ALXN1830 in healthy volunteers. Following successful completion of this Phase 1 study, Alexion plans to initiate Phase 2 studies of subcutaneous ALXN1830 in gMG and WAIHA in 2021, pending regulatory feedback.
- **ALXN2040 - Geographic Atrophy (GA):** In March 2021, Alexion submitted an Investigational New Drug (IND) application for ALXN2040 in GA and plans to initiate a Phase 2 study in the second half of 2021.
- **ALXN2040 - COVID-19:** Alexion has agreed to provide ALXN2040 to the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, for the ACTIV-5 Big Effect Trial in adults hospitalized with COVID-19. This Phase 2 platform trial is comparing different investigational therapies to a common control arm with the intent of identifying promising treatments to enter a more definitive study.
- **ALXN2050 - PNH:** Alexion has re-initiated additional enrollment in the Phase 2 study of ALXN2050 monotherapy in PNH patients, following the receipt of Phase 1 data that support further dose escalation in the Phase 2 study.
- **ALXN2050 - Renal Diseases:** Alexion plans to initiate a proof-of-concept study of ALXN2050 in patients with various renal diseases in 2021, pending regulatory feedback.
- **ALXN1720:** The 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, has been paused for a second time due to COVID-19, but is expected to resume in the second quarter of 2021. Additional cohorts have been added to the study to explore higher doses and enable the initiation of a Phase 3 study in gMG, pending successful completion of the Phase 1 study as has been agreed with the U.S. FDA. Data from the Phase 1 study are expected in the second half of 2021. Alexion also plans to initiate a study of ALXN1720 in DM.
- **ANDEXXA - Urgent Surgery:** ANDEXXA is currently being evaluated in a single-arm, open-label Phase 2 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 Phase 3 clinical trial to expand the label in this population.
- **ALXN2075 (cerdulatinib):** Acquired as part of the Portola acquisition, ALXN2075 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. Data are expected in the second quarter of 2021.
- **ALXN1820:** A Phase 1 study of ALXN1820, Alexion's bi-specific anti-properdin mini-body, is underway in healthy volunteers.
- **ALXN1850 - Hypophosphatasia (HPP):** Alexion plans to initiate a Phase 1 study of ALXN1850 in adults with HPP in the second quarter of 2021, pending regulatory feedback.

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 and the majority of studies that had been temporarily paused due to the pandemic have resumed. A small number of clinical trial sites are restricting site visits and imposing restrictions on the initiation of new trials and patient visits to protect both site staff and patients from possible COVID-19 exposure. Based on local dynamics where these studies are being conducted, 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. We are actively implementing remote and local procedures under the guidance of regulatory authorities.

- **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. 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.

Conference Call/Earnings Materials:

Given the agreement for Alexion to be acquired by AstraZeneca, Alexion will not be hosting a conference call. Earnings materials are available publicly on the Investor Relations page of our website at http://ir.alexion.com. Questions may be directed to the Investor Relations team via e-mail at InvestorRelations@Alexion.com or the contact information below.

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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Additional Information and Where to Find It

In connection with AstraZeneca's proposed acquisition of Alexion (the "proposed transaction"), AstraZeneca filed with the U.S. Securities and Exchange Commission ("SEC") a registration statement on Form F-4 which includes a proxy statement of Alexion and a prospectus of AstraZeneca. The registration statement was declared effective by the SEC on April 12, 2021, and mailing of the definitive joint proxy statement/prospectus to the shareholders of Alexion occurred on or about April 12, 2021. Each of Alexion and AstraZeneca may also file other relevant documents with the SEC regarding the proposed transaction. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE DEFINITIVE JOINT PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT MAY BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain free copies of the registration statement and the definitive proxy statement/prospectus and other documents containing important information about Alexion, AstraZeneca and the proposed transaction through the website maintained by the SEC at http://www.sec.gov. Copies of the documents filed with the SEC by Alexion will be available free of charge on Alexion's website at http://www.alexion.com or by contacting Alexion's Investor Relations Department by email at InvestorRelations@alexion.com. Copies of the documents filed with the SEC by AstraZeneca will be available free of charge on AstraZeneca's website at https://www.astrazeneca.com/investor-relations.html or by contacting AstraZeneca's Investor Relations department by email at global-mediateam@astrazeneca.com.

Participants in the Solicitation

Alexion, AstraZeneca, their respective directors and certain of their executive officers and other employees may be deemed to be participants in the solicitation of proxies from Alexion's shareholders in connection with the proposed transaction. Information about Alexion's directors and executive officers is available in Alexion's proxy statement for its 2020 annual meeting of shareholders, which was filed with the SEC on March 26, 2020, Alexion's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2020, which was filed with the SEC on February 16, 2021, and other documents subsequently filed by Alexion with the SEC. Information about AstraZeneca's directors and executive officers is available in AstraZeneca's Form 20-F filed with the SEC on February 16, 2021, and other documents subsequently filed by AstraZeneca with the SEC. Other information regarding the participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, are contained in the definitive joint proxy statement/prospectus filed with the SEC on April 12, 2021 and other relevant materials to be filed with the SEC regarding the proposed transaction when they become available. Free copies of these documents may be obtained as described in the paragraphs above.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

Forward Looking Statements

This communication contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can generally identify forward-looking statements by the use of forward-looking terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "explore," "evaluate," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," or "will," or the negative thereof or other variations thereon or comparable terminology. These forward-looking

statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond Alexion's and AstraZeneca's control. Statements in this communication regarding Alexion, AstraZeneca and the combined company that are forward-looking, including anticipated benefits of the proposed transaction, the impact of the proposed transaction on Alexion's and AstraZeneca's businesses and future financial and operating results, the amount and timing of synergies from the proposed transaction, the terms and scope of the expected financing for the proposed transaction, the aggregate amount of indebtedness of the combined company following the closing of the proposed transaction, are based on management's estimates, assumptions and projections, and are subject to significant uncertainties and other factors, many of which are beyond Alexion's and AstraZeneca's control. These factors include, among other things, market factors, competitive product development and approvals, pricing controls and pressures (including changes in rules and practices of managed care groups and institutional and governmental purchasers), economic conditions such as interest rate and currency exchange rate fluctuations, judicial decisions, claims and concerns that may arise regarding the safety and efficacy of in-line products and product candidates, changes to wholesaler inventory levels, variability in data provided by third parties, changes in, and interpretation of, governmental regulations and legislation affecting domestic or foreign operations, including tax obligations, changes to business or tax planning strategies, difficulties and delays in product development, manufacturing or sales including any potential future recalls, patent positions and the ultimate outcome of any litigation matter. Additional information concerning these risks, uncertainties and assumptions can be found in Alexion's and AstraZeneca's respective filings with the SEC, including the risk factors discussed in Alexion's most recent Annual Report on Form 10-K, as updated by its Quarterly Reports on Form 10-Q, in AstraZeneca's most recent Annual Report on Form 20-F and in each company's future filings with the SEC. Important risk factors could cause actual future results and other future events to differ materially from those currently estimated by management, including, but not limited to, the risks that: a condition to the closing the proposed acquisition may not be satisfied; a regulatory approval that may be required for the proposed acquisition is delayed, is not obtained or is obtained subject to conditions that are not anticipated; AstraZeneca is unable to achieve the synergies and value creation contemplated by the proposed acquisition; AstraZeneca is unable to promptly and effectively integrate Alexion's businesses; management's time and attention is diverted on transaction related issues; disruption from the transaction makes it more difficult to maintain business, contractual and operational relationships; the credit ratings of the combined company declines following the proposed acquisition; legal proceedings are instituted against Alexion, AstraZeneca or the combined company; Alexion, AstraZeneca or the combined company is unable to retain key personnel; and the announcement or the consummation of the proposed acquisition has a negative effect on the market price of the capital stock of Alexion or AstraZeneca or on Alexion's or AstraZeneca's operating results. No assurances can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do occur, what impact they will have on the results of operations, financial condition or cash flows of Alexion or AstraZeneca. Should any risks and uncertainties develop into actual events, these developments could have a material adverse effect on the proposed transaction and/or Alexion or AstraZeneca, AstraZeneca's ability to successfully complete the proposed transaction and/or realize the expected benefits from the proposed transaction. You are cautioned not to rely on Alexion's and AstraZeneca's forward-looking statements. These forward-looking statements are and will be based upon management's then-current views and assumptions regarding future events and operating performance, and are applicable only as of the dates of such statements. Neither Alexion nor AstraZeneca assumes any duty to update or revise forward-looking statements, whether as a result of new information, future events or otherwise, as of any future date.

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 modification of 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 Reconciliation of GAAP to non-GAAP Financial Results 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, 2021 and 2020.

(Tables Follow)

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

	Three months ended March 31,	
	2021	**2020**
Net product sales	$ 1,635.7	$ 1,444.6
Other revenue	0.8	0.2
Total revenues	1,636.5	1,444.8
Costs and expenses:		
Cost of sales (exclusive of amortization of purchased intangible assets)	125.4	111.7
Research and development	289.1	200.9
Selling, general and administrative	342.9	319.9
Amortization of purchased intangible assets	53.2	73.7
Change in fair value of contingent consideration	9.2	5.8
Acquired in-process research and development	193.3	—
Acquisition-related costs	13.2	38.1
Restructuring expenses	(0.7)	(0.8)

Gain on sale of assets	(25.3)	—
Total costs and expenses	1,000.3	749.3
Operating income	636.2	695.5
Other income and expense:		
Investment expense, net	(7.0)	(5.2)
Interest expense	(27.1)	(25.8)
Other income and (expense)	0.5	(0.9)
Income before income taxes	602.6	663.6
Income tax expense	113.4	106.0
Net income	489.2	557.6
Net loss attributable to noncontrolling interest	146.8	—
Net income attributable to Alexion	$ 636.0	$ 557.6
Earnings per common share attributable to Alexion:		
Basic	$ 2.89	$ 2.52
Diluted	$ 2.86	$ 2.50
Shares used in computing earnings per common share attributable to Alexion:		
Basic	220.1	221.6
Diluted	222.6	222.6

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,	
	2021	**2020**
GAAP net income attributable to Alexion	$ 636.0	$ 557.6
Before tax adjustments:		
Cost of sales:		
Share-based compensation	3.1	3.1
Fair value adjustment in inventory acquired [1]	8.5	—
Research and development expense:		
Share-based compensation	22.1	15.2
Selling, general and administrative expense:		
Share-based compensation	50.7	39.3
Litigation charges [2]	—	21.5
Amortization of purchased intangible assets	53.2	73.7
Change in fair value of contingent consideration [3]	9.2	5.8
Acquired in-process research and development [4]	47.1	—
Acquisition-related costs [5]	13.2	38.1
Restructuring expenses	(0.7)	(0.8)
Gain on sale of assets [6]	(25.3)	—
Investment expense, net:		
Losses related to strategic equity investments [7]	9.6	9.2
Adjustments to income tax expense [8]	(32.3)	(35.2)
Non-GAAP net income attributable to Alexion	$ 794.4	$ 727.5
GAAP earnings per common share attributable to Alexion - diluted	$ 2.86	$ 2.50
Non-GAAP earnings per common share attributable to Alexion - diluted	$ 3.52	$ 3.22
Shares used in computing diluted earnings per common share attributable to Alexion (GAAP)	222.6	222.6
Shares used in computing diluted earnings per common share attributable to Alexion (non-GAAP)	225.4	226.0

(1) During the three months ended March 31, 2021, we recorded $8.5 million within cost of sales 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. (Portola).

(2) During the three months ended March 31, 2020, we recorded $21.5 million in litigation charges in connection with legal proceedings.

(3) Changes in the fair value of contingent consideration expense for the three months ended March 31, 2021 reflect changes in the expected timing 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 months ended March 31, 2020 reflected the impact of the interest component of contingent consideration related to the passage of time.

(4) During the first quarter of 2021, we amended the terms of our agreement with Caelum Biosciences (Caelum). As a result of the amendment, we became the primary beneficiary of Caelum and began consolidating Caelum as a variable interest entity. Substantially all of the fair value of the gross assets of Caelum is concentrated in a single in-process research and development asset, CAEL-101. Due to the stage of development of this asset at the date of consolidation, the value of the acquired in-process research and development asset related to CAEL-101 of $193.3 million, of which $47.1 million is attributable to Alexion, was expensed during the three months ended March 31, 2021.

(5) For the three months ended March 31, 2021, we recorded $13.2 million of acquisition-related costs attributable to the Merger Agreement with AstraZeneca and the Portola acquisition. For the three months ended March 31, 2020, we recorded $38.1 million in connection with the Achillion Pharmaceuticals, Inc. acquisition. 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) For the three months ended March 31, 2021, we recognized $25.3 million in gain on sale of assets, primarily relating to variable consideration associated with the ALXN1101 program we previously sold to Origin Biosciences, Inc. (Origin) in 2018. In the first quarter of 2021, ALXN1101, now branded as NULIBRY™ (fosdenopterin), received approval from the FDA. Origin also received a Rare Pediatric Disease Priority Review Voucher in connection with this approval.

(7) Losses related to strategic equity investments include unrealized gains and losses in investment income to adjust our strategic equity investments to fair value.

(8) Alexion's non-GAAP income tax expense for the three months ended March 31, 2021 and 2020 excludes the tax effect of pre-tax adjustments to GAAP profit.

ALEXION PHARMACEUTICALS, INC.
TABLE 3: NET PRODUCT SALES BY GEOGRAPHY
(in millions)
(unaudited)

	Three months ended March 31,	
	2021	**2020**
SOLIRIS		
United States	$ 553.9	$ 556.2
Europe	251.3	263.5
Asia Pacific	102.4	87.1
Rest of World	120.0	116.1
Total SOLIRIS	$ 1,027.6	$ 1,022.9
ULTOMIRIS		
United States	$ 206.9	$ 131.5
Europe	63.8	33.8
Asia Pacific	73.3	57.1
Rest of World	2.9	0.4
Total ULTOMIRIS	$ 346.9	$ 222.8
STRENSIQ		
United States	$ 155.2	$ 128.1
Europe	18.9	24.0
Asia Pacific	17.0	13.6
Rest of World	6.4	6.5
Total STRENSIQ	$ 197.5	$ 172.2
ANDEXXA		
United States	$ 25.3	$ —
Europe	3.6	—
Asia Pacific	—	—
Rest of World	—	—
Total ANDEXXA	$ 28.9	$ —
KANUMA		
United States	$ 17.1	$ 16.4
Europe	10.8	7.5
Asia Pacific	1.2	0.9
Rest of World	5.7	1.9
Total KANUMA	$ 34.8	$ 26.7
Net Product Sales		
United States	$ 958.4	$ 832.2

Europe	348.4	328.8
Asia Pacific	193.9	158.7
Rest of World	135.0	124.9
Total Net Product Sales	$ 1,635.7	$ 1,444.6

ALEXION PHARMACEUTICALS, INC.
TABLE 4: CONDENSED CONSOLIDATED BALANCE SHEETS
(in millions)
(unaudited)

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 3,429.6	$ 2,964.5
Marketable securities	39.7	34.9
Trade accounts receivable, net	1,473.0	1,409.3
Inventories	803.9	775.7
Prepaid expenses and other current assets	706.4	648.6
Property, plant and equipment, net	1,244.8	1,238.8
Intangible assets, net	3,048.3	3,002.4
Goodwill	5,100.1	5,100.1
Right of use operating assets	216.8	223.1
Deferred tax assets	2,140.6	2,199.4
Other assets	447.0	506.2
Total assets	$18,650.2	$ 18,103.0
Accounts payable and accrued expenses	$ 1,036.0	$ 1,203.3
Current portion of long-term debt	143.2	142.4
Current portion of contingent consideration	120.0	114.9
Other current liabilities	127.0	164.1
Long-term debt, less current portion	2,388.8	2,419.6
Contingent consideration	303.5	299.4
Deferred tax liabilities	1,639.1	1,632.2
Noncurrent operating lease liabilities	170.8	177.1
Other liabilities	290.8	298.8
Total liabilities	6,219.2	6,451.8
Total Alexion stockholders' equity	12,416.8	11,651.2
Noncontrolling interest	14.2	—
Total stockholders' equity	12,431.0	11,651.2
Total liabilities and stockholders' equity	$18,650.2	$ 18,103.0

ALEXION PHARMACEUTICALS, INC.
TABLE 5: CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(in millions)
(unaudited)

	Three months ended March 31, 2021	2020
Cash flows from operating activities:		
Net income	$ 489.2	$ 557.6
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	75.6	89.3
Change in fair value of contingent consideration	9.2	5.8
Share-based compensation expense	76.6	57.6
Consolidation of Caelum, including non-cash expense for acquired IPR&D and cash acquired	210.2	—
Deferred taxes	52.9	49.0
Unrealized foreign currency loss	10.9	7.1
Unrealized gain on forward contracts	(19.3)	(15.0)
Unrealized loss on strategic equity investments	9.6	9.2
Gain on sale of assets	(25.3)	—
Other	2.8	13.7
Changes in operating assets and liabilities, excluding the effect of acquisitions:		
Accounts receivable	(87.9)	(120.9)
Inventories (inclusive of inventories reported in other assets)	(59.5)	37.3

Prepaid expenses, right of use operating assets and other assets	11.0	(72.9)
Accounts payable, accrued expenses, lease liabilities and other liabilities	(118.4)	(68.2)
Net cash provided by operating activities	637.6	549.6
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	—	(19.4)
Proceeds from maturity or sale of available-for-sale debt securities	—	141.4
Purchases of mutual funds related to nonqualified deferred compensation plan	(7.0)	(6.9)
Proceeds from sale of mutual funds related to nonqualified deferred compensation plan	3.3	3.3
Purchases of intangible assets	(110.0)	—
Purchases of property, plant and equipment	(20.2)	(12.2)
Payment for acquisition of businesses, net of cash and restricted cash acquired	—	(837.7)
Purchases of strategic equity investments and options	—	(34.5)
Net cash used in investing activities	(133.9)	(766.0)
Cash flows from financing activities:		
Payments on term loan	(32.6)	(32.6)
Repurchases of common stock	—	(107.1)
Net proceeds from issuance of common stock under share-based compensation arrangements	15.2	2.8
Other	(1.3)	(1.3)
Net cash used in financing activities	(18.7)	(138.2)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(13.1)	(13.2)
Net change in cash and cash equivalents and restricted cash	471.9	(367.8)
Cash and cash equivalents and restricted cash at beginning of period	3,034.6	2,723.6
Cash and cash equivalents and restricted cash at end of period	$ 3,506.5	$ 2,355.8

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Source: Alexion Pharmaceuticals, Inc.