UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): January 30, 2020

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-27756**	**13-3648318**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

121 Seaport Boulevard, Boston, Massachusetts 02210

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (475) 230-2596

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	ALXN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

☐ Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On January 30, 2020, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial condition for the quarter and year ended December 31, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The attached press release contains both U.S. Generally Accepted Accounting Principles, or GAAP, and non-GAAP financial measures. The non-GAAP results exclude the impact of the following GAAP items 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. Reconciliations between non-GAAP and GAAP financial measures are included in the press release set forth as Exhibit 99.1 furnished in this Form 8-K. Alexion believes, when considered together with the GAAP information, the non-GAAP financial information provides 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 financial measures are supplemental to and not a substitute for, measures of financial performance prepared in accordance with GAAP.

The press release, and the information set forth therein, is being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that Section. Nor shall such document be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release issued by Alexion Pharmaceuticals, Inc. on January 30, 2020 relating to its results of operations and financial condition for the quarter and year ended December 31, 2019.

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 30, 2020

ALEXION PHARMACEUTICALS, INC.

By: /s/ Doug Barry
Name: Doug Barry
Title: Vice President, Corporate Law

Alexion Reports Fourth Quarter and Full Year 2019 Results

- 4Q19 total revenues of $1,384.3 million, a 23 percent increase over 4Q18
- 4Q19 GAAP diluted EPS of $4.00; non-GAAP diluted EPS of $2.71
- Received Japanese approval for SOLIRIS® (eculizumab) for neuromyelitis optica spectrum disorder (NMOSD)
- Established ULTOMIRIS® (ravulizumab) as market leader for PNH in U.S., Germany and Japan within first year of launch
- Continued strong SOLIRIS gMG and NMOSD launches, making neurology largest franchise in U.S.
- Expanded pipeline with 19 clinical-stage development programs planned for 2020 across 10 assets, including 2 Factor D inhibitors, following completion of Achillion acquisition

BOSTON, January 30, 2020 - Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the fourth quarter and full year of 2019. Total revenues for the full year of 2019 were $4,991.1 million, a 21 percent increase compared to 2018. The negative impact of foreign currency on total revenues year-over-year was 1 percent, or $45.1 million, inclusive of hedging activities. On a GAAP basis, diluted EPS for the full year of 2019 was $10.70, inclusive of one-time tax benefits related to intra-entity asset transfers of intellectual property, compared to $0.35 in the prior year, inclusive of $1,183.0 million of expense related to the value of the in-process research and development assets acquired in 2018. Non-GAAP diluted EPS for the full year of 2019 was $10.53, a 33 percent increase versus the prior year.

Total revenues in the fourth quarter were $1,384.3 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 $13.1 million, inclusive of hedging activities. On a GAAP basis, diluted EPS in the quarter was $4.00, inclusive of one-time tax benefits related to intra-entity asset transfers of intellectual property, compared to $(0.20) in the prior year, inclusive of $379.3 million of expense related to the value of the in-process research and development asset acquired in connection with our acquisition of Syntimmune in the fourth quarter of 2018. Non-GAAP diluted EPS for the fourth quarter of 2019 was $2.71, a 27 percent increase versus the fourth quarter of 2018.

"In 2019, we continued to strengthen the foundation of our business by executing on our strategy to lead, expand and diversify. Our key achievements include establishing ULTOMIRIS as the market leader in PNH within the first year of launch, expanding our C5 portfolio to make neurology our largest franchise in the U.S., and further diversifying our pipeline with seven business development deals adding five clinical-stage assets to our portfolio," said Ludwig Hantson, Ph.D., Chief Executive Officer of Alexion. "I am confident we are well positioned for the future and will build on our momentum in 2020, with a continued focus on delivering long-term shareholder value by advancing our mission of developing and delivering transformative medicines for people with rare diseases."

Full Year 2019 Financial Highlights

- Net product sales were $4,990.0 million, compared to $4,130.1 million in 2018.
- SOLIRIS® (eculizumab) net product sales were $3,946.4 million, compared to $3,563.0 million in 2018, representing an 11 percent increase.
- ULTOMIRIS® (ravulizumab-cwvz) net product sales were $338.9 million in 2019.
- STRENSIQ® (asfotase alfa) net product sales were $592.5 million, compared to $475.1 million in 2018, representing a 25 percent increase.
- KANUMA® (sebelipase alfa) net product sales were $112.2 million, compared to $92.0 million in 2018, representing a 22 percent increase.
- GAAP cost of sales was $394.5 million, compared to $374.3 million in 2018. Non-GAAP cost of sales was $380.3 million, compared to $352.5 million in 2018.
- GAAP R&D expense was $886.0 million, compared to $730.4 million in 2018. Non-GAAP R&D expense was $720.9 million, compared to $646.2 million in 2018.
- GAAP SG&A expense was $1,261.1 million, compared to $1,111.8 million in 2018. Non-GAAP SG&A expense was $1,099.9 million, compared to $953.3 million in 2018.
- GAAP income tax benefit was $225.5 million, inclusive of one-time tax benefits related to intra-entity asset transfers of intellectual property, compared to expense of $164.6 million in 2018. Non-GAAP income tax expense was $359.4 million, compared to $310.0 million in 2018.
- GAAP diluted EPS was $10.70, inclusive of one-time tax benefits related to intra-entity asset transfers of intellectual property, compared to $0.35 in 2018, inclusive of $1,183.0 million of expense related to the value of the in-process research and development assets acquired in 2018. Non-GAAP diluted EPS was $10.53, compared to $7.92 in 2018.

Fourth Quarter 2019 Financial Highlights

- Net product sales were $1,384.2 million in the fourth quarter of 2019, compared to $1,128.5 million in the fourth quarter of 2018.
- SOLIRIS net product sales were $1,013.1 million, compared to $976.7 million in the fourth quarter of 2018, representing a 4 percent increase.
- ULTOMIRIS net product sales were $170.2 million in the fourth quarter of 2019.
- STRENSIQ net product sales were $166.8 million, compared to $126.1 million in the fourth quarter of 2018, representing a 32 percent increase.
- KANUMA net product sales were $34.1 million, compared to $25.7 million in the fourth quarter of 2018, representing a 33 percent increase.
- GAAP cost of sales was $114.3 million, compared to $96.8 million in the fourth quarter of 2018. Non-GAAP cost of sales was $110.8 million, compared to $93.0 million in the fourth quarter of 2018.

- GAAP R&D expense was $269.6 million, compared to $205.6 million in the fourth quarter of 2018. Non-GAAP R&D expense was $226.7 million, compared to $164.0 million in the fourth quarter of 2018.

- GAAP SG&A expense was $381.0 million, compared to $318.7 million in the fourth quarter of 2018. Non-GAAP SG&A expense was $340.0 million, compared to $278.0 million in the fourth quarter of 2018.

- GAAP income tax benefit was $287.0 million, inclusive of one-time tax benefits related to intra-entity asset transfers of intellectual property in the fourth quarter of 2019, compared to expense of $12.1 million in the fourth quarter of 2018. Non-GAAP income tax expense was $85.8 million, compared to $88.5 million in the fourth quarter of 2018.

- GAAP diluted EPS was $4.00, inclusive of one-time tax benefits related to intra-entity asset transfers of intellectual property in the fourth quarter of 2019, compared to $(0.20) in the fourth quarter of 2018, inclusive of $379.3 million of expense related to the value of the in-process research and development asset acquired in connection with our acquisition of Syntimmune. Non-GAAP diluted EPS was $2.71, compared to $2.14 in the fourth quarter of 2018.

Research and Development

PHASE 3

- **SOLIRIS - Neuromyelitis Optica Spectrum Disorder (NMOSD):** In November 2019, SOLIRIS was approved for adults with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD in Japan. Alexion plans to initiate a Phase 2/3 study in children and adolescents with NMOSD in the first quarter of 2020.

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

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

- **ULTOMIRIS - Atypical Hemolytic Uremic Syndrome (aHUS):** Applications for approval of ULTOMIRIS for aHUS are under review in the EU and Japan. A Phase 3 study of ULTOMIRIS in children and adolescents with aHUS is underway.

- **ULTOMIRIS - 100mg/mL:** In November and December 2019, applications for approval of ULTOMIRIS 100mg/mL formulation were submitted in the EU and U.S., respectively. This higher concentration formulation is designed to reduce infusion time by more than 50 percent to approximately 45 minutes. Alexion plans to file for regulatory approval of this formulation in Japan in mid-2020.

- **ULTOMIRIS - Subcutaneous:** Enrollment is complete **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 the first half of 2020.

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

- **ULTOMIRIS - NMOSD:** In December 2019, Alexion initiated a Phase 3 study of ULTOMIRIS in NMOSD.

- **ULTOMIRIS - Amyotrophic Lateral Sclerosis (ALS):** In December 2019, Alexion submitted an investigational new drug application (IND) for ULTOMIRIS in ALS to the U.S. Food and Drug Administration (FDA), and in January 2020, announced the planned initiation of a pivotal Phase 3 study in the first quarter of 2020.

- **ULTOMIRIS - Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy (HSCT-TMA):** Alexion plans to initiate limited dose-ranging studies of ULTOMIRIS in adults and children with HSCT-TMA in the first half of 2020, followed by Phase 3 trials in the second half of 2020, pending regulatory feedback.

- **ULTOMIRIS - Complement Mediated Thrombotic Microangiopathy (CM-TMA):** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in CM-TMA in the second half of 2020, pending regulatory feedback.

- **ALXN1840 (WTX101) - Wilson Disease:** Alexion is in the process of completing enrollment in a Phase 3 study of ALXN1840 (WTX101) in Wilson disease. Study results are expected in the first half of 2021.

- **CAEL-101 - Caelum Biosciences:** Alexion is collaborating with Caelum Biosciences to develop CAEL-101 for light chain (AL) amyloidosis. A pivotal Phase 2/3 program will investigate CAEL-101 as an add-on to current standard-of-care therapy. The Phase 2 dose selection portion of the program will initiate in the first half of 2020, with the Phase 3 portion of the program planned to begin later in 2020, pending dose selection.

- **AG10 - Eidos:** Alexion holds an exclusive license to develop and commercialize 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 first quarter of 2020. Alexion plans to expand the AG10 program into Japan in 2020, pending regulatory feedback.

PHASE 1/2

- **ALXN1830 (SYNT001):** Alexion plans to re-initiate a Phase 2 study of ALXN1830 (SYNT001), administered intravenously, in warm autoimmune hemolytic anemia (WAIHA) in early 2020. In December 2019, Alexion initiated a Phase 1 study of a subcutaneous formulation of ALXN1830 in healthy volunteers. Pending successful completion of this Phase 1 study, Alexion plans to initiate a Phase 2 study of subcutaneous ALXN1830 in gMG in the second half of 2020.

- **Danicopan (ACH-4471) & ACH-5228 - Achillion:** In January 2020, Alexion announced the completion of its acquisition of Achillion Pharmaceuticals, Inc. The acquisition adds two oral Factor D inhibitors to treat rare diseases associated with the complement alternative pathway to Alexion's clinical-stage pipeline - danicopan (ACH-4471) and ACH-5228. Phase 3 development is being initiated for danicopan as an add-on therapy for PNH patients with extravascular hemolysis (EVH). Danicopan is also in Phase 2 development for C3G, and ACH-5228 is in Phase 2 development for PNH.

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

- **ALXN1810 - Renal Diseases:** Alexion plans to initiate a proof-of-concept trial of ALXN1810 (subcutaneous ALXN1210 co-administered with Halozyme's ENHANZE® drug-delivery technology, recombinant human hyaluronidase enzyme (rHuPH20)) in patients with various renal diseases in 2020.

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

- **ALXN1720:** A Phase 1 study of ALXN1720, a novel anti-C5 albumin-binding bi-specific mini-body that binds and prevents activation of human C5, is underway in healthy volunteers.

PRE-CLINICAL

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

- **Dicerna - GalXC™ :** Alexion is collaborating with Dicerna Pharmaceuticals to jointly discover and develop subcutaneously delivered GalXC™ RNA interference (RNAi) candidates, currently in pre-clinical development, for the treatment of complement-mediated diseases. In December 2019, Alexion exercised its option for exclusive rights to two additional targets, expanding the collaboration to now encompass four targets within the complement pathway.

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

- **Immune Pharma - anti-eotaxin-1 antibody:** In November 2019, Alexion acquired an anti-eotaxin-1 antibody from Immune Pharma for potential development in inflammatory diseases.

2020 Financial Guidance

Total revenues	$5,500 to $5,560 million
SOLIRIS/ULTOMIRIS revenues	$4,755 to $4,800 million
Metabolic revenues	$745 to $760 million
R&D (% total revenues)	
GAAP	19.0% to 22.5%
Non-GAAP	17.5% to 18.5%
SG&A (% total revenues)	
GAAP	22.7% to 24.0%
Non-GAAP	19.5% to 20.5%
Operating margin	
GAAP	39.3% to 43.5%
Non-GAAP	53.5% to 54.5%
Earnings per share	
GAAP	$7.91 to $8.71
Non-GAAP	$10.65 to $10.85

2020 financial guidance assumes a GAAP effective tax rate of 15.5 to 16.5 percent and a non-GAAP effective tax rate of 16.0 to 17.0 percent for the year. The 2020 GAAP and non-GAAP tax rates do not benefit from one-time events that benefited the tax rates in 2019.

Updated guidance includes the financial impact of the recently announced agreement to acquire Achillion, which closed in January 2020.

Alexion’s financial guidance is based on current foreign exchange rates net of hedging activities and does not include the effect of acquisitions, license and 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 fourth quarter and full-year 2019 results today at 7:30 a.m. Eastern Time. To participate in the call, dial 866-762-3111 (USA) or 210-874-7712 (International), conference ID 3571658 shortly before 7:30 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 medicines. As the global leader in complement biology and inhibition for more than 20 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first and only approved complement inhibitor to treat anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD). Alexion also has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). In addition, the company is developing several mid-to-late-stage therapies, including a 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 anti-FcRn therapy, 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 the core therapeutic areas of hematology, nephrology, neurology, metabolic disorders and cardiology. 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.

[ALXN-E]

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); the strength of our business and continued growth; plans to expand the Company's pipeline; Company's goal of continuing to build on momentum as the year progresses; future plans for, and the timing for, the commencement of future clinical trials and the expected timing of the receipt of results of certain clinical trials and studies, including clinical programs for ULTOMIRIS in aHUS, NMOSD, HSCT-TMA, ALS, PNH, gMG, PPMS, a subcutaneous administration in PNH and aHUS, a higher concentration formulation of ULTOMIRIS, SOLIRIS in NMOSD and gMG, ALXN1840 in Wilson Disease, CAEL-101 in light chain (AL) amyloidosis, AG10 in ATTR-PN, danicopan in C3G and PNH patients with EVH, ACH-5228 for PNH and for ALXN1830 in WAIHA and gMG; potential benefits of current products and products under development and in clinical trials; plans for development programs with third parties including, Eidos, Affibody, Dicerna, Zealand, and Complement Pharma; the potential to treat a broad range of complement mediated diseases with the products to be developed with Zealand and Dicerna and the potential advantages of novel peptide therapies; the potential for the anti-eotaxin-1 antibody from Immune Pharma to treat inflammatory diseases; the potential for CP010 to treat multiple neurological disorders; 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 of from SOLIRIS to ULTOMIRIS; payer, physician and patient acceptance of ULTOMIRIS as an alternative to SOLIRIS; appropriate pricing for ULTOMIRIS; future competition from biosimilars and novel products; decisions of regulatory authorities regarding the adequacy of our research, marketing approval or material limitations on the marketing of our products; delays or failure of product candidates to obtain regulatory approval; delays or the inability to launch product candidates due to regulatory restrictions, anticipated expense or other matters; interruptions or failures in the manufacture and supply of our products and our product candidates; failure to satisfactorily address matters raised by the FDA and other regulatory agencies; results in early stage clinical trials may not be indicative of full results or results from later stage or larger clinical trials (or broader patient populations) and do not ensure regulatory approval; the possibility that results of clinical trials are not predictive of safety and efficacy and potency of our products (or we fail to adequately operate or manage our clinical trials) which could cause us to halt trials, delay or prevent us from making regulatory approval filings or result in denial of approval of our product candidates; unexpected delays in clinical trials; unexpected concerns that may arise from additional data or analysis obtained during clinical trials; future product improvements may not be realized due to expense or feasibility or other factors; uncertainty of long-term success in developing, licensing or acquiring other product candidates or additional indications for existing products; inability to complete planned acquisitions due to failure of regulatory approval or material changes in target or otherwise; inability to complete acquisitions and investments due to increased competition for technology; the possibility that current rates of adoption of our products are not sustained; the adequacy of our pharmacovigilance and drug safety reporting processes; failure to protect and enforce our data, intellectual property and proprietary rights and the risks and uncertainties relating to intellectual property claims, lawsuits and challenges against us (including intellectual property lawsuits relating to ULTOMIRIS brought by third parties against Alexion and inter partes review petitions submitted by third parties); the risk that third party payors (including governmental agencies) will not reimburse or continue to reimburse for the use of our products at acceptable rates or at all; failure to realize the benefits and potential of investments, collaborations, licenses and acquisitions; the possibility that expected tax benefits will not be realized; assessment of impact of recent accounting pronouncements; potential declines in sovereign credit ratings or sovereign defaults in countries where we sell our products; delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement; uncertainties surrounding legal proceedings, company investigations and government investigations, including investigations of Alexion by the U.S. Securities and Exchange Commission (SEC) and U.S. Department of Justice; the risk that estimates regarding the number of patients with PNH, aHUS, gMG, NMOSD, HPP and LAL-D and other future indications we are pursuing are inaccurate; the risks of changing foreign exchange rates; risks relating to the potential effects of the Company's restructuring; risks related to the acquisition of companies and co-development and collaboration efforts; and a variety of other risks set forth from time to time in Alexion's filings with the SEC, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the period ended September 30, 2019 and in our other filings with the SEC. Alexion disclaims any obligation to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

In addition to financial information prepared in accordance with GAAP, this press release also contains non-GAAP financial measures that Alexion believes, when considered together with the GAAP information, provide investors and management with supplemental information relating to performance, trends and prospects that promote a more complete understanding of our operating results and financial position during different periods. 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 twelve month periods ended December 31, 2019 and 2018 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 December 31,		Twelve months ended December 31,	
	2019	2018	2019	2018
Net product sales	$ 1,384.2	$ 1,128.5	$ 4,990.0	$ 4,130.1
Other revenue	0.1	0.3	1.1	1.1
Total revenues	1,384.3	1,128.8	4,991.1	4,131.2
Cost of sales	114.3	96.8	394.5	374.3
Operating expenses:				
Research and development	269.6	205.6	886.0	730.4
Selling, general and administrative	381.0	318.7	1,261.1	1,111.8
Acquired in-process research and development	—	379.3	(4.1)	1,183.0
Amortization of purchased intangible assets	73.9	80.0	309.6	320.1
Change in fair value of contingent consideration	4.4	5.6	11.6	116.5
Restructuring expenses	0.1	(0.9)	12.0	25.5
Total operating expenses	729.0	988.3	2,476.2	3,487.3
Operating income	541.0	43.7	2,120.4	269.6
Other income and expense:				
Investment income (expense)	49.7	(54.1)	100.3	65.3
Interest expense	(21.7)	(24.5)	(77.8)	(98.2)
Other income and (expense)	33.0	2.0	35.9	5.5
Income (loss) before income taxes	602.0	(32.9)	2,178.8	242.2
Income tax (benefit) expense	(287.0)	12.1	(225.5)	164.6
Net income (loss)	$ 889.0	$ (45.0)	$ 2,404.3	$ 77.6
Earnings (loss) per common share				
Basic	$ 4.02	$ (0.20)	$ 10.77	$ 0.35
Diluted	$ 4.00	$ (0.20)	$ 10.70	$ 0.35
Shares used in computing earnings (loss) per common share				
Basic	221.3	223.2	223.2	222.7
Diluted	222.5	223.2	224.8	224.5

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

	Three months ended December 31,		Twelve months ended December 31,	
	2019	2018	2019	2018
GAAP net income (loss)	$ 889.0	$ (45.0)	$ 2,404.3	$ 77.6
Before tax adjustments:				
Cost of sales:				
Share-based compensation	3.5	3.8	14.2	16.0
Restructuring related expenses (1)	—	—	—	5.8
Research and development expense:				
Share-based compensation	15.8	14.9	61.7	57.4
Upfront payments related to licenses and other strategic agreements (2)	27.1	26.7	103.4	26.7
Restructuring related expenses (1)	—	—	—	0.1
Selling, general and administrative expense:				
Share-based compensation	41.0	33.4	161.1	129.6
Restructuring related expenses (1)	—	1.4	—	19.4
Litigation charges	—	5.9	0.1	13.0
Gain on sale of asset	—	—	—	(3.5)
Acquired in-process research and development (3)	—	379.3	(4.1)	1,183.0
Amortization of purchased intangible assets	73.9	80.0	309.6	320.1
Change in fair value of contingent consideration (4)	4.4	5.6	11.6	116.5
Restructuring expenses (1)	0.1	(0.9)	12.0	25.5
Investment income (expense):				
(Gains) and losses related to strategic equity investments (5)	(39.0)	57.7	(59.7)	(43.1)
Other income and (expense):				
Gain related to purchase option(6)	(32.0)	—	(32.0)	—
Restructuring related expenses (1)	—	—	—	(0.1)
Adjustments to income tax expense (7)	(372.8)	(76.4)	(584.9)	(145.4)
Non-GAAP net income	$ 611.0	$ 486.4	$ 2,397.3	$ 1,798.6
GAAP earnings (loss) per common share - diluted	$ 4.00	$ (0.20)	$ 10.70	$ 0.35
Non-GAAP earnings per common share - diluted	$ 2.71	$ 2.14	$ 10.53	$ 7.92
Shares used in computing diluted earnings (loss) per common share (GAAP)	222.5	223.2	224.8	224.5
Shares used in computing diluted earnings per common share (non-GAAP)	225.6	227.4	227.6	227.1

(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 December 31, 2019				Three Months Ended December 31, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Research and development	—	—	—	—	—	—	—	—
Selling, general and administrative	—	—	—	—	—	1.4	—	1.4
Restructuring expenses	(0.3)	—	0.4	0.1	(2.3)	—	1.4	(0.9)
Other income and (expense)	—	—	—	—	—	—	—	—
	$ (0.3)	$ —	$ 0.4	$ 0.1	$ (2.3)	$ 1.4	$ 1.4	$ 0.5

	Twelve Months Ended December 31, 2019				Twelve Months Ended December 31, 2018			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ 5.8	$ —	$ 5.8
Research and development	—	—	—	—	—	0.1	—	0.1
Selling, general and administrative	—	—	—	—	—	19.4	—	19.4
Restructuring expenses	8.4	—	3.6	12.0	4.6	—	20.9	25.5
Other income and (expense)	—	—	—	—	—	—	(0.1)	(0.1)
	$ 8.4	$ —	$ 3.6	$ 12.0	$ 4.6	$ 25.3	$ 20.8	$ 50.7

(2) During the three months ended December 31, 2019, we recorded expense of $27.1 million in connection with upfront payments on strategic agreements that we entered into with Stealth BioTherapeutics Corp. (Stealth) and Immune Pharmaceuticals (Immune Pharma). During the twelve months ended December 31, 2019, we recorded expense of $103.4 million in connection with upfront payments on strategic agreements that we entered into with Stealth, Immune Pharma, Eidos Therapeutics, Inc., Affibody AB and Zealand Pharma A/S.

(3) During the second and fourth quarters of 2018, we completed the acquisitions of Wilson Therapeutics AB (Wilson) and Syntimmune, Inc. (Syntimmune), respectively. The acquisitions were both accounted for as asset acquisitions, as substantially all of the fair value of the gross assets acquired were concentrated in a single asset. The value of the acquired in-process research and development assets was expensed during the quarters the acquisitions were completed due to the stage of development of the assets. In connection with the agreement of the final working capital adjustment for the Syntimmune acquisition, we recognized a benefit of $4.1 million associated with previously acquired in-process research and development in the second quarter of 2019.

(4) Changes in the fair value of contingent consideration expense for the three and twelve months ended December 31, 2019 as well as the three months ended December 31, 2018 include the impact of changes in the expected timing of achieving contingent milestones, in addition to the interest component related to the passage of time. For the twelve months ended December 31, 2018, the change in the fair value of contingent consideration expense was primarily due to amending certain contingent milestone payments due under our prior merger agreement with Enobia Pharma Corp. in September 2018 as well as due to increases in the likelihood and anticipated timing of payments for contingent consideration.

(5) On December 9, 2019, we sold our Moderna Therapeutics Inc. strategic equity investment. We received $114.7 million in net proceeds, resulting in a realized gain of $77.2 million on our initial investment. During the three and twelve months ended December 31, 2019, we recognized a net gain of $19.7 million and $32.8 million in investment income, respectively, relating to our Moderna investment. Additionally, during the three and twelve months ended December 31, 2019, we recognized an unrealized gain of $19.3 million and $26.9 million, respectively, in investment income to adjust our remaining strategic equity investments to fair value. During the three and twelve months ended December 31, 2018, we recognized unrealized gains of $57.7 million and $43.1 million, respectively, in investment income to adjust our strategic equity investments to fair value.

(6) In December 2019, we amended the terms of our agreement with Caelum Biosciences (Caelum) with respect to the option to acquire the remaining equity in Caelum. In conjunction with this amendment, we recognized a gain of $32.0 million in other income and (expense), which reflects an increase in the fair value of the option, less incremental upfront funding and the change in the fair value of contingent payments which we also modified as part of the amendment.

(7) Alexion's non-GAAP income tax expense for the three and twelve months ended December 31, 2019 and 2018 excludes the tax effect of pre-tax adjustments to GAAP profit. Non-GAAP income tax expense for the three and twelve months ended December 31, 2019 excludes a one-time tax benefit of $382.2 million related to the intra-entity asset transfer of intellectual property within our captive foreign partnership. Non-GAAP income tax expense for the twelve months ended December 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 and a release of an existing valuation allowance, respectively, and excludes a one-time tax expense of $10.2 million related to the July 1, 2019 integration of Wilson intellectual property into the Alexion corporate structure. Non-GAAP income tax expense for the three and twelve months ended December 31, 2018 excludes adjustments to provisional estimates of the impact of Tax Cuts and Jobs Act we recorded in fourth quarter 2017.

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

	Twelve months ending December 31, 2020	
	Low	High
GAAP net income	$ 1,779	$ 1,960
Before tax adjustments:		
Share-based compensation	297	280
Contingent milestone payments (1)	130	—
Amortization of purchased intangible assets	295	295
Acquisition-related costs	40	20
Change in fair value of contingent consideration	17	17
Restructuring expenses	3	—
Gains and losses related to strategic equity investments	—	—
Adjustments to income tax expense	(143)	(109)
Non-GAAP net income	$ 2,418	$ 2,463
Diluted GAAP earnings per common share	$ 7.91	$ 8.71
Diluted non-GAAP earnings per common share	$ 10.65	$ 10.85
Operating expense and margin (% total revenues)		
GAAP research and development expense	22.5%	19.0%
Share-based compensation	1.6%	1.5%
Contingent milestone payments (1)	2.4%	0.0%
Non-GAAP research and development expense	18.5%	17.5%
GAAP selling, general and administrative expense	24.0%	22.7%
Share-based compensation	3.5%	3.2%
Non-GAAP selling, general and administrative expense	20.5%	19.5%
GAAP operating margin	39.3%	43.5%
Share-based compensation	5.4%	5.0%
Contingent milestone payments (1)	2.4%	—%
Amortization of purchased intangible assets	5.4%	5.3%
Acquisition-related costs	0.7%	0.4%
Change in fair value of contingent consideration	0.3%	0.3%
Restructuring expenses	0.1%	0.0%
Non-GAAP operating margin	53.5%	54.5%
Income tax expense (% of income before income taxes)		
GAAP income tax expense	16.5%	15.5%
Tax effect of pre-tax adjustments to GAAP net income	0.5%	0.5%
Non-GAAP income tax expense	17.0%	16.0%

(1) Represents contingent milestone payments associated with acquisitions of legal entities accounted for as asset acquisitions.
Amounts may not foot due to rounding.

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

	Three months ended December 31,		Twelve months ended December 31,	
	2019	2018	2019	2018
SOLIRIS				
United States	$ 557.2	$ 452.1	$ 2,014.0	$ 1,588.4
Europe	249.6	270.4	1,049.8	1,036.7
Asia Pacific	94.3	104.7	423.5	382.0
Rest of World	112.0	149.5	459.1	555.9
Total SOLIRIS	$ 1,013.1	$ 976.7	$ 3,946.4	$ 3,563.0
ULTOMIRIS				
United States	$ 92.9	$ —	$ 236.8	$ —
Europe	31.1	—	52.2	—
Asia Pacific	46.2	—	49.9	—
Rest of World	—	—	—	—
Total ULTOMIRIS	$ 170.2	$ —	$ 338.9	$ —
STRENSIQ				
United States	$ 128.0	$ 98.6	$ 451.7	$ 374.3
Europe	21.0	14.7	77.0	61.7
Asia Pacific	14.4	8.7	50.4	27.9
Rest of World	3.4	4.1	13.4	11.2
Total STRENSIQ	$ 166.8	$ 126.1	$ 592.5	$ 475.1
KANUMA				
United States	$ 14.9	$ 12.7	$ 60.0	$ 51.3
Europe	7.7	5.2	27.1	21.6
Asia Pacific	1.2	0.8	4.6	3.7
Rest of World	10.3	7.0	20.5	15.4
Total KANUMA	$ 34.1	$ 25.7	$ 112.2	$ 92.0
Net Product Sales				
United States	$ 793.0	$ 563.4	$ 2,762.5	$ 2,014.0
Europe	309.4	290.3	1,206.1	1,120.0
Asia Pacific	156.1	114.2	528.4	413.6
Rest of World	125.7	160.6	493.0	582.5
Total Net Product Sales	$ 1,384.2	$ 1,128.5	$ 4,990.0	$ 4,130.1

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 2,685.5	$ 1,365.5
Marketable securities	64.0	198.3
Trade accounts receivable, net	1,243.2	922.3
Inventories	627.6	472.5
Prepaid expenses and other current assets (1)	456.1	426.4
Property, plant and equipment, net (1)	1,163.3	1,471.5
Intangible assets, net	3,344.3	3,641.3
Goodwill	5,037.4	5,037.4
Right of use operating assets (1)	204.0	—
Deferred tax assets	2,290.2	101.8
Other assets	429.0	294.9
Total assets	$ 17,544.6	$ 13,931.9
Accounts payable and accrued expenses	$ 966.7	$ 698.2
Revolving credit facility	—	250.0
Current portion of long-term debt	126.7	93.8
Current portion of contingent consideration	—	97.6
Other current liabilities (1)	100.9	34.4
Long-term debt, less current portion	2,375.0	2,501.7
Contingent consideration	192.4	183.2
Facility lease obligations (1)	—	361.0
Deferred tax liabilities	2,081.4	391.1
Noncurrent operating lease liabilities	164.1	—
Other liabilities (1)	265.6	155.6
Total liabilities	6,272.8	4,766.6
Total stockholders' equity (1)	11,271.8	9,165.3
Total liabilities and stockholders' equity	$ 17,544.6	$ 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 December 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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