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): February 4, 2019

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	0-27756	13-3648318
(State or other jurisdiction of 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

Not Applicable

(Former address if changed since last report)

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))

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 February 4, 2019, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial condition for the quarter and year ended December 31, 2018. 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 collaborations, acquired in-process research and development assets, impairment of intangible assets, change in value of strategic equity investments, litigation charges, gain or loss on sale of a business or asset and certain adjustments to income tax expense. 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's management utilizes non-GAAP financial information to provide a useful measure of comparative operating performance of Alexion. 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 February 4, 2019 relating to its results of operations and financial condition for the quarter and year ended December 31, 2018.

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: February 4, 2019

ALEXION PHARMACEUTICALS, INC.

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

Alexion Reports Fourth Quarter and Full Year 2018 Results

- 4Q18 total revenues of $1,128.8 million, a 24 percent increase over 4Q17 and a 30 percent volume increase
- 4Q18 GAAP diluted EPS of $(0.20); non-GAAP diluted EPS of $2.14
- 2019 guidance: revenue $4,625 to $4,700 million; GAAP diluted EPS of $6.14 to $7.26; non-GAAP diluted EPS of $9.10 to $9.30
- SOLIRIS® (eculizumab) for Generalized Myasthenia Gravis (gMG) best Alexion launch in first year following regulatory approval
- U.S. launch underway for ULTOMIRIS™ (ravulizumab-cwvz) in adults with paroxysmal nocturnal hemoglobinuria (PNH); EU and Japanese applications under review
- Filed U.S. and EU submissions for SOLIRIS in neuromyelitis optica spectrum disorder (NMOSD) and on track to file in Japan later in 2019
- Announced collaboration with Caelum Biosciences

BOSTON, February 4, 2019- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the fourth quarter and full year of 2018. Total revenues for the full year of 2018 were $4,131.2 million, a 16 percent increase compared to 2017. The positive impact of foreign currency on total revenues year-over-year was less than one percent, or $5.9 million, inclusive of hedging activities. On a GAAP basis, diluted earnings per share (EPS) for the full year of 2018 was $0.35, an 82 percent decrease versus 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 2018 was $7.92, a 35 percent increase versus the prior year.

Total revenues in the fourth quarter were $1,128.8 million, a 24 percent increase compared to the same period in 2017. The negative impact of foreign currency on total revenues year-over-year was 1 percent, or $5.5 million, inclusive of hedging activities. On a GAAP basis, diluted EPS in the quarter was $(0.20), a 254 percent decrease versus 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. Non-GAAP diluted EPS for the fourth quarter of 2018 was $2.14, a 45 percent increase versus the fourth quarter of 2017.

"2018 was a transformational year for Alexion. I am proud of our many accomplishments, including entering rare neurology and making SOLIRIS for gMG Alexion's best launch ever, completing the Phase 3 program and launching ULTOMIRIS for PNH in the U.S., delivering groundbreaking Phase 3 data and submitting regulatory filings for SOLIRIS in NMOSD and rebuilding our pipeline through disciplined business development, all while continuing to grow our base business," said Ludwig Hantson, Ph.D., Chief

Executive Officer of Alexion. "As we look at 2019 and beyond, I am confident that this strong foundation positions us well to achieve our Four Pillars of growth, building durable, blockbuster franchises in PNH/aHUS, metabolics, neurology and FcRn."

Full Year 2018 Financial Highlights

- Total net product sales were $4,130.1 million, compared to $3,549.5 million in 2017.
- SOLIRIS® (eculizumab) net product sales were $3,563.0 million, compared to $3,144.1 million in 2017, representing a 13 percent increase. SOLIRIS volume increased 16 percent year-over-year.
- STRENSIQ® (asfotase alfa) net product sales were $475.1 million, compared to $339.8 million in 2017, representing a 40 percent increase. STRENSIQ volume increased 47 percent year-over-year.
- KANUMA® (sebelipase alfa) net product sales were $92.0 million, compared to $65.6 million in 2017, representing a 40 percent increase. KANUMA volume increased 60 percent year-over-year.
- GAAP cost of sales was $374.3 million, compared to $454.2 million in 2017. Non-GAAP cost of sales was $352.5 million, compared to $285.8 million in 2017.
- GAAP R&D expense was $730.4 million, compared to $878.4 million in 2017. Non-GAAP R&D expense was $646.2 million, compared to $736.3 million in 2017.
- GAAP SG&A expense was $1,111.8 million, compared to $1,094.4 million in 2017. Non-GAAP SG&A expense was $953.3 million, compared to $927.8 million in 2017.
- GAAP income tax expense was $164.6 million, compared to $104.5 million in 2017. Non-GAAP income tax expense was $310.0 million, compared to $186.7 million in 2017.
- GAAP diluted EPS was $0.35, inclusive of $1,183.0 million of expense related to the value of the in-process research and development assets acquired in 2018, compared to $1.97 in 2017. Non-GAAP diluted EPS was $7.92, compared to $5.86 in 2017.
- GAAP net income includes total restructuring and related expenses of $50.7 million in 2018, compared to $286.5 million in 2017. GAAP cost of sales includes restructuring related expenses of $5.8 million in 2018, compared to $152.1 million in 2017, GAAP R&D expense includes $0.1 million in 2018, compared to $16.3 million in 2017 and GAAP SG&A expense includes $19.4 million in 2018, compared to $10.9 million in 2017.

Fourth Quarter 2018 Financial Highlights

- Total net product sales were $1,128.5 million in the fourth quarter of 2018, compared to $909.4 million in the fourth quarter of 2017.
- SOLIRIS net product sales were $976.7 million, compared to $791.9 million in the fourth quarter of 2017, representing a 23 percent increase. SOLIRIS volume increased 28 percent year-over-year.
- STRENSIQ net product sales were $126.1 million, compared to $95.6 million in the fourth quarter of 2017, representing a 32 percent increase. STRENSIQ volume increased 43 percent year-over-year.

- KANUMA net product sales were $25.7 million, compared to $21.9 million in the fourth quarter of 2017, representing a 17 percent increase. KANUMA volume increased 51 percent year-over-year.

- GAAP cost of sales was $96.8 million, compared to $144.6 million in the fourth quarter of 2017. Non-GAAP cost of sales was $93.0 million, compared to $72.5 million in the fourth quarter of 2017.

- GAAP R&D expense was $205.6 million, compared to $265.0 million in the fourth quarter of 2017. Non-GAAP R&D expense was $164.0 million, compared to $188.6 million in the fourth quarter of 2017.

- GAAP SG&A expense was $318.7 million, compared to $296.4 million in the fourth quarter of 2017. Non-GAAP SG&A expense was $278.0 million, compared to $245.2 million in the fourth quarter of 2017.

- GAAP income tax expense was $12.1 million, compared to $59.3 million in the fourth quarter of 2017. Non-GAAP income tax expense was $88.5 million, compared to $46.8 million in the fourth quarter of 2017.

- GAAP diluted EPS was $(0.20), 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, compared to $0.13 in the fourth quarter of 2017. Non-GAAP diluted EPS was $2.14, compared to $1.48 in the fourth quarter of 2017.

- GAAP net income includes total restructuring and related expenses of $0.5 million in 2018, compared to $95.1 million in 2017. The 2017 statement of operations includes restructuring related expenses of $69.1 million in GAAP cost of sales, $15.3 million in GAAP R&D expense and $4.5 million in GAAP SG&A expense.

Research and Development

PHASE 3

- **ULTOMIRIS™ (ravulizumab-cwvz) - Paroxysmal Nocturnal Hemoglobinuria (PNH):** In December 2018, the U.S. Food and Drug Administration (FDA) approved ULTOMIRIS for adults with PNH. Applications for approval in the European Union (EU) and Japan are currently under review. In addition, a Phase 3 study of ULTOMIRIS in children and adolescents with PNH is currently underway.

- **ULTOMIRIS - Atypical Hemolytic Uremic Syndrome (aHUS):** In January 2019, Alexion announced positive topline results from a Phase 3 study of ULTOMIRIS in complement inhibitor naïve patients with aHUS. The study met its primary objective with 53.6 percent of patients demonstrating complete thrombotic microangiopathy (TMA) response. The safety profile of ULTOMIRIS was generally consistent with that seen in Phase 3 studies in PNH. No cases of meningococcal infection were observed. Based on these results, Alexion plans to file for regulatory approval in the U.S. in the first half of 2019 followed by the EU and Japan. In addition, a Phase 3 study of ULTOMIRIS in adolescents and children with aHUS is currently underway.

- **ULTOMIRIS - Subcutaneous:** In late 2018, Alexion initiated a single, PK-based Phase 3 study of ULTOMIRIS delivered subcutaneously once per week to support registration in PNH and aHUS. Data are expected in early 2020.

- **ULTOMIRIS - Generalized Myasthenia Gravis (gMG):** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in gMG in the first quarter of 2019.

- **ULTOMIRIS - Neuromyelitis Optica Spectrum Disorder (NMOSD):** Alexion plans to initiate a Phase 3 study of ULTOMIRIS in NMOSD.

- **SOLIRIS - NMOSD:** Alexion has submitted applications in the U.S. and the EU for the approval of eculizumab for NMOSD. These submissions are based on previously announced results from the Phase 3 PREVENT study, in which 97.9 percent of patients with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD receiving SOLIRIS on top of stable standard-of-care therapy were free of relapse at 48 weeks compared to 63.2 percent of patients receiving placebo. Alexion also plans to file for regulatory approval in Japan later this year.

- **ALXN1840 (WTX101) - Wilson Disease:** Enrollment is underway in a Phase 3 study of ALXN1840 (WTX101) in Wilson disease, a rare genetic disorder with devastating hepatic and neurological consequences. The study is now powered for superiority versus standard-of-care therapy. ALXN1840 is a first-in-class oral copper-binding agent with a unique mechanism of action to access and bind to serum copper and promote its removal from the liver.

PHASE 1/2

- **ALXN1830 (SYNT001):** In the fourth quarter of 2018, Alexion announced the completion of its acquisition of Syntimmune. The acquisition added anti-FcRn antibody ALXN1830 (SYNT001) to the company's clinical pipeline. ALXN1830 is currently in Phase 1b/2a development in patients with warm autoimmune hemolytic anemia (WAIHA) and in patients with pemphigus vulgaris (PV) or pemphigus foliaceus (PF). In 2019, the company plans to initiate two pivotal trials - one in WAIHA following successful completion of the current Phase 1b/2a study and one in gMG.

- **ALXN1810 - Subcutaneous:** A Phase 1 study of subcutaneous ALXN1210 co-administered with Halozyme's ENHANZE® drug-delivery technology, PH20, is underway. Pending co-formulation data, this next-generation subcutaneous formulation will be called ALXN1810 and has the potential to further extend the dosing interval to once every two weeks or once per month.

- **ULTOMIRIS - Amyotrophic Lateral Sclerosis (ALS):** Alexion plans to initiate a proof-of-concept study for ULTOMIRIS in ALS.

- **ULTOMIRIS - Primary Progressive Multiple Sclerosis (PPMS):** Alexion plans to initiate a proof-of-concept study for ULTOMIRIS in PPMS.

- **Caelum Biosciences - CAEL101 - Light Chain (AL) Amyloidosis:** In January 2019, Alexion entered into a collaboration with Caelum Biosciences to develop CAEL101 for AL amyloidosis, a rare systemic disorder that causes misfolded immunoglobulin light chain protein to build up in and around tissues, resulting in progressive and widespread organ damage. CAEL101 is a first-in-class amyloid fibril targeted therapy designed to improve organ function by reducing or eliminating amyloid deposits in patients with AL amyloidosis. In a Phase 1a/1b study, CAEL101 demonstrated improved organ function, including cardiac and renal function, in patients with relapsed and refractory AL amyloidosis.

PRE-CLINICAL

- **Dicerna - GalXC™ :** Alexion is collaborating with Dicerna Pharmaceuticals to jointly discover and develop up to four subcutaneously delivered GalXC™ RNA interference (RNAi) candidates, currently in pre-clinical development, for the treatment of complement-mediated diseases.

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

2019 Financial Guidance

Total revenues	$4,625 to $4,700 million
SOLIRIS/ULTOMIRIS revenues	$3,970 to $4,020 million
Metabolic revenues	$655 to $680 million
R&D (% total revenues)	
GAAP	17% to 18%
Non-GAAP	16% to 17%
SG&A (% total revenues)	
GAAP	23% to 24%
Non-GAAP	20% to 21%
Operating margin	
GAAP	36% to 43%
Non-GAAP	54% to 55%
Earnings per share	
GAAP	$6.14 to $7.26
Non-GAAP	$9.10 to $9.30

2019 financial guidance assumes a GAAP effective tax rate of 13 to 15 percent and non-GAAP effective tax rate of 14 to 16 percent.

Alexion's financial guidance is based on current foreign exchange rates net of hedging activities and does not include the effect of acquisitions, license and collaboration agreements, intangible asset impairments, litigation charges, changes in fair value of contingent consideration or restructuring and related activity outside of the previously announced activities that may occur after the issuance of this press release.

Conference Call/Webcast Information:

Alexion will host a conference call/audio webcast to discuss the fourth quarter and full year 2018 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 5972194 shortly before 8:00 a.m. Eastern Time. A replay of the call will be available for a limited period following the call. The audio webcast can be accessed on the Investor page of Alexion's website at: http://ir.alexion.com.

About Alexion

Alexion is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the discovery, development and commercialization of life-changing therapies. As the global leader in complement biology and inhibition for more than 20 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), as well as the first and only approved complement inhibitor to treat atypical hemolytic uremic syndrome (aHUS) and anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG), and is also developing it for patients with neuromyelitis optica spectrum disorder (NMOSD). Alexion also has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). In addition, the company is developing several mid-to-late-stage therapies, including a second complement inhibitor, a copper-binding agent for Wilson disease and an anti-neonatal Fc receptor (FcRn) antibody for rare Immunoglobulin G (IgG)-mediated diseases. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and its development efforts on the core therapeutic areas of hematology, nephrology, neurology and metabolic disorders. Alexion has been named to the *Forbes* list of the World's Most Innovative Companies seven years in a row and is headquartered in Boston, Massachusetts' Innovation District. The company also has offices around the globe and serves patients in more than 50 countries. This press release and further information about Alexion can be found at: www.alexion.com.

[ALXN-E]

Forward-Looking Statement

This press release contains forward-looking statements, including statements related to: guidance regarding anticipated financial results for 2019 (and the assumptions related to such guidance); the strength of our core business; plans to make future regulatory submissions/filings for approval of certain of our products, including eculizumab and ALXN1210, and the expected timing related to (as well as the expected timing of the receipt of certain regulatory approvals to market a product); the business's strong foundation positions the Company well to achieve the Four Pillars of growth, building durable, blockbuster franchises in PNH/aHUS, metabolics, neurology and FcRn; the timing for the commencement of future clinical trials and the expected timing of the receipt of results of certain clinical trials and studies; potential benefits of current products and products under development and in clinical trials (including further extended dosing intervals); Company's plans to initiate proof-of-concept studies in ALS and PPMS; Alexion's future clinical, regulatory, and commercial plans for ULTOMIRIS and other product candidates; and the goal of building out the clinical pipeline. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ materially from those forward-looking statements, including for example: our dependence on sales from our principal product (SOLIRIS); our ability to facilitate the timely conversion of PNH patients (and any future indications) from SOLIRIS to ULTOMIRIS; payer, physician and patient acceptance of ULTOMIRIS as an alternative to SOLIRIS; appropriate pricing for ULTOMIRIS; future competition from biosimilars and novel products; decisions of regulatory authorities regarding the adequacy of our research, marketing approval or

material limitations on the marketing of our products; delays or failure of product candidates to obtain regulatory approval; delays or the inability to launch product candidates due to regulatory restrictions, anticipated expense or other matters; interruptions or failures in the manufacture and supply of our products and our product candidates; failure to satisfactorily address matters raised by the FDA and other regulatory agencies; results in early stage clinical trials may not be indicative of full results or results from later stage or larger clinical trials (or broader patient populations) and do not ensure regulatory approval; the possibility that results of clinical trials are not predictive of safety and efficacy and potency of our products (or we fail to adequately operate or manage our clinical trials) which could cause us to halt trials, delay or prevent us from making regulatory approval filings or result in denial of approval of our product candidates; unexpected delays in clinical trials; unexpected concerns that may arise from additional data or analysis obtained during clinical trials; future product improvements may not be realized due to expense or feasibility or other factors; uncertainty of long-term success in developing, licensing or acquiring other product candidates or additional indications for existing products; inability to complete planned acquisitions due to failure of regulatory approval or material changes in target or otherwise; inability to complete acquisitions and investments due to increased competition for technology; the possibility that current rates of adoption of our products are not sustained; the adequacy of our pharmacovigilance and drug safety reporting processes; failure to protect and enforce our data, intellectual property and proprietary rights and the risks and uncertainties relating to intellectual property claims, lawsuits and challenges against us; the risk that third party payors (including governmental agencies) will not reimburse or continue to reimburse for the use of our products at acceptable rates or at all; failure to realize the benefits and potential of investments, collaborations, licenses and acquisitions; the possibility that expected tax benefits will not be realized; assessment of impact of recent accounting pronouncements; potential declines in sovereign credit ratings or sovereign defaults in countries where we sell our products; delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement; uncertainties surrounding legal proceedings, company investigations and government investigations, including investigations of Alexion by the U.S. Securities and Exchange Commission (SEC) and U.S. Department of Justice; the risk that estimates regarding the number of patients with PNH, aHUS, gMG, HPP and LAL-D and other future indications we are pursuing are inaccurate; the risks of changing foreign exchange rates; risks relating to the potential effects of the Company's restructuring; risks related to the acquisition of Syntimmune and other companies and co-development 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, 2018 and in our other filings with the SEC. Alexion disclaims any obligation to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

In addition to financial information prepared in accordance with GAAP, this press release also contains non-GAAP financial measures that Alexion believes, when considered together with the GAAP information, provide investors and management with supplemental information relating to performance, trends and prospects that promote a more complete understanding of our operating results and financial position during different periods. The non-GAAP results exclude the impact of the following GAAP items (see reconciliation tables below for additional information): share-based compensation expense, fair value adjustment of inventory acquired, amortization of purchased intangible assets, changes in fair value of contingent consideration, restructuring and related expenses, upfront payments related to licenses and collaborations, acquired in-process research and development assets, impairment of intangible assets, change in value of strategic equity investments, litigation charges, gain or loss on sale of a business or asset and certain adjustments to income tax expense. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP, and should be reviewed in conjunction with the relevant GAAP financial measures. Please refer to the attached Reconciliations of GAAP to non-GAAP 2018 Financial Results and GAAP to non-GAAP 2019 Financial Guidance for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three and twelve month periods ended December 31, 2018 and 2017 and projected twelve months ending December 31, 2019.

(Tables Follow)

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

	Three months ended December 31		Twelve months ended December 31	
	2018	2017	2018	2017
Net product sales	$ 1,128.5	$ 909.4	$ 4,130.1	$ 3,549.5
Other revenue	0.3	0.3	1.1	1.6
Total revenues	1,128.8	909.7	4,131.2	3,551.1
Cost of sales	96.8	144.6	374.3	454.2
Operating expenses:				
Research and development	205.6	265.0	730.4	878.4
Selling, general and administrative	318.7	296.4	1,111.8	1,094.4
Acquired in-process research and development	379.3	—	1,183.0	—
Amortization of purchased intangible assets	80.0	80.0	320.1	320.1
Change in fair value of contingent consideration	5.6	9.2	116.5	41.0
Restructuring expenses	(0.9)	5.9	25.5	104.6
Impairment of intangible assets	—	—	—	31.0
Total operating expenses	988.3	656.5	3,487.3	2,469.5
Operating income	43.7	108.6	269.6	627.4
Other income and expense:				
Investment (expense) income	(54.1)	5.6	65.3	18.5
Interest expense	(24.5)	(25.1)	(98.2)	(98.4)
Other income	2.0	0.2	5.5	0.3
Income (loss) before income taxes	(32.9)	89.3	242.2	547.8
Income tax expense	12.1	59.3	164.6	104.5
Net income (loss)	$ (45.0)	$ 30.0	$ 77.6	$ 443.3
Earnings (loss) per common share				
Basic	$ (0.20)	$ 0.13	$ 0.35	$ 1.98
Diluted	$ (0.20)	$ 0.13	$ 0.35	$ 1.97
Shares used in computing earnings (loss) per common share				
Basic	223.2	223.3	222.7	223.9
Diluted	223.2	225.0	224.5	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 December 31		Twelve months ended December 31	
	2018	2017	2018	2017
GAAP net income (loss)	$ (45.0)	$ 30.0	$ 77.6	$ 443.3
Before tax adjustments:				
Cost of sales:				
Share-based compensation	3.8	3.0	16.0	11.1
Fair value adjustment in inventory acquired	—	—	—	5.2
Restructuring related expenses (1)	—	69.1	5.8	152.1
Research and development expense:				
Share-based compensation	14.9	21.1	57.4	76.4
Upfront payments related to licenses and collaborations	26.7	40.0	26.7	49.4
Restructuring related expenses (1)	—	15.3	0.1	16.3
Selling, general and administrative expense:				
Share-based compensation	33.4	46.7	129.6	155.7
Restructuring related expenses (1)	1.4	4.5	19.4	10.9
Litigation charges (2)	5.9	—	13.0	—
Gain on sale of asset (3)	—	—	(3.5)	—
Acquired in-process research and development (4)	379.3	—	1,183.0	—
Amortization of purchased intangible assets	80.0	80.0	320.1	320.1
Change in fair value of contingent consideration (5)	5.6	9.2	116.5	41.0
Restructuring expenses (1)	(0.9)	5.9	25.5	104.6
Impairment of intangible assets	—	—	—	31.0
Investment (expense) income:				
Change in value of strategic equity investments (6)	57.7	—	(43.1)	—
Other income:				
Restructuring related expenses (1)	—	0.3	(0.1)	2.6
Adjustments to income tax expense (7)	(76.4)	12.5	(145.4)	(82.2)
Non-GAAP net income	$ 486.4	$ 337.6	$ 1,798.6	$ 1,337.5
GAAP earnings (loss) per common share - diluted	$ (0.20)	$ 0.13	$ 0.35	$ 1.97
Non-GAAP earnings per common share - diluted	$ 2.14	$ 1.48	$ 7.92	$ 5.86
Shares used in computing diluted earnings (loss) per common share (GAAP)	223.2	225.0	224.5	225.4
Shares used in computing diluted earnings per common share (non-GAAP)	227.4	227.6	227.1	228.1

(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, 2018				Three months ended December 31, 2017			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ —	$ —	$ —	$ —	$ 69.1	$ —	$ 69.1
Research and development	—	—	—	—	—	15.3	—	15.3
Selling, general and administrative	—	1.4	—	1.4	—	4.5	—	4.5
Restructuring expenses	(2.3)	—	1.4	(0.9)	1.0	—	4.9	5.9
Other expense	—	—	—	—	—	—	0.3	0.3
	$ (2.3)	$ 1.4	$ 1.4	$ 0.5	$ 1.0	$ 88.9	$ 5.2	$ 95.1

	Twelve months ended December 31, 2018				Twelve months ended December 31, 2017			
	Employee Separation Costs	Asset-Related Charges	Other	Total	Employee Separation Costs	Asset-Related Charges	Other	Total
Cost of sales	$ —	$ 5.8	$ —	$ 5.8	$ —	$ 152.1	$ —	$ 152.1
Research and development	—	0.1	—	0.1	—	16.3	—	16.3
Selling, general and administrative	—	19.4	—	19.4	—	10.9	—	10.9
Restructuring expenses	4.6	—	20.9	25.5	87.3	—	17.3	104.6
Other expense	—	—	(0.1)	(0.1)	—	—	2.6	2.6
	$ 4.6	$ 25.3	$ 20.8	$ 50.7	$ 87.3	$ 179.3	$ 19.9	$ 286.5

(2) During the year ended 2018, we recorded $13.0 million in litigation charges in connection with ongoing investigations.

(3) In September 2018, we sold all assets, rights and obligations of the ALXN1101 program to a third party and, as a result, we recognized a gain on the sale of ALXN1101 during the third quarter of 2018.

(4) During the second and fourth quarters of 2018, we completed the acquisitions of Wilson Therapeutics and 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 were expensed during the quarters the acquisitions were completed due to the stage of development of the assets.

(5) The change in the expense associated with the fair value of contingent consideration for the year ended December 31, 2018, as compared to the year ended 2017 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.

(6) Our investments include strategic equity investments in Moderna Therapeutics, Inc. and Dicerna Pharmaceuticals, Inc. During the year ended December 31, 2018, we recognized an unrealized gain of $43.1 million in investment income to adjust our strategic equity investments to fair value.

(7) Alexion's non-GAAP income tax expense excludes the tax effect of pre-tax adjustments to GAAP profit and adjustments to provisional estimates of the impact of Tax Cuts and Jobs Act we recorded in Q4 2017.

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

	Twelve months ending December 31, 2019	
	Low	High
GAAP net income	$ 1,388	$ 1,640
Before tax adjustments:		
Share-based compensation	231	214
Acquired in-process research and development	240	—
Amortization of purchased intangible assets	320	320
Change in fair value of contingent consideration	21	21
Restructuring and related expenses	25	20
Adjustments to income tax expense	(150)	(99)
Non-GAAP net income	$ 2,075	$ 2,116
Diluted GAAP earnings per common share	$ 6.14	$ 7.26
Diluted non-GAAP earnings per common share	$ 9.10	$ 9.30
Operating expense and margin (% total revenues)		
GAAP research and development expense	18%	17%
Share-based compensation	1%	1%
Non-GAAP research and development expense	17%	16%
GAAP selling, general and administrative expense	24%	23%
Share-based compensation	3%	3%
Restructuring related expenses	0%	0%
Non-GAAP selling, general and administrative expense	21%	20%
GAAP operating margin	36%	43%
Share-based compensation	5%	5%
Acquired in-process research and development	5%	—%
Amortization of purchased intangible assets	7%	7%
Change in fair value of contingent consideration	0%	0%
Restructuring and related expenses	1%	0%
Non-GAAP operating margin	54%	55%
Income tax expense (% of income before income taxes)		
GAAP income tax expense	15%	13%
Tax effect of pre-tax adjustments to GAAP net income	1%	1%
Non-GAAP income tax expense	16%	14%

Amounts may not foot due to rounding.

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

	Three months ended December 31		Twelve months ended December 31	
	2018	2017	2018	2017
SOLIRIS				
United States	$ 452.1	$ 321.5	$ 1,588.4	$ 1,235.0
Europe	270.4	246.9	1,036.7	985.2
Asia Pacific	104.7	86.7	382.0	328.1
Rest of World	149.5	136.8	555.9	595.8
Total Soliris	$ 976.7	$ 791.9	$ 3,563.0	$ 3,144.1
STRENSIQ				
United States	$ 98.6	$ 76.2	$ 374.3	$ 280.1
Europe	14.7	12.3	61.7	35.6
Asia Pacific	8.7	5.3	27.9	18.6
Rest of World	4.1	1.8	11.2	5.5
Total Strensiq	$ 126.1	$ 95.6	$ 475.1	$ 339.8
KANUMA				
United States	$ 12.7	$ 11.2	$ 51.3	$ 42.4
Europe	5.2	5.9	21.6	14.6
Asia Pacific	0.8	0.9	3.7	2.7
Rest of World	7.0	3.9	15.4	5.9
Total Kanuma	$ 25.7	$ 21.9	$ 92.0	$ 65.6
Net Product Sales				
United States	$ 563.4	$ 408.9	$ 2,014.0	$ 1,557.5
Europe	290.3	265.1	1,120.0	1,035.4
Asia Pacific	114.2	92.9	413.6	349.4
Rest of World	160.6	142.5	582.5	607.2
Total Net Product Sales	$ 1,128.5	$ 909.4	$ 4,130.1	$ 3,549.5

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

	December 31 2018	December 31 2017
Cash and cash equivalents	$ 1,365.5	$ 584.4
Marketable securities	198.3	889.7
Trade accounts receivable, net	922.3	726.5
Inventories	472.5	460.4
Prepaid expenses and other current assets	426.4	292.9
Property, plant and equipment, net	1,471.5	1,325.4
Intangible assets, net	3,641.3	3,954.4
Goodwill	5,037.4	5,037.4
Other assets	396.7	312.2
Total assets	$ 13,931.9	$ 13,583.3
Accounts payable and accrued expenses	$ 698.2	$ 710.2
Revolving credit facility	250.0	—
Current portion of long-term debt	93.8	167.4
Current portion of contingent consideration	97.6	—
Other current liabilities (1)	34.4	74.9
Long-term debt, less current portion	2,501.7	2,720.7
Contingent consideration	183.2	168.9
Facility lease obligations	361.0	342.9
Deferred tax liabilities	391.1	365.0
Other liabilities	155.6	140.2
Total liabilities	4,766.6	4,690.2
Total stockholders' equity (1)	9,165.3	8,893.1
Total liabilities and stockholders' equity	$ 13,931.9	$ 13,583.3

(1) In May 2014, the Financial Accounting Standards Board issued a comprehensive new standard which amends revenue recognition principles. We adopted this standard in the first quarter 2018. Upon adoption of the new standard, we reduced our deferred revenue balance reported in Other current liabilities by $10.4 million, with an offsetting increase of $6.0 million in retained earnings due to the cumulative impact of adopting this new standard. The adjusted deferred revenue balance, as of January 1, 2018, was $5.5 million.

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