

**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): October 24, 2018

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware ----- (State or other jurisdiction of of incorporation or organization)	0-27756 ----- (Commission File Number)	13-3648318 ----- (I.R.S. Employer Identification No.)
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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 October 24, 2018, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial condition for the quarter ended September 30, 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 equity securities without readily determinable fair values, 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 October 24, 2018 relating to its results of operations and financial condition for the quarter ended September 30, 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: October 24, 2018

ALEXION PHARMACEUTICALS, INC.

By: /s/ Doug Barry

Name: Doug Barry

Title: Vice President, Corporate Law



Alexion Reports Third Quarter 2018 Results

- 3Q18 total revenues of \$1,026.5 million, a 20 percent increase over 3Q17 and a 26 percent volume increase
- 3Q18 GAAP diluted EPS of \$1.47 per share; non-GAAP diluted EPS of \$2.02 per share
- Updated 2018 full-year guidance given the strength of the business
- Positive topline Phase 3 data for eculizumab in patients with neuromyelitis optica spectrum disorder (NMOSD); regulatory submissions planned for early 2019
- Announced agreement to acquire Syntimmune and collaboration with Dicerna

BOSTON, October 24, 2018- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the third quarter of 2018. Total revenues in the third quarter were \$1,026.5 million, a 20 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 \$8.9 million, inclusive of hedging activities. On a GAAP basis, diluted earnings per share (EPS) in the quarter was \$1.47 per share. The third quarter of 2018 included \$18.2 million of restructuring and related expenses compared to \$164.7 million in the third quarter of 2017. Non-GAAP diluted EPS for the third quarter of 2018 was \$2.02 per share, a 40 percent increase versus the third quarter of 2017.

"We continued to execute on our key objectives this quarter, further strengthening our core business and again delivering strong top and bottom-line growth," said Ludwig Hantson, Ph.D., Chief Executive Officer of Alexion. "Following the groundbreaking Phase 3 results of eculizumab in NMOSD, we are moving quickly to prepare global regulatory submissions, which could make it the first approved therapy for patients with this devastating disease. Our teams continue to demonstrate launch excellence with sustained growth of Soliris® in gMG. In addition, we made significant progress diversifying our portfolio with the anticipated acquisition of Syntimmune and our collaboration with Dicerna. We continue to look for additional opportunities while advancing internal programs to position us for further long-term growth."

Third Quarter 2018 Financial Highlights

- Total net product sales were \$1,026.5 million in the third quarter of 2018, compared to \$1,044.7 million in the second quarter of 2018. Second quarter revenue benefited from favorable timing of orders from certain non-U.S. markets that access Alexion medicines through a tender process as well as approximately \$18.2 million related to order timing ahead of the July 4th holiday in the United States, compared to the third quarter of 2018.
- Soliris® (eculizumab) net product sales were \$888.0 million, compared to \$755.4 million in the third quarter of 2017, representing an 18 percent increase. Soliris® volume increased 24 percent year-over-year.

- Strensiq® (asfotase alfa) net product sales were \$113.2 million, compared to \$87.0 million in the third quarter of 2017, representing a 30 percent increase. Strensiq® volume increased 37 percent year-over-year.
- Kanuma® (sebelipase alfa) net product sales were \$25.3 million, compared to \$16.4 million in the third quarter of 2017, representing a 54 percent increase. Kanuma® volume increased 74 percent year-over-year.
- GAAP cost of sales was \$90.6 million, compared to \$157.0 million in the same quarter last year. Non-GAAP cost of sales was \$87.3 million, compared to \$70.8 million in the same quarter last year.
- GAAP R&D expense was \$174.8 million, compared to \$195.7 million in the same quarter last year. Non-GAAP R&D expense was \$162.3 million, compared to \$175.7 million in the same quarter last year.
- GAAP SG&A expense was \$258.7 million, compared to \$270.6 million in the same quarter last year. Non-GAAP SG&A expense was \$224.5 million, compared to \$229.0 million in the same quarter last year.
- GAAP income tax expense was \$11.2 million, compared to an income tax benefit of \$19.8 million in the same quarter last year. Non-GAAP income tax expense was \$75.8 million, compared to \$35.7 million in the same quarter last year. Both GAAP and non-GAAP income tax benefit /expense for the third quarter of 2017 included a benefit from the conclusion of a routine IRS audit for the 2013-2014 years.
- GAAP diluted EPS was \$1.47 per share, compared to \$0.35 per share in the same quarter last year. The third quarter of 2018 included \$18.2 million of restructuring and related expenses compared to \$164.7 million in the third quarter of 2017. Non-GAAP diluted EPS was \$2.02 per share, compared to \$1.44 per share in the third quarter of 2017.

Research and Development

PHASE 3

- **Ultomiris™ - Paroxysmal Nocturnal Hemoglobinuria (PNH):** Applications for the approval of Ultomiris™ (also known as ALXN1210) in adults with PNH have been accepted by regulatory authorities in the U.S., the European Union (EU) and Japan. The U.S. Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) date of February 18, 2019, as part of an expedited eight-month review following the company's use of a rare disease priority review voucher. The applications are supported by comprehensive data from two rigorous Phase 3 clinical studies. In September 2018, Ultomiris™ was granted Orphan Drug Designation in Japan. In addition, a Phase 3 study of Ultomiris™ in children and adolescents with PNH is currently underway.
- **ALXN1210 - Atypical Hemolytic Uremic Syndrome (aHUS):** Enrollment is complete in the Phase 3 trial of ALXN1210 administered intravenously every eight weeks in complement inhibitor treatment-naïve adolescent and adult patients with aHUS. Results from this study are expected in early 2019. Alexion intends to file for regulatory approval in aHUS following approval in PNH. A Phase 3 study of ALXN1210 in children with aHUS is currently underway.
- **ALXN1210 - Subcutaneous:** In late 2018, Alexion plans to initiate a single, PK-based Phase 3 study of ALXN1210 delivered subcutaneously once per week to support registration in PNH and aHUS.

- **Eculizumab - Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD):** In September 2018, Alexion announced positive results from the Phase 3 PREVENT study, in which patients with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD received eculizumab or placebo on top of stable standard-of-care therapy. The study met its primary endpoint of time to first adjudicated on-trial relapse, demonstrating that treatment with eculizumab reduced the risk of relapse by 94.2 percent compared to placebo (p<0.0001). At 48 weeks, 97.9 percent of patients receiving eculizumab were free of relapse compared to 63.2 percent of patients receiving placebo. No cases of meningococcal infection were observed. Eculizumab was generally well tolerated with a safety profile consistent with that seen in previous clinical studies and real-world use in its three approved indications. Based on the significant need for an approved treatment, the company is rapidly preparing regulatory submissions in the U.S., EU and Japan, and expects to submit applications in early 2019.
- **WTX101 - Wilson Disease:** Enrollment is underway in a Phase 3 study of WTX101 in Wilson disease, a rare genetic disorder with devastating hepatic and neurological consequences. The study is now powered for superiority. WTX101 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

- **SYNT001:** In September 2018, Alexion announced an agreement to acquire Syntimmune. Pending relevant regulatory approvals, the acquisition is expected to close in the fourth quarter of 2018. The acquisition will add anti-FcRn antibody SYNT001 to the company's clinical pipeline. SYNT001 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 an undisclosed indication.
- **ALXN1810 - Subcutaneous:** Alexion initiated a Phase 1 study of subcutaneous ALXN1210 co-administered with Halozyme's ENHANZE® drug-delivery technology, PH20, in the third quarter of 2018. 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.

PRE-CLINICAL

- **Dicerna - GalXC™ :** In October 2018, Alexion began a collaboration with Dicerna Pharmaceuticals, Inc. 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.

2018 Financial Guidance

Alexion is increasing revenue guidance, non-GAAP operating margin guidance, and non-GAAP EPS guidance. Full guidance updates are outlined below.

	Previous (as of July 26, 2018)	Updated (as of October 24, 2018)
Total revenues	\$3,980 to \$4,010 million	\$4,020 to \$4,050 million
Soliris revenues	\$3,420 to \$3,440 million	\$3,460 to \$3,480 million
Metabolic revenues	\$560 to \$570 million	\$560 to \$570 million
R&D (% total revenues)		
GAAP	20% to 21%	18% to 19%
Non-GAAP	18% to 19%	16% to 17%
SG&A (% total revenues)		
GAAP	26% to 27%	26% to 27%
Non-GAAP	22% to 23%	22% to 23%
Operating margin		
GAAP	11% to 14%	0% to 5%
Non-GAAP	49% to 50%	51% to 52%
Earnings (loss) per share		
GAAP	\$1.25 to \$1.50	\$-0.08 to \$0.26
Non-GAAP	\$7.00 to \$7.15	\$7.45 to \$7.60

Updated 2018 financial guidance assumes the following:

- A foreign currency headwind, net of hedging activities, of approximately \$10 million.
- Unfavorable Soliris® revenue impact of \$90 to \$110 million from ALXN1210 and other clinical trial recruitment versus prior year.
- GAAP guidance reflects the preliminary financial impact of the announced agreement to acquire Syntimmune and the recently announced collaboration with Dicerna. Alexion expects to account for Syntimmune as an asset acquisition during the fourth quarter of 2018. In addition, non-GAAP financial guidance includes the preliminary impact of operating expenses for Syntimmune.
- GAAP effective tax rate of 70 to 150 percent impacted by non-deductible pre-tax acquisition charges; non-GAAP effective tax rate of 14 to 15 percent.

Alexion expects to incur additional restructuring and related expenses in 2018 of up to approximately \$125 million related to the Company's 2017 restructuring activities.

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 third quarter 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 5947065 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 the first and only approved complement inhibitor to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG). 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 two late-stage therapies, a second complement inhibitor and a copper-binding agent for Wilson disease. 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]

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995, including statements related to: updated guidance regarding anticipated financial results for 2018 (and the assumptions related to such guidance); the strength of our core business; plans to make future regulatory submissions for eculizumab and ALXN1210 and the timing related thereto (and that eculizumab could be the first approved therapy for patients with NMOSD); Soliris® in gMG is experiencing sustained growth; Company continues to look for additional business development opportunities and advancing internal programs to further long-term growth; timing for the initiation of clinical trials and the timing of expected receipt/release of results of clinical trials; the anticipated closing of, and closing date for, the acquisition of Syntimmune; potential benefits of current products and products under development and in clinical trials (including further extended dosing intervals); anticipated restructuring and related expenses in 2018; Alexion's future clinical, regulatory, and commercial plans for ALXN1210 and other product candidates; goal of building out the clinical pipeline; our strategy and plans; and potential of our commercial business and pipeline programs. 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®); future competition from biosimilars and other 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; 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 Soliris® in PNH, aHUS, gMG or other diseases 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 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 June 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: 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 equity securities without readily determinable fair values, litigation charges, gain or loss on sale of a business or asset and certain adjustments to income tax expense. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP, and should be reviewed in conjunction with the relevant GAAP financial measures. Please refer to the attached Reconciliations of GAAP to non-GAAP Financial Results and GAAP to non-GAAP 2018 Financial Guidance for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three and nine month periods ended September 30, 2018 and 2017 and projected twelve months ending December 31, 2018.

Prior year amounts may have been adjusted to conform to current year rounding presentation.

(Tables Follow)

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

	Three months ended		Nine months ended	
	September 30		September 30	
	2018	2017 ⁽¹⁾	2018	2017 ⁽¹⁾
Net product sales	\$ 1,026.5	\$ 858.8	\$ 3,001.6	\$ 2,640.1
Other revenue	—	0.3	0.8	1.3
Total revenues	1,026.5	859.1	3,002.4	2,641.4
Cost of sales	90.6	157.0	277.5	309.6
Operating expenses:				
Research and development	174.8	195.7	524.8	613.4
Selling, general and administrative	258.7	270.6	793.1	798.0
Acquired in-process research and development	—	—	803.7	—
Amortization of purchased intangible assets	80.0	80.0	240.1	240.1
Change in fair value of contingent consideration	53.5	3.7	110.9	31.8
Restructuring expenses	10.3	72.0	26.4	98.7
Impairment of intangible assets	—	—	—	31.0
Total operating expenses	577.3	622.0	2,499.0	1,813.0
Operating income	358.6	80.1	225.9	518.8
Other income and expense:				
Investment income	5.9	4.5	119.4	12.9
Interest expense	(24.6)	(25.0)	(73.7)	(73.3)
Other income (expense)	2.2	(1.4)	3.5	0.1
Income before income taxes	342.1	58.2	275.1	458.5
Income tax expense (benefit)	11.2	(19.8)	152.5	45.2
Net income	\$ 330.9	\$ 78.0	\$ 122.6	\$ 413.3
Earnings per common share				
Basic	\$ 1.48	\$ 0.35	\$ 0.55	\$ 1.84
Diluted	\$ 1.47	\$ 0.35	\$ 0.55	\$ 1.83
Shares used in computing earnings per common share				
Basic	222.9	223.3	222.5	224.1
Diluted	224.6	225.0	224.2	225.5

(1) Prior year amounts may have been adjusted to conform to current year rounding presentation.

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

	Three months ended September 30		Nine months ended September 30	
	2018	2017(8)	2018	2017(8)
GAAP net income	\$ 330.9	\$ 78.0	\$ 122.6	\$ 413.3
Before tax adjustments:				
Cost of sales:				
Share-based compensation	3.3	3.2	12.2	8.1
Fair value adjustment in inventory acquired	—	—	—	5.2
Restructuring related expenses (1)	—	83.0	5.8	83.0
Research and development expense:				
Share-based compensation	12.5	19.0	42.5	55.3
Upfront payments related to licenses and collaborations	—	—	—	9.4
Restructuring related expenses (1)	—	1.0	0.1	1.0
Selling, general and administrative expense:				
Share-based compensation	29.8	35.2	96.2	109.0
Restructuring related expenses (1)	7.9	6.4	18.0	6.4
Litigation charges (2)	—	—	7.1	—
Gain on sale of asset (3)	(3.5)	—	(3.5)	—
Acquired in-process research and development (4)	—	—	803.7	—
Amortization of purchased intangible assets	80.0	80.0	240.1	240.1
Change in fair value of contingent consideration (5)	53.5	3.7	110.9	31.8
Restructuring expenses (1)	10.3	72.0	26.4	98.7
Impairment of intangible assets	—	—	—	31.0
Investment income:				
Change in value of equity securities without readily determinable fair values (6)	—	—	(100.8)	—
Other income:				
Restructuring related expenses (1)	—	2.3	(0.1)	2.3
Adjustments to income tax expense (7)	(64.6)	(55.5)	(68.9)	(94.7)
Non-GAAP net income	<u>\$ 460.1</u>	<u>\$ 328.3</u>	<u>\$ 1,312.3</u>	<u>\$ 999.9</u>
GAAP earnings per common share - diluted	\$ 1.47	\$ 0.35	\$ 0.55	\$ 1.83
Non-GAAP earnings per common share - diluted	\$ 2.02	\$ 1.44	\$ 5.78	\$ 4.38
Shares used in computing diluted earnings per common share (GAAP)	224.6	225.0	224.2	225.5
Shares used in computing diluted earnings per common share (non-GAAP)	227.4	227.5	227.0	228.2

(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 September 30, 2018				Nine months ended September 30, 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	—	7.9	—	7.9	—	18.0	—	18.0
Restructuring Expense	2.8	—	7.5	10.3	6.9	—	19.5	26.4
Other (Income) Expense	—	—	—	—	—	—	(0.1)	(0.1)
	<u>\$ 2.8</u>	<u>\$ 7.9</u>	<u>\$ 7.5</u>	<u>\$ 18.2</u>	<u>\$ 6.9</u>	<u>\$ 23.9</u>	<u>\$ 19.4</u>	<u>\$ 50.2</u>

- (2) During the second quarter of 2018, we recorded \$7.1 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 three and nine months ended September 30, 2018.
- (4) During the second quarter of 2018, we completed the acquisition of Wilson Therapeutics AB. The acquisition was accounted for as an asset acquisition, as substantially all of the fair value of the gross assets acquired is concentrated in a single asset, WTX101, an early Phase III development asset. The value of the acquired in-process research and development asset related to WTX101 was expensed during the second quarter and nine months ended September 30, 2018 due to the stage of development of this asset.
- (5) The change in the expense associated with the fair value of contingent consideration for the three and nine months ended September 30, 2018, as compared to the same periods in 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) On January 1, 2018, we adopted a new standard that changes the accounting for equity investments and, as a result, we recognized an unrealized gain of \$100.8 million in investment income during the first quarter and nine months ended September 30, 2018, respectively, to adjust our investment in Moderna Therapeutics, Inc. 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.
- (8) Prior year amounts may have been adjusted to conform to current year rounding presentation.

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, 2018	
	Low	High
GAAP net (loss) income	\$ (17)	\$ 58
Before tax adjustments:		
Share-based compensation	215	200
Fair value adjustment of inventory acquired	—	—
Upfront payments related to licenses and collaborations	27	25
Acquired in-process research and development	1,204	1,204
Amortization of purchased intangible assets	320	320
Change in fair value of contingent consideration	111	111
Restructuring and related expenses	175	50
Change in value of equity securities without readily determinable fair values	(101)	(101)
Litigation charges	7	7
Gain on sale of asset	(4)	(4)
Adjustments to income tax expense	(247)	(146)
Non-GAAP net income	<u>\$ 1,691</u>	<u>\$ 1,725</u>
Diluted GAAP earnings (loss) per common share	\$ (0.08)	\$ 0.26
Diluted non-GAAP earnings per common share	\$ 7.45	\$ 7.60

Operating expense and margin (% total revenues)

GAAP research and development expense	19 %	18 %
Share-based compensation	1 %	1 %
Upfront payments related to licenses and collaborations	1 %	1 %
Restructuring related expenses	0 %	0 %
Non-GAAP research and development expense	<u>17 %</u>	<u>16 %</u>
GAAP selling, general and administrative expense	27 %	26 %
Share-based compensation	3 %	3 %
Restructuring related expenses	0 %	0 %
Litigation charges	0 %	0 %
Gain on sale of asset	0 %	0 %
Non-GAAP selling, general and administrative expense	<u>23 %</u>	<u>22 %</u>
GAAP operating margin	0 %	5 %
Share-based compensation	5 %	5 %
Upfront payments related to licenses and collaborations	1 %	1 %
Acquired in-process research and development	30 %	30 %
Litigation charges	0 %	0 %
Gain on sale of asset	0 %	0 %
Amortization of purchased intangible assets	8 %	8 %
Change in fair value of contingent consideration	3 %	3 %
Restructuring and related expenses	4 %	1 %
Non-GAAP operating margin	<u>51 %</u>	<u>52 %</u>
Income tax expense (% of income before income taxes)		
GAAP income tax expense	150 %	70 %
Tax effect of pre-tax adjustments to GAAP net income and adjustments to Q4 2017 tax reform provisional accounting	<u>(135)%</u>	<u>(56)%</u>
Non-GAAP income tax expense	<u>15 %</u>	<u>14 %</u>

Amounts may not foot due to rounding.

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

	Three months ended		Nine months ended	
	September 30		September 30	
	2018	2017(1)	2018	2017(1)
Soliris				
United States	\$ 404.5	\$ 307.6	\$ 1,136.3	\$ 913.5
Europe	262.1	248.4	766.3	738.3
Asia Pacific	98.2	81.8	277.3	241.4
Rest of World	123.2	117.6	406.4	459.0
Total Soliris	<u>\$ 888.0</u>	<u>\$ 755.4</u>	<u>\$ 2,586.3</u>	<u>\$ 2,352.2</u>
Strensiq				
United States	\$ 86.6	\$ 70.6	\$ 275.7	\$ 203.9
Europe	16.6	9.6	47.0	23.3
Asia Pacific	7.2	5.2	19.2	13.3
Rest of World	2.8	1.6	7.1	3.7
Total Strensiq	<u>\$ 113.2</u>	<u>\$ 87.0</u>	<u>\$ 349.0</u>	<u>\$ 244.2</u>
Kanuma				
United States	\$ 13.7	\$ 11.4	\$ 38.6	\$ 31.2
Europe	4.7	3.6	16.4	8.7
Asia Pacific	0.8	0.7	2.9	1.8
Rest of World	6.1	0.7	8.4	2.0
Total Kanuma	<u>\$ 25.3</u>	<u>\$ 16.4</u>	<u>\$ 66.3</u>	<u>\$ 43.7</u>
Net Product Sales				
United States	\$ 504.8	\$ 389.6	\$ 1,450.6	\$ 1,148.6
Europe	283.4	261.6	829.7	770.3
Asia Pacific	106.2	87.7	299.4	256.5
Rest of World	132.1	119.9	421.9	464.7
Total Net Product Sales	<u>\$ 1,026.5</u>	<u>\$ 858.8</u>	<u>\$ 3,001.6</u>	<u>\$ 2,640.1</u>

(1) Prior year amounts may have been adjusted to conform to current year rounding presentation.

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

	September 30 2018	December 31 2017(2)
Cash and cash equivalents	\$ 1,228.9	\$ 584.4
Marketable securities	306.2	889.7
Trade accounts receivable, net	910.2	726.5
Inventories	432.7	460.4
Prepaid expenses and other current assets	370.4	292.9
Property, plant and equipment, net	1,443.4	1,325.4
Intangible assets, net	3,713.6	3,954.4
Goodwill	5,037.4	5,037.4
Other assets	400.8	312.2
Total assets	<u>\$ 13,843.6</u>	<u>\$ 13,583.3</u>
Accounts payable and accrued expenses	\$ 592.0	\$ 710.2
Revolving credit facility	250.0	—
Current portion of long-term debt	61.2	167.4
Current portion of contingent consideration	95.8	—
Other current liabilities (1)	28.4	74.9
Long-term debt, less current portion	2,533.3	2,720.7
Contingent consideration	179.4	168.9
Facility lease obligation	361.2	342.9
Deferred tax liabilities	442.8	365.0
Other liabilities	129.8	140.2
Total liabilities	<u>4,673.9</u>	<u>4,690.2</u>
Total stockholders' equity (1)	<u>9,169.7</u>	<u>8,893.1</u>
Total liabilities and stockholders' equity	<u>\$ 13,843.6</u>	<u>\$ 13,583.3</u>

(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. We recognized this amount in revenue in the first quarter of 2018.

(2) Prior year amounts may have been adjusted to conform to current year rounding presentation.

Alexion Contacts:

Media

Megan Goulart, 857-338-8634
Senior Director, Corporate Communications

Investors

Susan Altschuller, Ph.D., 857-338-8788
Vice President, Investor Relations