

Alexion Pharmaceuticals Files Form 10-Q for Third Quarter 2016

- --The Audit and Finance Committee Concluded that the Company's Previously Issued Financial Results Do Not Require Restatement--
 - --Revenue and EPS for Full Year 2016 Expected to Be Within the Previously Guided Ranges--
 - --Alexion to Present at the 35th Annual J.P. Morgan Healthcare Conference on January 9th, 2017--
- --Alexion to Report Fourth Quarter and Full Year 2016 Results and Provide 2017 Guidance on February 16th, 2017--

NEW HAVEN, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals Inc. (NASDAQ:ALXN) announced today that it has filed with the Securities and Exchange Commission its Form 10-Q for the third quarter ended September 30, 2016. As previously announced, the Company had delayed the filing while the Audit and Finance Committee of the Board of Directors conducted an investigation stemming from allegations made by a former employee concerning certain of the Company's Soliris[®] (eculizumab) sales practices.

The Audit and Finance Committee concluded, based on the facts of the investigation, that the Company's previously issued financial results do not require restatement. In addition, no instances of improper revenue recognition associated with pull-in sales were identified, all Soliris orders were valid and placed by customers for patients in order to fulfill an actual need, and there were no instances where Soliris was sold to build stock of unwanted product. However, the Company concluded there was a material weakness in its internal controls over financial reporting that existed as of December 31, 2015 and subsequent quarters, caused by senior management not setting an appropriate tone at the top for an effective control environment.

David Brennan, Interim Chief Executive Officer of Alexion, said, "We are pleased to have filed the third quarter 2016 Form 10-Q and that the Audit and Finance Committee's investigation did not identify any facts requiring a restatement of previously issued financial results. We have already initiated remedial actions to maintain a strong internal control environment and are committed to setting a tone at the top that is fully aligned with our ethical standards and values. Importantly, the Alexion team is as passionate as ever about fulfilling our mission of serving patients with rare and devastating diseases and the outlook for Alexion is strong."

Investigation Findings

The Audit and Finance Committee investigation focused primarily on "pull-in" sales of Soliris, which are certain Soliris sales transactions, coordinated by Company personnel (primarily personnel in the customer operations department in their capacity as coordinators for the shipment of orders for customers), that increase revenue recognized in an earlier fiscal quarter than the one in which a sale otherwise would have occurred. Pull-in sales may occur, for example, when a customer, as a result of encouragement by an employee, places an order for a patient earlier than the customer might otherwise place the order. Pull-in sales are not inherently problematic or impermissible when executed in accordance with Company policies and procedures, and in accordance with U.S. Generally Accepted Accounting Principles (GAAP). The investigation reviewed the reasons for pull-in sales, whether such transactions were conducted in accordance with the Company's policies and procedures, and whether revenue from pull-in sales was properly recognized in accordance with GAAP.

The Audit and Finance Committee investigation did not identify any instances of improper revenue recognition associated with pull-in sales, instances where Soliris orders were not placed by customers for patients in order to fulfill an actual need, or instances where Soliris was sold to build stock of unwanted product. However, the investigation found that certain revenue pulled in from the first quarter of 2016 into the fourth quarter of 2015 was realized by employee actions that involved inappropriate business conduct, including violations of Company policies and procedures. The estimated total pull-in sales for the fourth quarter of 2015 represented less than 1% of total revenue for 2015. During the past two completed fiscal years and through the third quarter of 2016, but excluding the fourth quarter of 2015, pull-in sales were, in the aggregate, estimated to be 0% to 1% of total revenue.

To address the issues identified, the Company is undertaking a series of remedial actions including, but not limited to, expanded training programs and implementing new processes related to financial reporting, controls and compliance. Together with other process and procedure changes, management believes the material weakness will be effectively

remediated during 2017.

After evaluating the findings of the investigation, management, including the Company's new Interim Chief Executive Officer and new Chief Financial Officer, has concluded that the consolidated financial statements included in the Form 10-Q present fairly, in all material respects, the Company's financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

In addition to the Form 10-Q for the third quarter 2016, in January 2017 the Company intends to file an Amended Form 10-K for the fiscal year ended December 31, 2015 to reflect that its disclosure controls and procedures were not effective as of December 31, 2015, and that a material weakness existed, but this will not require a restatement of previously reported financial results, as noted above.

Corporate Outlook

Alexion will report 2016 results on February 16, 2017 and will also discuss its outlook for the year and provide guidance at that time.

The Company expects 2016 revenues to be within the previously guided range of \$3.05 to \$3.10 billion.

Alexion also expects 2016 GAAP EPS to be within the previously guided range of \$1.79 to \$2.09 per share and 2016 non-GAAP EPS to be within the previously guided range of \$4.50 to \$4.65 per share. Both GAAP and non-GAAP EPS guidance reflects a preliminary estimate of the legal, accounting, and other costs associated with the investigation, as well as employee separation costs.

Alexion's 2016 financial guidance does not include the effect of business combinations, license and collaboration agreements, asset acquisitions, intangible asset impairments, changes in fair value of contingent consideration, restructuring activity, or discrete tax items that may have occurred subsequent to October 27, 2016. GAAP guidance excludes expenses associated with the Company's annual impairment assessment of a clinical stage in-process research and development asset. Please refer to the Company's reconciliation of GAAP to non-GAAP 2016 financial guidance included in the table below.

Alexion plans to present at the 35th Annual J.P. Morgan Healthcare Conference in San Francisco on Monday, January 9, 2017.

About Alexion

Alexion is a global biopharmaceutical company focused on developing and delivering life-transforming therapies for patients with devastating and rare disorders. Alexion developed and commercializes Soliris[®] (eculizumab), the first and only approved complement inhibitor to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), two life-threatening ultra-rare disorders. As the global leader in complement inhibition, Alexion is strengthening and broadening its portfolio of complement inhibitors, including evaluating potential indications for eculizumab in additional severe and ultra-rare disorders. Alexion's metabolic franchise includes two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare disorders, Strensiq[®] (asfotase alfa) to treat patients with hypophosphatasia (HPP) and Kanuma[®] (sebelipase alfa) to treat patients with lysosomal acid lipase deficiency (LAL-D). In addition, Alexion is advancing the most robust rare disease pipeline in the biotech industry with highly innovative product candidates in multiple therapeutic areas. This press release and further information about Alexion can be found at: www.alexion.com.

[ALXN-G]

Forward-looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements often include words such as "anticipate," "believe," "expect," "will," or similar expressions. A number of important factors could cause actual results of the Company to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, (i) risks related to potential disruptions to our business as a result of the leadership changes and transition, (ii) the risk that hiring a new CEO may take longer than anticipated, (iii) legal proceedings and government investigations relating to the subject of the Audit and Finance Committee's investigation or related matters, and (iv) the risk factors detailed in Part I, Item 1A, "Risk Factors," of the Company's Annual Report on Form 10-K and the Company's Quarterly Reports on Form 10-Q, and other risk factors identified herein or from time to time in the Company's

periodic filings with the SEC. The Company therefore cautions you against relying on these forward-looking statements. All forward-looking statements attributable to the Company or persons acting on the Company's behalf are expressly qualified in their entirety by the foregoing cautionary statements. All such statements speak only as of the date made, and, except as required by law, the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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 projected 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, acquisition-related costs, restructuring expenses, upfront and milestone payments related to licenses and collaborations and adjustments to income tax expense. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP and should be reviewed in conjunction with the relevant GAAP financial measures. Please refer to the attached Reconciliation of GAAP to non-GAAP 2016 Financial Guidance for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the projected twelve months ended December 31, 2016.

ALEXION PHARMACEUTICALS, INC. TABLE 1: RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL GUIDANCE (in millions, except per share amounts) (unaudited)

	Twelve months ended December 31, 2016			
	Low		High	
GAAP net income	\$	408	\$	477
Before tax adjustments:				
Cost of sales:				
Share-based compensation		12		10
Fair value adjustment in inventory acquired		12		10
Research and development expense:				
Share-based compensation		65		55
Upfront and milestone payments related to licenses and collaborations		26		5
Selling, general and administrative expense:				
Share-based compensation		145		123
Amortization of purchased intangible assets		322		322
Change in fair value of contingent consideration		36		36
Acquisition-related costs		2		2
Restructuring expenses		2		2
Adjustments to income tax expense		5		28
Non-GAAP net income	\$	1,035	\$	1,070
Diluted GAAP earnings per share	\$	1.79	\$	2.09
Diluted Non-GAAP earnings per share	\$	4.50	\$	4.65
Shares used in computing diluted earnings per share (GAAP)		228		228
Shares used in computing diluted earnings per share (non-GAAP)		230		230

View source version on <u>businesswire.com</u>: <u>http://www.businesswire.com/news/home/20170104006504/en/</u>

Stephanie Fagan, 475-230-3777
Senior Vice President, Corporate Communications or
Kim Diamond, 475-230-3775
Executive Director, Corporate Communications or
Investors
Elena Ridloff, CFA, 475-230-3601
Vice President, Investor Relations

Source: Alexion Pharmaceuticals Inc.

News Provided by Acquire Media