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ALEXION PHARMACEUTICALS, INC. Form 10-K February 06, 2019 UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-K

x Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2018 or "Transition report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 For the transition period from to Commission file number: 0-27756 ALEXION PHARMACEUTICALS, INC. (Exact Name of Registrant as Specified in Its Charter) Delaware 13-3648318 (State or Other Jurisdiction of Incorporation or Organization)(I.R.S. Employer Identification No.)

121 Seaport Boulevard, Boston Massachusetts 02210

(Address of Principal Executive Offices) (Zip Code) 475-230-2596 (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value \$0.0001

Name of each exchange on which registered: The Nasdaq Stock Market LLC Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No "

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes "No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No "

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. Check One:

Large accelerated filer x Accelerated filer "Non-accelerated filer "Smaller reporting company "Emerging growth company "

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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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes "No x

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on The Nasdaq Stock Market LLC on June 29, 2018, was \$26,514,235,288.⁽¹⁾ The number of shares of Common Stock outstanding as of January 31, 2019 was 223,469,381.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be used in connection with its 2019 Annual Meeting of Stockholders currently anticipated to be held on May 14, 2019, are incorporated by reference into Part III of this report.

(1) Excludes 9,186,789 shares of common stock held by directors, executive officers and their respective affiliates at June 29, 2018. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

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PART I

Unless the context requires otherwise, references in this report to "Alexion," the "Company," "we," "our" or "us" refer to Alexion Pharmaceuticals, Inc. and its subsidiaries.

Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. Words such as "anticipates," "may," "forecasts," "expects," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such statements. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding:

the potential benefits and commercial potential of UTLOMIRISTM, SOLIRIS[®], STRENSIQ[®] and KANUMA[®] for approved indications and any expanded uses, sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, timing regarding development and regulatory approvals for additional indications or in additional territories;

plans for clinical trials (and proof of concept trials), status of our ongoing clinical trials for our product candidates, commencement dates for new clinical trials, clinical trial results and evaluation of our clinical trial results by regulatory agencies;

potential benefits offered by product candidates, including improved dosing intervals;

the medical and commercial potential of additional indications for our products;

the expected timing for the completion and/or regulatory approval of our facilities and facilities of our third-party manufacturers;

future expansion of our commercial organization;

future governmental and regulatory decisions regarding pricing (and discounts) and the adoption, implementation and interpretation of healthcare laws and regulations (and the impact on our business);

plans and prospects for future regulatory approval of products and product candidates;

competitors, potential competitors and future competitive products (including biosimilars);

plans to grow our product pipeline (and diversify our business, including through acquisitions) and anticipated benefits to the Company;

future objective to expand business and sales;

future plans to retain earnings and not pay dividends;