# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

### FORM 10-Q

X Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange
- Act of 1934: For the quarterly period ended January 31, 1997

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- - 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

(State or other jurisdiction of incorporation or organization)

25 SCIENCE PARK, SUITE 360, NEW HAVEN, CONNECTICUT 06511

(Address of principal executive offices) (Zip Code)

203-776-1790

(Registrant's telephone number, including area code)

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 \_\_\_

CLASS

OUTSTANDING AT MARCH 5, 1997

Common Stock, \$0.0001 par value 7,361,721

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ALEXION PHARMACEUTICALS, INC. (A Development Stage Company)

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### BALANCE SHEETS

	January 31, 1997	July 31, 1996
ASSETS	(UNAUDITED)	
Current Assets:		
Cash and cash equivalents	\$8,634,750	\$9,491,217
Marketable securities	6,762,296	9,106,534
Prepaid expenses	231,728	466,731
Total current assets	15,628,774	19,064,482
Equipment, net of accumulated		
depreciation and amortization	733,499	592,271
Other Assets:		
License technology rights, net	286,366	330,365
Patent application costs, net	189,951	194,004
Organization costs, net	0	5,280
Security deposits and other assets	264,853	267,578
Total other assets	741,170	797,227
TOTAL ACCETO	047 400 440	
TOTAL ASSETS	\$17,103,443 =======	\$20,453,980 =======
LIARTHITTES AND STOCKHOLDERS! FOULTY		
LIABILITIES AND STOCKHOLDERS' EQUITY Current Liabilities;		
Current portion of notes payable	\$276,566	\$322,508
Current obligations under capital leases	21,307	28,593
Accounts payable	366,867	280,913
Accrued expenses		400 E77
Deterred revenue	464,006 131,067	1,000,000
Total current liabilities	1,259,813	2,032,591
Notes Payable, less current portion included above	0	128,264
Obligations under Comital Large lass		
Obligatiors under Capital Leases, less current portion included above	913	8,200
·		
Stockholders' Equity:		
Series A convertible preferred stock \$.0001 par value; 5,000,000 shares authorized; no shares issued and	Θ	Θ
outstanding at January 31,1997 and July 31,1996 Common stock \$.0001 par value; 25,000,000 shares authorized; 7,371,896 and 7,334,909 shares issued at January 31,1997 and July 31,1996	737	733
Additional paid-in capital	43,030,577	42,858,975
Deficit accumulated during development stage	(27, 188, 495)	(24,574,681)
Deferred offering costs	0	0
Treasury stock, at cost; 11,875 shares	(102)	(102)
Total stockholders' equity	15,842,717	18,284,925
TOTAL LIABILITIES AND NET EQUITY	\$17,103,443 =======	\$20,453,980 =======

See accompanying notes to financial statements

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# Statements of Operations (UNAUDITED)

	Three months er	ided January 31,	Six months ended January 31,		January 28,1992 (inception)
	1997	1996	1997	1996	through January 31, 1997
CONTRACT RESEARCH REVENUES	\$ 1,437,984	\$ 616,485	\$ 2,248,739	\$ 1,069,913	\$ 5,025,069
OPERATING EXPENSES:					
Research and Development General and Administrative	1,921,113 758,306	1,362,727 395,776	3,895,051 1,407,361	2,771,536 749,845	25,049,879 8,098,227
Total Operating Expenses	2,679,419	1,758,503		3,521,381	33,148,106
OPERATING LOSS OTHER INCOME (EXPENSE), Net	(1,241,435) 205,231	(1,142,018) 9,196	(3,053,673) 439,859	(2,451,468) 32,387	(28,123,037) 934,542
NET LOSS	(\$1,036,204) =======	(\$1,132,822) =======	(\$2,613,814) =======	(\$2,419,081) =======	(\$27, 188, 495) ========
NET LOSS PER COMMON SHARE (Note 3)	(\$0.14) ======	(\$0.25) ======	(\$0.36) ======	(\$0.54) ======	
SHARES USED IN COMPUTING NET LOSS PER COMMON SHARE	7,341,939 =======	4,515,926 ======	7,335,173 ======	4,513,990 =======	

See accompanying notes to financial statements.

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# Statements of Cash Flows (UNAUDITED)

	Six months end	through		
	1997	1996	January 31,1997	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net Loss Adjustments to reconcile net loss to net cash used in operating activities:	(\$2,613,814)	(\$2,419,081)	(\$27,188,495)	
Depreciation and amortization Compensation expense related to grant of stock options Net realized loss (gain) on marketable securities Change in assets and liabilities:			2,765,077 122,500 45,390	
Prepaid expenses Accounts payable Accrued expenses Deferred revenue	235,003 85,954 63,429 (868,933)	(112,825) (243,242) (40,931) (160,500)	(231,728) 366,867 464,006 131,067	
	(2.720.000)	(2, 520, 016)	(22 525 246)	
Net cash used in operating activities	(2,730,860)	(2,539,816)	(23,525,316)	
CASH FLOWS FROM INVESTING ACTIVITIES:  (Purchases of) Proceeds from marketable securities, net Proceeds from marketable securities	2,363,941 0	0 0	(6,753,824) 0	
(Purchases of) Proceeds from marketable securities, net Proceeds from marketable securities Purchases of equipment Licensed technology costs Patent application costs Organization costs  Net cash (used in) provided by investing activities	(434,394) 0 (21,003)	(141,631) 0 (29,855)	(2,607,137) (615,989) (356,807)	
Organization costs	0	0	(63,530)	
Net cash (used in) provided by investing activities	1,908,544	(171, 486)	(10,397,287)	
CASH FLOWS FROM FINANCING ACTIVITIES:				
Net proceeds from issuance of preferred and common stock Deferred offering costs Advances from stockholder Repayments of capital lease obligations Borrowings under notes payable	151,903 0	6,591 (119,198)	41,701,586	
Repayments of capital lease obligations Borrowings under notes payable	(14,573) 0	(52,559) 0	(355,844) 1,179,135	
Repayments of notes payable Security deposits and other assets Repurchase of common stock	(174,206) 2,725 0	(157,506) (12,350) 0	1,179,135 (902,569) (264,853) (102)	
Net cash provided by (used in) financing activities	(34,151)	(335,022)	42,557,353	
NETINCREASE(@ECREASE)IN CASH CASH at beginning of period	(856,467) 9,491,217	(3,046,324) 5,079,212	8,634,750 0	
CASH AT END OF PERIOD	\$8,634,750	\$2,032,888	\$8,634,750 ======	
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION Cash paid (refunded) for income taxes	(\$7,950)	\$0	\$22,734	
Cash paid fer interest expense	\$30,395	\$57,954	\$436,360	
SUPPLEMENTAL DISCLOSURE OF NONCASH FINANCING ACTIVITIES Conversion of advances from stockholder info common stock	<b>======</b> \$0	======= \$0	\$1 200 000	
Equipment acquired pursuant to capital lease obligations	======= \$0 =======	======== \$0 ========	\$378 064 =======	
Deferred offering costs accrued	\$0 ======	\$226,930 ======	\$0 ======	

See accompanying notes to financial statements  $% \left( x\right) =\left( x\right) +\left( x\right) +\left($ 

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## NOTES TO FINANCIAL STATEMENTS (Unaudited)

### 1. Operations and Basis of Presentation -

Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") was organized in January 1992 and is engaged in the research and development of proprietary immunoregulatory compounds for the treatment of cardiovascular disorders (perioperative bleeding and inflammation associated with cardiopulmonary bypass, myocardial infarction, and stroke) and autoimmune diseases (lupus nephritis, rheumatoid arthritis, multiple sclerosis). As an outgrowth of its core technologies, the Company is developing, in collaboration with third parties (see Note 5), non-human organ ("xenograft" organs) products designed for transplantation into humans without clinical rejection and immunoprotected retroviral vectors and producer cells for gene therapy.

The Company is in the development stage and is devoting substantially all of its efforts toward product research and development. The Company has incurred losses since inception and has cumulative net losses of approximately \$27.2 million through January 31, 1997. The Company has made no product sales to date and has recognized cumulative revenues from research support funding and licensing aggregating \$5.0 million through January 31, 1997. During 1996, the Company completed an initial public offering ("IPO") of 2,530,000 shares of common stock resulting in net proceeds of approximately \$18.4 million (see Note 6). In addition, the Company has received various grants to fund certain research activities (see Note 5).

The Company will need additional financing to obtain regulatory approvals, fund early operating losses, and, if deemed appropriate, establish a manufacturing, sales, and marketing capability. In addition to normal risks associated with development stage companies, there can be no assurance that the Company's research and development will be successfully completed, that adequate patent protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. In addition, the Company operates in an environment of rapid change in technology, substantial competition from pharmaceutical and biotechnology companies and is dependent upon the services of its employees and its consultants.

The Company expects to incur substantial expenditures in the foreseeable future for the research and development and commercialization of its products. The Company will require funds in addition to those previously described, which it will seek to raise through public or private equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. The Company has no banking or other capital sources and no arrangements or commitments with regards to obtaining any further funds.

The financial statements included herein have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and include, in the opinion of management, all adjustments, consisting of normal, recurring adjustments, necessary for a fair presentation of interim period results. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The results for the interim periods presented are not necessarily indicative of results to be expected for any future period. It is suggested that these condensed financial

### NOTES TO FINANCIAL STATEMENTS (Unaudited)

statements be read in conjunction with the audited financial statements and notes thereto included in the Company's Form 10-K Annual Report for the fiscal year ended July 31, 1996.

#### 2. Cash and Cash Equivalents and Marketable Securities -

Cash and cash equivalents are stated at cost, which approximates market, and include short-term highly liquid investments with original maturities of less than three months.

The Company invests in marketable securities of highly rated financial institutions and investment-grade debt instruments and limits the amount of credit exposure with any one entity. The Company follows Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Pursuant to this Statement, the Company has classified its marketable securities as "available for sale" and, accordingly, carries such securities at aggregate fair value. Unrealized gains or losses are included in stockholders' equity as a component of additional paid-in capital.

#### 3. Net Loss Per Share -

Net loss per common share is computed using the weighted average number of common shares outstanding during the period. Common equivalent shares from stock options and warrants are excluded from the computation as their effect is antidilutive, except pursuant to the requirements of the SEC. Pursuant to these requirements, common stock issued by the Company during the 12 months immediately preceding the initial public offering, plus shares of common stock which became issuable during the same period pursuant to the grant of common stock options and warrants, have been included in the calculation of weighted average number of common shares outstanding for the period from August 1, 1995 to January 31, 1996 using the treasury stock method. The inclusion of additional shares assuming the conversion of Series A convertible preferred stock into common stock would have been antidilutive for all periods presented and, accordingly, has been excluded from the computation of net loss per common share.

### 4. Revenue Recognition -

Contract research revenues are recognized as the related work is performed under the terms of the contracts and expenses for development activities are incurred. License fee payments are recognized as revenue upon receipt. Any revenue contingent upon future funding by the Company is deferred and recognized as the future funding is expended. Any revenues resulting from the achievement of milestones would be recognized when the milestone is achieved.

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### NOTES TO FINANCIAL STATEMENTS (Unaudited)

#### 5. Contract Research and License Fee Revenues -

Contract research revenues recorded by the Company consist of: (1) research and development support under separate collaborations with United States Surgical Corporation ("US Surgical") and Genetics Therapy Inc. ("GTI/Novartis"), a wholly owned subsidiary of Novartis; (2) Small Business Innovation Research ("SBIR") grants awarded in July and September 1995 from the National Institutes of Health ("NIH"), and (3) funding from the Commerce Department's National Institute of Standards and Technology ("NIST").

License fee revenues represent non-refundable payments received in accordance to contractural agreements for various access and rights to the Company's technologies, research, potential products and markets.

In January 1997, the Company announced that it had entered into an agreement with GTI/Novartis. The Company granted to GTI/Novartis exclusive worldwide rights to use the Company's technology to develop and market immunoprotected retroviral gene therapy products for direct in vivo gene therapy. Terms of the agreement call for the Company to receive upfront license fees, research payments and milestone payments totaling up to \$10 million. In addition, the Company would also receive royalties on net sales of such products.

In September 1995, the Company was awarded a Phase II SBIR grant for approximately \$750,000 over two years from the NIH to support research and clinical development of the Company's product to treat complications of cardiovascular surgery.

In August 1995, the Company was awarded funding from NIST under its Advanced Technology Program ("ATP"). Through the ATP, the Company may receive up to approximately \$2 million over three years to support the Company's UniGraft program in universal donor organs for transplantation.

In July 1995, the Company entered into a research and development agreement with US Surgical. US Surgical agreed to fund preclinical development of the Company's xenotransplant products in return for exclusive worldwide manufacturing, marketing and distribution rights of such products by paying the Company up to \$7.5 million allocated as follows: (1) up to \$4.0 million of the cost of preclinical development in four semi-annual installments of up to \$1.0 million (the first installment of which was paid on July 31, 1995), and (2) \$3.5 million upon achieving certain milestones. In furtherance of this joint collaboration, US Surgical also purchased \$4.0 million of the Company's common stock.

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# NOTES TO FINANCIAL STATEMENTS (Unaudited)

### 6. Initial Public Offering -

During fiscal year 1996, the Company completed an initial public offering of 2,530,000 shares of common stock at a price of \$8.25 per share of common stock, par value of \$0.0001, resulting in net proceeds of approximately \$18.4 million. In connection with the Company's IPO, the preferred stockholders converted all of their shares into 794,554 shares of common stock.

In connection with the Company's public offering, the Company sold to its underwriter for nominal consideration, warrants to purchase from the Company 220,000 shares of common stock. These warrants are initially exercisable at a price of \$9.90 per share for a period of forty-two (42) months commencing on August 27, 1997.

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## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report contains forward looking statements which involve risks and uncertainties. Such statements are subject to certain factors and uncertainties which may cause the Company's plans to differ. Factors and uncertainties that may cause such differences include, but are not limited to, the rate of progress, if any, of the Company's research and development programs, the Company's ability to compete successfully, the Company's ability to attract and retain qualified personnel, the Company's ability to successfully enter into collaborations with third parties, the Company's ability to enter into and progress in clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in obtaining and enforcing patents and any necessary licenses, the ability of the Company to establish development and commercialization relationships and strategic alliances with third parties, the cost of manufacturing, the Company's ability to obtain additional funds, and those other risks discussed in the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 1996.

### OVERVIEW

Since its inception in January 1992, Alexion has devoted substantially all of its resources to its drug discovery, research and product development programs. To date, the Company has not received any revenues from the sale of products. The Company has been unprofitable since inception, and expects to incur substantial and increasing operating losses for the next several years due to expenses associated with product research and development, preclinical and clinical testing, regulatory activities and manufacturing development and scale-up. For the period from inception to January 31, 1997, the Company incurred a cumulative net loss of approximately \$27.2 million.

The Company's plan is to develop and commercialize on its own those product candidates for which the clinical trial and marketing requirements can be funded by the Company. For certain of the Company's C5 Inhibitor and Apogen products for which greater resources will be required, Alexion's strategy is to form corporate partnerships with major pharmaceutical companies for product development and commercialization. While there can be no assurance as to the terms of future corporate partnerships, if any, for licensed applications, a corporate partner would likely be expected to bear the substantial cost and much of the manpower-intensive effort of clinical development, scale-up production, seeking U.S. Food and Drug Administration ("FDA") approval and marketing. Alexion has entered into strategic alliances with United States Surgical Corporation ("US Surgical") with respect to the Company's UniGraft program and with Genetics Therapy Inc. ("GTI/Novartis"), a wholly-owned subsidiary of Novartis, with respect to the Company's immunoresistant retroviral vector program. The Company intends to seek additional strategic alliances with major pharmaceutical companies.

The Company recognizes research and development revenues when the development expenses are incurred and the related work is performed under the terms of the contracts. Any revenue contingent upon future funding by the Company is deferred and recognized as the future funding is expended. Any revenues resulting from the achievement of milestones would be recognized when the milestone is achieved.

#### RESULTS OF OPERATIONS

Three Months Ended January 31, 1997 Compared with Three Months Ended January 31, 1996

The Company's contract research and license revenues increased to \$1,438,000 for the three months ended January 31, 1997 from \$616,000 for the same period ended January 31, 1996. This increase was due primarily to the receipt of an upfront license fee from GTI/Novartis. Contract research revenues represent principally the Company's collaborative research and development agreements with US Surgical and GTI/Novartis and the Company's research grants from the National Institutes of Health ("NIH") and the Commerce Department's National Institute of Standards and Technology ("NIST").

Research and development expenses increased to \$1,921,000 for the three months ended January 31, 1997 from \$1,362,000 for the three months ended January 31, 1996. The increase resulted principally from incurred costs related to the clinical trials of the Company's lead C5 Inhibitor, 5G1.1-SC, manufacturing validation costs, expanded preclinical development and manufacturing process development costs for the Company's recombinant product candidates, and increased external research related to preclinical development of the Company's xenotransplant products.

General and administrative related expenses increased to \$758,000 for the three months ended January 31, 1997 from \$396,000 for the same period ended January 31, 1996. This increase was due principally to a concentration of patent related activities in this quarter plus increased external professional services, costs related to investor and shareholder relations and insurance costs as a public company, business development, recruiting, and increased travel and administrative expenses related to the Company's increased clinical and regulatory activities and presentations at scientific conferences.

The Company earned other income, net, of \$205,000 for the three months ended January 31, 1997 as compared to other income, net, of \$9,000 for the three months ended January 31, 1996. This other income, net, resulted principally from greater interest income from higher cash balances available for investment and decreased interest expense associated with maturing notes payable and maturing capital equipment leases used to finance the purchase of certain equipment.

As a result of the above factors, the Company incurred a net loss of \$1,036,000 for the three months ended January 31, 1997 as compared to a net loss of \$1,133,000 for the same three month period in 1996.

Six Months Ended January 31, 1997 Compared with Six Months Ended January 31, 1996

The Company's earned contract research and license revenues increased to \$2,249,000 for the six months ended January 31, 1997 from \$1,070,000 for the six months ended January 31, 1996. The increase was primarily due to the receipt of an upfront license fee received from GTI/Novartis.

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During the six months ended January 31, 1997 and 1996, the Company expended \$3,895,000 and \$2,772,000, respectively on research and development activities. The increase of 41% or \$1,123,000 resulted principally from costs incurred related to the clinical trials of the Company's lead C5 Inhibitor, 5G1.1-SC, manufacturing validation costs, expanded preclinical development and manufacturing process development costs for the Company's recombinant product candidates, and increased external research related to preclinical development of the Company's xenotransplant products.

General and administrative expenses increased to \$1,407,000 for the six months ended January 31, 1997 from \$750,000 for the six months ended January 31, 1996. The increase was due principally to the high level of patent related activities in the most recent three months plus increased external professional services related to investor and shareholder relations and insurance costs as a public company, business development, recruiting, legal fees, and increased travel and administrative expenses related to the Company's increased clinical and regulatory activities and presentations at scientific conferences.

Other income, net was \$440,000 for the six months ended January 31, 1997 as compared to other income, net of \$32,000 for same period a year ago. This other income, net was due primarily to greater interest income from higher cash balances available for investment.

As a result of the above factors, the Company's net loss increased to \$2,642,000 from \$2,419,000 for the six months ended January 31, 1997 and 1996, respectively.

### LIQUIDITY AND CAPITAL RESOURCES

Since its inception, the Company has financed its operations and capital expenditures primarily through private placements and its initial public offering of equity securities resulting in aggregate net proceeds of approximately \$41.7 million. The Company has financed the purchase of certain equipment through \$1.2 million of secured notes payable to a financing institution and \$378,000 of capital lease obligations. Through January 1997, the Company has received approximately \$3.9 million in research and development support and license fees under its collaborations with US Surgical and GTI/Novartis. The Company has also received \$711,000 from its SBIR grants from the NIH and \$516,000 under the ATP from NIST, respectively, through January 1997.

The proceeds of the Company's initial public offering, private placements, notes payable and capital leases, and the cash generated from the corporate collaborations and SBIR and ATP grants have been used to fund operating activities of approximately \$23.5 million and investments of approximately \$2.6 million in equipment and approximately \$973,000 in licensed technology rights and patents through January 31, 1997. During the six months ended January 31, 1997 and January 31, 1996, the Company's capital expenditures totaled \$434,000 and \$142,000, respectively, primarily for the acquisition of laboratory and manufacturing scale-up equipment. As of January 31, 1997, the Company had cash, cash equivalents and marketable securities of approximately \$15.4 million.

The Company leases its administrative and research and development facilities under three operating leases expiring in June 1998, December 1997, and March 1999, respectively, each with an option for up to an additional three years.

The Company anticipates that its existing available capital resources and interest earned on available cash and marketable securities should be sufficient to fund its operating expenses and capital requirements as currently planned for at least the next twelve months. The Company's future capital requirements will depend on many factors, the progress of the Company's research and development programs, progress in clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in obtaining and enforcing patents and any necessary licenses, the ability of the Company to establish development and commercialization relationships, and the costs of manufacturing scale-up.

The Company expects to incur substantial additional costs, including costs associated with research, preclinical and clinical testing, manufacturing process development, contract manufacturing, and additional capital expenditures associated with facility expansion and manufacturing requirements in order to commercialize its products currently under development. The Company will need to raise substantial additional funds through additional financings including public or private equity offerings and collaborative research and development arrangements with corporate partners. There can be no assurance that funds will be available on terms acceptable to the Company, if at all, or that discussions with potential collaborative partners will result in any agreements. The unavailability of additional financing could require the Company to delay, scale back or eliminate certain of its research and product development programs or to license third parties to commercialize products or technologies that the Company would otherwise undertake itself, any of which could have a material adverse effect on the Company.

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- PART II. OTHER INFORMATION
- Item 5. Other Information.
- Item 6. Exhibits and Reports on Form 8-K

Exhibits

10.1 License and Collaborative Research Agreement between Alexion Pharmaceuticials, Inc. and Genetic Therapy, Inc. (Incorporated by reference from the Company's Registration Statement on Form S-1 (File No. 333-19905) (Confidential Treatment has been requested for portions of such Exhibit)

Form 8-K

Form 8-K filed on February 21, 1997 relating to the adoption of a Shareholder Rights Plan.  $\,$ 

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### **SIGNATURES**

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 thereunto duly authorized.

### ALEXION PHARMACEUTICALS, INC.

Date: March 13, 1996 By: /s/ LEONARD BELL, M.D.

Leonard Bell, M.D.

President and Chief Executive Officer, Secretary and Treasurer (principal

executive officer)

Date: March 13, 1996 By: /s/ DAVID W. KEISER

David W. Keiser

Executive Vice President and Chief Operating Officer (principal

financial officer)

By: /s/ BARRY P. LUKE Date: March 13, 1996

Barry P. Luke

Senior Director of Finance and

Administration (principal accounting

officer)

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