

ALEXION PHARMACEUTICALS INC
Form S-8
October 14, 2004
Table of Contents

As filed with the Securities and Exchange Commission on October 14, 2004

Registration No. 333-_____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-8
REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction)

13-3648318
(IRS Employer Identification No.)

(of incorporation or organization)

352 Knotter Drive, Cheshire, CT
(Address of Principal Executive Offices)

06410
(Zip Code)

Alexion Pharmaceuticals, Inc. 2000 Stock Option Plan

Alexion Pharmaceuticals, Inc. 1992 Stock Option Plan for Outside Directors

(Full title of the plan)

Thomas I.H. Dubin, Esq.

Vice President and General Counsel

Alexion Pharmaceuticals, Inc.

352 Knotter Drive

Cheshire, Connecticut 06410

(203) 272-2596

Copies to:

Merrill M. Kraines, Esq.

Lawrence A. Spector, Esq.

Fulbright & Jaworski L.L.P.

666 Fifth Avenue

New York, New York 10103-3198

(212) 318-3000

(Name, address, and telephone number, including area code, of agent for service)

CALCULATION OF REGISTRATION FEE

Title of securities to be registered	Amount to be registered (2)(3)	Proposed maximum offering price per share (4)	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, \$.0001 par value per share (1)	1,000,000	\$17.64	\$17,640,000	\$2,236

(1) All shares of common stock of the registrant carry rights to purchase Junior Participating Cumulative Preferred Stock, par value \$1.00 per share. Such purchase rights are attached to and trade with the common stock. Value attributable to such rights, if any, is reflected in the market price of the common stock.

(2) In addition, pursuant to Rule 416(c) under the Securities Act of 1933, as amended, this registration statement also covers an indeterminate amount of interests to be offered or sold pursuant to the employee benefit plans described herein.

(3)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form S-8

Pursuant to Rule 429 of the Securities Act of 1933, as amended, the prospectus contained herein also relates to: (i) 1,500,000 shares of Common Stock previously registered on Registration Statement No. 333-69478 issued or issuable under the Alexion Pharmaceuticals, Inc. 2000

Table of Contents

Stock Option Plan (the 2000 Plan) and (ii) 1,250,000 shares previously registered on Registration Statement No. 333-106854 issuable under the 2000 Plan and the Alexion Pharmaceuticals 1992 Stock Option Plan for Outside Directors. Registration fees were previously paid for shares registered on Registration Statement Nos. 333-69478 and 333-106854, filed on September 14, 2001 and July 7, 2003, respectively.

- (4) Computed in accordance with Rule 457(h)(1) based on the average of the high and low prices of the Common Stock as quoted on the Nasdaq National Market on October 13, 2004 of \$17.64 per share.

EXPLANATORY NOTE

As permitted by Rule 429 of the Securities Act of 1933, as amended, the prospectus filed together with this registration statement on Form S-8 is a combined resale prospectus which shall be deemed a post-effective amendment to the registrant's Registration Statement Nos. 333-69478 and 333-106854, each on Form S-8.

This registration statement registers offers and sales of shares of common stock, issuable upon the exercise of options granted under the Alexion Pharmaceuticals, Inc. 2000 Stock Option Plan (the 2000 Plan) and the Alexion Pharmaceuticals, Inc. 1992 Stock Option Plan for Outside Directors. Shares issuable under the 2000 Plan may include shares that constitute control securities under General Instruction C to Form S-8. These control securities may be offered and sold on a continuous or delayed basis in the future under Rule 415 of the Securities Act.

This registration statement contains two parts. The first part contains a reoffer prospectus prepared in accordance with Part I of Form S-3 (in accordance with Instruction C of Form S-8). The second part contains information required in the registration statement pursuant to Part II of Form S-8.

Table of Contents

PART I

INFORMATION REQUIRED IN THE SECTION 10(A) PROSPECTUS

The documents containing the information specified in this Part I will be sent or given to directors, officers, employees and consultants as specified by Rule 428(b)(1) of the Securities Act of 1933, as amended (the Securities Act). Such documents need not to be filed with the Securities and Exchange Commission either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 of the Securities Act. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

Table of Contents

PROSPECTUS

3,400,000 shares

ALEXION PHARMACEUTICALS, INC.

COMMON STOCK

(par value \$.0001 per share)

UNDER THE ALEXION PHARMACEUTICALS, INC.

2000 STOCK OPTION PLAN

This Prospectus relates to the reoffer and resale of up to 3,400,000 shares of our common stock by certain selling stockholders who may be deemed to be our affiliates (the "Selling Stockholders"). These Selling Stockholders may acquire these shares (the "Shares") upon the exercise of stock options. The stock options have been or will be granted pursuant to the Alexion Pharmaceuticals, Inc. 2000 Stock Option Plan (the "2000 Plan"). If and when such options are granted to persons required to use this Prospectus to reoffer and resell the Shares underlying such options, we will distribute a prospectus supplement. The Shares are being reoffered and resold for the account of the Selling Stockholders and we will not receive any of the proceeds from the resale of the Shares. The Selling Stockholders have advised us that the resale of their Shares may be effected from time to time in one or more transactions on the Nasdaq National Market, in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated. See "Plan of Distribution." We will bear all expenses in connection with the preparation of this Prospectus.

Our common stock is traded on the Nasdaq National Market under the symbol ALXN. On October 13, 2004, the closing price for our common stock, as reported by the Nasdaq National Market, was \$17.11.

Our principal executive offices are located at 352 Knotter Drive, Cheshire, Connecticut 06410, and our telephone number there is (203) 272-2596.

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form S-8

THE COMMON STOCK OFFERED HEREBY INVOLVES A HIGH DEGREE OF RISK. SEE RISK FACTORS BEGINNING ON PAGE 3.

From time to time, the Selling Stockholders may sell the Shares in transactions on The Nasdaq National Market, in negotiated transactions, through the writing of options on the Shares, or a combination of such methods of sale at fixed prices which may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. The Selling Stockholders may effect such transactions by selling the Shares to or through broker-dealers, and such broker-dealers may receive compensation in the form of discounts, concessions or commissions from the holders or the purchasers of the Shares for whom such broker-dealers may act as agent or to whom they sell as principal, or both (which compensation to a particular broker-dealer might be in excess of customary commissions). See Plan of Distribution.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

All expenses of the registration of securities covered by this Prospectus are to be borne by Alexion, except that the Selling Stockholders will pay underwriting discounts, selling commissions, and fees and the expenses, if any, of counsel or other advisers to the Selling Stockholders.

The date of this Prospectus is October 14, 2004

Table of Contents

<u>PROSPECTUS SUMMARY</u>	1
<u>THE COMPANY</u>	1
<u>RISK FACTORS</u>	3
<u>USE OF PROCEEDS</u>	14
<u>SELLING STOCKHOLDERS</u>	14
<u>PLAN OF DISTRIBUTION</u>	14
<u>LEGAL MATTERS</u>	15
<u>EXPERTS</u>	15
<u>NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	15
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	15

Table of Contents

PROSPECTUS SUMMARY

This summary provides an overview of selected information and does not contain all the information you should consider. You should read the entire prospectus, including the section entitled Risk Factors, carefully before making an investment decision.

THE COMPANY

We are engaged in the discovery and development of therapeutic products to treat patients with a wide array of severe disease states, including hematologic, cardiovascular, and autoimmune disorders. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development.

We have significant expertise in the discovery and development of antibody therapeutics, as well as in understanding and inhibiting the aberrant manifestation of a component of the human immune system known as complement. Antibodies are proteins that bind specifically to selected targets, or antigens, in the body. After the antibody binds to its target, it may activate the body's immune system against the target, block activities of the target or stimulate activities of the target. Our two lead product candidates are therapeutic antibodies that address specific diseases that arise when the human immune system produces inflammation in the human body. One of our product candidates, eculizumab, is in Phase III clinical development for treatment of a chronic hematologic disease and our second product candidate, pexelizumab, is in Phase III clinical development for two distinct acute cardiac indications. We designed both of these product candidates with the goal of eliciting the intended clinically therapeutic effect by inhibiting the aberrant manifestation of complement.

We are developing eculizumab, an antibody that inhibits complement, for the treatment of a rare blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. We are developing pexelizumab in collaboration with Procter and Gamble Pharmaceuticals, or P&G, a single-chain antibody that also inhibits complement, as a therapeutic to reduce the incidence of death, myocardial infarction or heart attack, and other complications associated with coronary artery bypass graft, or CABG, surgery. We are also developing pexelizumab as a therapeutic to reduce the incidence of death and morbidity often experienced by patients suffering acute myocardial infarction, or AMI, who receive angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart.

To date, we have studied our two lead antibody product candidates in a variety of clinical development programs enrolling over 6,600 patients in clinical trials. In addition to our Phase III programs, we have other product candidates in earlier stages of development, and we may also pursue additional indications for eculizumab.

To date, we have not received any revenues from the sale of our products. We have incurred operating losses since our inception. As of July 31, 2004, we had an accumulated deficit of approximately \$339.4 million. We expect to incur substantial and increasing operating losses for the next several years due to expenses associated with product research and development, pre-clinical studies and clinical testing, regulatory activities, manufacturing development, scale-up and commercial manufacturing, pre-commercialization activities and developing a sales and marketing force. We will need to obtain additional financing to cover these costs.

We were incorporated in Delaware in 1992. The address of our principal executive offices is 352 Knotter Drive, Cheshire, CT 06410.

Table of Contents

Recent Developments

On May 18, 2004, we announced that the *Journal of the American Medical Association* published the results of our previously completed PRIMO-CABG Phase III trial in its May 19, 2004 issue. The article highlighted the significant reduction in death or myocardial infarction in the intent-to-treat population of the PRIMO-CABG Phase III trial, including patients undergoing CABG surgery with or without concomitant valve surgery. We conducted this trial with our partner, P&G, and initially reported a summary of the trial observations at the Late Breaking Clinical Trials Session of the American Heart Association Scientific Sessions in November 2003.

On February 4, 2004, we announced that *The New England Journal of Medicine* published the results of our clinical trial of eculizumab in patients with PNH. The article highlighted the reductions in red blood cell destruction, hemoglobinuria and blood transfusions in our three-month open label trial involving 11 transfusion-dependent PNH patients all receiving eculizumab.

Table of Contents

RISK FACTORS

You should carefully consider the following risk factors before you decide to invest in our Company and our business because these risk factors may have a significant impact on our business, operating results, financial condition, and case flow. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected.

If we continue to incur operating losses, we may be unable to continue our operations.

We have incurred losses since we started our company in January 1992. As of July 31, 2004, we had an accumulated deficit of approximately \$339 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. Since we began our business, we have focused on research and development of product candidates. We have no products that are available for sale and do not know when we will have products available for sale, if ever. We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our future profitability depends on our receiving regulatory approval of our product candidates and our ability to successfully manufacture and market approved drugs. The extent and the timing of our future losses and our profitability, if we are ever profitable, are highly uncertain.

We are subject to extensive government regulation; if we do not obtain regulatory approval for our drug products, we will not be able to sell our drug products.

We and our partners cannot sell or market our drugs without regulatory approval. If we or our partners do not obtain and maintain regulatory approval for our products, the value of our company and our results of operations will be harmed. In the United States, we or our partners must obtain and maintain approval from the FDA for each drug that we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed outside the United States, whose approval can also be lengthy, expensive and highly uncertain. None of our product candidates has received regulatory approval to be marketed and sold in the United States or any other country. We may not receive regulatory approval for any of our product candidates for at least the next several years, if ever.

We and our partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other countries. These regulations apply both before and after approval of our product candidates, if our product candidates are ever approved, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, and export of biologics. Failure to comply with the laws, including statutes and regulations, administered by the FDA or other agencies could result in administrative and judicial sanctions, including, warning letters; fines and other civil penalties; delay in approving or refusal to approve a product candidate; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution.

The FDA has granted fast track status for pexelizumab for use during CPB and for treatment of AMI, and for eculizumab in treatment of membranous nephritis. Although fast track status may expedite development and FDA review of an application, there can be no assurance that pexelizumab or eculizumab will be reviewed more expeditiously for their fast-track indications than would otherwise have been the case or will be approved promptly, or at all. Further, the FDA could revoke fast track status for pexelizumab or eculizumab.

Table of Contents

The FDA has granted orphan drug designation for eculizumab in the treatment of PNH and membranous nephritis. Orphan drug designation does not convey any advantage in, or shorten the duration of, the FDA review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances.

If our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our products.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval for our products. We need to conduct both preclinical animal testing and clinical human trials. These tests and trials may not achieve favorable results. We would need to reevaluate any drug that did not test favorably and either alter the study, the drug or the dose and perform additional or repeat tests, or abandon the drug development project. In those circumstances, we would not be able to obtain regulatory approval on a timely basis, if ever. Even if approval is granted, the approval may require limitations on the indicated uses for which the drug may be marketed.

Clinical trials completed to date have not achieved their primary endpoints.

In December 1999, we completed a Phase IIb trial of pexelizumab for the treatment of complications in patients after CABG with CPB including the reduction of the frequency and severity of myocardial infarctions and frequency of death. The primary therapeutic pre-set goal of the trial, referred to as the primary endpoint, was not achieved. However, in the pre-specified population that included approximately 90% of the patient population, (i.e. the 800 patients who had CABG surgery without valve surgery), those that received pexelizumab at the highest dose level experienced a statistically significant reduction in larger post-surgical heart attacks. Based on these results, in January 2002, we commenced enrollment of a Phase III clinical trial of pexelizumab in patients undergoing CABG with CPB. We completed the target patient enrollment of approximately 3,000 patients in February 2003. In August 2003, we disclosed preliminary results that indicated that the primary endpoint was not achieved with statistical significance. The primary endpoint in this Phase III trial was a composite of the incidence of death or myocardial infarction, measured at 30 days post-procedure, in patients undergoing CABG without simultaneous valve surgery.

We have concluded two Phase II studies with pexelizumab in AMI: one study in patients receiving angioplasty, a procedure for opening up narrowed or blocked arteries that supply blood to the heart, and the other in patients receiving thrombolytic therapy, a procedure for dissolving clots that block heart vessels. The angioplasty study, called COMMA, and the thrombolytic study, called COMPLY, completed patient enrollment in April 2002 and January 2002, respectively. Results from both studies were reported at the November 2002 annual meeting of the American Heart Association. In both studies, the primary endpoint of a reduction of myocardial infarction, was not reached; however in the COMMA study, pexelizumab treatment was associated with a statistically significant, dose-dependent reduction in death.

In 2001, we announced the completion of a Phase IIa trial of eculizumab for the treatment of rheumatoid arthritis, or RA. The primary endpoint for this trial was met by the group of patients who received the mid-level, monthly dosing regimen of eculizumab, but patients who received higher or lower doses of eculizumab in the clinical trial did not achieve the primary endpoint. The primary endpoint in this Phase IIa trial was ACR 20 at 3.25 months.

Table of Contents

In January 2004, we announced preliminary results of a Phase IIb study of eculizumab in approximately 350 RA patients. Results of the trial indicate that the primary endpoint was achieved with statistical significance in the one of the dosing regimens (the monthly dosing arm), but not in the higher, bimonthly dosing arm.

Completion of these and other trials does not guarantee that we will initiate additional trials for our product candidates, that if the trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if the trials are completed, the results will provide a sufficient basis to proceed with further trials or to apply for or receive regulatory approvals or to commercialize products. Results of trials could be inconclusive, requiring additional or repeat trials. If the results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates our company could be materially adversely affected. Failure of a trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies will be required if we determine to continue development of the product candidate, and reduces the likelihood of timely development of and regulatory approval to market the product candidate.

There are many reasons why drug testing could be delayed or terminated.

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. Also, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Unfavorable results or insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program.

Additional factors that can cause delay or termination of our clinical trials include:

slow patient enrollment;

long treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product candidate;

adverse medical events or side effects in treated patients;

the failure of patients taking the placebo to continue to participate in our clinical trials;

lack of effectiveness of the product candidate being tested; and

lack of sufficient funds.

We may expand our business through new acquisitions that could disrupt our business and harm our financial condition.

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form S-8

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions to do so. Acquisitions involve numerous risks, including:

substantial cash expenditures;

potentially dilutive issuance of equity securities;

-5-

Table of Contents

incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;

difficulties in assimilating the operations of the acquired companies;

diverting our management's attention away from other business concerns;

risks of entering markets in which we have limited or no direct experience; and

the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our stock, which could dilute current stockholders' ownership interest in our company, or securities convertible into our stock, which could dilute current stockholders' ownership interest in our company upon conversion.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development.

We believe we have sufficient capital to fund our operations and product development for at least twenty-four months. We may need to raise additional capital before or after that time to complete the development and commercialization of our product candidates. We are currently conducting or initiating several clinical trials. Funding needs may shift between programs and potentially accelerate and increase if we initiate new pivotal trials for our product candidates, including any pivotal clinical trial of pexelizumab for AMI patients undergoing angioplasty. We rely heavily on P&G to fund development of pexelizumab. If P&G were to terminate the pexelizumab collaboration, we could have to raise additional capital or find new collaboration partners in order to continue the development of pexelizumab.

Additional financing could take the form of public or private debt or equity offerings, equity line facilities, bank loans, collaborative research and development arrangements with corporate partners and/or the sale or licensing of some of our property. The amount of capital we may need depends on many factors, including:

the existence, terms and status of collaborative arrangements and strategic partnerships, such as our collaboration with P&G;

the progress, timing and scope of our research and development programs;

the progress, timing and scope of our preclinical studies and clinical trials;

the time and cost necessary to obtain regulatory approvals;

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form S-8

the time and cost necessary to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;

-6-

Table of Contents

the time and cost necessary to develop sales, marketing and distribution capabilities;

the cost necessary to sell, market and distribute our products, if any are approved;

changes in applicable governmental regulatory policies; and

any new collaborative, licensing and other commercial relationships that we may establish.

We may not get funding when we need it or funding may only be available on unfavorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate our research and development activities or future operations. We might have to license our technology to others. This could result in sharing revenues that we might otherwise retain for ourselves. Any of these actions would harm our business.

We are significantly leveraged.

We currently have outstanding \$120 million principal amount of 5 3/4% convertible subordinated notes. The degree to which we are leveraged could, among other things:

make it difficult for us to make payments on our notes;

make it difficult for us to obtain financing for working capital, acquisitions or other purposes on favorable terms, if at all;

make us more vulnerable to industry downturns and competitive pressures; and

limit our flexibility in planning for, or reacting to changes in, our business.

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

If our collaboration with P&G is terminated or P&G reduces its commitment to our collaboration, our ability to develop and commercialize pexelizumab in the time expected, or at all, and our business would be harmed.

We rely heavily on P&G to perform development, obtain commercial manufacturing, and provide sales and marketing for pexelizumab. While we cannot assure you that pexelizumab will ever be successfully developed and commercialized, if P&G does not perform its obligations in a timely manner, or at all, our ability to commercialize pexelizumab will be significantly adversely affected. We rely on P&G to provide funding and additional resources for the development and commercialization of pexelizumab. These include funds and resources for:

clinical development and clinical and commercial manufacturing;

obtaining regulatory approvals; and

sales, marketing and distribution efforts worldwide.

Table of Contents

P&G has the right to terminate the collaboration or sublicense its collaboration rights at any time. Termination of our agreement with P&G would cause significant delays in the development of pexelizumab and result in significant additional development costs to us. If we were to continue development of pexelizumab following termination by P&G, we would need to fund the development and commercialization of pexelizumab on our own or identify a new development partner. We would need to develop or acquire replacement expertise in many areas necessary for the development and potential commercialization of pexelizumab, or enter into agreements with other companies with respect to those matters. We do not have the resources to replace some of the functions provided or funded by P&G. Accordingly, we might have to stop the development of pexelizumab or shift resources from other product development programs until alternative resources were obtained. Sublicense by P&G also could cause significant delays in the development of pexelizumab and result in substantial additional development costs to us. We might also have to repeat testing already completed with P&G. In addition, sublicense would introduce a new collaboration partner which could create new and additional risks to the development of pexelizumab that cannot be identified at this time.

We cannot guarantee that P&G will devote the resources necessary to successfully develop and commercialize pexelizumab in a timely manner, if at all. Furthermore, P&G may devote the necessary resources, but we may still not successfully develop and commercialize pexelizumab.

If we are unable to engage and retain third-party collaborators, our research and development efforts may be delayed.

We depend upon third-party collaborators to assist us in the development of our product candidates. If any of our existing collaborators breaches or terminates its agreement with us or does not perform its development work under an agreement in a timely manner, or at all, we would experience significant delays in the development or commercialization of our product candidates. We would also experience significant delays if we could not engage additional collaborators when required. In either event, we would be required to devote additional funds or other resources to these activities or to terminate them. This would divert funds or other resources from other parts of our business.

We cannot assure you that:

current collaboration arrangements will be continued in their current form;

we will be able to negotiate acceptable collaborative agreements to develop or commercialize our product candidates;

any arrangements with third parties will be successful; or

current or potential collaborators will not pursue treatments for other diseases or seek other ways of developing treatments for our disease targets.

If the trading price of our common stock continues to fluctuate in a wide range, our stockholders will suffer considerable uncertainty with respect to an investment in our stock.

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors' operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, including, but not limited to P&G, changes in our prospects, and market conditions for biotechnology stocks in general could have a significant impact on the future trading prices of our common stock and our convertible subordinated notes. In particular,

the trading price of the common

Table of Contents

stock of many biotechnology companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, the announcement of the results of our clinical trials or product development and the results of our attempts to obtain FDA approval for our products. In particular, since August 1, 1999, the sales price of our common stock has ranged from a low of \$9.05 per share to a high of \$119.88 per share. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our stock may result in considerable uncertainty for an investor.

If we cannot protect the confidentiality and proprietary nature of our trade secrets, our business and competitive position will be harmed.

Our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, since we are a small company, we also rely heavily on collaboration with suppliers, outside scientists and other drug companies. Collaboration presents a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

In order to protect our drugs and technology more effectively, we need to obtain patents covering the drugs and technologies we develop. We may obtain patents through ownership or license. Our drugs are expensive and time-consuming to test and develop. Without patent protection, competitors may copy our methods, or the chemical structure or other aspects of our drugs. Even if we obtain patents, the patents may not be broad enough to protect our drugs from copycat products.

If we are found to be infringing on patents owned by others, we may be forced to pay damages to the patent owner and obtain a license to continue the manufacture, sale or development of our drugs and/or pay damages. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our drugs.

Parts of our, including our in-licensed, technology, techniques and proprietary compounds and potential drug candidates may conflict with patents owned by or granted to others. If we cannot resolve these conflicts, we may be liable for damages, be required to obtain costly licenses or be stopped from manufacturing, using or selling our products or conducting other activities. For example, we are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Many of our product candidates are genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, and recombinant human single chain antibodies.

We have received notices from the owners of some of these patents claiming that their patents may be relevant to the development, manufacture or sale of some of our drug candidates, including pexelizumab and eculizumab. In response to some of these notices, we have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have either determined in our judgment that:

our products do not infringe the patents;

we do not believe the patents are valid; or

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form S-8

we have identified and are testing various modifications that we believe should not infringe the patents and which should permit commercialization of our product candidates.

Table of Contents

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If any patent holder successfully challenges our judgment that our products do not infringe their patents or that their patents are invalid, we could be required to pay costly damages or to obtain a license to sell or develop our drugs. A required license may be costly or may not be available on acceptable terms, if at all.

There can be no assurance that we would prevail in a patent infringement action; will be able to obtain a license to any third party patent on commercially reasonable terms; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture or sell approved forms of our product candidates could have a material adverse effect on our business and prospects.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing and sale of drugs for use in humans exposes us to product liability risks. Side effects and other problems from using our products could give rise to product liability claims against us. We might have to recall our products, if any, from the marketplace. Some of these risks are unknown at this time.

In addition, we may be sued by people who participate in our trials. A number of patients who participate in such trials are already very ill when they enter the trial. Any informed consents or waivers obtained from people who sign up for our trials may not protect us from liability or litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any covered liabilities. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating to a product liability claim may make it more difficult, or impossible, for us to recruit patients for our clinical trials or to market and sell our products. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Use of C5 Inhibitors, such as pexelizumab and eculizumab, is associated with an increased risk for infection with Neisseria bacteria. One patient in our trials of eculizumab for the treatment of membranous nephritis became infected with Neisseria bacteria. Serious cases of Neisseria infection can result in brain damage, loss of limbs or parts of limbs, kidney failure, or death.

We are subject to the environmental laws and potential exposure to environmental liabilities.

We are subject to various federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, including medical and biological wastes, and emissions and discharges into the environment, including air, soils and water sources. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating its property or locations to which wastes were sent from its facilities, without regard to whether the owner or operator knew of, or necessarily caused, the contamination. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition.

Table of Contents

If we cannot manufacture our drug candidates in sufficient amounts at acceptable costs and on a timely basis, we may be unable to have the necessary materials for product testing, and later for potential sale in the market. Either event would harm our business.

For our drug trials, we need to produce sufficient amounts of product for testing. Our small manufacturing plant cannot manufacture enough of our product candidates for later stage clinical development or commercial supply. In addition, we do not have the capacity to produce more than one product candidate at a time. We depend on a few outside suppliers for manufacturing. If we experience interruptions in the manufacture of our products, our drug development and commercialization efforts will be delayed. If any of our outside manufacturers stops manufacturing our products or reduces the amount manufactured, or is otherwise unable to manufacture our required amounts at our required quality, we will need to find other alternatives. If we are unable to find an acceptable outside manufacturer on reasonable terms, we will have to divert our own resources to manufacturing, which may not be sufficient to produce the necessary quantity or quality of product. As a result, our ability to conduct testing and drug trials and our plans for commercialization would be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed. Our competitive position and our prospects for achieving profitability would be materially and adversely affected.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA and other domestic and foreign authorities. We cannot assure you that we or our third-party collaborators will successfully comply with all of those regulations, which failure would have a materially adverse effect on our business.

Manufacture of our drug products is highly technical and only a few third-parties have the ability and capacity to manufacture our drug products for our development and commercialization needs. We can not assure you that these potential third-party collaborators will agree to manufacture our products on our behalf on commercially reasonable terms, if at all. If we do achieve agreement from one or more third parties to manufacture our drug products, we can not assure you that they will be able or willing to honor the terms of the agreements, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Due to the highly technical requirements of manufacturing our drug products, our third-party collaborators and we may be unable to manufacture our drug products despite their and our efforts. Inability to contract with third-party manufacturers on commercially reasonable terms, or failure or delay by our third-party manufacturers, if any, in manufacturing our drug products in the volumes and quality required, would have a material adverse effect on our business.

We have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales. If we are unable to establish and maintain commercial scale manufacturing within our planned time and cost parameters, sales of our products and our financial performance would be adversely affected.

Currently, we are relying on P&G to retain appropriate commercial manufacturing for pexelizumab through one or more third-party manufacturers. P&G has contracted with one third-party manufacturer for the large-scale commercial manufacture of pexelizumab. The failure of P&G to obtain appropriate commercial manufacturing for pexelizumab on a timely basis, or at all, may prevent or impede the commercialization of pexelizumab. We have executed a large-scale product supply agreement with Lonza Biologics, plc for the long-term manufacture of eculizumab. The failure of Lonza to manufacture appropriate supplies of eculizumab on a timely basis, or at all, may prevent or impede the commercialization of eculizumab.

Table of Contents

Due to the nature of the current market for third-party commercial manufacturing arrangements, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity contracted for. We could owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity we contracted for, and we could be required to share on an equal basis with P&G substantial penalty payments owed by P&G for its failure to utilize the manufacturing capacity it contracted for with third-party manufacturers for the supply of pexelizumab. The payment of a substantial penalty would harm our financial condition.

If we are unable to establish sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell future drug products.

We have no sales or distribution personnel or capabilities. We have only recently established core pre-commercial marketing capabilities. If we are unable to continue developing those capabilities, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell our future drug products. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third-party providers on acceptable terms, if at all. Currently, we are relying on P&G for sales, marketing and distribution of pexelizumab. P&G, or any future third-party collaborators, may not succeed at selling, marketing or distributing any of our future drug products.

If we are unable to obtain reimbursement for our future products from government health administration authorities, private health insurers and other organizations, our products may be too costly for regular use and our ability to generate revenues would be harmed.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if we cannot depend on governmental and private third-party payors to defray the cost of our products to the consumer. If these entities refuse to provide reimbursement with respect to our products or determine to provide an insufficient level of reimbursement, our products may be too costly for general use. Our profitability may be adversely impacted if we choose to offer our products at a reduced price. Any limitation on the use of our products or any decrease in the price of our products without a corresponding decrease in expenses will have a material adverse effect on our ability to achieve profitability.

If our competitors get to the marketplace before we do with better or cheaper drugs, our drugs may not be profitable to sell or to continue to develop.

Each of Abbott Laboratories Inc., Adprotech Ltd., Avant Immunotherapeutics, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc., Neurogen Corporation, Tanox, Inc., and XOMA have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that GlaxoSmithKline, plc, Merck & Co., Inc., and Pfizer, Inc. are also attempting to develop complement inhibitor therapies. Each of Cambridge Antibody Technology Group, plc, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Abgenix, Inc. and Medarex, Inc. has publicly announced intentions to develop therapeutic human antibodies from mice that have been bred to include some human antibody genes. These and other pharmaceutical companies, many of which have significantly greater resources than we, may develop, manufacture and market better or cheaper drugs than our product candidates. They may establish themselves in the marketplace before we are able even to finish our clinical trials. Other pharmaceutical

Table of Contents

companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

If we fail to recruit and retain personnel, our research and product development programs may be delayed.

We are highly dependent upon the efforts of our senior management and scientific personnel, particularly Dr. Leonard Bell, M.D., our Chief Executive Officer and a member of our Board of Directors, David W. Keiser, our President, Chief Operating Officer and a member of our Board of Directors, and Stephen P. Squinto, Ph.D., our Executive Vice President and Head of Research. There is intense competition in the biotechnology industry for qualified scientific and technical personnel. Since our business is very science-oriented and specialized, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. We have a key man insurance policy for Dr. Bell and employment agreements with Dr. Bell, Mr. Keiser and Dr. Squinto. None of our key personnel is nearing retirement age or to our knowledge, planning to retire. To our knowledge, there is no tension between any of our key personnel and the Board of Directors. If we lose the services of our management and scientific personnel and fail to recruit other scientific and technical personnel, our research and product development programs will be materially and adversely affected.

In particular, we highly value the services of Dr. Bell, our Chief Executive Officer. The loss of his services could materially and adversely affect our ability to achieve our development objectives.

Our ability to use net operating loss carryforwards to reduce future tax payments may be limited if there is a change in ownership of Alexion.

As of July 31, 2004, we had approximately \$320 million of net operating loss carryforwards, or NOLs, available to reduce taxable income in future years. We believe that some of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

Our ability to utilize our NOLs may be further limited if we undergo an ownership change, as defined in section 382, as a result of subsequent changes in the ownership of our outstanding stock. We would undergo an ownership change if, among other things, the stockholders, or group of stockholders, who own or have owned, directly or indirectly, 5% or more of the value of our stock, or are otherwise treated as 5% stockholders under section 382 and the regulations promulgated thereunder, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOLs. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused limitation may be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOLs arising after the date of an ownership change would not be affected.

Table of Contents

We do not believe that we experienced a change in ownership within the meaning of section 382 as a result of the offering of our common stock on July 30, 2004. However, there can be no assurance that the Internal Revenue Service could not successfully challenge our conclusion. Even if the offering of our common stock did not cause an ownership change to occur immediately, the issuance, directly or indirectly, of a relatively large number of shares in that offering may mean that we may not be able to engage in transactions involving the issuance or deemed issuance of stock within the subsequent three-year period without triggering an ownership change within the meaning of section 382. In addition, there are circumstances beyond our control, such as market purchases of our stock by investors who are existing 5% shareholders, or become 5% shareholders as a result of such purchases, which could result in an ownership change with respect to our stock. Thus, there can be no assurance that our future actions, or future actions by our stockholders, will not result in the occurrence of an ownership change, which may limit our use of the NOLs and negatively affect future cash flows.

USE OF PROCEEDS

We will not receive any proceeds from the sale of Shares of common stock by the Selling Stockholders, although we will receive the exercise prices of the stock options.

SELLING STOCKHOLDERS

We will supplement this Prospectus from time to time to include certain information concerning the security ownership of the Selling Stockholders and the position, office or other material relationship which a Selling Stockholder has had within the past three years with us or any of our predecessors or affiliates.

PLAN OF DISTRIBUTION

We are registering the Shares covered by this Prospectus on behalf of the Selling Stockholders. All costs, expenses and fees in connection with the registration of the Shares will be paid by us. Brokerage commissions, if any, attributable to the sale of the Shares will be paid by the Selling Stockholders or their donees or pledgees.

Sales of the Shares may be effected from time to time in transactions (which may include block transactions) on the Nasdaq National Market, in negotiated transactions, or a combination of such methods of sale, at fixed prices which may be changed, at market prices prevailing at the time of sale, or at negotiated or other prices. The Selling Stockholders may also sell these Shares pursuant to Rule 144 promulgated under the Securities Act or may pledge Shares as collateral for margin accounts and such Shares could be resold pursuant to the terms of such accounts. Pursuant to this Prospectus, the Selling Stockholders may also donate a certain de minimus number (as allowed by the Securities and Exchange Commission) of their Shares of common stock, and such Shares could be resold pursuant to rules set forth by the Securities and Exchange Commission. The Selling Stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. The Selling Stockholders may effect such transactions by selling common stock directly to purchasers or to or through broker-dealers which may act as agents or principals. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from each Selling Stockholder and/or the purchasers of the Shares for whom the broker-dealers may act as agents or to whom they sell as principal, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). The Selling Stockholders and any broker-dealers that act in connection with the sale of the Shares might be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act and any commission received by them and any profit on the resale of the Shares as principal might be deemed to be underwriting discounts and commissions.

Table of Contents

under the Securities Act. The Selling Stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the Shares against certain liabilities, including liabilities arising under the Securities Act. Liabilities under the federal securities laws cannot be waived.

Because the Selling Stockholders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, the Selling Stockholders will be subject to prospectus delivery requirements under the Securities Act. Furthermore, in the event of a distribution of the Shares, the Selling Stockholder, any selling broker or dealer and any affiliated purchasers may be subject to Regulation M under the Exchange Act of 1934, as amended (the Exchange Act). Such regulation would prohibit, with certain exceptions, any such person from bidding for or purchasing any security which is the subject of the distribution until his, her or its participation in that distribution is completed. In addition, Regulation M prohibits any stabilizing bid or stabilizing purchase for the purpose of pegging, fixing or stabilizing the price of common stock in connection with this offering.

LEGAL MATTERS

Legal matters relating to our common stock have been passed upon for us by Fulbright & Jaworski L.L.P., New York, New York.

EXPERTS

The consolidated financial statements as of July 31, 2004 and 2003 and for each of the three years ended July 31, 2004 incorporated into this Registration Statement by reference to the Annual Report on Form 10-K for the year ended July 31, 2004 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus (including the documents incorporated by reference in this prospectus) contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) and information about our financial condition, results of operations and business that are based on our current and future expectations. You can find many of these statements by looking for words such as estimate, project, believe, anticipate, intend, expect and similar expressions. These statements reflect our current views with respect to future events and are subject to risks and uncertainties, including those discussed under Risk Factors, that could cause our actual results to differ materially from those contemplated in the forward-looking statements. We caution you that no forward-looking statement is a guarantee of future performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. We do not undertake any obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events which may cause our actual results to differ from those expressed or implied by the forward-looking statements contained in this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form S-8

We are subject to the information requirements of the Securities Exchange Act. Therefore, we file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. Our filings are available to the public over the internet at the Securities and Exchange Commission's web site at <http://www.sec.gov>. You may also read and copy all of our filings at the Securities and Exchange Commission's public reference facilities in Washington, D.C. You may

-15-

Table of Contents

obtain information on the operation of the Securities and Exchange Commission's public reference facilities by calling the Securities and Exchange Commission at 1-800-SEC-0300. You can also read and copy all of our filings at the office of the Nasdaq Stock Market, 1735 K Street N.W., Washington, D.C. 20006.

The Securities and Exchange Commission allows us to incorporate by reference the documents that we file with the Securities and Exchange Commission. This means that we can disclose important information to you by referring you to those documents. Any information incorporated in this manner is considered part of this Registration Statement. Any information we file with the Securities and Exchange Commission after the date of this Registration Statement will automatically update and supersede the information contained in this Registration Statement.

We incorporate by reference the following documents that have been filed with the Securities and Exchange Commission and any filings that we will make with the Securities and Exchange Commission in the future under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act until we file a post-effective amendment to this Registration Statement indicating this offering has been completed:

- (i) our annual report on Form 10-K, for the fiscal year ended July 31, 2004, filed on September 28, 2004;
- (ii) our current reports on Form 8-K, filed on September 24, 2004;
- (iv) our registration statement on Form 8-A, filed on February 21, 1997, as amended by Amendment No. 1 to Form 8-A filed on October 6, 2000 and Amendment No. 2 to Form 8-A filed on February 12, 2002; and
- (v) our registration statement on Form 8-A, filed on February 12, 1996.

You should read the information relating to us in this Prospectus together with the information in the documents incorporated by reference.

Any statement contained in a document incorporated by reference herein, unless otherwise indicated therein, speaks as of the date of the document. Statements contained in this Prospectus may modify or replace statements contained in the documents incorporated by reference.

Alexion will furnish without charge to you, upon written or oral request, a copy of any or all of the documents described above, except for exhibits to such documents, unless such exhibits are specifically incorporated by reference into such documents. Requests should be addressed to: Alexion Pharmaceuticals, Inc., 352 Knotter Drive, Cheshire, Connecticut 06410, (203) 272-2596, Attention: Thomas I.H. Dubin, Vice President and General Counsel. We will furnish our stockholders with an annual report containing audited financial statements. In addition, we may furnish such other reports as may be authorized, from time to time, by our Board of Directors.

This Prospectus is part of a registration statement we filed with the Securities and Exchange Commission. You should rely only on the information incorporated by reference or provided in this Prospectus or any supplement. We have not authorized anyone else to provide you with different information. The Selling Stockholders will not make an offer of these Shares in any state where the offer is not permitted. You should not assume that information in this Prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

Table of Contents

NO PERSON (INCLUDING ANY SALESMAN OR BROKER) IS AUTHORIZED TO PROVIDE ORAL OR WRITTEN INFORMATION ABOUT THIS OFFERING NOT CONTAINED IN THIS PROSPECTUS. YOU SHOULD NOT ASSUME THAT THE INFORMATION CONTAINED IN THIS PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE INDICATED BELOW.

Table of Contents

3,400,000 Shares

ALEXION PHARMACEUTICALS, INC.

COMMON STOCK

PROSPECTUS

October 14, 2004

Table of Contents

PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

ITEM 3. Incorporation of Documents by Reference.

The following documents filed by us with the Securities and Exchange Commission pursuant to the Securities Act and the Exchange Act are incorporated by reference in this Registration Statement:

- (i) our annual report on Form 10-K for the fiscal year ended July 31, 2004, filed on September 28, 2004;
- (ii) our current report on Form 8-K, filed on September 24, 2004;
- (iii) our registration statement on Form 8-A, filed on February 21, 1997, as amended by Amendment No. 1 to Form 8-A filed on October 6, 2000 and Amendment No. 2 to Form 8-A filed on February 12, 2002; and
- (iv) our registration statement on Form 8-A, filed on February 12, 1996.

All documents subsequently filed by us with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, prior to the filing of a post-effective amendment which (i) indicates that all securities offered under this Registration Statement have been sold or (ii) which deregisters all securities remaining unsold, shall be deemed to be incorporated by reference into this Registration Statement and to be a part of this Registration Statement from the date of filing of such documents.

ITEM 4. Description of Securities.

Not applicable.

ITEM 5. Interest of Named Experts and Counsel.

Not applicable.

ITEM 6. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law (the "DGCL") empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation) by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. A corporation may, in advance of the final disposition of any civil, criminal, administrative or investigative action, suit or proceeding, pay the expenses (including attorneys' fees) incurred by any officer, director, employee or agent in defending such action, provided that the director or officer undertakes to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the corporation. A corporation may indemnify such person against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if he acted in good faith and in a manner

Table of Contents

he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

A Delaware corporation may indemnify officers and directors in an action by or in the right of the corporation to procure a judgment in its favor under the same conditions, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses (including attorneys fees) which he actually and reasonably incurred in connection therewith. The indemnification provided is not deemed to be exclusive of any other rights to which an officer or director may be entitled under any corporation's by-law, agreement, vote or otherwise.

In accordance with Section 145 of the DGCL, Section EIGHTH of the Company's Certificate of Incorporation, as amended (the Certificate) provides that the Company shall indemnify each person who is or was a director, officer, employee or agent of the Company (including the heirs, executors, administrators or estate of such person) or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, to the fullest extent permitted. The indemnification provided by the Certificate shall not be deemed exclusive of any other rights to which any of those seeking indemnification or advancement of expenses may be entitled under any by-law, agreement, vote of stockholder or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person. Expenses (including attorneys' fees) incurred in defending a civil, criminal, administrative or investigative action, suit or proceeding shall be paid by the Company in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of the indemnified person to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the Company. Section NINTH of the certificate provides that a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Company or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit.

Table of Contents

ITEM 7. Exemption from Registration Claimed.

Not Applicable.

ITEM 8. Exhibits.

Exhibit No.	Description
4.1	Alexion Pharmaceuticals, Inc. 2000 Stock Option Plan, as amended*
4.2	Alexion Pharmaceuticals, Inc. 1992 Stock Option Plan for Outside Directors, as amended**
5.1	Opinion of Fulbright & Jaworski L.L.P.
23.1	Consent of Counsel (contained in Exhibit 5.1)
23.2	Consent of Independent Registered Public Accounting Firm

* Incorporated by reference to our Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2004 filed on March 15, 2004.

** Incorporated by reference to our Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2003 filed on March 18, 2003.

ITEM 9. Undertakings.

(a) The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of

Table of Contents

the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Town of Cheshire, State of Connecticut on October 14, 2004.

ALEXION PHARMACEUTICALS, INC.

By: /s/ DAVID W. KEISER
David W. Keiser

President and Chief Operating Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

/s/ Leonard Bell	Chief Executive Officer	October 14, 2004
Leonard Bell	(Principal Executive Officer)	
/s/ David W. Keiser	President, Chief Operating Officer	October 14, 2004
David W. Keiser	and Director	
/s/ Carsten Boess	Vice President and Chief Financial Officer	October 14, 2004
Carsten Boess		
/s/ Barry P. Luke	Vice President, Finance and Administration	October 14, 2004
Barry P. Luke	(Principal Accounting Officer)	
/s/ Max Link	Director	October 14, 2004
Max Link		
/s/ Jerry T. Jackson	Director	October 14, 2004
Jerry T. Jackson		

Table of Contents

<u>/s/ Joseph A. Madri</u>	Director	October 14, 2004
Joseph A. Madri		
<u>/s/ R. Douglas Norby</u>	Director	October 14, 2004
R. Douglas Norby		
<u>/s/ Alvin S. Parven</u>	Director	October 14, 2004
Alvin S. Parven		
<u>/s/ Larry L. Mathis</u>	Director	October 14, 2004
Larry L. Mathis		

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
4.1	Alexion Pharmaceuticals, Inc. 2000 Stock Option Plan, as amended*
4.2	Alexion Pharmaceuticals, Inc. 1992 Stock Option Plan for Outside Directors, as amended**
5.1	Opinion of Fulbright & Jaworski L.L.P.
23.1	Consent of Counsel (contained in Exhibit 5.1)
23.2	Consent of Independent Registered Public Accounting Firm

* Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2004 filed on March 15, 2004.

** Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2003 filed on March 18, 2003.