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ALEXION PHARMACEUTICALS INC

Form S-3/A

July 25, 2001

As filed with the Securities and Exchange Commission on July 25, 2001

Registration No. 333-59702

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

AMENDMENT NO. 2 TO  
FORM S-3  
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 of Incorporation  
or Organization)

13-3648318  
(I.R.S. Employer Identification Number)

352 Knotter Drive  
Cheshire, CT 06410  
(203) 272-2596  
(Address, Including Zip Code, and Telephone Number, Including Area Code, or  
Registrant's Principal Executive Offices)

Leonard Bell, M.D.  
Alexion Pharmaceuticals, Inc.  
352 Knotter Drive  
Cheshire, CT 06410  
(203) 272-2596  
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code,  
of Agent for Service)

Copies of all communications, including all communications set to the agent for  
service, should be sent to:

Merrill M. Kraines, Esq.  
Lawrence A. Spector, Esq.  
Fulbright & Jaworski L.L.P.  
666 Fifth Avenue  
New York, New York 10103-3198

Approximate date of commencement of proposed sale to the public: From time  
to time after the effective date of this Registration Statement. If the only  
securities being registered on this Form are being offered pursuant to dividend  
or interest reinvestment plan, please check the following box: [ ]

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

This registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor offers to buy be accepted before the registration statement becomes effective. This prospectus is not an offer to sell securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not valid.

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The information in this prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted before the registration statement becomes effective. This prospectus is not an offer to sell securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.  
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Subject to Completion, Dated July 25, 2001

[ALEXION LOGO]

187,114 Shares of Common Stock

Alexion Pharmaceuticals, Inc.'s common stock trades on the Nasdaq National Market under the ticker symbol "ALXN." On July 24, 2001, the closing sale price of the common stock was \$18.80.

The stockholders of Alexion Pharmaceuticals, Inc. listed in this prospectus are offering and selling an aggregate of 187,114 shares of our common stock

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under this prospectus.

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SEE "RISK FACTORS" BEGINNING ON PAGE 3 FOR A DISCUSSION OF CERTAIN FACTORS THAT YOU SHOULD CONSIDER BEFORE YOU INVEST IN THE SHARES BEING SOLD WITH THIS PROSPECTUS.

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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.

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The date of this Prospectus is \_\_\_\_\_, 2001.

### TABLE OF CONTENTS

	Page
	----
Our Company.....	1
Risk Factors.....	4
Special Note Regarding Forward-Looking Statements.....	9
Use of Proceeds.....	10
Dividend Policy.....	10
Selling Stockholders.....	11
Plan of Distribution.....	12
Legal Matters.....	12
Experts.....	13
Where You Can Find More Information.....	13

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### OUR COMPANY

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.

We are engaged in the development of therapeutic products for the treatment of a wide array of severe diseases, including cardiovascular and autoimmune disorders and cancer. Our two lead product candidates are antibodies that address specific diseases that arise when the human immune system attacks the human body itself and produces undesired inflammation. Antibodies are proteins that bind specifically to selected targets 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 antibodies that do not naturally occur in humans, but which have been genetically engineered to avoid being treated as foreign in humans. These types of antibodies are known as "humanized" antibodies.

Our two lead antibody product candidates are designed to block a component of the human immune system that causes undesired inflammation, while allowing

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beneficial components of the immune system to remain functional. The specific component of the human immune system that these two product candidates are designed to block is called "complement."

We are currently testing our two lead humanized antibody product candidates in humans for safety, dosing and effectiveness. We call one of the antibodies we are testing in humans pexelizumab. We completed a trial of the safety and effectiveness of pexelizumab in a Phase IIb clinical trial of patients suffering from acute inflammation caused by the trauma of cardiopulmonary bypass surgery or CPB. Preliminary results from this trial show that pexelizumab blocked complement, reduced inflammation and appeared to be safe and well-tolerated. Some patients in the trial experienced serious adverse events which included irregular heartbeat, infection, right heart failure and internal bleeding. The most common adverse events were irregular heartbeat, nausea and anemia. The primary therapeutic goal of the trial, referred to as the primary endpoint, was not achieved. However, results from the highest level dose in the largest of the trial's two sub-groups, which was comprised of patients undergoing coronary artery bypass graft surgery, or CABG, along with CPB, showed a reduction in the occurrence of large heart attacks and death. This sub-group represented 800 of the trial's total patient population of 914.

We are currently evaluating the data from this trial and expect to hold discussions with the FDA. If our final analysis is positive, and if the FDA agrees with that analysis, we expect to initiate a Phase III trial of the safety and effectiveness of pexelizumab. We expect that this trial would focus on treating patients undergoing CABG along with CPB, and would be conducted with Procter & Gamble Pharmaceuticals, our partner in the development and commercialization of pexelizumab. If our final analysis, or the FDA's views of that analysis, do not justify initiation of a Phase III clinical trial, our progress in developing pexelizumab for the treatment of patients

1

undergoing CABG along with CPB will be delayed and we would need to conduct another Phase II clinical trial to pursue use of pexelizumab in patients undergoing CABG along with CPB.

We are conducting two additional Phase II clinical trials with Procter & Gamble Pharmaceuticals that test the safety and effectiveness of pexelizumab for the treatment of acute inflammation in patients during heart attacks.

We call our second lead humanized antibody product candidate 5G1.1. We retain all of our proprietary rights to 5G1.1.

We completed a Phase II clinical trial testing the safety and effectiveness of 5G1.1 in patients with rheumatoid arthritis, a chronic autoimmune disease. Preliminary results show that 5G1.1 appeared to be safe and well tolerated in patients in this trial. The most commonly observed adverse events were nausea and diarrhea. The primary endpoint, or therapeutic goal, for this trial was met by the group of patients who received mid-level doses of 5G1.1. Patients who received higher or lower doses of 5G1.1 in the clinical trial, did not achieve the primary endpoint. We continue to evaluate the data from this trial in rheumatoid arthritis patients. We expect to initiate another trial of the safety and effectiveness of 5G1.1 in rheumatoid arthritis patients at the earliest possible opportunity. We will determine the design, patient population and phase of the next trial following our final evaluation of the data from the completed trial and discussions with the FDA. It is not certain at this time whether the next trial of 5G1.1 in patients with rheumatoid arthritis will be a Phase III trial or a Phase II trial. If we undertake another Phase II clinical trial of 5G1.1 in patients with rheumatoid arthritis rather than a Phase III clinical trial, our progress in developing 5G1.1 for the treatment of rheumatoid

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arthritis will be delayed.

We are also testing 5G1.1 for the treatment of two kidney diseases, membranous nephritis and lupus nephritis. In addition, we are testing 5G1.1 in patients suffering from dermatomyositis, a severe inflammatory muscle disorder and pemphigoid, a severe inflammatory skin disorder.

We recently completed a Phase I clinical trial to investigate the safety of 5G1.1 in psoriasis patients. 5G1.1 appeared to be safe and well tolerated in this patient population. According to a standard measure of disease activity, 5G1.1 treatment did not influence the outcome of psoriasis in this trial. Following complete evaluation of the data from this trial and consideration of product development alternatives, we may conduct further trials of 5G1.1 in patients with psoriasis or psoriatic arthritis.

In addition to our program for developing products that inhibit the inflammatory effects of complement and our technology programs that focus on discovering and developing human antibodies, we are developing another type of anti-inflammatory drug known as apogens. Apogens are designed to block disease-causing T-cells, another component of the human immune system. The FDA has accepted the plan for a Phase I clinical trial of our lead apogen candidate, MP4, which targets the treatment of patients with multiple sclerosis. We are uncertain whether we will conduct this trial or continue to develop MP4. We may seek to license our rights to MP4 or to otherwise collaborate in its development.

We are also developing methods of blocking the human immune system to permit the use of cells and tissue from non-human species for the treatment of diseases in humans. This product development program is initially targeting the use of genetically altered pig cells to treat Parkinson's disease and spinal cord injury. We refer to our lead product candidate for Parkinson's disease as "UniGraft-PD" and our lead product candidate for spinal cord injury as "UniGraft-SCI." We are continuing to study these products in animals.

We were incorporated in Delaware in January 1992. Since our inception, we have devoted substantially all of our resources to drug discovery, research and product development. Since mid-1996, we have increasingly focused our resources and efforts on structuring and conducting trials in humans for our two lead antibody product candidates.

In September 2000, we added to our antibody product discovery and development program through the acquisition of Prolifaron, Inc., now known as Alexion Antibody Technologies, Inc. or AAT. AAT's technology allows for the rapid creation of humanized antibodies. AAT is initially focusing its efforts on autoimmune diseases, inflammation and cancer. AAT has applied for several patents, none of which has yet been issued.

2

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

3

### RISK FACTORS

You should carefully consider the following risk factors before you decide to invest in the securities. If any of these risks actually occurs, our business, financial condition, operating results or cash flows could be harmed.

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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 April 30, 2001, we had an accumulated deficit of approximately \$116.7 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 of our future losses and the timing of our profitability, if we are ever profitable, are highly uncertain.

If we do not obtain regulatory approval for our drug products we will not be able to sell our drug products.

We cannot sell or market our drugs without regulatory approval. If we do not obtain regulatory approval for our products, the value of our company and our results of operations will be harmed. In the United States, we must obtain approval from the U.S. Food and Drug Administration, or 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 do not anticipate receiving regulatory approval of any of our product candidates, if ever, for at least the next several years.

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 it may entail limitations on the indicated uses for which the drug may be marketed.

We have announced the completion of a Phase IIb trial of pexelizumab for the treatment of myocardial infarction in patients after cardiopulmonary bypass surgery, including the reduction of the frequency and severity of myocardial infarctions and frequency of death, and completion of a Phase II trial of 5G1.1 for the treatment of rheumatoid arthritis. Completion of these trials does not guarantee that we will initiate additional trials for our product candidates, that if the trials are initiated, they will be completed, or that if the trials are completed, they will be sufficient to proceed with further trials, to apply for or receive regulatory approvals or to commercialize products.

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 for each clinical indication, at various doses and formulations. 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

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could delay or cause us to abandon a product development program. Results of these trials could be inconclusive, necessitating additional or repeat trials.

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;

4

- . adverse medical events or side effects in treated patients;
- . 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.

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

- . substantial cash expenditures;
- . potentially dilutive issuance of equity securities;
- . incurrance of debt and contingent liabilities;
- . 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 long-term benefits to us or that our management will be able to manage the acquired businesses effectively. We may also 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 give assurances 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 nor may they be readily 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 your ownership interest in our company.

On September 22, 2000, we purchased all of the capital stock and other outstanding securities of Prolifaron, Inc., a privately held biopharmaceutical company that is developing therapeutic antibodies addressing multiple disease, including cancer, for approximately 400,000 shares of our outstanding capital

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stock. We cannot give assurances that the integration of our businesses with the businesses of Prolifaron will be successful or that we will be able to achieve the synergies we anticipate.

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 thirty-six months. We may need to raise additional capital after that time to complete the development and commercialization of our product candidates. Additional financing could take the form of public or private debt or equity offerings, equity line facilities, bank loans and/or collaborative research and development arrangements with corporate partners. The amount of capital we may need depends on many factors, including:

- . 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;
  - . 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;
  - . the time and cost necessary to develop sales, marketing and distribution capabilities;
  - . changes in to applicable governmental regulatory policies; and
- 5
- . any new collaborative, licensing and other commercial relationships that we may establish.

We may not get funding when we need it or on favorable 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 which we might otherwise retain for ourselves. Any of these actions may harm our business.

If our collaboration with Procter & Gamble is terminated, we may be unable to commercialize pexelizumab or 5G1.1-SC in the time expected, if at all, and our business would be harmed.

We rely exclusively on Procter & Gamble to provide funding and additional resources for the development and commercialization of pexelizumab or 5G1.1-SC. These include funds and resources for:

- . clinical development and clinical and commercial manufacturing;
- . obtaining regulatory approvals; and
- . sales, marketing and distribution efforts worldwide.

We cannot guarantee that Procter & Gamble will devote the resources necessary to successfully develop and commercialize pexelizumab. Either party



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may terminate our collaboration agreement for specified reasons, including a material breach.

Termination of our agreement with Procter & Gamble would cause significant delays in the development of pexelizumab and result in additional development costs. We would need to fund the development and commercialization of pexelizumab on our own or identify a new development partner. We might also have to repeat testing already completed with Procter & Gamble.

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, 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:

- . we will be able to negotiate acceptable collaborative agreements to develop or commercialize our products;
- . 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, 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 the notes. In particular, the trading price of the common stock of many biotechnology companies, including us, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of such 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 \$10.00 per share to a high of \$119.88 per share. While we cannot predict our future performance, if our stock continues to fluctuate in a wide range, an investment in our stock may result in considerable uncertainty for an investor.

6

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 which we protect as trade secrets. However, since we are a

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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. 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 drug. Even if we obtain patents, the patents may not be broad enough to protect our drugs from copy-cat products.

If we are found to be infringing on patents owned by others, we may be forced to obtain a license to continue the sale or development of our drugs and/or pay damages.

Parts of our 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, recombinant human single chain antibodies, and genetically engineered animals. Many of our products are genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, and recombinant human single chain antibodies, and other products are tissues from genetically engineered animals.

We have received notices from the owners of some of these patents claiming that their patents may be relevant to the development of some of our drug candidates. In response to some of these notices, we have obtained 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
- . we have identified and are testing various modifications which we believe should not infringe the patents and which should permit commercialization of our product candidates.

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 of these actions are successful, we could be required to pay damages or to obtain a license to sell or develop our drugs. A required license may not be available on acceptable terms, if at all.

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. For example, little is known about the potential long-term health risks of transplanting pig tissue into humans, a goal of our UniGraft product development program. Use of C5 Complement Inhibitors, such as 5G1.1 and pexelizumab, is associated with an increased risk for infection with Neisseria bacteria. Serious cases of Neisseria infection can result in brain damage or death.

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In addition, we may be sued by people who participate in our clinical trials. A number of patients who participate in such trials are already critically ill when they enter a study. 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. 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.

7

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. 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 for testing, our drug development efforts will be delayed. If any of our outside manufacturers stops manufacturing our products or reduces the amount manufactured, 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 would be materially adversely affected. Submission of products and new development programs for regulatory approval would be delayed. Our competitive position and our prospects for achieving profitability could be materially and adversely affected.

Manufacture of drug products 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 would have a materially 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.

Other than our agreement with Procter & Gamble to develop and commercialize pexelizumab, we have no arrangements to manufacture our products on a commercial basis. We have not proceeded far enough in negotiations with any other potential partner to predict the cost of a commercial manufacturing arrangement for our other potential products nor have we explored the cost or time required to establish our own commercial manufacturing facility.

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, marketing or distribution personnel or capabilities. If we are unable to establish those capabilities, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell our products. In that event, we will not be able to generate

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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 Procter & Gamble for sales, marketing and distribution of pexelizumab. Procter & Gamble, 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 from government health administration authorities, private health insurers and other organizations for our future products, our products may be too costly for regular use and our ability to generate revenues would be harmed.

Our products, once commercialized, like similar products in the market place, 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 a low 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 on the price of our products without a corresponding decrease in expenses will have a material adverse effect on our ability to achieve profitability.

8

Even if we successfully develop our products for transplanting animal cells into humans, this technology may not be accepted by the market due to medical concerns or unanticipated regulation.

Our program for the development of animal cells for transplantation into humans may never result in any therapeutic products. This technology is subject to extensive clinical testing and we are not aware of any such technology that has been approved for sale by the FDA or comparable foreign regulatory authorities. Even if we succeed in developing these products, our products may not be widely accepted by the medical community or third-party payors until more facts are established and ethical consensus is reached regarding the use of animal cells. In addition, concerns relating to the risk of introducing new animal viruses to infect the human species through the transplantation process may also create additional regulatory hurdles for FDA approval. If accepted, the degree of acceptance may limit the size of the market for our products. Moreover, due to the controversial nature of transplantation of animal cells into humans generally, market prices for our securities, may be subject to increased volatility.

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 Avant Immunotherapeutics, Inc, Leukosite Inc., a subsidiary of Millenium Pharmaceuticals, Inc., Tanox, Inc., Abbott Laboratories, Baxter Healthcare Corporation, Gliatech Inc. and Biocryst Pharmaceuticals have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that Pfizer, Inc., SmithKline Beecham Plc and Merck & Co., Inc. are also attempting to develop complement inhibitor therapies. Each of Cambridge Antibody Technology, PLC, MorphoSys AG and Dyax Corporation have publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Abgenix Inc. and Medarex, Inc. have publicly announced intentions to develop therapeutic human antibodies from mice that have been bred to include some human antibody genes. These and other large pharmaceutical

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companies with significantly greater resources than ours, may develop, manufacture and market better or cheaper drugs than our product candidates. They may establish themselves in the marketplace before we are able to even finish our clinical trials. Larger pharmaceutical 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 specific 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, Leonard Bell, M.D., our president, chief executive officer and director, David W. Keiser, our executive vice president and chief operating officer 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 we have employment agreements with each of Dr. Bell, Mr. Keiser and Dr. Squinto. To our knowledge, none of our key personnel is planning to retire or is nearing retirement age. Further, to our knowledge, there is no tension between any of our key personnel and the Board. If we lose the services of our management and scientific personnel or fail to recruit other scientific and technical personnel, our research, our research and product development programs would be significantly and detrimentally affected.

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

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains some "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 and information relating to us that are based on the beliefs of our management, as well as assumptions made by and the information currently available to our management. When used in this prospectus, the words "estimate," "project," "believe," "anticipate," "intend," "expect" and similar expressions are intended to

9

identify forward-looking statements. These statements reflect our current views with respect to future events and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in these forward-looking statements, including those risks discussed in this prospectus. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus.

### USE OF PROCEEDS

We will not receive any proceeds from the sale of common stock by the selling stockholders.

### DIVIDEND POLICY

We have never declared or paid any dividends on our stock. We currently anticipate that we will retain all future earnings to support our growth

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strategy. Accordingly, we do not anticipate paying cash dividends on our stock in the foreseeable future. The payment of any future dividends will be at the discretion of our board of directors and will depend upon, among other things, future earnings, operations, capital requirements, our general financial condition, and general business conditions.

10

### SELLING STOCKHOLDERS

The following table sets forth information regarding the selling stockholders' beneficial ownership of our common stock as of March 26, 2001.

Selling Stockholder (1)	Number of Shares of Common Stock Beneficiary owned Prior to Offering	Number of Shares of Common Stock Registered Herein	Nu Sh Comm Bene Own this O
Carlos F. Barbas	19,019	9,509	
Shana M. Barbas	20,316	9,509	
Carlos Barbas (TRSI)	201	100	
John Bentley	5,187	2,593	
Ernest Beutler and Bonnie Beutler TTEE Ernest Beutler and Bonnie M. Beutler Trust U/A DTE 12/4/69	2,500	1,764	
Katherine Bowdish (3)	46,684	41,496	
Dennis R. Burton	38,037	19,018	
Christopher John Connolly and Rhonda Marie Connolly Family Trust	3,187	2,593	
Chris Cruce	70	35	
Glen Dautherty	18,393	9,196	
Beth Fawsett	103	51	
James C. Gilstrap Trust dated 1/16/95	15,561	7,780	
Ernie Huang	1,296	648	
James E. Iverson and Patricia Iverson	30,689	14,696	
Kasirer Yeladim Holdings, LLC	10,374	5,187	
August Kee	70	35	
John R. Larson	13,832	6,916	
Richard Alan Lerner, Nicole Green Lerner, Trustees U.D.T. dated 11/14/94	50,141	25,070	
Richard Lerner (TRSI)	201	100	
Marshall Linn and Joyce Linn	2,687	2,593	
Lippman Living Trust DTD 8/11/89	19,748	10,374	
Benjamin List (TRSI)	57	28	
Paul Mailander	282	141	
Thomas McDermott	25	25	
Doug Mertz	141	70	
Katharine Tate Overton Trust, Katharine Overton Coady, TTEE	7,874	5,187	
Staats M. Pellett, Jr.	7,187	2,593	
Lavern Punke	5,187	5,187	
Christoph Rader (TRSI)	21	10	
Daniel B. Rifkin	1,764	1,764	

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Don Sandberg	211	105
Joy Sprink	70	35
Robin M. Thomas	5,187	2,593
Juergen Wagner (3)	72	72
Sue Wood	70	35
Guofu Zhong (TRSI)	72	36
	-----	-----
	326,516	187,114
	=====	=====

11

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- (1) The selling stockholders received their shares of common stock in connection with our acquisition of Prolifaron, Inc. on September 23, 2000.
  - (2) Assumes that all shares offered by each selling stockholder are sold in this offering.
  - (3) Had not previously registered shares in S-3 Registration statement filed on December 28, 2000.

### PLAN OF DISTRIBUTION

Pursuant to an agreement and plan of merger effective September 23, 2000, we acquired Prolifaron, Inc., a privately held biopharmaceutical company located in San Diego, California. In the merger, we issued 355,594 shares of our common stock to the former stockholders of Prolifaron and we are obligated to issue up to 44,364 shares of our common stock upon the exercise of fully vested options granted under Prolifaron's stock option plan. We agreed to register the possible resale of those shares of common stock by the Prolifaron stockholders. The shares of common stock are being registered to permit the resale of the common stock by the holders thereof from time to time after the date of this prospectus. We have agreed, among other things, to bear all expenses, other than underwriting discounts, selling commissions and fees and expenses of other advisors to holders of the common stock, in connection with the registration and sale of the common stock covered by this prospectus.

We will not receive any of the proceeds from the offering of the shares of common stock by the selling securityholders. We have been advised by the selling securityholders that the selling securityholders (and their donees and pledgees) may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time on any exchange on which the securities are listed on terms to be determined at the times of such sales. The selling securityholders may also make private sales directly or through a broker or brokers. Alternatively, any of the selling securityholders may from time to time offer the shares of common stock beneficially owned by them through underwriters, dealers or agents, who may receive compensation in the form of underwriting discounts, commissions or concessions from the selling securityholders and the purchasers of the shares of common stock for whom they may act as agent. The aggregate proceeds to the selling securityholders from the shares of common stock offered by them hereby will be the purchase price of such shares of common stock less discounts and commissions, if any.

Our outstanding common stock is listed for trading on the Nasdaq National Market.

The shares of common stock may be sold from time to time in one or more transactions at fixed offering prices, which may be changed, or at varying

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prices determined at the time of sale or at negotiated prices. Such prices will be determined by the holders of such securities or by agreement between such holders and underwriters or dealers who may receive fees or commissions in connection therewith.

In order to comply with the securities laws of certain states, if applicable, the shares of common stock will be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares of common stock may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

The selling securityholders and any broker-dealers, agents or underwriters that participate with the selling securityholders in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, in which event any commissions received by such broker-dealers, agents or underwriters and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

### LEGAL MATTERS

Fulbright & Jaworski L.L.P. New York, New York will pass upon the validity of the securities offered hereby and some other legal matters on behalf of Alexion.

12

### EXPERTS

The audited consolidated financial statements of Alexion Pharmaceuticals, Inc. and the audited financial statements of Prolifaron, Inc. incorporated by reference in this prospectus and elsewhere in the registration statement, to the extent and for the periods indicated in their reports, have been audited by Arthur Andersen LLP, independent public accountants and are included herein in reliance upon the authority of said firm as experts in giving said reports.

### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information filed by us at the Commission's public reference room at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549 and the regional offices of the Commission located at Seven World Trade Center, 13th Floor, New York, New York 10048, and 500 West Madison Street, Chicago, Illinois 60661. Copies of such material can be also obtained from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, and its public reference rooms in New York, New York and Chicago, Illinois, at prescribed rates. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Copies of such information may also be inspected at the reading room of the library of the National Association of Securities Dealers, Inc., 1735 K Street, N.W., Washington, D.C. 20006. Our filings with the Commission are also available to the public from commercial document retrieval services and at the Commission's web site at "<http://www.sec.gov>."

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We



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incorporate by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until the selling stockholders sell all their shares of Alexion stock.

- (i) our amended current report on Form 8-K/A, filed on November 20, 2000;
- (ii) our current reports on Form 8-K, filed on September 25, 2000, October 3, 2000, October 27, 2000, January 23, 2001, January 29, 2001 and June 7, 2001;
- (iii) our quarterly reports on Form 10-Q for the quarters ended October 31, 2000, January 31, 2001 and April 30, 2001, filed on December 15, 2000, March 15, 2001 and June 13, 2001, respectively;
- (iv) our annual report on Form 10-K for the fiscal year ended July 31, 2000, filed on October 6, 2000;
- (v) our registration statement on Form 8-A, filed on February 21, 1997, as amended on October 6, 2000; and
- (vi) our registration statement on Form 8-A, filed on February 12, 1996.

We 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: David W. Keiser, Executive Vice President and Chief Operating Officer.

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.

13

### PART II

#### Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth Alexion Pharmaceuticals, Inc. (the "Company") estimates (other than the SEC registration fee) of the expenses in connection with the issuance and distribution of the securities being registered. None of the following expenses are being paid by the selling stockholders.

SEC registration fee.....	\$ 1,000
Legal fees and expenses.....	\$50,000
Accounting fees and expenses.....	\$13,000
Printing fees.....	\$ 4,000
Miscellaneous expenses.....	\$ 6,000
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Total:.....	\$74,000
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### Item 15. 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 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 shareholders 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

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violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed 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.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

- 2.1 Agreement and Plan of Merger by and among Alexion Pharmaceuticals, Inc., PI Acquisition Company, Inc. and Prolifaron, Inc., dated as of September 22, 2000.\*
- 5.1 Opinion of Fulbright & Jaworski L.L.P. regarding legality. ++
- 23.1 Consent of Fulbright & Jaworski L.L.P. (included in Exhibit 5.1). ++
- 23.2 Consent of Arthur Andersen LLP. +
- 23.3 Consent of Arthur Andersen LLP. +
- 24.1 Power of Attorney. ++

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\* Incorporated by reference on our report on Form 8-K, filed on October 3, 2000

+ Filed herewith

++ Previously filed

(b) Financial Statement Schedules.

None.

Item 17. 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 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

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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 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 of the Registrant 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.

II-2

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-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cheshire and State of Connecticut on the 25th day of July, 2001.

Alexion Pharmaceuticals, Inc.

By: /s/ Leonard Bell  
-----  
Leonard Bell, M.D.  
President, Chief Executive  
Officer, Secretary and Treasurer

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

Name	Title
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By: /s/ Leonard Bell ----- Leonard Bell, M.D.	President, Chief Executive Officer, Secretary, Treasurer and Director (principal executive officer)

Jul

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<p style="text-align: center;">/s/ David W. Keiser</p> <hr/> <p style="text-align: center;">David W. Keiser</p> <p style="text-align: center;">*</p> <hr/> <p style="text-align: center;">Barry P. Luke</p> <p style="text-align: center;">*</p> <hr/> <p style="text-align: center;">John H. Fried, Ph.D.</p> <p style="text-align: center;">*</p> <hr/> <p style="text-align: center;">Jerry T. Jackson</p> <p style="text-align: center;">*</p> <hr/> <p style="text-align: center;">Max Link, Ph.D.</p> <p style="text-align: center;">*</p> <hr/> <p style="text-align: center;">Joseph A. Madri, Ph.D., M.D.</p> <p style="text-align: center;">*</p> <hr/> <p style="text-align: center;">R. Douglas Norby</p>	<p>Executive Vice President and Chief Operating Officer (principal financial officer) Jul</p> <p>Vice President of Finance and Administration (principal accounting officer) Jul</p> <p>Chairman of the Board of Directors Jul</p> <p>Director Jul</p> <p>Director Jul</p> <p>Director Jul</p> <p>Director Jul</p> <p>Director Jul</p>
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II-3

<p>* By: /s/ Leonard Bell</p> <hr/> <p style="text-align: center;">(Leonard Bell) Attorney-in-Fact</p>	<p>Director Jul</p>
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II-4

EXHIBIT INDEX

Exhibit Number	Exhibit
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2.1 Agreement and Plan of Merger by and among Alexion Pharmaceuticals, Inc., PI Acquisit

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- Company, Inc.and Prolifaron, Inc., dated as of September 22, 2000.\*
- 5.1 Opinion of Fulbright & Jaworski L.L.P. regarding legality.++
  - 23.1 Consent of Fulbright & Jaworski L.L.P. (included in Exhibit 5.1). ++
  - 23.2 Consent of Arthur Andersen LLP. +
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  - 24.1 Power of Attorney. ++

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\* Incorporated by reference on our report on Form 8-K, filed on October 3, 2000

+ Filed herewith

++ Previously filed