UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 22, 2000

ENZON, INC.
(Exact name of registrant as specified in its charter)

Delaware	0-12957	22-2372868
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

20 Kingsbridge Road	Piscataway, New Jersey	08854
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code (732) 980-4500

Item 5. Other Events.

The following risk factors and descriptions of patents and legal proceedings are incorporated by reference into the prospectus included in each of our two Registration Statements on Form S-3 (File Nos. 333-32093 and 333-58269) currently on file with the Securities and Exchange Commission. The following risk factors replace and supersede the risk factors set forth in such prospectuses and the risk factors set forth in the section entitled "Risk Factors" in our annual report on Form 10-K, as amended, for the fiscal year ended June 30, 1999.

RISK FACTORS

An investment in our security involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in this prospectus before deciding whether to purchase shares of our common stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently believe to be immaterial may also adversely affect our business. If any of the following risks actually occur, our business and operating results could be harmed. This could cause the trading price of our common stock to decline, and you may lose all or part of your investment.

Risks Related To Enzon

We have a history of losses and we may never be profitable.

We have incurred substantial losses since our inception. As of December 31, 1999, we had an accumulated deficit of approximately $126.8 million. We expect to incur operating losses for the foreseeable future. The size of these losses will depend primarily on the receipt and timing of regulatory approval of PEG-Intron and Schering-Plough's effective marketing of PEG-Intron, as well as on the rate of growth in our other product sales or royalty revenue and on the level of our expenses. Our two FDA-approved products are not generating significant revenues because neither product has become widely used due to a small patient population base and limitations on their indicated uses. Our ability to achieve long-term profitability will depend upon our or our

licensees' ability to obtain regulatory approvals for additional product candidates. Even if our product candidates receive regulatory approval, we cannot assure you that our products will achieve market acceptance or will be commercialized successfully or that our operations will be profitable.

Our near term success is heavily dependent on FDA approval of PEG-Intron and Schering-Plough's effective marketing of PEG-Intron.

Under our agreement with Schering-Plough, pursuant to which we applied our PEG technology to develop a modified form of Schering-Plough's INTRON A, we will receive royalties on worldwide sales of PEG-Intron, if any. Schering-Plough is responsible for conducting and funding the clinical studies, obtaining regulatory approval and marketing the product worldwide on an exclusive basis. In November 1999, Schering-Plough announced that it had submitted a Marketing Authorization Application to the European Agency for the Evaluation of Medicinal Products, or EMEA, seeking marketing approval of PEG-Intron in Europe for the treatment of hepatitis C. In February 2000, Schering-Plough announced that the Committee for Proprietary Medicinal Products of the EMEA issued an opinion recommending approval of the application. Product approval by the EMEA is typically issued three

months from the time the Committee renders its opinion. In December 1999, Schering-Plough completed submission of a Biologics License Application, or BLA, to the FDA seeking marketing approval of PEG-Intron for the treatment of hepatitis C. Schering-Plough had requested priority review status from the FDA of this BLA. In February 2000, the FDA accepted Schering-Plough's BLA for PEG-Intron for standard review, rather than priority review. Standard review typically takes 12 months from the date of filing. We have not had access to and do not know the results of the Phase III clinical trial that were included in Schering-Plough's BLA, nor have we been able to review the BLA. If Schering-Plough does not receive marketing approval from the FDA or the EMEA in a timely manner, or at all, it will have a material adverse effect on our business, financial condition and results of operation.

Schering-Plough currently markets INTRON A together with REBETOL as combination therapy for the treatment of hepatitis C and INTRON A as a stand-alone treatment for hepatitis C. If the current BLA is approved by the FDA, Schering-Plough will be able to market PEG-Intron only as a stand-alone or monotherapy treatment for hepatitis C. Schering-Plough is conducting a Phase III clinical trial of PEG-Intron as combination therapy with REBETOL for hepatitis C and Phase III clinical trials of PEG-Intron for the treatment of chronic myelogenous leukemia and malignant melanoma. If those trials are successful, PEG-Intron may be the subject of future BLAs for those indications. We cannot assure you that Schering-Plough will seek or obtain marketing approval to sell PEG-Intron for these additional indications or for combination therapy. Although Schering-Plough is obligated under our agreement to use commercial efforts to market PEG-Intron, we cannot assure you that Schering-Plough will be successful in marketing PEG-Intron or that Schering-Plough will not continue to market INTRON A, either as a stand-alone product or in combination therapy with REBETOL, even if PEG-Intron receives FDA approval. The amount and timing of resources dedicated by Schering-Plough to the development and marketing of PEG-Intron is not within our control. If Schering-Plough breaches or terminates its agreement with us, or fails to work diligently toward FDA approval of the product for additional indications, the commercialization of PEG-Intron could be slowed or blocked completely. Our revenues will be negatively affected if Schering-Plough continues to market INTRON A in competition with PEG-Intron or if it cannot meet the manufacturing demands of the market. If Schering-Plough does not use commercial efforts to market PEG-Intron, or it otherwise breaches the agreement, a dispute may arise between us. A dispute would be both expensive and time-consuming and may result in delays in the development and commercialization of PEG-Intron, which would likely have a material adverse affect on our business, financial condition and results of operations.

There is currently patent litigation, which could have a significant adverse impact on our business.

Hoffmann-La Roche has sued Schering-Plough and claimed that the PEG technology used in PEG-Intron infringes a patent held by Hoffmann-La Roche. The litigation is at a very early stage, and we cannot predict its outcome. Prior to the commencement of this litigation we obtained an opinion of patent counsel

that the patent held by Hoffmann-La Roche is invalid. However, this opinion is not binding on any court or the U.S. Patent and Trademark Office. We cannot assure you that the patent opinion will prove to be correct and that a court would find any of the claims of such patents to be invalid or that the product developed by us or our collaborator does not infringe such patents. If this litigation is not resolved favorably for Schering-Plough and Schering-Plough is prevented from marketing PEG-Intron, we would not receive any royalties on sales of PEG-Intron. This would have a material adverse effect on our business, financial condition and results of operations.

In December 1998, we filed a patent infringement suit against Shearwater Polymers, a company that has reportedly developed a Branched PEG, or U-PEG, used in Hoffmann-La Roche's Pegasys

product, a PEG-modified version of its alpha-interferon product called Roferon-A. We believe that Pegasys utilizes a type of Branched PEG, for which we have been granted a patent in the United States and have similar patents pending in Europe, Japan and Canada. Shearwater has filed a counterclaim in this litigation alleging that our Branched PEG patent is invalid and unenforceable. While an adverse outcome in the litigation will not prevent Schering-Plough from commercializing PEG-Intron, if we are not successful in our infringement suit or if our patent is held to be invalid, we may not be able to preclude Shearwater from selling its Branched PEG or preclude Hoffmann-La Roche from commercializing Pegasys if it obtains regulatory approval. If we are unable to enforce our patent rights in this area against others, it may have a material adverse effect on our business, financial condition and results of operations.

During the course of our litigation proceedings with Shearwater Polymers and Schering-Plough's litigation with Hoffmann-La Roche, interim information about the status of each of these litigations may be released. Although these interim releases may differ from the final determinations in these litigations, such information may have a material adverse effect on the market price of our common stock.

We are subject to extensive regulation. Compliance with these regulations can be costly, time consuming and subject us to unanticipated delays in developing our products.

The manufacturing and marketing of pharmaceutical products in the United States and abroad are subject to stringent governmental regulation. The sale of any of our products for use in humans in the United States will require the prior approval of the FDA. Similar approvals by comparable agencies are required in most foreign countries. The FDA has established mandatory procedures and safety standards that apply to the clinical testing, manufacture and marketing of pharmaceutical products. Obtaining FDA approval for a new therapeutic product may take several years and involve substantial expenditures. ADAGEN was approved by the FDA in 1990. ONCASPAR was approved in the United States and in Germany in 1994, and in Canada in 1997, in each case for patients with acute lymphoblastic leukemia who are hypersensitive to native forms of L-asparaginase. ONCASPAR was approved in Russia in April 1993 for therapeutic use in a broad range of cancers. Except for these approvals, none of our other products has been approved for sale and use in humans in the United States or elsewhere.

We cannot assure you that we or our licensees will be able to obtain FDA or other relevant marketing approval for any of our other products. In addition, any approved products are subject to continuing regulation. If we or our licensees fail to comply with applicable requirements it could result in:

- criminal penalties,
- civil penalties,
- fines,
- recall or seizure,
- injunctions requiring suspension of production,
- orders requiring ongoing supervision by the FDA, or

- refusal by the government to approve marketing or export applications or to allow us to enter into supply contracts.

If we or our licensees fail to obtain or maintain requisite governmental approvals or fail to obtain or maintain approvals of the scope requested, it will delay or preclude us or our licensees or marketing partners from marketing our products. It could also limit the commercial use of our products. Any such failure or limitation may have a material adverse affect on our business, financial condition and results of operations.

We have experienced problems complying with the FDA's regulations for manufacturing our products, and we may not be able to resolve these problems.

Manufacturers of drugs also must comply with the applicable FDA good manufacturing practice regulations, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed as part of the product approval process before they can be used in commercial manufacturing. We or our present or future suppliers may be unable to comply with the applicable good manufacturing practice regulations and other FDA regulatory requirements.

During 1998, we began to experience manufacturing problems with one of our FDA-approved products, ONCASPAR. The problems were due to increased levels of white particulates in batches of ONCASPAR, which resulted in an increased rejection rate for this product. During fiscal 1999, we agreed with the FDA to temporary labeling and distribution restrictions for ONCASPAR and instituted additional inspection and labeling procedures prior to distribution. During May 1999, the FDA required us to limit distribution of ONCASPAR to only those patients who are hypersensitive to native L-asparaginase. In November 1999, the FDA withdrew this distribution restriction.

Recently, we have noticed an unacceptable level of black particulates in a batch of ADAGEN filled by our third-party contract filler. We believe these particulates are caused by the filling process, and our third-party filler has taken steps to resolve this issue. Because we use the same outside filler for ADAGEN and ONCASPAR, this problem could affect ONCASPAR as well.

In July 1999, the FDA conducted an inspection of our manufacturing facility in connection with our product license for ADAGEN. Following that inspection, the FDA documented several deviations from Current Good Manufacturing Practices, known as cGMP, in a Form 483 report. We provided the FDA with a corrective action plan. In November 1999, the FDA issued a warning letter citing the same cGMP deviations listed in the July 1999 Form 483, but it also stated that the FDA was satisfied with our proposed corrective actions. As a result of the deviations, the FDA decided not to approve product export requests from us for both ADAGEN and ONCASPAR until it determines that all noted ADAGEN cGMP deviations have been corrected.

In January 2000, the FDA conducted another inspection of our manufacturing facility relating to the ONCASPAR product license and as a follow-up to the July 1999 inspection relating to ADAGEN. Following this most recent inspection, the FDA issued a Form 483 report, citing deviations from cGMP in the manufacture of ONCASPAR and two cGMP deviations for ADAGEN. We have responded to the FDA with a corrective action plan to the January 2000 Form 483. However, we cannot assure you that the FDA will not issue a warning letter with respect to the manufacture of ONCASPAR or that the FDA will approve product export requests that we may make in the future.

While we expect to resolve these manufacturing problems by the second quarter of the calendar year, we cannot be certain that the solution will be acceptable to the FDA. If we cannot satisfactorily

resolve these problems, the FDA may not permit us to continue to distribute

ONCASPAR or ADAGEN. If we cannot market and distribute ONCASPAR or ADAGEN for an extended period, future sales of the products may suffer, which could adversely affect our financial results.

Rhone-Poulenc Rorer, or RPR, which has the exclusive right to sell ONCASPAR in North America, has asserted that we should be responsible for its lost profits while ONCASPAR is under the temporary labeling and distribution restrictions resulting from the white particulate problem. RPR contends that its lost profits through December 31, 1999 were $5.2 million. We are also currently in discussions with RPR related to a disagreement over the purchase price we charged RPR for ONCASPAR under our supply agreement with it. RPR has asserted that we have overcharged it in the amount of $2.3 million. We believe our costing of ONCASPAR complies with the supply agreement. Although we do not agree with RPR's claims, the ultimate resolution of either matter could have a material adverse effect on our financial position.

Schering-Plough will be responsible for the manufacture of PEG-Intron.

Our clinical trials could take longer to complete and cost more than we expect.

We will need to conduct clinical studies of all of our product candidates. These studies are costly, time consuming and unpredictable. Any unanticipated costs or delays in our clinical studies could harm our business, financial condition and results of operations.

Schering-Plough is conducting clinical trials of our lead product candidate, PEG-Intron, which is in Phase III trials as combination therapy with REBETOL for treatment of hepatitis C and as stand-alone therapy for two cancer indications. We are currently conducting early stage clinical trials of our next PEG product, PROTHECAN. Clinical trials can be very costly and time-consuming. The rate of completion of clinical trials depends upon many factors, including the rate of enrollment of patients. If we or Schering-Plough are unable to accrue sufficient clinical patients in our respective trials during the appropriate period, such trials may be delayed and will likely incur significant additional costs. In addition, FDA or institutional review boards may require us to delay, restrict, or discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The cost of human clinical trials varies dramatically based on a number of factors, including:

- the order and timing of clinical indications pursued,
- the extent of development and financial support from corporate collaborators,
- the number of patients required for enrollment,
- the difficulty of obtaining clinical supplies of the product candidate, and
- the difficulty in obtaining sufficient patient populations and clinicians.

All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of our clinical trials. Any unanticipated costs or delays in our clinical studies could harm our business, financial condition and results of operations.

In some cases, we rely on corporate collaborators or academic institutions to conduct some or all aspects of clinical trials involving our product candidates. We will have less control over the timing and

other aspects of these clinical trials than if we conducted them entirely on our own. We cannot assure you that these trials will commence or be completed as we expect or that they will be conducted successfully.

If pre-clinical and clinical trials do not yield positive results, our

products will fail.

If pre-clinical and clinical testing of one or more of our product candidates do not demonstrate the safety and efficacy of the desired indications, those potential products will fail. Numerous unforeseen events may arise during, or as a result of, the testing process, including the following:

- the results of pre-clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials,
- potential products may not have the desired effect or may have undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved,
- results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials, and
- after reviewing test results, we or our corporate collaborators may abandon projects which we might previously have believed to be promising.

Clinical testing is very costly and can take many years. The failure to adequately demonstrate the safety and efficacy of a therapeutic product under development would delay or prevent regulatory approval, which could adversely affect our business and financial performance.

Even if we obtain regulatory approval for our products, they may not be accepted in the marketplace.

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe. Even if our products obtain regulatory approval, we cannot assure you that they will achieve market acceptance of any kind. The degree of market acceptance will depend on many factors, including:

- the receipt, timing and scope of regulatory approvals,
- the timing of market entry in comparison with potentially competitive products,
- the availability of third-party reimbursement, and
- the establishment and demonstration in the medical community of the clinical safety, efficacy and cost-effectiveness of drug candidates, as well as their advantages over existing technologies and therapeutics.

If any of our products do not achieve market acceptance, we will likely lose our entire investment in that product.

We depend on our collaborative partners. If we lose our collaborative partners or they do not apply adequate resources to our collaborations, our product development and financial performance may suffer.

We rely heavily and will depend heavily in the future on collaborations with corporate partners, primarily pharmaceutical companies, for one or more of the research, development, manufacturing, marketing and other commercialization activities relating to many of our product candidates. If we lose our collaborative partners, or if they do not apply adequate resources to our collaborations, our product development and financial performance may suffer.

The amount and timing of resources dedicated by our collaborators to their collaborations with us is not within our control. If any collaborator breaches or terminates its agreements with us, or fails to conduct its collaborative activities in a timely manner, the commercialization of our product candidates could be slowed or blocked completely. We cannot assure you that our collaborative partners will not change their strategic focus or pursue alternative technologies or develop alternative products as a means for developing treatments for the diseases targeted by these collaborative programs.

Our collaborators could develop competing products. In addition, our revenues will be affected by the effectiveness of our corporate partners in marketing any successfully developed products.

We cannot assure you that our collaborations will be successful. Disputes may arise between us and our collaborators as to a variety of matters, including financing obligations under our agreements and ownership of intellectual property rights. These disputes may be both expensive and time-consuming and may result in delays in the development and commercialization of products.

We are dependent upon a single outside supplier for each of the crucial raw materials necessary to the manufacture of each of our products and product candidates.

We cannot assure you that sufficient quantities of our raw material requirements will be available to support the continued research, development or manufacture of our products. We purchase the unmodified compounds utilized in our approved products and products under development from outside suppliers. We may be required to enter into supply contracts with outside suppliers for certain unmodified compounds. We do not produce the unmodified adenosine deaminase used in the manufacture of ADAGEN or the unmodified forms of L-asparaginase used in the manufacture of ONCASPAR. We have a supply contract with an outside supplier for the supply of each of these unmodified compounds. If we experience a delay in obtaining or are unable to obtain any unmodified compound, including unmodified adenosine deaminase or unmodified L-asparaginase, on reasonable terms, or at all, it could have a material adverse effect on our business, financial condition and results of operations.

If we are required to obtain an alternate source for an unmodified compound utilized in a product, the FDA and relevant foreign regulatory agencies will likely require that we perform additional testing to demonstrate that the alternate material is biologically and chemically equivalent to the unmodified compound previously used in our clinical trials. This testing could delay or stop development of a product, limit commercial sales of an approved product and cause us to incur significant additional expenses. If we are unable to demonstrate that the alternate material is chemically and biologically equivalent to the previously used unmodified compound, we will likely be required to repeat some or all of the pre-clinical and clinical trials conducted for the compound. The marketing of an FDA approved drug could be disrupted while such tests are conducted. Even if the alternate material is shown to be chemically and biologically equivalent to the previously used compound, the FDA or relevant foreign regulatory agency may require that we conduct additional clinical trials with the alternate material.

The United States and foreign patents upon which our original PEG technology was based have expired. We depend on patents and proprietary rights, which may offer only limited protection against potential infringement and the development by our competitors of competitive products.

Research Corporation Technologies, Inc. held the patent upon which our original PEG technology was based and had granted us a license under such patent. Research Corporation's patent contained broad claims covering the attachment of PEG to polypeptides. However, this United States patent and its corresponding foreign patents have expired. Based upon the expiration of the Research Corporation patent, other parties will be permitted to make, use or sell products covered by the claims of the Research Corporation patent, subject to other patents, including those which we hold. We have obtained several patents with claims covering improved methods of attaching or linking PEG to therapeutic compounds. We cannot assure you that any of these patents will enable us to prevent infringement or that competitors will not develop alternative methods of attaching PEG to compounds potentially resulting in competitive products outside the protection that may be afforded by our patents. We are aware that others have also filed patent applications and have been granted patents in the United States and other countries with respect to the application of PEG to proteins and other compounds. We cannot assure that the expiration of the Research Corporation patent or other patents related to PEG that have been granted to third parties will not have a material adverse effect on our business, financial condition and results of operations.

The pharmaceutical industry places considerable importance on obtaining

patent and trade secret protection for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong patent position for our products and technologies both in the United States and in other countries. We have been licensed, and been issued, a number of patents in the United States and other countries, and we have other patent applications pending to protect our proprietary technology. Although we believe that our patents provide certain protection from competition, we cannot assure you that such patents will be of substantial protection or commercial benefit to us, will afford us adequate protection from competing products, or will not be challenged or declared invalid. In addition we cannot assure you that additional United States patents or foreign patent equivalents will be issued to us. The scope of patent claims for biotechnological inventions is uncertain and our patents and patent applications are subject to this uncertainty.

To facilitate development of our proprietary technology base, we may need to obtain licenses to patents or other proprietary rights from other parties. If we are unable to obtain such licenses, our product development efforts may be delayed or blocked.

We are aware that certain organizations are engaging in activities that infringe certain of our PEG and SCA technology patents. We cannot assure you that we will be able to enforce our patent and other rights against such organizations.

We expect that there will continue to be significant litigation in the biotechnology and pharmaceutical industries regarding patents and other proprietary rights. We have become involved in patent litigation, and we may likely become involved in additional patent litigation in the future. We may incur substantial costs in asserting any patent rights and in defending suits against us related to intellectual property rights. Such disputes could substantially delay our product development or commercialization activities, and could have a material adverse effect on our business, financial condition and results of operations. As discussed in "Legal Proceedings" below, there are two pending litigation

matters either involving or affecting our products and patents. The adverse disposition of either of these litigations will adversely affect our business, financial condition and results of operations.

We also rely on trade secrets, know-how and continuing technological advancements to protect our proprietary technology. We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and we may not be able to successfully protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how.

We have limited sales and marketing experience, which makes us dependent on our marketing partners.

Other than ADAGEN, which we market on a worldwide basis to a small patient population, we have not engaged in the direct commercial marketing of any of our products and therefore we do not have significant experience in sales, marketing or distribution. For some of our products, we have provided exclusive marketing rights to our corporate partners in return for milestone payments and royalties to be received on sales. To the extent that we enter into licensing arrangements for the marketing and sale of our products, any revenues we receive will depend primarily on the efforts of these third parties. We will not control the amount and timing of marketing resources that such third parties devote to our products. In addition, if we market products directly, significant additional expenditures and management resources would be required to create an internal sales force. In any sales or marketing effort, we would compete with many other companies that currently have extensive and well-funded sales operations. Our marketing and sales efforts may be unable to compete successfully against other such companies.

We may need to obtain additional financing to meet our future capital needs and this financing may not be available when we need it.

Our current development projects require substantial capital. We may require substantial additional funds to conduct research activities, pre-clinical studies, clinical trials and other activities relating to the successful commercialization of potential products. In addition, we may seek to acquire additional technologies. We do not expect to achieve significant sales or royalty revenue from our current FDA-approved products, ADAGEN and ONCASPAR. In addition, we cannot be sure that we will obtain significant revenue from PEG-Intron in the near future, or ever. Additional funds from other sources may not be available on acceptable terms, if at all. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially and adversely affect our business, financial condition and operations.

While we believe that our cash, cash equivalents and investments, will be adequate to satisfy our capital needs for the foreseeable future, our actual capital requirements will depend on many factors, including:

- the level of revenues we receive from our FDA-approved products and product candidates,
- continued progress of our research and development programs,
- our ability to establish additional collaborative arrangements,
- changes in our existing collaborative relationships,

- progress with pre-clinical studies and clinical trials,
- the time and costs involved in obtaining regulatory clearance for our products,
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, competing technological and market developments, and
- our ability to market and distribute our products and establish new collaborative and licensing arrangements.

We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources which may be dilutive to existing stockholders. We cannot assure you that we will be able to obtain additional funds on acceptable terms, if at all. If adequate funds are not available, we may be required to:

- delay, reduce the scope or eliminate one or more of our development projects,
- obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves, or
- license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our business.

Because of the specialized scientific nature of our business, we are highly dependent upon qualified scientific, technical and managerial personnel. There is intense competition for qualified personnel in the pharmaceutical field. Therefore, we may not be able to attract and retain the qualified personnel necessary for the development of our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner would harm our research and development programs and our business.

The failure of computer systems to be year 2000 compliant could negatively impact our business.

In 1999, we completed a review of our business systems, including computer systems and manufacturing equipment, and queried our customers and vendors as to their progress in identifying and addressing problems that their systems may face in correctly interrelating and processing date information in the year 2000. To date, we have not experienced any significant problems related to the year 2000 problem, either in our systems or the systems of our vendors or customers. The failure of our computer systems to be year 2000 compliant could negatively impact our business.

Risks Related To Our Industry

We face rapid technological change and intense competition, which could harm our business and results of operations.

The biopharmaceutical industry is characterized by rapid technological change. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. Rapid technological development by others may result in our products and technologies becoming obsolete.

We face intense competition from established biotechnology and pharmaceutical companies, as well as academic and research institutions that are pursuing competing technologies and products. We know that competitors are developing or manufacturing various products that are used for the prevention, diagnosis or treatment of diseases that we have targeted for product development. Many of our competitors have substantially greater research and development capabilities and experiences and greater manufacturing, marketing and financial resources than we do. Accordingly, our competitors may develop technologies and products that are superior to those we or our collaborators are developing and render our technologies and products or those of our collaborators obsolete and noncompetitive. In addition, many of our competitors have much more experience than we do in pre-clinical testing and human clinical trials of new drugs, as well as obtaining FDA and other regulatory approval. If we cannot compete effectively, our business and financial performance would suffer.

We may be sued for product liability.

Because our products and product candidates are new treatments, with limited, if any, past use on humans, their use during testing or after approval could expose us to product liability claims. We maintain product liability insurance coverage in the total amount of $10.0 million for claims arising from the use of our products in clinical trials prior to FDA approval and for claims arising from the use of our products after FDA approval. We cannot assure you that we will be able to maintain our existing insurance coverage or obtain coverage for the use of our other products in the future. Also, this insurance coverage and our resources may not be sufficient to satisfy any liability resulting from product liability claims and a product liability claim may have a material adverse effect on our business, financial condition or results of operations.

Sales of our products could be adversely affected if the costs for these products are not reimbursed by third-party payors.

In recent years, there have been numerous proposals to change the health care system in the United States. Some of these proposals have included measures that would limit or eliminate payments for medical procedures and treatments or subject the pricing of pharmaceuticals to government control. In addition, government and private third-party payors are increasingly attempting to contain health care costs by limiting both the coverage and the level of reimbursement of drug products. Consequently, significant uncertainty exists as to the reimbursement status of newly-approved health care products.

Our ability to commercialize our products will depend, in part, on the extent to which reimbursement for the cost of the products and related treatments will be available from third-party payors. If we or any of our collaborators succeeds in bringing one or more products to market, we cannot assure you that third-party payors will establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. In addition, lifetime limits on benefits

included in most private health plans may force patients to self-pay for treatment. For example, patients who receive ADAGEN are expected to require injections for their entire lives. The cost of this treatment may exceed certain plan limits and cause patients to self-fund further treatment. Furthermore, inadequate third-party coverage may lead to reduced market acceptance of our products. Significant changes in the health care system in the United States or elsewhere could have a material adverse effect on our business and financial performance.

Risks Related To The Price Of Our Stock

The price of our common stock has been, and may continue to be, volatile.

Historically, the market price of our common stock has fluctuated over a wide range and it is likely that the price of our common stock will fluctuate in the future. The market price of our common stock could be impacted due to a variety of factors, including:

- the results of pre-clinical testing and clinical trials by us, our corporate partners or our competitors,
- announcements of technical innovations or new products by us, our corporate partners or our competitors,
- the status of corporate collaborations and supply arrangements entered into by us, our corporate partners or our competitors,
- regulatory approvals of our products or those of our competitors,
- changes in government regulation,
- developments in the patents or other proprietary rights owned or licensed by us or our competitors,
- public concern as to the safety and efficacy of products developed by us or others,
- litigation, and
- general market conditions in our industry.

In addition, due to one or more of the foregoing factors in one or more future quarters, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could be materially and adversely affected.

The stock market has recently experienced extreme price and volume fluctuations. These fluctuations have especially affected the market price of the stock of many high technology and healthcare-related companies. Such fluctuations have often been unrelated to the operating performance of these companies. Nonetheless, these broad market fluctuations may negatively affect the market price of our common stock.

Events with respect to our share capital could cause the price of our common stock to decline.

Sales of substantial amounts of our common stock in the open market, or the availability of such shares for sale, could adversely affect the price of our common stock. We had 38,049,632 shares of common stock outstanding as of

February 15, 2000, excluding shares reserved for issuance upon the exercise of outstanding stock options and warrants, and the conversion of outstanding preferred stock. The following securities that may be exercised for, or are convertible into, shares of our common stock were issued and outstanding as of

February 15, 2000:

- Options. Stock options to purchase 3,205,136 shares of our common stock at a weighted average exercise price of approximately $6.23 per share; of this total, 2,647,536 are currently exercisable at a weighted average exercise price of $3.88 per share.

- Warrants. Various warrants to purchase 457,731 shares of our common stock, all of which are currently exercisable, at a weighted average exercise price of $5.75 per share.

- Series A preferred stock. 27,000 shares of our Series A preferred stock are outstanding, all of which are currently convertible into 61,364 shares of our common stock.

The shares of our common stock that may be issued under the warrants and options are either currently registered with the SEC, or will be registered with the SEC before the shares are purchased by the holders of the warrants and options. The shares of common stock that may be issued upon conversion of the Series A preferred stock are eligible for sale without any volume limitation pursuant to Rule 144(k) under the Securities Act of 1933, as amended.

Our charter documents and Delaware law may discourage a takeover of our company.

Provisions of our certificate of incorporation, bylaws and Delaware law could make it more difficult for a third party to acquire or merge with us, even if doing so would be beneficial to our stockholders.

Our board of directors has the authority to issue up to 3,000,000 shares of our preferred stock, par value $0.01 per share, and to determine the price and terms, including preferences and voting rights, of those shares without stockholder approval. Although we have no current plans to issue additional shares of our preferred stock, any such issuance could:

- have the effect of delaying, deferring or preventing a change in control of our company,

- discourage bids for our common stock at a premium over the market price, or

- adversely affect the market price of and the voting and other rights of the holders of our common stock.

In addition, certain provisions of our certificate of incorporation establishing a classified board of directors, and our agreements with our executive officers that provide significant payments to them following a change in control of our company, could each have the effect of discouraging potential takeover attempts.

PATENTS

We have licensed, and been issued, a number of patents in the United States and other countries and have other patent applications pending to protect our proprietary technology. Although we believe that our patents provide adequate protection for the conduct of our business, we cannot assure you that such patents:

- will be of substantial protection or commercial benefit to us,

- will afford us adequate protection from competing products, or

- will not be challenged or declared invalid.

We also cannot assure you that additional United States patents or foreign patent equivalents will be issued to us.

The patent covering our original PEG technology, which we had licensed from Research Corporation Technologies Inc., contained broad claims covering the attachment of PEG to polypeptides. However, this United States patent and its

corresponding foreign patents have expired. Based upon the expiration of the Research Corporation patent, other parties will be permitted to make, use, or sell products covered by the claims of the Research Corporation patent, subject to other patents, including those which we hold. We have obtained and intend to continue to pursue patents with claims covering improved methods of attaching or linking PEG to therapeutic compounds. We also have obtained patents relating to the specific composition of the PEG-modified compounds that we have identified or created. We will continue to seek such patents as we develop additional PEG-enhanced products. We cannot assure you that any of these patents will enable us to prevent infringement or that competitors will not develop competitive products outside the protection that may be afforded by our patents.

We are aware that others have also filed patent applications and have been granted patents in the United States and other countries with respect to the application of PEG to proteins and other compounds. Owners of any such patents may seek to prevent us or our collaborators from selling our products. In January 2000, Hoffmann-La Roche filed lawsuits in both the U.S. and France against Schering-Plough alleging that PEG-Intron infringes certain patents held by Hoffmann-La Roche. The validity and scope of Hoffmann-La Roche's patents in this segment of the industry could be judicially determined during these proceedings. If Schering-Plough does not prevail in this litigation, Hoffmann-La Roche may completely block Schering-Plough from commercializing PEG-Intron. Among other things, the outcome will likely depend not only upon whether the Hoffmann-La Roche patents are determined valid and infringed, but upon the reasoning behind such determinations. Prior to the commencement of this litigation we obtained an opinion of patent counsel that the patent held by Hoffmann-La Roche is invalid. We are also aware of certain patents held by Biopure Corporation that are relevant to PEG-hemoglobin. We have obtained an opinion of counsel that no valid claims of such Biopure patents would be infringed by the sale of PEG-hemoglobin. These opinions have been relied upon by us and our collaborators in continuing to pursue

development of these products; however, these opinions are not binding on any court or the U.S. Patent and Trademark Office. We cannot assure you that the patent opinions will prove to be correct and that a court would find any of the claims of such patents to be invalid or that the product developed by us or our collaborator does not infringe such patents.

We also believe that there are PEG-modified products being developed by third parties that infringe on one or more of our current PEG technology patents. On December 7, 1998, we filed a patent infringement suit against Shearwater Polymers Inc., a company that reportedly has developed a Branched PEG, or U-PEG, used in Hoffmann-La Roche's Pegasys product, a PEG-modified version of its alpha-interferon product called Roferon-A. According to published reports, Pegasys utilizes a type of Branched PEG for which we have been granted a patent in the U.S. and have a similar patent pending in Europe. Shearwater has filed a counterclaim in this litigation alleging that our Branched PEG patent is invalid and unenforceable.

In the field of SCA proteins, we have several United States and foreign patents and pending patent applications, including a patent granted in August 1990 covering the genes needed to encode SCA proteins. Creative BioMolecules, Inc., or Creative, provoked an interference with the patent and on June 28, 1991, the United States Patent and Trademark Office entered summary judgment terminating the interference proceeding and upholding our patent. Creative subsequently lost its appeal of this decision in the United States Court of Appeals and did not file a petition for review of this decision by the United States Supreme Court within the required time period.

In November 1993, Creative signed collaborative agreements with us in the field of our SCA protein technology and Creative's Biosynthetic Antibody Binding Site protein technology. Under the agreements, each company is free, under a non-exclusive, worldwide license, to develop and sell products utilizing the technology claimed by both companies' antibody engineering patents, without paying royalties to the other. Each company is also free to market products in collaboration with third parties, but the third parties will be required to pay royalties on products covered by the patents which will be shared by the companies, except in certain instances. We have the exclusive right to market licenses under both companies' patents other than to Creative's collaborators. In addition, the agreements provide for the release and discharge by each

company of the other from any and all claims based on past infringement of the technology which is the subject of the agreements. The agreement also provides for any future disputes between the companies regarding new patents in the area of engineered monoclonal antibodies to be resolved pursuant to agreed-upon procedures.

The degree of patent protection to be afforded to biotechnological inventions is uncertain and our products are subject to this uncertainty. We are aware of certain issued patents and patent applications, and there may be other patents and applications, containing subject matter which we or our licensees or collaborators may require in order to research, develop or commercialize at least some of our products. We cannot assure you that we will be able to obtain a license to such subject matter on acceptable terms, or at all.

In addition to the litigation described above, we expect that there may be significant litigation in the industry regarding patents and other proprietary rights and, to the extent we become involved in such litigation, it could consume a substantial amount of our resources. An adverse decision in any such litigation could subject us to significant liabilities. In addition, we rely heavily on our proprietary technologies for which pending patent applications have been filed and on unpatented know-how developed by us. Insofar as we rely on trade secrets and unpatented know-how to maintain our competitive technological position, we cannot assure you that others may not independently develop the

same or similar technologies. Although we have taken steps to protect our trade secrets and unpatented know-how, third-parties nonetheless may gain access to such information.

LEGAL PROCEEDINGS

We are being sued, in the United States District Court for the District of New Jersey, by LBC Capital Resources, Inc., a former financial advisor. LBC is asserting that under the May 2, 1995 letter agreement between us and LBC, LBC was entitled to a commission in connection with our January and March 1996 private placements, comprised of $500,000 and warrants to purchase approximately 1,000,000 shares of our common stock at an exercise price of $2.50 per share. LBC has claimed $3.0 million in compensatory damages, plus punitive damages, counsel fees and costs for the alleged breach of the letter agreement. We have entered into an agreement with LBC, known as the Stipulation of Damages, which provides that if we are found liable to LBC in this suit, the damages for these claims would be limited to $2.75 million in cash. LBC has also asserted that it is entitled to an additional fee of $175,000 and warrants to purchase 250,000 shares of our common stock to the extent any of the warrants issued to investors in the private placements are exercised. We believe that no such compensation is due to LBC under this letter agreement and deny any liability under the letter agreement. We intend to defend this lawsuit vigorously and believe the ultimate resolution of this matter will not have a material adverse effect on our financial position. However, if we were required to issue warrants to LBC we would be required to incur a non-cash expense for each warrant issued equal to the difference between the exercise price of the warrants ($2.50) and the then current market price of our common stock.

In December 1998, we filed a patent infringement suit against Shearwater Polymers Inc., a company that has reportedly developed a Branched PEG, or U-PEG, used in Hoffmann-La Roche's Pegasys product, a PEG-modified version of its alpha-interferon product called Roferon-A. We believe that Pegasys utilizes a type of Branched PEG for which we have been granted a patent in the U.S. and have similar patents pending in Europe, Japan and Canada. Shearwater has filed a counter-claim in this litigation alleging that our Branched PEG patent is invalid and unenforceable.

In January 2000, Hoffmann-La Roche filed lawsuits in both the U.S. and France against Schering-Plough alleging that PEG-Intron infringes certain patents held by Hoffmann-La Roche. The validity and scope of Hoffmann-La Roche's patents in this segment of the industry could be judicially determined during these proceedings. If Schering-Plough does not prevail in this litigation, Hoffmann-La Roche may completely block Schering-Plough from commercializing PEG-Intron. Among other things, the outcome will likely depend not only upon whether the patents are determined valid and infringed, but upon the reasoning

behind such determinations. We are presently unable to predict either the effect or degree of effect this litigation will have on our business and financial condition.

We have two research and license agreements with the Green Cross Corporation regarding rHSA. We were recently involved in an arbitration to resolve the amount of royalties to which we are entitled under these agreements. In April 1998, Yoshitomi Pharmaceutical Industries, Ltd., the successor to Green Cross' business, filed documents in such arbitration seeking a declaratory judgment that under its agreement with us no royalties are payable. In February 2000, the arbitrators awarded us a 1 % royalty on Yoshitomi sales of rHSA in Japan, South East Asia, India, China, Australia, New Zealand and North and South America for a period of 15 years after the first commercial sale of Yoshitomi's rHSA following market approval of that product in Japan or the United States.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 17, 2000

ENZON, INC.

(Registrant)

By: /s/ KENNETH J. ZUERBLIS

Kenneth J. Zuerblis
Vice President, Finance
and Chief Financial Officer