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

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

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Commission

For the fiscal year ended June 30, 1999

File Number 0-12957

[LOGO] ENZON, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

22-2372868
(I.R.S. Employer Identification No.)

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

08854 (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.01 par value (Title of class)

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

Indicate by check mark if disclosure of delinquent filers pursuant to item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

The aggregate market value of the Common Stock, par value \$.01 per share, held by non-affiliates based upon the reported last sale price of the Common Stock on September 17, 1999 was approximately \$1,078,697,000. There is no market for the Series A Cumulative Convertible Preferred Stock, the only other class of voting stock.

As of September 17, 1999, there were 36,721,599 shares of Common Stock, par value \$.01 per share, outstanding.

The Index to Exhibits appears on page 30.

Documents Incorporated by Reference

The registrant's definitive Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on December 7, 1999, to be filed with the Commission not later than 120 days after the close of the registrant's fiscal year, has been incorporated by reference, in whole or in part, into Part III Items 10, 11, 12 and 13 of this Annual Report on Form 10-K.

ENZON, INC.

1999 Form 10-K Annual Report

TABLE OF CONTENTS

			Page
		PART I	
Item	1.	Business	3
Item	2.	Properties	18
Item	3.	Legal Proceedings	18
Item	4.	Submission of Matters to a Vote of Security Holders	18
		PART II	
Item	5.	Market for the Registrant's Common Equity and	
		Related Stockholder Matters	19
Item	6.	Selected Financial Data	20
Item	7.	Management's Discussion and Analysis of Financial	20
		Condition and Results of Operations	
Item	7a.	Quantitative and Qualitative Disclosures About Market Risk	29
Item	8.	Financial Statements and Supplementary Data	29
Item	9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	29
		PART III	
Item	10.	Directors and Executive Officers of the Registrant	30
Item	11.	Executive Compensation	30
		Security Ownership of Certain Beneficial Owners and Management	30
		Certain Relationships and Related Transactions	30
		PART IV	
Item	14.	Exhibits, Financial Statement Schedules and Reports on Form 8-K	30

The following trademarks and service marks appear in this Annual Report: ADAGEN(R), ONCASPAR(R) and PROTHECAN(R) are registered trademarks of Enzon, Inc.; SCA(R) is a registered trademark of SCA Ventures Inc., formerly Enzon Labs Inc.; Elspar(R) is a registered trademark of Merck & Co., Inc; INTRON(R) A is a registered trademark of Schering-Plough Corporation; REBETRON(TM) and PEG-Intron(TM) are trademarks of Schering-Plough Corporation; REBETOL(R) is a registered trademark of ICN Pharmaceuticals, Inc.; Hycamtin(TM) is a trademark of SmithKline Beecham plc; Camptosar(R) is a registered trademark of Rhone-Poulenc Rorer Pharmaceuticals Inc.; Roferon(R)-A is a registered trademark of Hoffmann-LaRoche, Inc. and Pegasys(TM) is a trademark of Hoffman-LaRoche.

2

PART I

Item 1. BUSINESS

Overview

Enzon, Inc. ("Enzon" or the "Company") is a biopharmaceutical company that develops, manufactures and markets enhanced therapeutics for life-threatening diseases through the application of its two proprietary technologies: (i) polyethylene glycol ("PEG") Modification or the PEG Process and (ii) single-chain antigen-binding ("SCA(R)") proteins. Enzon is focusing its internal research activities on applying its proprietary technologies to compounds of known therapeutic efficacy in order to enhance the performance of these compounds. The Company is commercializing its proprietary technologies by developing products internally and in cooperation with strategic partners. To date, the Company and its partners have successfully commercialized two products, ONCASPAR(R) and ADAGEN(R) (described below). The Company currently has two products in clinical development as well as several compounds in preclinical development and has established more than 15 strategic alliances and license relationships for the development of products using the Company's proprietary technologies. The Company believes that its partners are dedicating substantial resources to the development of products which incorporate Enzon's proprietary technologies. These efforts include the development of PEG-Intron(TM), a PEG modified version of Schering-Plough Corporation's ("Schering-Plough") product and, INTRON(R) A (interferon alfa 2b), a genetically-engineered

anticancer-antiviral drug. Schering-Plough is currently conducting late stage clinical trials for PEG-Intron in several indications.

#### PEG Technology

The PEG process involves chemically attaching PEG, a relatively non-reactive and non-toxic polymer, to proteins, chemicals and certain other pharmaceuticals for the purpose of enhancing their therapeutic value (the "PEG Process"). The attachment of PEG helps to disguise the compound and reduce the recognition of the compound by the immune system, generally lowering potential immunogenicity and extending the life of such compounds in the circulatory system. The PEG Process also increases the solubility of the modified compound, which enhances the delivery of the native compound. To date, Enzon's commercialized products are PEG modified proteins. Through enhancements, Enzon is applying its PEG technology to more traditional pharmaceutical "organic" compounds.

The Company has made significant improvements to the original PEG Process, collectively referred to as Second Generation PEG Technology, and has applied for and received certain patents covering some improvements. One of the components of the Second Generation PEG Technology is new linker chemistries; the chemical binding of PEG to unmodified proteins. These new linkers provide an enhanced binding of the PEG to the protein resulting in a more stable compound with increased circulation life and may result in more activity of the modified protein.

The Company also has developed a Third Generation PEG Technology that is designed to enable the technology to be expanded to certain organic compounds and would give such PEG modified compounds "Pro Drug" attributes. This is accomplished by attaching PEG to a compound by means of a covalent bond that is designed to break down over time, thereby releasing the active ingredient in the proximity of various tissues. In animal models the Company has been able to demonstrate that Third Generation PEG modified compounds preferentially accumulate in tumors. The attachment of PEG can also increase the solubility of organic compounds, which are typically insoluble. The Company believes that the "Pro Drug/Transport Technology" can be applied to a wide range of small molecules, such as cancer chemotherapy agents, antibiotics, anti-fungals and immunosuppressants, as well as to proteins and peptides, including enzymes and growth factors. There can be no assurance that such application will result in safe, effective, or commercially viable pharmaceutical products.

3

#### PEG Products under Development

The Company currently has two products that utilize its PEG Technology in human clinical trials as well as additional compounds in preclinical trials. The first product is PEG-Intron, a PEG modified version of Schering-Plough's product, INTRON A (interferon alfa 2b), a genetically-engineered anticancer-antiviral drug. Schering-Plough is currently conducting late stage clinical trials for use of PEG-Intron in the treatment of hepatitis C and cancer. The second product under development is PROTHECAN(R), a PEG modified version of camptothecin, a potent topoisomerase-1 inhibitor, for use in certain cancers. PROTHECAN, which utilizes the Company's Third Generation PEG Technology, is currently in a Phase I safety trial being conducted by Enzon. In addition, the Company has several additional Third Generation PEG Technology products in preclinical testing.

PEG-Intron was developed by the Company in conjunction with Schering-Plough to have potentially longer lasting activity, an enhanced safety profile and improved efficacy compared to the currently marketed form of INTRON A. PEG-Intron is currently in large scale Phase III clinical trials in hepatitis C patients as a monotherapy and in combination with REBETOL(R) (ribavirin) in the United States, Europe and Japan. PEG-Intron is also in large scale Phase III clinical trials for two cancer indications, chronic myelogenous leukemia and malignant melanoma. The product is also in several earlier stage clinical trials for the treatment of solid tumors and other leukemias. It is expected that PEG-Intron will be administered once per week, compared to the current regimen for unmodified INTRON A of three times or more per week. Moreover, it is anticipated that PEG-Intron will have an improved side effect profile and an improved therapeutic index. Currently, some patients on unmodified INTRON A experience debilitating flu-like symptoms.

Pursuant to an agreement with Schering-Plough, the Company will receive royalties on worldwide sales of PEG-Intron and milestone payments. Schering-Plough's combined sales of INTRON A and REBETOL (REBETRON(TM) Combination Therapy) were approximately \$719 million in 1998. The worldwide market for alpha interferon products is estimated to be in excess of \$1.5 billion for all approved indications. The Company's Second Generation PEG Technology patents that cover the modified product should afford Schering-Plough extended patent life for PEG-Intron.

#### Marketed PEG Products

The Company received marketing approval from the United States Food and Drug Administration ("FDA") for two first generation PEG technology products: (i) ADAGEN, the PEG formulation of adenosine deaminase ("ADA"), the first successful application of enzyme replacement therapy for an inherited disease to treat a rare form of Severe Combined Immunodeficiency Disease ("SCID"), commonly known as the "Bubble Boy Disease" and (ii) ONCASPAR, the PEG formulation of asparaginase, for the indication of acute lymphoblastic leukemia ("ALL") in patients who are hypersensitive to native forms of L-asparaginase.

ADAGEN is marketed by Enzon on a worldwide basis. ONCASPAR is marketed in the U.S. and Canada by Rhone-Poulenc Rorer Pharmaceuticals, Inc. and certain of its affiliated entities ("RPR") and in Europe by Medac GmbH ("MEDAC"). Currently, the Company is temporarily distributing ONCASPAR in the U.S. and Canada on a limited basis due to a manufacturing problem encountered during the year. It is anticipated that this problem will be resolved in the next year and that RPR will resume distribution of the product. The Company has also granted exclusive licenses to RPR to sell ONCASPAR in the Pacific Rim and Mexico. When ONCASPAR is distributed by RPR, the Company is entitled to royalties on the sales of ONCASPAR in North America and manufacturing revenue from the production of ONCASPAR. The Company's agreements with RPR for the Pacific Rim and with MEDAC require the partners to purchase ONCASPAR from the Company at a set price, which increases over the term of the agreements. In addition, the agreements provide for minimum purchase quantities. The Company manufactures both ADAGEN and ONCASPAR in its South Plainfield, New Jersey facility.

#### SCA Technology

Enzon's other proprietary technology is SCA protein technology. SCA proteins are genetically engineered proteins designed to expand on the therapeutic and diagnostic applications possible with monoclonal antibodies.

4

SCA proteins have the binding specificity and affinity of monoclonal antibodies, and Enzon believes that SCA proteins offer at least five additional benefits that expand the utility of antigen binding proteins: (i) greater tissue penetration for both diagnostic imaging and therapy, (ii) more specific localization to target sites in the body, (iii) a significant decrease in immunogenic problems when compared with mouse-based antibodies, (iv) easier and more cost effective scale-up for manufacturing when compared with monoclonal antibodies and (v) enhanced screening capabilities which allow for the more rapid assessment of SCA proteins of desired specificity using high throughput screening methods. In addition to these benefits, fully-human SCA proteins can be isolated directly from human SCA libraries without the need for costly and time consuming "humanization" procedures. SCA proteins are also readily produced through intracellular expression (inside cells) allowing for their use in gene therapy applications where SCA molecules act as specific inhibitors of cell function.

Currently, there are eleven SCA proteins that have either completed or are in Phase I or II clinical trials by various organizations, including licensees of the Company and academic institutions. Some of the areas being explored are cancer therapy, cardiovascular indications and AIDS. The Company has begun a program to develop SCA compounds in-house. The Company has granted non-exclusive licenses to more than a dozen companies, including Bristol-Myers Squibb Company, Baxter Healthcare Corporation, Eli Lilly & Co., Alexion Pharmaceuticals Inc., and the Gencell division of RPR. These licenses generally provide for upfront payments, milestone payments and royalties on sales of FDA approved products.

Information contained in this Annual Report contains "forward-looking

statements" which can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should" or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy. No assurance can be given that the future results covered by the forward-looking statements will be achieved. The matters set forth in the section entitled Risk Factors, constitute cautionary statements identifying important factors with respect to such forward-looking statements, including certain risks and uncertainties, that could cause actual results to vary materially from the future results indicated in such forward-looking statements. Other factors could also cause actual results to vary materially from the future results indicated in such forward-looking statements.

#### Products on the Market

The Company has received U.S. marketing approval from the FDA for two First Generation PEG Technology products, ADAGEN and ONCASPAR. The Company received approval from the FDA for ADAGEN in March 1990 and for ONCASPAR in February 1994.

#### ADAGEN

ADAGEN, the Company's first FDA approved product, is currently being used to treat 61 patients in 7 countries. ADAGEN represents the first successful application of enzyme replacement therapy for an inherited disease. ADAGEN, the enzyme ADA modified through the PEG Process, was developed by the Company for the treatment of ADA deficiency associated with SCID, commonly known as the "Bubble Boy Disease". SCID is a congenital disease that results in children being born without fully functioning immune systems, leaving them susceptible to a wide range of infectious diseases. Injections of unmodified ADA would not be effective because of its short circulating life (less than thirty minutes) and the potential for immunogenic reactions to a bovine-sourced enzyme. The attachment of PEG to ADA allows ADA to achieve its full therapeutic effect by increasing its circulating life and masking the ADA to avoid immunogenic reactions.

ADAGEN is being marketed on a worldwide basis and sold in the United States by Enzon. Distribution of ADAGEN in Europe and Japan is being handled by a European firm. Enzon believes many newborns with ADA-deficient SCID go undiagnosed and is therefore focusing its marketing efforts for ADAGEN on new patient identification. The Company's marketing efforts include educational presentations and publications designed to encourage early diagnosis and subsequent ADAGEN treatment.

Sales of ADAGEN for the fiscal years ended June 30, 1999, 1998 and 1997 were \$11,246,000, \$10,107,000 and \$8,935,000, respectively. Currently, the only alternative to ADAGEN treatment is a well-matched bone marrow transplant. Patients that are unable to receive successful bone marrow transplants are expected to

5

require ADAGEN injections for the rest of their lives. Sales of ADAGEN are expected to continue to be limited due to the small patient population worldwide.

#### ONCASPAR

ONCASPAR, the enzyme L-asparaginase modified by the PEG Process, is currently approved in the United States, Canada and Germany, and is used in conjunction with other chemotherapeutics to treat patients with ALL who are hypersensitive (allergic) to native (unmodified) forms of L-asparaginase. ONCASPAR is marketed in the U.S. and Canada by RPR and in Europe by MEDAC.

L-asparaginase is an enzyme which depletes the amino acid asparagine, a non-essential amino acid upon which certain leukemic cells are dependent for survival. Accordingly, the depletion of plasma asparagine levels selectively starves these leukemic cells. L-asparaginase is a component of standard pediatric ALL remission induction therapies. Unmodified L-asparaginase is currently marketed in the U.S. by Merck & Co. as Elspar(R).

Native L-asparaginase sold by other companies is used in Europe to treat adult ALL and non-Hodgkins lymphoma, in addition to pediatric ALL. The

therapeutic value of unmodified L-asparaginase is limited by two inherent aspects of the enzyme. First, its short half-life in blood (less than 1.5 days) requires every-other-day injections, causing significant discomfort and inconvenience to patients. Secondly, the enzyme's non-human source makes it inherently immunogenic, resulting in a high incidence of allergic reactions, some of which may be severe, necessitating the discontinuance of the L-asparaginase therapy.

Through PEG Modification, Enzon believes ONCASPAR offers significant therapeutic advantages over unmodified L-asparaginase. ONCASPAR has a significantly increased half-life in blood (greater than five days), allowing every-other-week administration, making its use more tolerable to patients than unmodified L-asparaginase. PEG Modification also disguises the enzyme's foreign nature, generally reducing its immunogenicity, and enabling its use in patients who are allergic to unmodified L-asparaginase.

ONCASPAR was launched in the United States by RPR during March 1994. The Company has granted RPR an exclusive license (the "Amended RPR U.S. License Agreement") in the United States to sell ONCASPAR, and any other PEG-asparaginase product (the "Product") developed by Enzon or RPR during the term of the Amended RPR U.S. License Agreement. During fiscal 1999, the FDA and the Company agreed to institute temporary labeling modifications for ONCASPAR and assumed the responsibility for distribution of ONCASPAR. The temporary labeling and distribution modifications were a result of an increased level of particulates in certain batches of ONCASPAR, manufactured by the Company. The Company has been able to manufacture several batches of ONCASPAR which contain acceptable levels of particulates and anticipates a final resolution of the problem during fiscal 2000. It is expected that RPR will resume distribution of ONCASPAR at that time. There can be no assurance that this solution will be acceptable to the FDA. If the Company is unable to resolve this problem it is possible that the FDA may not permit the Company to continue to distribute this product. An extended disruption in the marketing and distribution of ONCASPAR could have a material adverse impact on future ONCASPAR sales. During May 1999, the FDA further limited the distribution of ONCASPAR to patients who are hypersensitive to other forms of L-asparaginase.

#### RPR Agreements

Under the Company's Amended RPR U.S. License Agreement, Enzon has received licensing payments totaling \$6,000,000 and is entitled to a base royalty of 23.5% until 2008, on net sales of ONCASPAR up to agreed upon amounts. Additionally, the Amended RPR U.S. License Agreement provides for a super royalty of 43.5% until 2008, on net sales of ONCASPAR which exceed certain agreed upon amounts, with the limitation that the total royalties earned for any such year shall not exceed 33% of net sales. The Amended RPR U.S. License Agreement also provides for a payment of \$3,500,000 in advance royalties, which was received in January 1995.

The payment of base royalties to Enzon under the Amended RPR U.S. License Agreement will be offset by an original credit of \$5,970,000, which represents the royalty advance plus reimbursement of certain amounts due to RPR under the original RPR U.S. License Agreement and interest expense. Super royalties will be paid to the

6

Company when earned. The royalty advance is shown as a long term liability, with the corresponding current portion included in accrued expenses on the Consolidated Balance Sheets as of June 30, 1999 and 1998. The royalty advance will be reduced as base royalties are recognized under the agreement.

The Amended RPR U.S. License Agreement prohibits RPR from selling a competing PEG-asparaginase product anywhere in the world during the term of such agreement and for five years thereafter. The agreement terminates in December 2008, subject to early termination by either party due to a default by the other or by RPR at any time upon one year's prior notice to Enzon. Upon any termination all rights under the Amended RPR U.S. License Agreement revert to Enzon. A separate supply agreement with RPR requires RPR to purchase from Enzon all Product requirements for sales in North America.

The Company and RPR are currently in discussions related to a disagreement over the purchase price of ONCASPAR under the supply agreement between the two

companies. RPR has asserted that the Company has overcharged RPR under the supply agreement in the amount of \$2,329,000. The Company believes its costing and pricing of ONCASPAR to RPR complies with the supply agreement. RPR has also asserted that the Company should be responsible for its lost profits while ONCASPAR is under the temporary labeling and distribution modifications. RPR contends that its lost profits through June 30, 1999 were \$2,968,000. The Company does not agree with RPR's claims. The Company does not believe the ultimate resolution of either matter will have a materially adverse effect on the Company's financial position or results of operations.

Under a separate license, RPR has exclusive rights to sell ONCASPAR in Canada and Mexico. These agreements provide for RPR to obtain marketing approval of ONCASPAR in Canada and Mexico and for the Company to receive royalties on sales of ONCASPAR in these countries, if any.

The Company also has a license agreement with RPR for the Pacific Rim region, specifically, Australia, New Zealand, Japan, Hong Kong, Korea, China, Taiwan, Philippines, Indonesia, Malaysia, Singapore, Thailand and Viet Nam, (the "Pacific Rim"). The agreement provides for RPR to purchase ONCASPAR for the Pacific Rim from the Company at certain established prices, which increase over the ten year term of the agreement. Under the agreement, RPR is responsible for obtaining additional approvals and indications in the licensed territories. The agreement also provides for minimum purchase requirements for the first four years of the agreement.

#### MEDAC Agreement

The Company has also granted an exclusive license with MEDAC to sell ONCASPAR in Europe and Russia. The agreement provides for MEDAC to purchase ONCASPAR from the Company at certain established prices, which increase over the initial five year term of the agreement. Under the agreement, MEDAC is responsible for obtaining additional approvals and indications in the licensed territories, beyond the currently approved hypersensitive indication in Germany. Under the agreement, MEDAC is required to meet certain minimum purchase requirements.

#### Research and Development

The Company's primary source of new products is its internal research and development activities. Research and development expenses for the fiscal years ended June 30, 1999, 1998 and 1997 were approximately \$6,836,000,\$8,654,000 and \$8,520,000,\$8,654,000 respectively.

The Company's research and development activities during fiscal 1999 concentrated primarily on preclinical work on PROTHECAN, the Company's first product to use Third Generation Pro Drug/Transport Technology and continued research and development of the Company's proprietary technologies.

# Technologies and Capabilities

The Company's technologies are focused in the area of drug delivery. The Company's PEG Modification technology is able to lower the potential immunogenicity, extend the circulating life and enhance solubility of the modified compound. The Company believes its SCA and Pro Drug/Transport Technologies may be able to achieve

7

targeting of the modified compound to a desired site in the body. It is believed that this will result in less toxicity to the surrounding tissue and increased therapeutic effect due to a high concentration of the compound in the targeted tissue. The Company is currently applying its technologies to compounds with known therapeutic efficacy that suffer from delivery problems. This encompasses undeveloped compounds as well as products already on the market.

# PEG Modification

Enzon's proprietary technology, PEG Modification or the PEG Process, involves chemically attaching PEG to therapeutic proteins or chemical compounds that are difficult to deliver. PEG is a relatively non-reactive and non-toxic polymer that is typically used in many food and pharmaceutical products. Attachment of PEG disguises the protein and reduces its recognition by the

immune system, thereby generally lowering potential immunogenicity and extending its circulating life, in some cases from minutes to days. Chemical compounds have an added drawback in that they are typically water-insoluble, which makes delivery difficult, or in some cases, impossible. The Company believes the attachment of PEG to chemical substances not only disguises the chemical, thereby lowering potential immunogenicity and extending its circulatory life, but also greatly increases the solubility of these compounds. Enzon believes that compounds modified by the PEG Process may offer significant advantages over their unmodified forms. These advantages include: (i) extended circulating life, (ii) reduced incidence of allergic reactions, (iii) reduced dosages with corresponding lower toxicity without diminished efficacy, (iv) increased drug stability and (v) enhanced drug solubility. Modification of proteins with the PEG Process often causes these proteins to have characteristics that significantly improve their therapeutic performance, and in some cases enables proteins to be therapeutically effective which, in their unmodified forms, have proven to be non-efficacious. The PEG Process was originally covered by a broad patent which expired in late 1996.

The Company has developed and patented proprietary know-how, collectively referred to as Second Generation PEG Technology, which significantly improves the PEG Process over that described in the original patent covering this technology. This proprietary know-how enables the Company to tailor the PEG Process in order to produce the desired results for the particular substance being modified. This know-how includes, among other things, proprietary linkers for the attachment of PEG to compounds, the selection of the appropriate attachment sites on the surface of the compound, and the amount and type of PEG used. These improvements allow PEG to bind to different parts of the molecules, which may result in more activity of the modified protein. Attachment of PEG to the wrong site on the protein can result in a loss of its activity or therapeutic effect. The main objective of the First and Second Generation Technologies is to permanently attach PEG to the unmodified protein. The PEG modified version of Schering-Plough's INTRON A, which is in several Phase III clinical trials in the U.S. and Europe, utilizes the Company's Second Generation PEG Technology. See "Strategic Alliances and License Agreements - Schering". The Company has received patents for numerous improvements to the PEG Process. See "Patents".

# Pro Drug/Transport Technology

The Company recently has developed a Third Generation PEG technology that gives PEG modified compounds "Pro Drug" attributes. This is accomplished by attaching PEG to a compound by means of a covalent bond that is designed to temporarily inactivate the compound, and then deteriorate over time, thereby releasing the therapeutic moiety in the proximity of the target tissue. These attributes could significantly enhance the therapeutic value of new chemicals, as well as drugs already marketed by others. The Company believes that this technology has broad usefulness and that it can be applied to a wide range of drugs, such as cancer chemotherapy agents, antibiotics, anti-fungals and immunosuppressants, as well as to proteins and peptides, including enzymes and growth factors. The markets for these drugs and biologicals have large potential patient populations.

The Company is currently applying its Pro Drug/Transport Technology to cancer chemotherapy agents and anti-fungals. One such compound, PROTHECAN, a PEG modified version of camptothecin, a topo-1 inhibitor, is in a Phase I clinical trial. The Company believes that the covalent attachment of PEG can inactivate the drug's toxic mechanisms, while allowing the drug to circulate in the bloodstream for longer periods of time, thereby allowing the compound to accumulate in the proximity of the tumor site. Preliminary animal studies have shown that a compound modified with the Company's Third Generation PEG Technology preferentially accumulates in tumors. The covalent bond used in the Third Generation Technology to attach the PEG to the drug is designed to deteriorate over time, resulting in the PEG falling off and allowing the compound to resume its activity. Animal studies conducted by the

8

Company thus far have demonstrated increases in the therapeutic index of compounds modified by the Company's Pro Drug/Transport Technology. However, there can be no assurance that these advantages can be attained or that drugs based on this technology will be approved by the FDA.

The Company has several patent applications relating to its Pro Drug/Transport Technology that have been allowed or are under review. See "Patents".

Single-Chain Antigen-Binding (SCA) Proteins

Enzon's proprietary SCA proteins are genetically engineered proteins designed to expand on the therapeutic and diagnostic applications possible with monoclonal antibodies. SCA proteins have the binding specificity and affinity of monoclonal antibodies, and Enzon believes that human SCA proteins offer at least five additional benefits that expand the utility of antigen-binding proteins: (i) greater tissue penetration for both diagnostic imaging and therapy, (ii) more specific localization to target sites in the body, (iii) a significant decrease in immunogenic problems when compared with mouse-based antibodies, (iv) easier and more cost effective scale-up for manufacturing when compared with monoclonal antibodies and (v) enhanced screening capabilities which allow for the more rapid assessment of SCA proteins of desired specificity using high throughput screening methods. In addition to these benefits, fully-human SCA proteins can be isolated directly from human SCA libraries without the need for costly and time consuming "humanization" procedures. SCA proteins are also readily produced through intracellular expression (inside cells) allowing for their use in gene therapy applications where SCA molecules act as specific inhibitors of cell function.

Beyond these established benefits we anticipate the future of antibody derived therapeutics will employ "designer antibodies" exhibiting tailored affinity, valency, effector and pharmacological properties. The simplicity of the single gene, single polypeptide SCA designs may form the basis for the next generation of immunotherapy drugs.

Enzon and numerous other academic and industrial laboratories have demonstrated the binding specificity of SCA proteins through the preparation and in vitro testing of dozens of different SCA proteins. The Company, in collaboration with Dr. Jeffrey Schlom of the Laboratory of Tumor Immunology and Biology at the National Cancer Institute ("NCI"), has convincingly shown in published preclinical studies that SCA proteins localize to specific tumors and rapidly penetrate the tumors.

Currently, there are eleven SCA proteins that have either completed or are in Phase I or II clinical trials by various organizations, including licensees of the Company and academic institutions. Some of the areas being explored are cancer therapy, cardiovascular indications and AIDS. The Company believes that those organizations that have not yet licensed this technology will need a license from Enzon to commercialize these products, but there can be no assurance that this will prove to be the case. The following are some examples of research being conducted in the SCA area:

The Company's licensee, Alexion Pharmaceuticals, Inc. ("Alexion") has developed a humanized SCA protein, 5G-1.1SC, directed against complement protein C5. Complement protein C5 is a component of the body's normal defense against foreign pathogens. Inappropriate complement activation during cardiopulmonary bypass and myocardial infarction can lead to clinical problems. Phase I trials of 5G-1.1SC during cardiopulmonary bypass have demonstrated clinically significant improvements in cardiac and neurological function as well as reduced blood loss. Alexion in conjunction with its partner Procter & Gamble is evaluating 5G-1.1SC in a Phase IIb study of 1,000 subjects undergoing cardiopulmonary bypass surgery. Alexion and Procter & Gamble are also planning to study 5G-1.1SC in two Phase II acute myocardial infarction trials later in 1999.

Another application of the Company's SCA technology is in the area of "T-Bodies". T-Body technology involves the expression of an SCA protein in a T-Cell that has been removed from the body. T-Cells, a type of lymphocyte cell, represent an important component of the immune system responsible for cell-mediated immunity and represent one of the body's natural defenses against foreign materials such as cancer cells and infectious organisms. Using SCA technology T-Cells can be modified through molecular biology methods to express an SCA on the cell surface that can then recognize and bind to a specific

antigen, thereby targeting the T-Cell to a specific location. Cell Genesys, an Enzon licensee, has had success in applying T-Bodies in preclinical studies with the CC49 SCA protein targeted to the TAG-72 cancer antigen. In its recently completed Phase I/II trial Cell Genesys reported that the treatment could be safely administered in an outpatient setting although no antitumor activity was observed.

SCA proteins are also being used in antibody engineering, through the use of phage display library technology, for the isolation of high specificity antibody binding regions. Using phage display technology, it is possible to conveniently isolate a fully human high-affinity SCA protein specific to virtually any target antigen, including anti-self targets. Cambridge Antibody Technology Ltd. ("CAT"), an Enzon licensee, is a pioneer in the development of combinatorial antibody libraries (the "Phage Antibody System"). CAT currently has several licensing agreements with global pharmaceutical and biotechnology companies to apply their library to the identification and isolation of high specificity antibody proteins. Any companies working with CAT will be required to negotiate a license with Enzon for any SCA protein that they might wish to commercialize.

Scientists at the Dana-Farber Cancer Institute and the University of Alabama are conducting research utilizing SCA proteins called intrabodies. These are SCA proteins produced in an intracellular environment (inside the cell) via gene therapy. The Dana Farber Cancer Institute is studying the use of a very specific intrabody for HIV/AIDS while the University of Alabama is studying a separate intrabody for ovarian cancer targeted to the erbB-2 receptor. Animal data generated from these studies have revealed that SCA proteins produced through intracellular expression can provide an important therapeutic response. The University of Alabama has completed a Phase I trial and the Dana-Farber Cancer Institute expects to initiate its trial shortly.

The Company believes it has a dominant patent position in SCA protein technology and has received numerous patents encompassing basic SCA designs and applications, the most recent of which expires in 2016 (see "Patents"). The Company is developing several new technology platforms combining its proprietary SCA and PEG technologies. These platforms are expected to further expand the utility of SCA proteins in particular by allowing for the development of highly specific SCA proteins that have a circulating half-life matching the therapeutic indication. Enzon is also evaluating the feasibility of licensing in SCA proteins for internal development, in addition to licensing the basic SCA technology to other companies for use in discovery and therapeutic product programs. To date, the Company has granted SCA product licenses to more than fifteen companies, including Bristol-Myers Squibb, Baxter Healthcare, Eli Lilly and RPR Gencell. These product licenses generally provide for upfront payments, milestone payments and royalties on sales of commercialized products. See "Strategic Alliances and License Agreements".

# Products Under Development

The Company currently has two products that utilize its PEG technology in clinical trials as well as several in preclinical trials. The first is PEG-Intron, a PEG modified version of Schering-Plough's product, INTRON A (interferon alfa 2b), a genetically-engineered anticancer-antiviral drug, for which Schering-Plough is currently conducting several Phase III clinical trials for use in the treatment of hepatitis C and cancer. The second product under development is PROTHECAN, a PEG-modified version of camptothecin, a potent topoisomerase-1 inhibitor, for use in certain cancers, which is currently in Phase I clinical trials being conducted by Enzon. During 1998, Enzon completed a Phase Ib clinical trial for PEG-hemoglobin, a proprietary bovine hemoglobin-based oxygen-carrier being developed for the radiosensitization of solid hypoxic tumors. The Company has ceased development of this product until a partner can be identified to fund Phase II clinical trials.

## PEG-Intron

PEG-Intron was developed by the Company in conjunction with Schering-Plough to potentially have longer lasting activity, an enhanced safety profile and better efficacy compared to the currently marketed form of Schering-Plough's INTRON A. It is expected that PEG-Intron will be administered once per week, compared to the current regimen for unmodified INTRON A of three or more times per week. Currently, some patients on unmodified INTRON A experience debilitating flu-like symptoms.

Schering-Plough's combined sales of INTRON A and REBETOL (REBETRON Combination Therapy) were approximately \$719 million in 1998 for all approved indications. The worldwide market for alpha interferon products is estimated to be in excess of \$1.5 billion for all approved indications.

Schering-Plough is currently developing PEG-Intron for hepatitis C as a monotherapy and as a combination therapy with an antiviral compound, REBETOL (REBETRON Combination Therapy). Both indications are in Phase III clinical trials. Schering's unmodified INTRON A is currently approved as a monotherapy and in combination with ribavirin, marketed as REBETOL. It is expected that PEG-Intron will be administered once per week, as compared to the current regimen of three times per week; the side effect profile will be improved and the product may be potentially more efficacious then unmodified INTRON A. It is estimated that roughly one half of Schering-Plough's sales of INTRON A are for hepatitis indications.

An estimated ten million people worldwide are infected with the hepatitis C virus, including nearly four million in the U.S. The majority of people in the United States are thought to have contracted the virus through blood transfusions. Prior to 1992 the blood supply was not screened for the hepatitis C virus. The majority of people infected with the virus are thought to be unaware of the infection because the hepatitis C virus can exist for up to ten years before patients become symptomatic. Today it is estimated that roughly only 50,000 patients are currently being treated in the U.S. for hepatitis C. Because of the side effect profile of INTRON A and the other competing therapy, patients who have been diagnosed with the hepatitis C virus are sometimes reluctant to take the product.

Schering-Plough is also developing PEG-Intron for use in cancer. PEG-Intron is in Phase III clinical trials for chronic myelogenous leukemia and malignant melanoma, as well as earlier stage clinical trials for various solid tumors and other leukemias. Due to the potential for improved side effects it is anticipated that higher doses of PEG-Intron will be used, as compared to the current unmodified INTRON A, which could lead to increased efficacy and additional indications or usage. PEG-Intron is expected to be administered once per week, as opposed to up to five times per week for current cancer regimens with unmodified INTRON A. Published Phase I clinical data has shown that some patients who previously did not respond to unmodified INTRON A treatment did respond to PEG-Intron.

The Company's Second Generation PEG Technology patents that have been licensed to Schering-Plough should provide extended patent life for Intron A.

#### PROTHECAN

PROTHECAN or PEG-camptothecin is the first product to utilize the Company's Third Generation-Pro/Drug Transport Technology. The compound, a PEG modified version of camptothecin, a topo-1 inhibitor, is being developed as an oncolytic, anticancer compound. Camptothecin, which was originally developed at the NIH and is now off patent is believed be the most potent of the topo-1 inhibitors.

For many years camptothecin has been known to be a very effective oncolytic agent with drug delivery problems. Recently, camptothecin derivatives, Hycamtin(TM) and Camptosar(R), have been approved by the FDA. While these two new products improved the solubility of camptothecin, the efficacy rate on the compounds is relatively low. The Company believes that its Pro Drug/Transport Technology has additional delivery advantages and increased therapeutic value over the compounds on the market.

The Company believes that by adjusting the way PEG is covalently attached to camptothecin, PEG attachment can be used to inactivate the compound's toxic mechanism, while allowing it to circulate in the bloodstream for long periods of time, thereby allowing the compound to accumulate in the proximity of tumor sites. Preliminary animal tests have shown that Third Generation PEG-modified compounds preferentially accumulate in tumors. The covalent bond used in the camptothecin to attach PEG to the drug is designed to deteriorate over time, resulting in the PEG falling off and allowing the compound to resume its activity.

The Company is currently conducting a Phase I clinical trial on the compound.

#### Hemoglobin-Based Oxygen-Carrier

In 1998, the Company concluded a Phase Ib clinical trial for a hemoglobin-based oxygen-carrier, PEG-hemoglobin, for use as a radiosensitizer, in conjunction with radiation treatment of solid hypoxic tumors. The Company has halted the development of its hemoglobin-based oxygen-carrier pending the identification of a partner to fund Phase II clinical trials. To date, no such agreement has been concluded and there can be no assurance that any such agreement will be consummated. Furthermore, there can be no assurance of market acceptability of a hemoglobin-based oxygen-carrier produced from bovine hemoglobin.

Single-Chain Antigen-Binding (SCA) Proteins

The Company is currently evaluating the feasibility of licensing in, for internal development, several SCA compounds currently under development.

Currently, there are eleven SCA proteins that have either completed or are in Phase I or II clinical trials conducted by various corporations and institutions, including a product developed by one of the Company's licensees, Alexion, which is in a Phase IIb clinical trial. Some of the areas being explored with SCAs are cancer therapy, cardiovascular indications and AIDS.

#### Strategic Alliances and License Agreements

In addition to internal product development, the Company utilizes joint development and licensing arrangements with other pharmaceutical and biopharmaceutical companies, to expand the pipeline of products utilizing its proprietary PEG and SCA protein technologies. Enzon believes that its technologies can be used to improve products which are already on the market or that are under development, thus producing therapeutic products which will provide a safer, more effective and more convenient therapy. Currently, the Company's partners have two products in late stages of the approval progress; PEG-Intron and Human Serum Albumin, as well as several SCA compounds in Phase I and Phase II clinical trials.

# Schering Agreement

The Company and Schering Corporation ("Schering"), a subsidiary of Schering-Plough, entered into an agreement in November 1990 (the "Schering Agreement") to apply the Company's PEG Process to develop a modified form of Schering-Plough's INTRON A (interferon alfa 2b), a genetically-engineered anticancer and antiviral drug, with longer activity. A PEG-modified version of INTRON A is currently in four large scale Phase III clinical trials in the United States, Europe and Japan for hepatitis C and cancer as well as earlier stage trials for various solid tumors and leukemias. The trials call for administration of PEG-Intron once per week as compared to the current regimen for unmodified INTRON A of three times per week. PEG-Intron utilizes the Company's Second Generation PEG Technology.

INTRON A is currently approved in the United States for use in chronic hepatitis B, chronic hepatitis C, AIDS-related Kaposi's sarcoma, venereal warts, hairy cell leukemia and malignant melanoma. It is approved for use in 82 countries for 16 disease indications. Schering-Plough reported 1998 combined sales of INTRON A and REBETOL (REBETRON Combination Therapy) of \$719 million worldwide.

Under the license agreement, which was amended in 1995 and 1999, the Company will receive royalties on worldwide sales of PEG-Intron, if any. Schering is responsible for conducting and funding the clinical studies, obtaining regulatory approval and marketing the product worldwide on an exclusive basis. During 1999, the Company and Schering amended the agreement that resulted in an increase in the effective royalty rate in return for the elimination of Enzon's exclusive U.S. manufacturing rights for the product and a license under one of the Company's Second Generation PEG patents for Branched or U-PEG. The license for Branched PEG gives Schering the ability to sublicense the patent to any party developing a competing interferon product.

basis, upon the expiration of the last to expire of any future patents covering the product which may be issued to Enzon, or 15 years after the product is approved for commercial sale, whichever shall be the later to occur. This agreement is subject to Schering's right of early termination if the product does not meet specifications, if Enzon fails to obtain or maintain the requisite product liability insurance, or if Schering makes certain payments to Enzon. If Schering terminates the agreement because the product does not meet specifications, Enzon may be required to refund certain of the milestone payments. Revenue will not be recognized on these payments until the product is deemed to meet specification.

## Green Cross Agreement

The Company has a license agreement with Green Cross Corporation ("Green Cross") (which was acquired by Yoshitomi Pharmaceutical, Inc.) for the development of a recombinant Human Serum Albumin (rHSA), as a blood volume expander. Green Cross has reported that it filed for approval of this product in Japan in November 1997. The agreement, which the Company acquired as part of the acquisition of Genex Corporation in 1991, entitles Enzon to a royalty on sales of an rHSA product sold by Green Cross in much of Asia and North and South America. Currently, Green Cross is only developing this product for the Japanese market. The royalty is payable under the agreement for the first fifteen years of commercial sales. The parties are currently in binding arbitration to resolve a dispute regarding the royalty rate called for in the agreement. Green Cross has filed papers in the arbitration taking the position that no royalty will be due to Enzon. Enzon disputes such a position and is vigorously pursuing its claim in the arbitration for the royalty stated in the agreement. There can be no assurance that Enzon will prevail in the arbitration.

## SCA Protein Technology Licenses

The Company's SCA protein licenses are primarily on a non-exclusive basis, and in most cases, provide for the partner to pay for all development costs and to market the products. Enzon receives a royalty on the sale of any SCA protein product developed, as well as in most cases, payments based on the achievement of certain milestones in the product development. The Company has more than 15 non-exclusive SCA protein licenses. The following is a partial list of the Company's SCA protein licenses.

Corporate Partner	Agreement Date	Product	Disease or Indication	Program Status
Alexion Pharmaceuticals, Inc.	May 1996	Complement Protein C5	Cardiopulmonary bypass and myocar- dial infarction	Phase IIb
Baxter Healthcare Corporation	November 1992	SCA proteins	Cancer	Research
Bristol-Myers Squibb Company Seattle Genetics	September 1993/July 1994 September 1998*	SCA proteins BR96	All Therapeutics Cancer	Research Phase I
Cambridge Antibody Technology Ltd.	September 1996	Phage Display Library	All Therapeutics	Research
Cell Genesys Inc.	November 1993	SCA/Receptor Technology	Colon Cancer	Phase I/II
Eli Lilly and Co.	December 1992	SCA proteins	Undetermined	Research
Gencell Division of RPR	December 1995	SCA proteins	Gene Therapy	Research

\*Bristol-Myers Squibb sublicensed BR96 SCI to Seattle Genetics. This is the only compound that is sublicensed under the Bristol Agreement.

#### Marketing

Other than ADAGEN, which the Company markets on a worldwide basis to a small patient population, the Company does not engage in the direct commercial marketing of any of its products and therefore does not have an established sales force. For certain of its products, the Company has provided exclusive marketing rights to its corporate partners in return for royalties on sales.

With respect to ONCASPAR, the Company has granted exclusive marketing rights to (i) RPR for North America and the Pacific Rim, (ii) MEDAC for Europe and Russia and (iii) Tzamal Pharma Ltd. for Israel, pursuant to the agreements described in "Products on the Market - ONCASPAR".

13

The Company expects to evaluate whether to create a sales force to market certain products in the United States or to continue to enter into license and marketing agreements with others for United States and foreign markets. These agreements generally provide that all or a significant portion of the marketing of these products will be conducted by the Company's licensees or marketing partners. In addition, under certain of these agreements, the Company's licensee or marketing partners may have all or a significant portion of the development and regulatory approval responsibilities.

#### Raw Materials and Manufacturing

In the manufacture of its products, the Company couples activated forms of PEG to the unmodified proteins. In the case of PEG, the Company does not have a long-term supply agreement, but maintains what it believes to be an adequate inventory which should provide the Company sufficient time to find an alternate supplier of PEG, in the event it becomes necessary, without material disruption of its business.

The Company manufactures its two FDA approved products, ADAGEN and ONCASPAR, in its South Plainfield, New Jersey facility. Prior to the approval of its product, the Company's facility was inspected by two branches of the FDA, the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, for compliance with the FDA's current Good Manufacturing Practices. These inspections continue on a periodic basis after FDA marketing approval. The facility has also been inspected by the Canadian Health Protection Branch and the German Federal Institute for Drugs and Medical Devices, the equivalent of the FDA in those countries. The manufacturing facility was granted an establishment license by the FDA in February 1994.

The Company purchases the unmodified compounds utilized in its approved products and products under development from outside suppliers. The Company has a supply contract with an outside supplier for the unmodified ADA used in the manufacture of ADAGEN and the unmodified L-asparaginases used in the manufacture of ONCASPAR. The Company's supply contract for the L-asparaginase used in the production of product for the North American market expires in December 1999. The Company is currently in discussions to extend this agreement. The Company purchases the unmodified L-asparaginase used in the production of ONCASPAR for the European market from a different supplier than that used for the U.S. market.

Delays in obtaining or an inability to obtain any unmodified compound, including unmodified ADA or L-asparaginase, could have a material adverse effect on the Company. In the event the Company is required to locate an alternate supplier for an unmodified compound utilized in a product which is being sold commercially or which is in clinical development, the Company will likely be required to do additional testing, which could cause delay and additional expense, to demonstrate that the alternate supplier's material is biologically and chemically equivalent to the unmodified compound previously used. Such evaluations could include one or all of the following: chemical, preclinical and clinical studies. Requirements for such evaluations would be determined by the stage of the product's development and the reviewing division of the FDA. If such alternate material is not demonstrated to be chemically and biologically equivalent to the previously used unmodified compound, the Company will likely be required to repeat some or all of the preclinical and clinical trials with such 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 may require the Company to conduct additional clinical trials with such alternate material.

## Government Regulation

The manufacturing and marketing of pharmaceutical products in the United States requires the approval of the FDA under the Federal Food, Drug and Cosmetic Act. Similar approvals by comparable agencies are required in most

foreign countries. The FDA has established mandatory procedures and safety standards which apply to the clinical testing, manufacture and marketing of pharmaceutical products. Obtaining FDA approval for a new therapeutic may take several years and involve substantial expenditures. Pharmaceutical manufacturing facilities are also regulated by state, local and other authorities.

As an initial step in the FDA regulatory approval process, preclinical studies are conducted in animal  ${\cal P}$ 

14

models to assess the drug's efficacy and to identify potential safety problems. The results of these studies are submitted to the FDA as a part of the Investigational New Drug Application ("IND"), which is filed to obtain approval to begin human clinical testing. The human clinical testing program may involve up to three phases. Data from human trials are submitted to the FDA in a New Drug Application ("NDA") or Biologic License Application ("BLA"). Preparing an NDA or BLA involves considerable data collection, verification and analysis.

ADAGEN was approved by the FDA in March 1990. ONCASPAR was approved for marketing in the U.S. and Germany in 1994 and in Canada in December 1997 for patients with ALL who are hypersensitive to native forms of L-asparaginase, and in Russia in April 1993 for therapeutic use in a broad range of cancers. Except for these approvals, none of the Company's other products have been approved for sale and use in humans in the United States or elsewhere. Difficulties or unanticipated costs may be encountered by the Company or its licensees or marketing partners in their respective efforts to secure necessary governmental approvals, which could delay or preclude the Company or its licensees or marketing partners from marketing their products.

With respect to patented products, delays imposed by the government approval process may materially reduce the period during which the Company will have the exclusive right to exploit them. See "Patents".

#### Competition

Many established biotechnology and pharmaceutical companies with greater resources than the Company are engaged in activities that are competitive with those of Enzon and may develop products or technologies which compete with those of the Company. Although Enzon believes that the experience of its personnel in biotechnology, the patents which have been licensed by or issued to the Company and the proprietary know-how developed by the Company provide it with a competitive advantage in its field, there can be no assurance that the Company will be able to maintain any competitive advantage, should it exist, in view of the greater size and resources of many of the Company's competitors.

Enzon is aware that other companies are conducting research on chemically modified therapeutic proteins and that certain companies are modifying pharmaceutical products, including proteins, by attaching PEG. Other than the Company's products ONCASPAR and ADAGEN, the Company is unaware of any PEG modified therapeutic proteins, which are currently available commercially for therapeutic use. Nevertheless, other drugs or treatment modalities which are currently available or that may be developed in the future, and which treat the same diseases as those which the Company's products are designed to treat, may be competitive with the Company's products.

Prior to the development of ADAGEN, the Company's first FDA approved product, the only treatment available to patients afflicted with ADA deficient SCID was a bone marrow transplant. Completing a successful transplant depends upon finding a matched donor, the probability of which is low. More recently, researchers at the National Institute of Health, ("NIH") have been attempting to treat SCID patients with gene therapy, which if successfully developed, would compete with, and could eventually replace ADAGEN as a treatment. The patients in these trials are also receiving ADAGEN treatment in addition to the gene therapy. The theory behind gene therapy is that cultured T-lymphocytes that are genetically engineered and injected back into the patient will express permanently and at normal levels, adenosine deaminase, the deficient enzyme in people afflicted with ADA deficient SCID. To date, patients in gene therapy clinical trials have not been able to stop ADAGEN treatment and therefore, the trial has been inconclusive.

Current standard treatment of patients with ALL includes administering

unmodified L-asparaginase along with the drugs vincristine, prednisone and daunomycin. Studies have shown that long-term treatment with L-asparaginase increases the disease free survival in high risk patients. ONCASPAR, the Company's PEG modified L-asparaginase product, is used to treat patients with ALL who are hypersensitive to unmodified forms of L-asparaginase. The long-term survival and cure of ALL patients generally depends upon achieving a sustainable first remission. Currently, there is one unmodified form of L-asparaginase available in the United States (Elspar) and several available in Europe. The Company believes that ONCASPAR has two advantages over these unmodified forms of L-asparaginase: increased circulating blood life and generally reduced immunogenicity.

The current market for Intron A, Schering Plough's interferon alpha 2b product, is a highly competitive

15

market with Schering, Hoffmann-LaRoche, Inc. ("Hoffman-LaRoche) and Amgen, Inc. as well as several other companies selling similar products. The Company believes that PEG-Intron will have several potential advantages over the interferon products currently on the market, principally once per week dosing versus the current three times per week dosing, with an improved side effect profile and increased efficacy. It has also been reported that Hoffmann-LaRoche also has a potentially longer lasting version of its interferon product, Roferon(R)-A, in Phase III clinical trials, called Pegasys(TM). The Company believes that this product infringes a patent which covers one of the Company's Second Generation PEG Technologies, called Branched PEG. The Company has initiated patent infringement litigation against the supplier of the PEG technology used in Hoffmann-LaRoche's PEGASYS(TM), Shearwater Polymers Inc., which seeks to block this product from entering the market. (see "Patents").

Several companies are actively pursuing the development of agents to increase the oxygen level in solid tumors and thereby enhance the efficacy of radiation and/or chemotherapy that could compete with PEG-hemoglobin. Some of these agents are also being tested in clinical trials. In addition, many conventional cytotoxic agents are currently used in combination with each other and/or with radiation to give additive or synergistic anti-cancer effects.

There are several technologies which compete with the Company's SCA protein technology, including chimeric antibodies, humanized antibodies, human monoclonal antibodies, recombinant antibody Fab fragments, low molecular weight peptides and mimetics. These competing technologies can be categorized into two areas: (i) those modifying the monoclonal to minimize immunological reaction to a foreign protein, which is the strategy employed with chimerics, humanized antibodies and human monoclonal antibodies and (ii) those creating smaller portions of the monoclonal which are more specific to the target and have fewer side effects, as is the case with Fab fragments and low molecular weight peptides. Enzon believes that the smaller size of its SCA proteins should permit better penetration into the tumor, result in rapid clearance from the blood and cause a significant decrease in the immunogenic problems associated with conventional monoclonal antibodies. A number of organizations have active programs in SCA proteins. The Company believes that its patent position on SCA proteins will likely require companies that have not licensed its SCA protein patents to obtain licenses from Enzon in order to commercialize their products, but there can be no assurance that this will prove to be the case.

#### Patents

The Company has licensed, and been issued, a number of patents in the United States and other countries and has other patent applications pending to protect its proprietary technology. Although the Company believes that its patents provide adequate protection for the conduct of its business there can be no assurance that such patents will be of substantial protection or commercial benefit to the Company, will afford the Company adequate protection from competing products, will not be challenged or declared invalid, or that additional United States patents or foreign patent equivalents will be issued to the Company. The degree of patent protection to be afforded to biotechnological inventions is uncertain and the Company's products are subject to this uncertainty. The Company is aware of certain issued patents and patent applications, and there may be other patents and applications, containing subject matter which the Company or its licensees or collaborators may require in order to research, develop or commercialize at least some of the Company's

products. There can be no assurance that licenses under such subject matter will be available on acceptable terms. In certain cases, the Company has obtained opinions of patent counsel that certain of such patents, including patents relevant to PEG-hemoglobin held by Biopure Inc. and patents relevant to PEG-Intron held by Hoffman-LaRoche, are not infringed by the products of the Company or its collaborators or would not be held to be valid if litigated. Such opinions have been relied upon by the Company and its collaborators in continuing to pursue development of the subject product. Such opinions are not binding on any court and there can be no assurance that such 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 the Company or its collaborator does not infringe such patents.

The Company also believes that there are PEG modified products being developed that infringe on one or more of the Company's Second Generation PEG Technology patents. During fiscal 1999 the Company filed a patent infringement suit against Shearwater Polymers Inc., a company that reportedly has developed a PEG modified version of ROFERON-A, Hoffmann-La-Roche's version of alpha interferon, called Pegasys. According to published reports, Pegasys utilizes a type of PEG called Branched or U-PEG for which Enzon has been granted a patent in the U.S. and has a similar patent pending in Europe. While the Company believes its patent which covers Branched PEG

16

will be held valid and could prevent this product from being introduced into the market, there can be no assurance that the Company will be successful in this area.

The Company expects that there may be significant litigation in the industry regarding patents and other proprietary rights and, if Enzon were to become involved in such litigation, it could consume a substantial amount of the Company's resources. In addition, the Company relies heavily on its proprietary technologies for which pending patent applications have been filed and on unpatented know-how developed by the Company. Insofar as the Company relies on trade secrets and unpatented know-how to maintain its competitive technological position, there can be no assurance that others may not independently develop the same or similar technologies. Although the Company has taken steps to protect its trade secrets and unpatented know-how, third-parties nonetheless may gain access to such information.

The original PEG Process patent which was licensed from Research Technologies Corp. expired in December 1996. The Company has made significant improvements to the original PEG Process called Second Generation PEG Technology and has applied for and received numerous patents for such improvements. The Company believes, based on new patents received and applications pending, that the expiration of the original PEG Process patent will not have a material impact on its business.

In the field of SCA proteins, the Company has 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. ("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 the Company's 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, Enzon and Creative signed collaborative agreements in the field of Enzon's SCA protein technology and Creative's Biosynthetic Antibody Binding Site (BABSO) 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 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. Enzon has 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.

#### Employees

As of June 30, 1999, Enzon employed 83 persons, of whom 36 were engaged in research and development activities, 26 were engaged in manufacturing, and 21 were engaged in administration and management. As of June 30, 1999, the Company had 15 employees who hold Ph.D. degrees. The Company believes that it has been successful in attracting skilled and experienced scientific personnel; however, competition for such personnel is intensifying. None of the Company's employees are covered by a collective bargaining agreement. All of the Company's employees are covered by confidentiality agreements. Enzon considers relations with its employees to be good.

17

### Item 2. Properties

The Company owns no real property. The following are all of the facilities that Enzon currently leases:

Location	Principal Operations	Approx. Square Footage	Approx. Annual Rent	Lease Expiration
20 Kingsbridge Road Piscataway, NJ	Research & Development and Administrative	56,000	\$496,000(1)	June 15, 2007
300 Corporate Ct. S. Plainfield, NJ	Manufacturing	24,000	183,000	March 31, 2007

(1) Under the terms of the lease, annual rent increases over the remaining term of the lease from \$496,000 to \$581,000.

The Company believes that its facilities are well maintained and generally adequate for its present and future anticipated needs.

## Item 3. Legal Proceedings

The Company is being sued, in the United States District Court for the District of New Jersey, by a former financial advisor asserting that under the May 2, 1995 letter agreement ("Letter Agreement") between Enzon and LBC Capital Resources Inc. ("LBC"), LBC was entitled to a commission in connection with the Company's January and March 1996 private placements, comprised of \$500,000 and warrants to purchase 1,000,000 shares of Enzon common stock at an exercise price of \$2.50 per share. LBC has also asserted that it is entitled to an additional fee of \$175,000 and warrants to purchase 250,000 shares of Enzon common stock when and if any of the warrants obtained pursuant to the private placements are exercised. LBC has claimed \$3,000,000 in compensatory damages, plus punitive damages, counsel fees and costs for the alleged breach of the Letter Agreement. The Company believes that no such commission was due under the Letter Agreement and denies any liability under the Letter Agreement. The Company intends to defend this lawsuit vigorously and believes the ultimate resolution of this matter will not have a material adverse effect on the financial position of the Company.

There is no other pending material litigation to which the Company is a party or to which any of its property is subject.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Market for the Registrant's Common Equity and
 Related Stockholder Matters

The Company's Common Stock is traded in the over-the-counter market and is quoted on the NASDAQ National Market under the trading symbol "ENZN".

The following table sets forth the high and low sale prices for the Common Stock for the years ended June 30, 1999 and 1998, as reported by the NASDAQ National Market. The quotations shown represent inter-dealer prices without adjustment for retail markups, markdowns or commissions, and may not necessarily reflect actual transactions.

	High	Low
Year Ended June 30, 1999 First Quarter Second Quarter Third Quarter Fourth Quarter	7.13 13.94 16.69 20.56	3.97 5.13 13.25 11.50
Year Ended June 30, 1998 First Quarter Second Quarter Third Quarter Fourth Quarter	5.19 7.25 7.19 6.88	2.00 4.75 5.13 4.56

As of September  $\,$  17, 1999 there were 2,232  $\,$  holders of record of the Common Stock.

The Company has paid no dividends on its Common Stock since its inception and does not plan to pay dividends on its Common Stock in the foreseeable future. Except as may be utilized to pay dividends payable on the Company's outstanding Series A Cumulative Convertible Preferred Stock ("Series A Preferred Shares" or "Series A Preferred Stock"), any earnings which the Company may realize will be retained to finance the growth of the Company. In addition, no dividends may be paid or set apart for payment on the Common Stock unless the Company shall have paid in full, or made appropriate provision for the payment in full of, all dividends which have then accumulated on the Series A Preferred Shares.

19

Item 6. Selected Financial Data

Set forth below is the selected financial data for the Company for the five fiscal years ended June 30, 1999.

Consolidated Statement of Operations Data:

					Year End	ded June	30			
		1999		1998	19	97		1996		1995
Revenues	\$13,	158,207	\$14,	644,032	\$12,727,0	)52	\$12,	681,281	\$15,8	326,437
Net Loss	\$ (4,	919,208)	3,	617,133)	(457,0	25)	(5,	175,279)	(6,2	291,491)
Net Loss per Share	\$	(0.14)	\$	(0.12)	(0.	.16)	\$	(.20)	\$	(.26)
Dividends on										
Common Stock		None		None	No	one		None		None

			June 30,		
	1999	1998	1997	1996	1995
ations	\$34,916,315 \$	\$13,741,378 \$	\$16,005,278 \$	\$21,963,856 \$ 1,728	

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations

Long-Term Obligations

Total Assets

Fiscal Years Ended June 30, 1999, 1998 and 1997

Revenues. Revenues for the year ended June 30, 1999 decreased to \$13,158,000 as compared to \$14,644,000 for fiscal 1998 due to a decrease in contract revenue. The components of revenues are sales, which consist of sales of the Company's products and royalties on the sale of such products by others, and contract revenues. Sales increased by 4% to \$12,856,000 for the year ended June 30, 1999 as compared to \$12,313,000 for the prior year. The increase was due to an increase in ADAGEN sales of approximately 11%, resulting from an increase in patients receiving ADAGEN treatment. Net sales of ADAGEN, which is marketed by Enzon, for the years ended June 30, 1999 and 1998 were \$11,246,000 and \$10,107,000, respectively. The Company markets its other approved product, ONCASPAR, through marketing agreements in the U.S. and Canada with RPR and in Europe with MEDAC. ONCASPAR revenues under the Company's Amended RPR U.S. License Agreement are comprised of manufacturing revenues, as well as royalties on sales of ONCASPAR by RPR. ONCASPAR revenues for fiscal 1999 decreased due to a decline in manufacturing and royalty revenues resulting from difficulties encountered in the Company's manufacturing process and the resulting changes in labeling and distribution described below.

During 1998 the Company began to experience manufacturing problems with ONCASPAR. The problems were due to an increase in the levels of particulates in batches of ONCASPAR which resulted in an increased rejection rate for this product. During fiscal 1999, as a result of these manufacturing problems the Company and the FDA agreed to temporary labeling and distribution modifications for ONCASPAR. The Company, rather then RPR, took over distribution of ONCASPAR directly to patients on an as-needed basis and instituted additional inspection and labeling procedures prior to distribution. In addition during May 1999, the FDA required the Company to limit distribution of the product to only those patients who are hypersensitive to native L-asparaginase.

The Company has been able to manufacture several batches of ONCASPAR which contain acceptable levels of particulates and anticipates a final resolution of the problem during fiscal 2000. It is expected that RPR will resume distribution of ONCASPAR at that time. There can be no assurance that this solution will be acceptable

20

to the FDA. If the Company is unable to resolve this problem it is possible that the FDA may not permit the Company to continue to distribute this product. An extended disruption in the marketing and distribution of ONCASPAR could have a material adverse impact on future ONCASPAR sales.

The Company expects sales of ADAGEN to increase at rates comparable to those achieved during the last two years as additional patients are treated. The Company also anticipates ONCASPAR sales will remain at reduced levels until the manufacturing problem is resolved and RPR resumes normal distribution of the product. There can be no assurance that any particular sales levels of ADAGEN or ONCASPAR will be achieved or maintained.

Contract revenue for the year ended June 30, 1999 decreased to \$302,000, as compared to \$2,331,000 for fiscal 1998. The decrease was principally due to the fact that the Company received milestone payments in 1998 under the Company's

licensing agreement for PEG-Intron with Schering-Plough and no such payments were received in 1999. During the year ended June 30, 1998, the Company recognized \$2,200,000 in milestone payments received as a result of Schering-Plough advancing PEG-Intron into a Phase III clinical trial. PEG-Intron is a modified form of Schering-Plough's INTRON A (interferon alfa-2b, recombinant), developed by Enzon to have longer-acting properties. INTRON A is a genetically engineered anticancer and antiviral agent, developed and marketed worldwide by Schering-Plough. Combined sales of INTRON A and REBETOL by Schering-Plough were \$719 million in 1998. The worldwide market for alpha interferon is estimated to be in excess of \$1.5 billion for all approved indications. Under the Company's licensing agreement with Schering-Plough, Enzon will be entitled to royalties of PEG-Intron sales and additional milestone payments.

During the years ended June 30, 1999 and 1998, the Company had export sales of \$3,075,000 and \$2,641,000, respectively. Of these amounts, sales in Europe were \$2,559,000 and \$2,117,000 for the years ended June 30, 1999 and 1998, respectively.

Revenues for the year ended June 30, 1998 increased to \$14,644,000 as compared to \$12,727,000 for fiscal 1997. Sales increased by 6% to \$12,313,000 for the year ended June 30, 1998 as compared to \$11,596,000 for the prior year. The increase was due to an increase in ADAGEN sales of approximately 13%, resulting from an increase in patients receiving ADAGEN treatment. Net sales of ADAGEN, which is marketed by Enzon, for the years ended June 30, 1998 and 1997 were \$10,107,000 and \$8,935,000, respectively. ONCASPAR revenues in 1998 decreased due to a decline in manufacturing revenue resulting from difficulties encountered in the Company's manufacturing process, previously discussed. The decrease in manufacturing revenue was partially offset by increased royalties due to an increase in sales of ONCASPAR by RPR.

Contract revenue for the year ended June 30, 1998 increased to \$2,331,000, as compared to \$1,131,000 for fiscal 1997. The increase was principally due to an increase in milestone payments received under the Company's licensing agreement for PEG-Intron with Schering-Plough. During the year ended June 30, 1998, the Company recognized \$2,200,000 in milestone payments received as a result of Schering-Plough advancing PEG-Intron into a Phase III clinical trial. During the prior year, the Company received a \$1,000,000 milestone payment under the same licensing agreement with Schering-Plough.

During the years ended June 30, 1998 and 1997, the Company had export sales of \$2,641,000 and \$2,377,000, respectively. Sales in Europe were \$2,117,000 and \$1,937,000 for the years ended June 30, 1998 and 1997, respectively.

Cost of Sales. Cost of sales, as a percentage of sales, increased to 34% for the year ended June 30, 1999 as compared to 30% in 1998. The increase was primarily due to a charge taken in the first quarter 1999 related to a write-off of ONCASPAR finished goods on hand and in the distribution pipeline, as well as increased ONCASPAR production costs. The increased write-off of ONCASPAR finished goods was attributable to the manufacturing problems previously discussed.

Cost of sales, as a percentage of sales, decreased to 30% for the year ended June 30, 1998 as compared to

21

33% for fiscal 1997. The decrease was primarily due to the prior year's expense of excess ONCASPAR raw material and purchase commitments related to the Company's supply agreement for this material. During the fiscal year ended June 1998, the Company amended its supply agreement for this material which extended the period available for the Company to accept delivery of its remaining purchase commitment through 1999, in exchange for a \$1,300,000 advance payment of the remaining purchase commitment. (See Note 10 to the Consolidated Financial Statements).

Research and Development. Research and development expenses for the year ended June 30, 1999 decreased by 21% to \$6,836,000 from \$8,654,000 last year. The decrease in research and development expenses resulted from (i) a decrease in facility costs resulting from the elimination of a leased facility and the consolidation of research and development operations and (ii) a decline in clinical trial costs. The decrease in clinical trial costs, was a result of the

completion of a Phase Ib clinical trial for PEG-hemoglobin in 1998. Research and development expenses are expected to increase to previous levels as a result of the commencement of Phase I clinical trials for PEG-camptothecin.

Research and development expenses for the year ended June 30, 1998 remained relatively unchanged at \$8,654,000 as compared to \$8,520,000 for the same period in 1997. The Company's research and development efforts were focused on the continued development of its Third Generation Pro Drug/Transport Technology, which included preclinical activities for PROTHECAN (PEG-camptothecin), as well as clinical trial costs for PEG hemoglobin.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended June 30, 1999 increased by 27% to \$8,133,000, as compared to \$6,426,000 in 1998. The increase was primarily due to an increase in marketing and distribution costs for ONCASPAR. Due to the changes in distribution previously discussed, the Company is responsible for all marketing and distribution for this product. During the prior year these costs were the responsibility of RPR.

Selling, general and administrative expenses for the year ended June 30, 1998 increased by 16% to \$6,426,000 as compared to \$5,528,000 for the year ended June 30, 1997. The increase was due to (i) increased investor and public relations activities, as well as (ii) consulting fees related to the development of a strategic business plan for the Company's SCA protein technology.

Other Income/Expense. Other income/expense increased by \$737,000 to \$1,201,000 for the year ended June 30, 1999, as compared to \$464,000 for last year. The increase was attributable to an increase in interest income due to an increase in interest bearing investments.

Other income/expense decreased by \$141,000 to \$464,000 for the year ended June 30, 1998 as compared to \$605,000 for the year ended June 30, 1997. The decrease was due principally to a decline in interest income due to a decrease in interest bearing investments.

Liquidity and Capital Resources

Total cash reserves, including cash and cash equivalents as of June 30, 1999 were \$24,674,000, as compared to \$6,478,000 in the previous year. The increase in total cash reserves was due to the completion of a private placement during July 1998, in which the Company sold 3,983,000 shares of Common Stock to a small group of investors resulting in net proceeds of approximately \$17,600,000. The Company invests its excess cash in a portfolio of high-grade marketable securities and United States government-backed securities.

The Company's Amended RPR License Agreement for ONCASPAR provided for a payment of \$3,500,000 in advance royalties which was received from RPR in January 1995. Royalties due under the Amended RPR License Agreement will be offset against an original credit of \$5,970,000, which represents the royalty advance plus reimbursement of certain amounts due RPR under the previous agreement and interest expense, before cash payments will be made under the agreement. The royalty advance is shown as a long-term liability, with the corresponding current portion included in accrued expenses on the consolidated balance sheets to be reduced as royalties are recognized under the agreement. Through June 30, 1999, an aggregate of \$4,380,000 in royalties

22

payable by RPR has been offset against the original credit.

As of June 30, 1999, 942,808 shares of Series A Preferred Shares had been converted into 3,097,955 shares of Common Stock. Accrued dividends on the converted Series A Preferred Shares in the aggregate of \$1,824,000 were settled by the issuance of 235,231 shares of Common Stock. The Company does not presently intend to pay cash dividends on the Series A Preferred Shares. As of June 30, 1999, there were accrued and unpaid dividends totaling \$1,984,000 on the Series A Preferred Shares. These dividends are payable in cash or Common Stock at the Company's option and accrue on the outstanding Series A Preferred Shares at the rate of \$214,000 per year.

The Company and RPR are currently in discussions related to a disagreement over the purchase price of ONCASPAR under the supply agreement between the two

companies. RPR has asserted that the Company has overcharged RPR under the supply agreement in the amount of \$2,329,000. The Company believes its costing and pricing of ONCASPAR to RPR complies with the supply agreement. RPR has also asserted that the Company should be responsible for its lost profits while ONCASPAR is under the temporary labeling and distribution modifications. RPR contends that its lost profits through June 30, 1999 were \$2,968,000. The Company does not agree with RPR's claims. The Company does not believe the ultimate resolution of either matter will have a materially adverse effect on the Company's financial position.

The Company is being sued, in the United States District Court for the District of New Jersey, by a former financial advisor asserting that under the May 2, 1995 letter agreement ("Letter Agreement") between Enzon and LBC Capital Resources Inc. ("LBC"), LBC was entitled to a commission in connection with the Company's January and March 1996 private placements, comprised of \$500,000 and warrants to purchase 1,000,000 shares of Enzon common stock at an exercise price of \$2.50 per share. LBC has also asserted that it is entitled to an additional fee of \$175,000 and warrants to purchase 250,000 shares of Enzon common stock when and if any of the warrants obtained pursuant to the private placements are exercised. LBC has claimed \$3,000,000 in compensatory damages, plus punitive damages, counsel fees and costs for the alleged breach of the Letter Agreement. The Company believes that no such commission was due under the Letter Agreement and denies any liability under the Letter Agreement. The Company intends to defend this lawsuit vigorously and believes the ultimate resolution of this matter will not have a material adverse effect on the financial position of the Company.

To date, the Company's sources of cash have been the proceeds from the sale of its stock through public and private placements, sales of ADAGEN, sales of ONCASPAR, sales of its products for research purposes, contract research and development fees, technology transfer and license fees and royalty advances. The Company's current sources of liquidity are its cash, cash equivalents and interest earned on such cash reserves, sales of ADAGEN, sales of ONCASPAR, sales of its products for research purposes and license fees. Based upon its currently planned research and development activities and related costs and its current sources of liquidity, the Company anticipates its current cash reserves will be sufficient to meet its capital and operational requirements for the foreseeable future.

Upon exhaustion of the Company's current cash reserves, the Company's continued operations will depend on its ability to realize significant revenues from the commercial sale of its products, raise additional funds through equity or debt financing, or obtain significant licensing, technology transfer or contract research and development fees. There can be no assurance that these sales, financings or revenue generating activities will be successful.

In management's opinion, the effect of inflation on the Company's past operations has not been significant.

Year 2000

The Company has completed a review of its business systems, including its computer systems and manufacturing equipment, and has queried its customers and vendors as to their progress in identifying and addressing problems that their systems may face in correctly interrelating and processing date information as the year 2000 approaches and is reached. Based on this review, the Company has implemented a plan to achieve year 2000 compliance. The Company believes that it will achieve year 2000 compliance in a manner which will be non-disruptive to its operations. In addition, the Company has prepared various types of contingency planning to address

23

potential problem areas with internal systems and with suppliers and other third parties. Year 2000 compliance should not have a material adverse effect on the Company, including the Company's financial condition, results of operations or cash flow.

However, the Company may encounter problems with suppliers and or revenue sources which could adversely affect the Company's financial condition, results of operations or cash flow. The Company cannot accurately predict the occurrence and or outcome of any such problems, nor can the dollar amount of any such

problem be estimated.

#### Risk Factors

Accumulated Deficit and Uncertainty of Future Profitability. The Company was originally incorporated in 1981. To date, the Company's sources of cash have been the proceeds from the sale of its stock through public offerings and private placements, sales of its FDA approved products, ADAGEN(R) and ONCASPAR(R); sales of its products for research purposes; contract research and development fees; technology transfer and license fees; and royalty advances. At June 30, 1999, the Company had an accumulated deficit of approximately \$121,761,000. The Company expects to incur operating losses for the foreseeable future. To date, ADAGEN and ONCASPAR are the only products of the Company which have been approved for marketing in the United States by the FDA, having been approved in March 1990 and February 1994, respectively. In addition, ONCASPAR has been approved for marketing in Canada, Germany and Russia.

During 1998 the Company began to experience manufacturing problems with ONCASPAR. The problems were due to an increase in the levels of particulates in batches of ONCASPAR which resulted in an increased rejection rate for this product. During fiscal 1999, as a result of these manufacturing problems the Company and the FDA agreed to temporary labeling and distribution modifications for ONCASPAR. The Company, rather then RPR, took over distribution of ONCASPAR directly to patients on an as-needed basis and instituted additional inspection and labeling procedures prior to distribution. In addition during May 1999 the FDA required the Company to limit distribution of the product to only those patients who are hypersensitive to native L-asparaginase.

The Company has been able to manufacture several batches of ONCASPAR which contain acceptable levels of particulates and anticipates a final resolution of the problem during fiscal 2000. It is expected that RPR will resume distribution of ONCASPAR at that time. There can be no assurance that this solution will be acceptable to the FDA. If the Company is unable to resolve this problem it is possible that the FDA may not permit the Company to continue to distribute this product. An extended disruption in the marketing and distribution of ONCASPAR could have a material adverse impact on future ONCASPAR sales.

In order to achieve profitable operations on a continuing basis, the Company, either alone or through its partners, must successfully manufacture, market and sell its ADAGEN and ONCASPAR products and develop, manufacture and market the Company's products which are under development. These products are in various stages of development, and the period necessary to achieve regulatory approval and market acceptance of any individual product is uncertain and typically lengthy, if achievable at all. Potential investors should be aware of the difficulties a biopharmaceutical enterprise such as the Company encounters, especially in view of the intense competition in the pharmaceutical industry in which the Company competes. There can be no assurance that the Company's plans will either materialize or prove successful, that its products under development will be successfully developed or that its products will generate revenues sufficient to enable the Company to achieve profitability.

Raw Materials and Dependence Upon Suppliers. The Company purchases the unmodified compounds utilized in its approved products and products under development from outside suppliers. The Company may be required to enter into supply contracts with outside suppliers for certain unmodified compounds. The Company does not produce the unmodified adenosine deaminase used in the manufacture of ADAGEN, the unmodified forms of L-asparaginase used in the manufacture of ONCASPAR and the unmodified camptothecin used in the Company's PROTHECAN(R) product which is under development and has a supply contract with an outside supplier for the supply of each of these unmodified

24

compounds. Delays in obtaining or an inability to obtain any unmodified compound, including unmodified adenosine deaminase, unmodified L-asparaginase, or unmodified camptothecin on reasonable terms, or at all, could have a material adverse effect on the Company's business, financial condition and results of operations. In the event the Company is required to obtain an alternate source for an unmodified compound utilized in a product which is being sold commercially or which is in clinical development, the FDA and relevant foreign regulatory agencies will likely require the Company to perform additional testing, which would cause delays and additional expenses, to demonstrate that

the alternate material is biologically and chemically equivalent to the unmodified compound previously used. Such evaluations could include chemical, pre-clinical and clinical studies and could delay development of a product which is in clinical trials, limit commercial sales of an approved product and cause the Company to incur significant additional expenses. If such alternate material is not demonstrated to be chemically and biologically equivalent to the previously used unmodified compound, the Company will likely be required to repeat some or all of the pre-clinical and clinical trials conducted for such 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 the Company to conduct additional clinical trials with such alternate material.

Patents and Proprietary Technology. The Company has licensed, and been issued, a number of patents in the United States and other countries and has other patent applications pending to protect its proprietary technology. Although the Company believes that its patents provide certain protection from competition, there can be no assurance that such patents will be of substantial protection or commercial benefit to the Company, will afford the Company adequate protection from competing products, will not be challenged or declared invalid, or that additional United States patents or foreign patent equivalents will be issued to the Company. The scope of patent claims for biotechnological inventions is uncertain and the Company's patents and patent applications are subject to this uncertainty. The Company is aware of certain issued patents and patent applications belonging to third parties, and there may be other patents and patent applications, containing subject matter which the Company or its licensees or collaborators may require in order to research, develop or commercialize at least some of the Company's products. There can be no assurance that licenses under such patents and patent applications will be available on acceptable terms or at all. If the Company does not obtain such licenses, it or its partners could encounter delays in product market introductions while it attempts to design around such patents or could find that the development, manufacture or sale of products requiring such licenses could be foreclosed. If the Company does obtain such licenses it will in all likelihood be required to make royalty and other payments to the licensers, thus reducing the profits realized by the Company from the products covered by such licenses. The Company is aware that certain organizations are engaging in activities that infringe certain of the Company's PEG technology and SCA patents. There can be no assurance that the Company will be able to enforce its patent and other rights against such organizations. The Company expects that there may be significant litigation in the industry regarding patents and other proprietary rights and, if Enzon were to become involved in such litigation, it could consume a substantial amount of the Company's resources. In addition, the Company relies heavily on its proprietary technologies for which pending patent applications have been filed and on unpatented know-how developed by the Company. Insofar as the Company relies on trade secrets and unpatented know-how to maintain its competitive technological position, there can be no assurance that others may not independently develop the same or similar technologies. Although the Company has taken steps to protect its trade secrets and unpatented know-how, third-parties nonetheless may gain access to such information. The Company has two research and license agreements with The Green Cross Corporation ("Green Cross") regarding rHSA. The Company and Yoshitomi Pharmaceutical Industries, Ltd. ("Yoshitomi"), the successor to Green Cross' business, are currently in arbitration to resolve the amount of royalties that will be due the Company, if any. In April 1998, Yoshitomi filed documents in such arbitration seeking a declaratory judgment that under its agreement with the Company no royalties are payable. Any adverse decision from such an arbitration proceeding could result in a material adverse effect to the Company's future business, financial condition and results of operations. Research Corporation Technologies, Inc. ("Research Corporation") held the original patent upon which the PEG Process is based and had granted the Company a license under such patent. Research Corporation's patent for the PEG Process in the United States and its corresponding foreign patents have expired. Although the Company has obtained several improvement patents in connection with the PEG Process, there can be no assurance that any of these patents will enable the Company to prevent infringement or that competitors will not develop competitive products outside the protection

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. 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 held by the Company. There can be no assurance that the expiration of the Research Corporation patent will not have a material adverse effect on the business, financial condition and results of operations of the Company.

Limited Sales and Marketing Experience; Dependence on Marketing Partners. Other than ADAGEN, which the Company markets on a worldwide basis to a small patient population, the Company does not engage in the direct commercial marketing of any of its products and therefore does not have significant sales and marketing experience. For certain of its products, the Company has provided exclusive marketing rights to its corporate partners in return for royalties to be received on sales. With respect to ONCASPAR, the Company has granted exclusive  $\mbox{marketing}$   $\mbox{rights in North}$   $\mbox{America and the}$   $\mbox{Pacific Rim to RPR.}$   $\mbox{The}$ Company has also granted exclusive marketing rights in Europe and Russia to Medac Gmbh and in Israel to Tzamal Pharma Ltd.. The Company expects to retain marketing partners to market ONCASPAR in other foreign markets, principally South America. There can be no assurance that such efforts will result in the Company concluding such arrangements. Regarding the marketing of certain of the Company's other future products, the Company expects to evaluate whether to create a sales force to market certain products in the United States or to continue to enter into license and marketing agreements with others for United States and foreign markets. These agreements generally provide that all or a significant portion of the marketing of these products will be conducted by the Company's licensees or marketing partners. In addition, under certain of these agreements, the Company's licensees or marketing partners may have all or a significant portion of the development and regulatory approval responsibilities. There can be no assurance that the Company will be able to control the amount and timing of resources that any licensee or marketing partner may devote to the Company's products or prevent any licensee or marketing partner from pursuing alternative technologies or products that could result in the development of products that compete with the Company's products and the withdrawal of support for the Company's products. Should the licensee or marketing partner fail to develop a marketable product (to the extent it is responsible for product development) or fail to market a product successfully, if it is developed, the Company's business, financial condition and results of operations may be adversely affected. There can be no assurance that the Company's marketing strategy will be successful. Under the Company's marketing and license agreements, the Company's marketing partners and licensees may have the right to terminate the agreements and abandon the applicable products at any time for any reason without significant payments. The Company is aware that certain of its marketing partners are pursuing parallel development of products on their own and with other collaborative partners which may compete with the licensed products and there can be no assurance that the Company's other current or future marketing partners will not also pursue such parallel courses.

Reimbursement from Third-Party Payors. Sales of the Company's products will be dependent in part on the availability of reimbursement from third-party payors, such as governmental health administration authorities, private health insurers and other organizations. Government and other third-party payors are increasingly sensitive to the containment of health care costs and are limiting both coverage and levels of reimbursement for new therapeutic products approved for marketing, and are refusing, in some cases, to provide any coverage for indications for which the FDA and other national health regulatory authorities have not granted marketing approval. There can be no assurance that such third-party payor reimbursement will be available or will permit the Company to sell its products at price levels sufficient for it to realize an appropriate return on its investment in product development. Since patients who receive ADAGEN will be required to do so for their entire lives (unless a cure or another treatment is developed), lifetime limits on benefits which are included in most private health insurance policies could permit insurers to cease reimbursement for ADAGEN. Lack of or inadequate reimbursement by government and other third party payors for the Company's products would have a material adverse effect on the Company's business, financial condition and results of operations.

Government Regulation. The manufacturing and marketing of pharmaceutical products in the United States and abroad is subject to stringent governmental regulation and the sale of any of the Company's 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

testing, manufacture and marketing of pharmaceutical products. Pharmaceutical manufacturing facilities are also regulated by state, local and other authorities. Obtaining FDA approval for a new therapeutic may take several years and involve substantial expenditures. ADAGEN was approved by the FDA in March 1990. ONCASPAR was approved by the FDA in February 1994, in Germany in November 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 for therapeutic use in a broad range of cancers. Except for these approvals, none of the Company's other products have been approved for sale and use in humans in the United States or elsewhere. There can be no assurance that the Company will be able to obtain FDA approval for any of its other products. In addition, any approved products are subject to continuing regulation, and noncompliance by the Company with applicable requirements can 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 the Company to enter into supply contracts. Failure to obtain or maintain requisite governmental approvals or failure to obtain or maintain approvals of the scope requested, will delay or preclude the Company or its licensees or marketing partners from marketing their products, or limit the commercial use of the products, and thereby may have a material adverse affect on the Company's business, financial condition and results of operations.

Intense Competition and Risk of Technological Obsolescence. Many established biotechnology and pharmaceutical companies with resources greater than those of the Company are engaged in activities that are competitive with the Company's and may develop products or technologies which compete with those of the Company. The Company is aware that other companies are engaged in utilizing PEG technology in developing drug products. There can be no assurance that the Company's competitors will not successfully develop, manufacture and market competing products utilizing PEG technology or otherwise. Other drugs or treatment modalities which are currently available or that may be developed in the future, and which treat the same diseases as those which the Company's products are designed to treat, may be competitive with the Company's products. There can be no assurance that the Company will be able to compete successfully against current or future competitors or that such competition will not have a material adverse effect on the Company's business, financial condition and results of operations. Rapid technological development by others may result in the Company's products becoming obsolete before the Company recovers a significant portion of the research, development and commercialization expenses incurred with respect to those products. The Company's success, in large part, depends upon developing and maintaining a competitive position in the development of products and technologies in its area of focus. There can be no assurance that the Company's competitors will not succeed in developing technologies or products that are more effective than any which are being sold or developed by the Company or which would render the Company's technologies or products obsolete or noncompetitive. The Company's failure to develop and maintain a competitive position with respect to its products and/or technologies would have a material adverse effect on its business, financial condition and results of operations.

Uncertainty of Market Acceptance. The Company's products, ONCASPAR and ADAGEN, have been approved by the FDA to treat patients with acute lymphoblastic leukemia and a rare form of severe combined immunodeficiency disease, respectively. Neither product has become widely used due to the small patient population and limited indications approved by the FDA. The Company's current research and development efforts are focused on applying its proprietary technologies to compounds of known therapeutic efficacy in order to enhance the performance of these compounds. Assuming that the Company is able to develop such compounds and secure the requisite FDA approvals, the market acceptance of any such products will depend upon the acceptance by the medical community of the use of such technologies. There can be no assurance that any additional products will be approved by the FDA or that, if approved, the medical community will use them. In addition, the use of any such new products will depend upon the extent of third party medical reimbursement, increased awareness of the effectiveness of such technologies and sales efforts by the Company or any

marketing partner. The Company's proprietary PEG technology has received only limited market acceptance to date. Failure of the Company to develop new FDA approved products and to achieve market acceptance for such products would have a material adverse effect on the Company's business, financial condition and results of operation.

Potential Product Liability. The use of the Company's products during testing or after regulatory approval

27

entails an inherent risk of adverse effects which could expose the Company to product liability claims. The Company maintains product liability insurance coverage in the total amount of \$10 million for claims arising from the use of its products in clinical trials prior to FDA approval and for claims arising from the use of its products after FDA approval. There can be no assurance that the Company will be able to maintain its existing insurance coverage or obtain coverage for the use of its other products in the future. There can be no assurance that such insurance coverage and the resources of the Company would be sufficient to satisfy any liability resulting from product liability claims or that a product liability claim would not have a material adverse effect on the Company's business, financial condition or results of operations.

Future Capital Needs; Uncertainty of Additional Financing. The Company's current sources of liquidity are its cash reserves, and interest earned on such cash reserves, sales of ADAGEN and ONCASPAR, sales of its products for research purposes, and license fees. There can be no assurance as to the level of sales of the Company's FDA approved products, ADAGEN and ONCASPAR, or the amount of royalties realized from the commercial sale of ONCASPAR pursuant to the Company's licensing agreements. Total cash reserves, including short term investments, as of June 30, 1999, were approximately \$24,674,000. Based upon its currently planned research and development activities and related costs and its current sources of liquidity, the Company anticipates its current cash reserves will be sufficient to meet its capital and operational requirements for the foreseeable future. The Company's future needs and the adequacy of available funds will depend on numerous factors, including without limitation, the successful commercialization of its products, progress in its product development efforts, the magnitude and scope of such efforts, progress with preclinical studies and clinical trials, progress with regulatory affairs activities, the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, competing technological and market developments, and the development of strategic alliances for the marketing of its products. There can be no assurance that the Company will not require additional financing for its currently planned capital and operational requirements. In addition, the Company may seek to acquire additional technology, enter into strategic alliances and engage in additional research and development programs, which may require additional financing. The Company does not have any committed sources of additional financing, and there can be no assurance that additional funding, if necessary, will be available on acceptable terms, if at all. To the extent the Company is unable to obtain financing, it may be required to curtail its activities or sell additional securities. There can be no assurance that any of the foregoing fund raising activities will successfully meet the Company's anticipated cash needs. If adequate funds are not available, the Company's business, financial condition and results of operations will be materially and adversely affected.

Dividend Policy and Restrictions. The Company has paid no dividends on its Common Stock, since its inception and does not plan to pay dividends on its Common Stock in the foreseeable future. Except as may be utilized to pay the dividends payable on the Company's Series A Cumulative Convertible Preferred Stock (the "Series A Preferred Stock"), any earnings which the Company may realize will be retained to finance the growth of the Company. In addition, the terms of the Series A Preferred Stock restrict the payment of dividends on other classes and series of stock.

Possible Volatility of Stock Price. Historically, the market price of the Company's Common Stock has fluctuated over a wide range and it is likely that the price of the Common Stock will fluctuate in the future. Announcements regarding technical innovations, the development of new products, the status of corporate collaborations and supply arrangements, regulatory approvals, patent or proprietary rights or other developments by the Company or its competitors could have a significant impact on the market price of the Common Stock. In

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

Anti-takeover Considerations. The Company has the authority to issue up to 3,000,000 shares of Preferred Stock of the Company in one or more series and to fix the powers, designations, preferences and relative rights thereof without any further vote of shareholders. The issuance of such Preferred Stock could dilute the voting powers of holders of Common Stock and could have the effect of delaying, deferring or preventing a change in control of the Company. Certain provisions of the Company's Articles of Incorporation and By-laws, including those providing for

28

a staggered Board of Directors, as well as Delaware law, may operate in a manner that could discourage or render more difficult a takeover of the Company or the removal of management or may limit the price certain investors may be willing to pay for shares of Common Stock.

Item 7a. Quantitative and Qualitative Disclosures About Market Risk

The following discussion about our exposure to market risk of financial instruments contains forward-looking statements. Actual results may differ materially from those described.

Our holdings of financial instruments are comprised of debt securities, and time deposits. All such instruments are classified as securities available for sale. We do not invest in portfolio equity securities or commodities or use financial derivatives for trading purposes. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We manage these funds accordingly. We seek reasonable assuredness of the safety of principal and market liquidity by investing in rated fixed income securities while at the same time seeking to achieve a favorable rate or return. Our market risk exposure consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We typically invest in the shorter-end of the maturity spectrum, and at June 30, 1999 all of our holdings were in instruments maturing in one year or less

Item 8. Financial Statements and Supplementary Data

The response to this item is submitted as a separate section of this report commencing on Page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

Not applicable.

29

# PART III

The information required by Item 10 - Directors and Executive Officers of the Registrant; Item 11 - Executive Compensation; Item 12 - Security Ownership of Certain Beneficial Owners and Management; and Item 13 - Certain Relationships and Related Transactions is incorporated into Part III of this Annual Report on Form 10-K by reference to the Company's Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on December 7, 1999.

PART IV

- Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K
- (a)(1) and (2). The response to this portion of Item 14 is submitted as a separate section of this report commencing on page F-1.

# (a) (3) and (c). Exhibits (numbered in accordance with Item 601 of Regulation S-K).

		Page Number
		Or
Exhibit		Incorporation
Number	Description	By Reference
2 ( )		
	Certificate of Incorporation, as amended	~~
	By-laws, as amended	* (4.2)
3(iv)		##3(iv)
10.1	Form of Change of Control Agreements dated as of January 20, 1995 entered	
	into with the Company's Executive Officers	### (10.2)
10.2		***(10.3)
10.4	· · · · · · · · · · · · · · · · · · ·	
	20 Kingsbridge Road and 40 Kingsbridge Road, Piscataway, New Jersey	###(10.6)
10.5	11 1 3 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
	Piscataway, New Jersey	###(10.7)
	Form of Lease - 40 Cragwood Road, South Plainfield, New Jersey	****(10.9)
10.7		++(10.10)
10.8		
	Eastman Kodak Company	****(10.7)
10.9	Amendment dated June 19, 1989 to Stock Purchase Agreement between the	
	Company and Eastman Kodak Company	**(10.10)
10.10	Form of Stock Purchase Agreement between the Company and the	
	purchasers of the Series A Cumulative	
	Convertible Preferred Stock	+(10.11)
10.11	Amendment to License Agreement and Revised License Agreement	
	between the Company and RCT dated April 25, 1985	+++(10.5)
10.12	Amendment dated as of May 3, 1989 to Revised License Agreement	
	dated April 25, 1985 between the Company and Research Corporation	**(10.14)
10.13	License Agreement dated September 7, 1989 between the Company and	
	Research Corporation Technologies, Inc.	**(10.15)
10.14	Master Lease Agreement and Purchase Leaseback Agreement dated	
	October 28, 1994 between the Company and Comdisco, Inc.	#(10.16)
10.15	Employment Agreement with Peter G. Tombros dated as of	
	April 5, 1997	^^(10.15)

30

10.16	Stock Purchase Agreement dated as of June 30, 1995	~(10.16)
10.17	Securities Purchase Agreement dated as of January 31, 1996	~(10.17)
10.18	Registration Rights Agreements dated as of January 31, 1996	~(10.18)
10.19	Warrants dated as of February 7, 1996 and issued pursuant to the Securities	
	Purchase Agreement dated as of January 31, 1996	~(10.19)
10.20	Securities Purchase Agreement dated as of March 15, 1996	~~(10.20)
10.21	Registration Rights Agreement dated as of March 15, 1996	~~(10.21)
10.22	Warrant dated as of March 15, 1996 and issued pursuant to the Securities Purchase	
	Agreement dated as of March 15, 1996	~~(10.22)
10.23	Amendment dated March 25, 1994 to License Agreement dated	
	September 7, 1989 between the Company and Research Corporation	
	Technologies, Inc.	~~~(10.23)
10.24	Independent Directors' Stock Plan	~~~(10.24)
10.25	Stock Exchange Agreement dated February 28, 1997, by and between the	
	Company and GFL Performance Fund Ltd.	^(10.25)
10.26	Agreement Regarding Registration Rights Under Registration Rights Agreement	
	dated March 10, 1997, by and between the Company and Clearwater Fund IV	
	LLC	^(10.26)
10.27	Common Stock Purchase Agreement dated June 25, 1998	^^^(10.27)
10.28	Placement Agent Agreement dated June 25, 1998 with SBC Warburg	
	Dillon Read, Inc.	^^^^(10.28)
21.0	Subsidiaries of Registrant	0
23.0	Consent of KPMG LLP	0
27.0	Financial Data Schedule	0

0

- $^{\star}$  Previously filed as an exhibit to the Company's Registration Statement on Form S-2 (File No. 33-34874) and incorporated herein by reference thereto.
- \*\* Previously filed as exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 1989 and incorporated herein by reference thereto.
- \*\*\* Previously filed as an exhibit to the Company's Registration Statement on Form S-18 (File No. 2-88240-NY) and incorporated herein by reference thereto.
- \*\*\*\* Previously filed as exhibits to the Company's Registration Statement on Form S-1 (File No. 2-96279) filed with the Commission and incorporated herein by reference thereto.
- + Previously filed as an exhibit to the Company's Registration Statement on Form S-1 (File No. 33-39391) filed with the Commission and incorporated herein by reference thereto.
- ++ Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 1993 and incorporated herein by reference thereto.
- +++ Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 1985 and incorporated herein by reference thereto.
- # Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 1994 and incorporated herein by reference thereto.

31

(b) Reports on Form 8-K.

On April 5, 1999, the Company filed with the Commission a Current Report on Form 8-K dated April 1, 1999, related to its filing of an Investigational New Drug ("IND") application with the Food and Drug Administration ("FDA") for PEG-camptothecin ("PROTHECAN(R)").

32

# Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENZON, INC.

Dated: September 28, 1999 by: Peter G. Tombros

Peter G. Tombros President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Name Title Date

----

/S/ Peter G. Tombros	President, Chief Executive Officer and Director	September 28, 1999
Peter G. Tombros	(Principal Executive Officer)	
/S/ Kenneth J. Zuerblis	Vice President, Finance and Chief Financial Officer	September 28, 1999
Kenneth J. Zuerblis	(Principal Financial and Accounting Officer)	
/S/ Randy H. Thurman	Chairman of the Board	September 28, 1999
Randy H. Thurman		
/S/ David S. Barlow	Director	September 28, 1999
David S. Barlow		
/S/ Rolf A. Classon	Director	September 28, 1999
Rolf A. Classon		
/S/ Rosina B. Dixon	Director	September 28, 1999
Rosina B. Dixon		
/S/ David W. Golde	Director	September 28, 1999
David W. Golde		
/S/ Robert LeBuhn	Director	September 28, 1999
Robert LeBuhn		
/S/ A.M. "Don" MacKinnon	Director	September 28, 1999
A.M. "Don" MacKinnon		

# ENZON, INC. AND SUBSIDIARIES

# Index

	Page
Independent Auditors' Report	F-2
Consolidated Financial Statements:	
Consolidated Balance Sheets - June 30, 1999 and 1998	F-3
Consolidated Statements of Operations - Years ended	
June 30, 1999, 1998 and 1997	F-4
Consolidated Statements of Stockholders' Equity -	
Years ended June 30, 1999, 1998 and 1997	F-5
Consolidated Statements of Cash Flows - Years ended	
June 30, 1999, 1998 and 1997	F-7
Notes to Consolidated Financial Statements - Years	
ended June 30, 1999, 1998 and 1997	F-8

#### INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders Enzon, Inc.:

We have audited the consolidated financial statements of Enzon, Inc. and subsidiaries as listed in the accompanying index. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Enzon, Inc. and subsidiaries as of June 30, 1999 and 1998, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 1999, in conformity with generally accepted accounting principles.

KPMG LLP

Short Hills, New Jersey September 8, 1999

F-2

# ENZON, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS June 30, 1999 and 1998

ASSETS	1999	1998
Current Assets:		
Cash and cash equivalents	\$ 24,673,636	\$ 6,478,459
Accounts receivable		2,300,046
Inventories		1,022,530
Prepaid expenses and other current assets	1,034,327	447,952
Total current assets	31,639,411	10,248,987
Property and equipment	12,054,505	15,134,075
Less accumulated depreciation and amortization	10,649,661	13,368,330
	1,404,844	1,765,745
Other assets: Investments	68 823	69,002
Deposits and deferred charges		464,747
Patents, net		1,192,897
	1,872,060	1,726,646
Total assets	\$ 34,916,315 	
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,716,089	\$ 1,711,856
Accrued expenses	6,261,640	4,375,822

Total current liabilities		
	7,977,729	6,087,678
Accrued rent	·	727,160
Royalty advance - RPR	728,977	
	1,363,637	727,160
Commitments and contingencies		
Stockholders' equity:		
Preferred stock-\$.01 par value, authorized 3,000,000 shares;		
Issued and outstanding 107,000 shares in 1999 and 1998		
(liquidation preference aggregating \$4,659,000 in 1999		
and \$4,445,000 in 1998)	1,070	1,070
Common stock-\$.01 par value, authorized 60,000,000 shares;	•	·
issued and outstanding 36,488,684 shares in 1999 and		
31,341,353 shares in 1998	364,886	313,414
Additional paid-in capital	146,970,289	123,453,874
Accumulated deficit		(116,841,818)
Total stockholders' equity	25,575,219	6,926,540
Total liabilities and stockholders' equity	\$ 34,916,315	\$ 13,741,378
	==========	=========

The accompanying notes are an integral part of these consolidated financial statements.

F-3

# ENZON, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS Years ended June 30, 1999, 1998 and 1997

	1999	1998	1997
Revenues:			
Sales	\$ 12,855,995	\$ 12,312,730	\$ 11,595,985
Contract revenue	302,212	2,331,302	1,131,067
Total revenues	13,158,207	14,644,032	12,727,052
Costs and expenses:			
Cost of sales	4,309,956	3,645,281	3,840,198
Research and development expenses	6,835,521	8,653,567	8,520,366
Selling, general and administrative expenses	8,133,366	6,426,241	5,528,174
Total costs and expenses	19,278,843	18,725,089	
Operating loss	(6,120,636)	(4,081,057)	(5,161,686)
Other income (expense):			
Interest and dividend income	-,,	460,922	584,384
Interest expense	(8,348)	(13,923)	(14,891)
Other	64,767	16,925	35,168
	1,201,428	463,924	604,661
Net loss	(\$ 4,919,208)	(\$ 3,617,133)	
Basic and diluted net loss per common share	(\$0.14)	(\$0.12)	(\$0.16)
basic and diraced net loss per common share	(90.14)	(90.12)	(\$0.16)
Weighted average number of common			
shares outstanding	35,699,133	31,092,369	29,045,605
	=========		========

The accompanying notes are an integral part of these consolidated financial statements.

# ENZON, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY Years ended June 30, 1999, 1998 and 1997

	Preferred stock			C	Additional		
		Number of Shares	Par Value		Number of	Par	paid-in capital
Balance, July 1, 1996 Common stock issued for exercise of		169,000	\$1,690		27,706,396	\$277,064	\$121,272,024
non-qualified stock options Common stock issued for Independent				2.36	11,219	112	26,499
Directors' Stock Plan Consulting expense for issuance of stock				2.97	25,903	259	76,598
options Common stock issued on conversion of							80,984
Series B Preferred Stock Common stock issued on conversion of	\$ 1.95	(40,000)	(400)		2,038,989		(19,993)
Series D Preferred Stock Net Loss	1.97	(20,000)	(200)		1,015,228	10,152	(9,953)
Balance, June 30, 1997		109,000	\$1,090		\$30,797,735		\$121,426,159
Common stock issued for exercise of non- qualified stock options				2.23	505,072	5,051	1,653,557
Common stock issued on conversion of Series A Preferred Stock Dividends issued on Series A Preferred Stock	25.00	(2,000)	(20)	11.00 11.00	4,544	45 29	(42)
Common stock issued for Independent Directors' Stock Plan				4.11	2,848	169	31,300 69,231
Common stock issued for consulting services Consulting expense for issuance of stock				4.77	14,250	143	67,854
options Net Loss							205,815
Balance, June 30, 1998, carried forward		107,000	\$1,070			\$313,414	\$123,453,874
	Accumulat Deficit		Tota				
Balance, July 1, 1996 Common stock issued for exercise of	(\$108,636,	320)	\$12,914	,458			
non-qualified stock options Common stock issued for Independent			26,611				
Directors' Stock Plan Consulting expense for issuance of stock			76,857				
Options Common stock issued on conversion of			80	,984			
Series B Preferred Stock Common stock issued on conversion of				(3)			
Series D Preferred Stock Net Loss	(4,557,		(4,557				
Balance, June 30, 1997	(\$113,193,		\$8,541				
Common stock issued for exercise of non- Qualified stock options Common stock issued on conversion of			1,658,608				
Series A Preferred Stock Dividends issued on Series A Preferred Stock Common stock issued for Independent	(31,	340)		(17) (11)			
Directors' Stock Plan Common stock issued for consulting services Consulting expense for issuance of stock			67	,400 ,997			
Options Net Loss	(3,617,		205 (3,617				
Balance, June 30, 1998, carried forward	(\$116,841,		\$6,926				

The accompanying notes are an integral part of these consolidated financial statements.

F-5

ENZON, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)
Years ended June 30, 1999, 1998 and 1997

Prefe	erred st	ock		Comr	non sto	c k		
								Additional
Amount	Number	of	Par	Amount	Number	of	Par	paid-in

	per share	Shares	Value	per share	Shares	Value	capital
Balance, June 30,1998, brought forward Common stock issued for exercise of		107,000	\$1,070		31,341,353	\$313,414	\$123,453,874
non-qualified stock-options Common stock issued on exercise of				4.40	1,000,919	10,009	4,396,477
common stock warrants				2.50	150,000	1,500	373,500
Net proceeds from Private Placement, July 1996 Common stock issued for Independent	3			4.75	3,983,000	39,830	17,510,265
Directors' Stock Plan Common stock options and warrants issued for				8.88	8,514	84	75,539
consulting services							1,130,683
Common stock issued for consulting services				6.13	4,898	49	29,951
Net loss							
Balance, June 30, 1999		107,000	\$1,070 =====		36,488,684		\$146,970,289
	Accumulate Deficit		Total				
Common stock issued for exercise of	(\$116,841,8	818)	\$6,926				
non-qualified stock-options Common stock issued on exercise of			4,406				
common stock warrants				,000			
Net proceeds from Private Placement, July 1999 Common stock issued for Independent	3		17,550				
Directors' Stock Plan Common stock options and warrants issued for			75	,623			
consulting services			1,130	,683			
Common stock issued for consulting services				,000			
Net loss	(4,919,2		(4,919				
Balance, June 30, 1999	(\$121,761,0	026)	\$25,575 =====	,219			

The accompanying notes are an integral part of these consolidated financial statements.

F-6

# ENZON, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS Years Ended June 30, 1999, 1998 and 1997

	1999	1998	1997
Cash flows from operating activities: Net loss Adjustments to reconcile net loss to net cash used in operating activities:	(\$ 4,919,208)	(\$ 3,617,133)	(\$ 4,557,025)
Depreciation and amortization (Gain) loss on retirement of assets Non-cash expense for issuance of common stock, warrants, stock		1,217,423 97,037	
and options	1,236,306	343,212	157,841
Changes in assets and liabilities: (Increase) decrease in accounts receivable (Increase) decrease in inventories (Increase) decrease in prepaid expenses and other current		133,716 (162,657)	
assets (Increase) decrease in other assets		(430,172)	,
Increase (decrease) in accounts payable Increase (decrease) in accrued expenses Decrease in accrued rent	4,233 2,691,353 (92,770)	(198,881) 796,403 (142,852)	(168,187) (522,761) (110,896)
Decrease in royalty advance - RPR Decrease in other liabilities	(76,558)	(1,101,501)	(780,081) (1,728)
Net cash used in operating activities		(3,425,625)	
Cash flows from investing activities: Capital expenditures Proceeds from sale of equipment		(160,940) 83,129	
Decrease in investments	179	9,291	
Net cash used in investing activities	(292,559)	(68,520)	
Cash flows from financing activities: Proceeds from issuance of common stock, preferred stock and warrants Principal payments of obligations under capital leases	22,331,581	1,658,580 (1,728)	26,607 (2,348)
· · · · · · · · · · · · · · · ·			

Net cash provided by financing activities	22,331,581	1,656,852	24,259
Net increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of period	18,195,177 6,478,459	(1,837,293) 8,315,752	(4,350,298) 12,666,050
Cash and cash equivalents at end of period	\$24,673,636 ======	\$6,478,459	\$8,315,752

The accompanying notes are an integral part of these consolidated financial statements.

F-7

# ENZON, INC. AND SUBSIDIARIES Notes to Consolidated Financial Statements

Years ended June 30, 1999, 1998 and 1997

### (1) Company Overview

Enzon, Inc. ("Enzon" or "Company") is a biopharmaceutical company that develops, manufactures and markets enhanced therapeutics for life-threatening diseases through the application of its proprietary technologies. The Company was originally incorporated in 1981. To date, the Company's sources of cash have been the proceeds from the sale of its stock through public offerings and private placements, sales of ADAGEN(R), sales of ONCASPAR(R), sales of its products for research purposes, contract research and development fees, technology transfer and license fees and royalty advances. The manufacturing and marketing of pharmaceutical products in the United States is subject to stringent governmental regulation, and the sale of any of the Company's products for use in humans in the United States will require the prior approval of the United States Food and Drug Administration ("FDA"). To date, ADAGEN and ONCASPAR are the only products of the Company which have been approved for marketing by the FDA.

### (2) Summary of Significant Accounting Policies

#### Consolidated Financial Statements

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances are eliminated in consolidation. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Investments

Cash equivalents include investments which consist primarily of debt securities and time deposits. The Company invests its excess cash in a portfolio of marketable securities of institutions with strong credit ratings and U.S. Government backed securities.

The Company classifies its investment securities as held-to-maturity. Held-to-maturity securities are those securities which the Company has the ability and intent to hold to maturity. Held-to-maturity securities are recorded at cost which approximated the fair value of the investments at June 30, 1999 and 1998.

## Inventory Costing and Idle Capacity

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method and includes the cost of raw materials, labor and overhead.

Costs associated with idle capacity at the Company's manufacturing

F-8

ENZON, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements, Continued

#### Patents

The Company has licensed, and been issued, a number of patents in the United States and other countries and has other patent applications pending to protect its proprietary technology. Although the Company believes that its patents provide adequate protection for the conduct of its business, there can be no assurance that such patents will be of substantial protection or commercial benefit to the Company, will afford the Company adequate protection from competing products, or will not be challenged or declared invalid, or that additional United States patents or foreign patent equivalents will be issued to the Company. The degree of patent protection to be afforded to biotechnological inventions is uncertain, and the Company's products are subject to this uncertainty.

Patents related to the acquisition of SCA Ventures, Inc., formerly Genex Corporation, were recorded at their fair value at the date of acquisition and are being amortized over the estimated useful lives of the patents ranging from 8 to 17 years. Accumulated amortization as of June 30, 1999 and 1998 was \$1,099,000 and \$956,000, respectively.

Costs related to the filing of patent applications related to the Company's products and technology are expensed as incurred.

#### Property and Equipment

Property and equipment are carried at cost. Depreciation is computed using the straight-line method. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is recognized in operations for the period. The cost of repairs and maintenance is charged to operations as incurred; significant renewals and betterments are capitalized.

#### Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in business circumstances occur that indicate that the carrying amount of the assets may not be recoverable. The Company assesses the recoverability of long-lived assets held and to be used based on undiscounted cash flows and measures the impairment, if any, using discounted cash flows.

# Revenue Recognition

Reimbursement from third party payors for ADAGEN is handled on an individual basis due to the high cost of treatment and limited patient population. Because of the uncertainty of reimbursement and the Company's commitment of supply to the patient regardless of whether or not the Company will be reimbursed, revenues for the sale of ADAGEN are recognized when reimbursement from third party payors becomes likely.

Revenues from the sale of the Company's other products that are sold are recognized at the time of shipment and provision is made for estimated returns.

Contract revenues are recorded as the earnings process is completed.

Royalties  $\mbox{ under the Company's license } \mbox{ agreements with third parties } \mbox{ are recognized } \mbox{ when earned.}$ 

Research and Development

Research and development costs are expensed as incurred.

Stockholders' Equity

The Company maintains a Non-Qualified Stock Option Plan (the "Stock Option Plan") for which it applies Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for the Stock Option Plan. Stock options issued to employees are granted with an exercise price equal to the market price and in accordance with APB No. 25, compensation expense is not recognized.

Cash Flow Information

The Company considers all highly liquid securities with original maturities of three months or less to be cash equivalents.

During the year ended June 30, 1998, 2,000 shares of Series A Cumulative Convertible Preferred Stock ("Series A Preferred Stock" or "Series A Preferred Shares") were converted to 4,544 shares of Common Stock. Accrued dividends of \$31,000 on the Series A Preferred Shares that were converted were settled by issuing 2,848 shares of Common Stock and cash payments totaling \$28 for fractional shares. There were no conversions of Series A Preferred Stock for the years ended June 30, 1999 and 1997.

Cash payments for interest were approximately \$8,000, \$14,000 and \$15,000 for the years ended June 30, 1999, 1998 and 1997, respectively. There were no income tax payments made for the years ended June 30, 1999, 1998 and 1997.

Net Loss Per Common Share

Basic and diluted loss per common share is based on the net loss for the relevant period, adjusted for cumulative, undeclared Series A Preferred Stock dividends of \$214,000, \$216,000 and \$218,000 for the years ended June 30, 1999, 1998 and 1997, respectively, divided by the weighted average number of shares issued and outstanding during the period. For purposes of the diluted loss per share calculation, the exercise or conversion of all dilutive potential common shares is not included, due to the net loss recorded for the years ended June 30, 1999, 1998 and 1997. As of June 30, 1999, the Company had approximately 5,857,000 dilutive potential common shares outstanding that could potentially dilute future earnings per share calculations.

F-10

ENZON, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements, Continued

Comprehensive Income

Effective July 1, 1998, the Company adopted Statement of Financial Accounting Standards No. 130 ("SFAS 130"), Reporting Comprehensive Income. SFAS 130 establishes new rules for the reporting and display of comprehensive income and its components. The adoption of SFAS 130 had no impact on the Company's results of operations for the years ended June 30, 1999, 1998 and 1997. The net loss is equal to the comprehensive loss for those periods.

	June 30,	
	1999	1998
Raw materials	\$503,000	\$510,000
Work in process	548,000	398,000
Finished goods	276,000	115,000
	\$1,327,000	\$1,023,000
	========	========

### (4) Property and Equipment

Property and equipment consist of the following:

	June	30,	
	1999 	1998	Estimated useful lives
Equipment Furniture and fixtures Vehicles Leasehold improvements	\$8,024,000 1,438,000 24,000 2,569,000	\$8,647,000 1,501,000 29,000 4,957,000	3-7 years 7 years 3 years 3-15 years
neasenora improvemento	\$12,055,000	\$15,134,000	3 13 years

During the year ended June 30, 1999, the Company's fixed asset disposals were approximately \$3,504,000. The disposals were primarily attributable to the Company's consolidation of research operations and the elimination of its leased facility at 40 Cragwood Road. Depreciation and amortization charged to operations, relating to property and equipment, totaled \$692,000, \$1,063,000 and \$1,499,000 for the years ended June 30, 1999, 1998 and 1997, respectively.

# (5) Stockholders' Equity

During the year ended June 30, 1999, the Company sold 3,983,000 shares of Common Stock in a private placement to a small group of investors. The private placement resulted in gross proceeds of approximately \$18,919,000 and net proceeds of approximately \$17,550,000.

During the year ended June 30, 1997, all of the outstanding shares of Series B Preferred Stock were converted into Common Stock. The 40,000 shares of Series B Preferred Stock which were converted resulted in the issuance of 2,038,989 shares of Common Stock.

F-11

ENZON, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements, Continued

During March 1997, all of the outstanding Series C Preferred Stock was exchanged for newly issued Series D Preferred Stock. The Series D Preferred Stock contained the same provisions as the Series C Preferred Stock, with the exception of the elimination of a restriction on the maximum number of shares which could be held by the holding institution. During March 1997, all of the outstanding Series D Preferred Stock was converted into Common Stock. The 20,000 shares of Series D Preferred Stock which were converted resulted in the issuance of 1,015,228 shares of Common Stock.

Series A Preferred Stock

Stock at a conversion rate of \$11 per share. The value of the Series A Preferred Shares for conversion purposes is \$25 per share. Holders of the Series A Preferred Shares are entitled to an annual dividend of \$2 per share, payable semiannually, but only when and if declared by the Board of Directors, out of funds legally available. Dividends on the Series A Preferred Shares are cumulative and accrue and accumulate but will not be paid, except in liquidation or upon conversion, until such time as the Board of Directors deems it appropriate in light of the Company's then current financial condition. No dividends are to be paid or set apart for payment on the Company's Common Stock, nor are any shares of Common Stock to be redeemed, retired or otherwise acquired for valuable consideration unless the Company has paid in full or made appropriate provision for the payment in full of all dividends which have then accumulated on the Series A Preferred Shares. Holders of the Series A Preferred Shares are entitled to one vote per share on matters to be voted upon by the stockholders of the Company. As of June 30, 1999 and 1998, undeclared accrued dividends in arrears were \$1,984,000 or \$18.54 per share and \$1,770,000 or \$16.54 per share, respectively. All Common Shares are junior in rank to the Series A Preferred Shares, with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution or winding up of the Company.

During the year ended June 30, 1998, 2,000 shares of Series A Preferred Shares were converted to 4,544 shares of Common Stock. Accrued dividends of \$31,000 were settled by issuing 2,848 shares of Common Stock and cash payments totaling \$16 for fractional shares. There were no conversions of Series A Preferred Shares during the years ended June 30, 1999 or 1997.

#### Common Stock

Holders of shares of Common Stock are entitled to one vote per share on matters to be voted upon by the stockholders of the Company.

As of June 30, 1999, the Company has reserved its common shares for special purposes as detailed below:

Shares issuable upon conversion of
Series A Preferred Shares 424,000
Shares issuable upon exercise of outstanding warrants 1,089,000
Non-Qualified Stock Option Plan 4,344,000
-----5,857,000

## Common Stock Warrants

During the year ended June 30, 1999, 150,000 warrants were exercised to purchase 150,000 shares of the Company's Common Stock at \$2.50 per share. These warrants were issued during the year ended June 30, 1996, as part of the commission due to a real estate broker in connection with the termination of the Company's former lease at 40 Kingsbridge Road.

F-12

ENZON, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements, Continued

During the year ended June 30, 1999, the Company issued 200,000 five-year warrants to purchase Enzon Common Stock at \$6.50 per share, the closing price of the Common Stock on the date of grant. The warrants are consideration for consulting services to be rendered through February 2002. The estimated fair value of the warrants of approximately \$917,000 is being amortized over the service period of three years. The unamortized portion is included as a component of other assets with the corresponding current portion included in other current assets on the consolidated balance sheet as of June 30, 1999.

Series B and C Preferred Stock Warrants

As of June 30, 1999 and 1998, warrants to purchase 688,686 shares of Common Stock at \$4.11 and 200,000 shares of Common Stock at \$5.63, issued

in connection with the private placements of Series B and C  $\,$  Preferred Shares, were outstanding.

#### (6) Independent Directors' Stock Plan

On December 3, 1996, the stockholders voted to approve the Company's Independent Directors' Stock Plan, which provides for compensation in the form of quarterly grants of Common Stock to non executive, independent directors serving on the Company's Board of Directors. Each independent director is granted shares of Common Stock equivalent to \$2,500 per quarter plus \$500 per Board of Director's meeting attended. The number of shares issued is based on the fair market value of Common Stock on the last trading day of the applicable quarter. During the years ended June 30, 1999, 1998 and 1997, the Company issued 8,514, 16,904 and 25,903 shares of Common Stock, respectively, to independent directors, pursuant to the Independent Directors' Stock Plan.

### (7) Non-Qualified Stock Option Plan

In November 1987, the Company's Board of Directors adopted a Non-Qualified Stock Option Plan (the "Stock Option Plan"). The number of shares reserved for issuance upon adoption of the Company's Stock Option Plan was 6,200,000. As of June 30, 1999, 4,344,000 shares of Common Stock were reserved for issuance pursuant to options which may be granted to employees, non-employee directors or consultants to the Company. The exercise price of the options granted must be at least 100% of the fair market value of the stock at the time the option is granted. Options may be exercised for a period of up to ten years from the date they are granted. The other terms and conditions of the options generally are to be determined by the Board of Directors, or an option committee appointed by the Board, at their discretion.

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "Accounting for Stock-Based Compensation". The Company continues to use APB No. 25, "Accounting for Stock Issued to Employees," to account for the Stock Option Plan. All options granted under the Stock Option Plan are granted with exercise prices which equal or exceed the fair market value of the stock at the date of grant. Accordingly, there is no compensation expense recognized for options granted to employees. The Company records compensation expense equal to the value of stock options granted for consulting services rendered to the Company by non-employees. The value of the options granted to non-employees is determined by the Black-Scholes option-pricing model.

F-13

# ENZON, INC. AND SUBSIDIARIES Notes to Consolidated Financial Statements, Continued

The following pro forma financial information shows the effect and the Company's net loss and loss per share, had compensation expense been recognized consistent with SFAS No. 123.

	1999	1998	1997
Net loss - as reported	(\$4,919,000)	(\$3,617,000)	(\$4,557,000)
Net loss - pro forma	(\$7,289,000)	(\$5,638,000)	(\$5,927,000)
Loss per share - as reported	(\$0.14)	(\$0.12)	(\$0.16)
Loss per share - pro forma	(\$0.21)	(\$0.19)	(\$0.21)

The pro forma effect on the loss for the three years ended June 30, 1999 is not necessarily indicative of the pro forma effect on earnings in future years since it does not take into effect the pro forma compensation expense related to grants made prior to the year ended June 30, 1996. The fair value of each option granted during the three years ended June 30, 1999 is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions: (i) dividend yield of

0%, (ii) expected term of five years, (iii) expected volatility of 86%, 84%, and 82%, and (iv) a risk-free interest rate of 5.06%, 5.57%, and 6.45% for the years ended June 30, 1999, 1998, and 1997, respectively. The weighted average fair value at the date of grant for options granted during the years ended June 30, 1999, 1998 and 1997 was \$9.68, \$5.85 and \$2.78 per share, respectively.

The following is a summary of the activity in the Company's Stock Option Plan:

	Shares	Weighted Average Exercise Price	
Outstanding at July 1, 1996	3,558,000	\$4.75	\$1.88 to \$14.88
Granted at exercise prices which exceeded the			
fair market value on the date of grant Granted at exercise prices which equaled the	3,000	2.81	\$2.81
fair market value on the date of grant	1,469,000	2.78	\$2.31 to \$3.41
Exercised	(11,000)	2.37	\$2.00 to \$2.63
Canceled	822,000)	6.26	\$2.00 to \$14.25
Outstanding at June 30, 1997	4,197,000	3.77	\$1.88 to \$14.88
Granted at exercise prices which equaled the			
fair market value on the date of grant	719,000	5.85	\$2.03 to \$6.56
Exercised	(305,000)	2.73	\$2.06 to \$5.13
Canceled	(189,000)	6.69	\$2.09 to \$14.88
Outstanding at June 30, 1998	4,422,000	4.06	\$1.88 to \$10.88
Granted at exercise prices which equaled			
the fair market value on the date of grant	455,000	9.68	\$4.88 to \$15.75
Exercised	(1,001,000)	4.40	\$2.00 to \$9.88
Canceled	(172,000)	7.25	\$2.81 to \$14.50
Outstanding at June 30, 1999	3,704,000	4.51	\$1.88 to \$15.75
	========		

F-14

ENZON, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements, Continued

As of June 30, 1999, the Plan had options outstanding and exercisable by price range as follows:

Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
\$1.88 to \$2.63	535,000	6.22	\$2.34	535,000	\$2.34
\$2.69 to \$2.81	793,000	6.95	\$2.75	793,000	\$2.75
\$2.88 to \$3.50	582,000	6.79	\$3.19	482,000	\$3.24
\$3.56 to \$4.50	576,000	5.40	\$4.25	576,000	\$4.25
\$4.56 to \$6.00	669,000	7.89	\$5.76	427,000	\$5.68
\$6.13 to \$15.75	549,000	8.71	\$9.29	78,000	\$8.28
\$1.88 to \$15.75	3,704,000	7.01	\$4.51	2,891,000	\$3.64
	=======			=======	

### (8) Income Taxes

The Company adopted Statement of Financial Accounting Standards No. 109 (SFAS No. 109), "Accounting for Income Taxes" as of July 1, 1993. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are recognized for the estimated future tax consequences

attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under SFAS No. 109, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The effects of adopting SFAS No. 109 were not material to the financial statements at July 1, 1993.

At June 30, 1999 and 1998, the tax effects of temporary differences that give rise to the deferred tax assets and deferred tax liabilities are as follows:

1999	1998
\$272,000	\$111,000
86,000	86,000
20,000	19,000
127,000	115,000
1,031,000	827,000
371,000	402,000
1,497,000	543,000
	2,133,000
	7,447,000
56,111,000	51,683,000
(55,405,000)	(50,977,000)
706,000	706,000
(706,000)	(706,000)
(706,000)	(706,000)
s 0	s 0
	\$272,000 86,000 20,000 127,000 1,031,000 371,000 371,000 44,531,000 56,111,000 (55,405,000) 

F-15

# ENZON, INC. AND SUBSIDIARIES Notes to Consolidated Financial Statements, Continued

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The net change in the total valuation allowance for the years ended June 30, 1999 and 1998 was an increase of \$4,428,000 and \$2,221,000, respectively. The tax benefit assumed using the Federal statutory tax rate of 34% has been reduced to an actual benefit of zero due principally to the aforementioned valuation allowance. Subsequently recognized tax benefits as of June 30, 1999 of \$1,677,000 relating to the valuation allowance for deferred tax assets will be allocated to additional paid-in capital.

At June 30, 1999, the Company had federal net operating loss carryforwards of approximately \$114,639,000 for tax reporting purposes, which expire in the years 2000 to 2019. The Company also has investment tax credit carryforwards of approximately \$1,900 and research and development tax credit carryforwards of approximately \$6,696,000 for tax reporting purposes which expire in the years 2000 to 2019.

As part of the Company's acquisition of Enzon Labs Inc., the Company acquired the net operating loss carryforwards of Enzon Labs Inc. As of June 30, 1999, the Company had a total of \$55,731,000 of acquired Enzon Labs net operating loss carryforwards, which expire between December 31, 1999 and October 31, 2006. As a result of the change in ownership, the utilization of these carryforwards is limited to \$613,000 per year.

Schering Agreement

The Company and Schering Corporation ("Schering"), a subsidiary of Schering-Plough, entered into an agreement in November 1990 (the "Schering Agreement") to apply the Company's PEG Process to develop a modified form of Schering-Plough's INTRON(R)A (interferon alfa 2b), a genetically-engineered anticancer and antiviral drug with longer activity. A PEG-modified version of INTRON A ("PEG-Intron(TM)") is currently in four large scale Phase III clinical trials in the United States, Europe and Japan for hepatitis C and cancer as well as earlier stage trials for cancer and certain leukemias. The trials call for administration of PEG-Intron once per week as compared to the current regimen for unmodified INTRON A of three times per week. PEG-Intron utilizes the Company's Second Generation PEG Technology.

Under the license agreement, which was amended in 1995 and 1999, the Company will receive royalties on worldwide sales of PEG-Intron, if any. Schering is responsible for conducting and funding the clinical studies, obtaining regulatory approval and marketing the product worldwide on an exclusive basis. During 1999, the Company and Schering amended the agreement that resulted in an increase in the effective royalty rate in return for Enzon's exclusive U.S. manufacturing rights for the product and a license under one of the Company's Second Generation PEG patents for Branched or U-PEG. The license for Branched PEG gives Schering the ability to sublicense the patent for a competing interferon product.

F-16

# ENZON, INC. AND SUBSIDIARIES Notes to Consolidated Financial Statements, Continued

Enzon is entitled to an additional \$3,000,000 in payments from Schering, subject to the achievement of certain milestones in the product's development. The Schering Agreement terminates, on a country-by-country basis, upon the expiration of the last to expire of any future patents covering the product which may be issued to Enzon, or 15 years after the product is approved for commercial sale, whichever shall be the later to occur. This agreement is subject to Schering's right of early termination if the product does not meet specifications, if Enzon fails to obtain or maintain the requisite product liability insurance, or if Schering makes certain payments to Enzon. If Schering terminates the agreement because the product does not meet specifications, Enzon may be required to refund certain of the milestone payments. Revenue will not be recognized on these payments until the product is deemed to meet specification.

# Rhone-Poulenc Rorer Agreement

Under the Company's Amended RPR U.S. License Agreement, Enzon granted an exclusive license to RPR to sell ONCASPAR in the U.S. Enzon has received licensing payments totaling \$6,000,000 and is entitled to a base royalty of 23.5% until 2008, on net sales of ONCASPAR up to agreed upon amounts. Additionally, the Amended RPR U.S. License Agreement provides for a super royalty of 43.5% until 2008, on net sales of ONCASPAR which exceed certain agreed upon amounts, with the limitation that the total royalties earned for any such year shall not exceed 33% of net sales. The Amended RPR U.S. License Agreement also provides for a payment of \$3,500,000 in advance royalties, which was received in January 1995.

The payment of base royalties to Enzon under the Amended RPR U.S. License Agreement will be offset by an original credit of \$5,970,000, which represents the royalty advance plus reimbursement of certain amounts due to RPR under the original RPR U.S. License Agreement and interest expense. Super royalties will be paid to the Company when earned. The royalty advance is shown as a long term liability, with the corresponding current portion included in accrued expenses on the Consolidated Balance Sheets as of June 30, 1999 and 1998. The royalty advance will be reduced as base royalties are recognized under the agreement.

The Amended RPR U.S. License Agreement prohibits RPR from selling a competing PEG-asparaginase product anywhere in the world during the term of such agreement and for five years thereafter. The agreement terminates in December 2008, subject to early termination by either party due to a default by the other or by RPR at any time upon one year's prior notice to Enzon. Upon any termination all rights under the Amended RPR U.S. License Agreement revert to Enzon. A separate supply agreement with RPR requires RPR to purchase from Enzon all ONCASPAR requirements for sales in North America.

The Company and RPR are currently in discussions related to a disagreement over the purchase price of ONCASPAR under the supply agreement between the two companies. RPR has asserted that the Company has overcharged RPR under the supply agreement in the amount of \$2,329,000. The Company believes its costing and pricing of ONCASPAR to RPR complies with the terms of the supply agreement. RPR has also asserted that the Company should be responsible for its lost profits while ONCASPAR is under the temporary labeling and distribution modifications agreed to by the Company and the FDA. RPR contends that its lost profits due to this matter, through June 30, 1999 were \$2,968,000. The Company does not agree with RPR's claim.

Under a separate license, RPR has exclusive rights to sell ONCASPAR in Canada and Mexico. These agreements provide for RPR to obtain marketing approval of ONCASPAR in Canada and Mexico and for the Company to receive royalties on sales of ONCASPAR in these countries, if any.

F-17

ENZON, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements, Continued

The Company also has a license agreement with RPR for the Pacific Rim region, specifically, Australia, New Zealand, Japan, Hong Kong, Korea, China, Taiwan, Philippines, Indonesia, Malaysia, Singapore, Thailand and Viet Nam, (the "Pacific Rim"). The agreement provides for RPR to purchase ONCASPAR for the Pacific Rim from the Company at certain established prices which increase over the ten year term of the agreement. Under the agreement, RPR is responsible for obtaining additional approvals and indications in the licensed territories. The agreement also provides for minimum purchase requirements for the first four years of the agreement.

## MEDAC Agreement

The Company has also granted an exclusive license to MEDAC to sell ONCASPAR in Europe and Russia. The agreement provides for MEDAC to purchase ONCASPAR from the Company at certain established prices which increase over the initial five year term of the agreement. Under the agreement, MEDAC is responsible for obtaining additional approvals and indications in the licensed territories, beyond the currently approved hypersensitive indication in Germany. Under the agreement, MEDAC is required to meet certain minimum purchase requirements.

#### (10) Commitments and Contingencies

The Company is being sued by a former financial advisor asserting that under a May 2, 1995, letter agreement ("Letter Agreement") between Enzon and LBC Capital Resources Inc. ("LBC"). LBC claims it was entitled to a commission in connection with the Company's January and March 1996 private placements, comprised of \$500,000 and warrants to purchase approximately 1,000,000 shares of Enzon common stock at an exercise price of \$2.50 per share. LBC has also asserted that it is entitled to an additional fee of \$175,000 and warrants to purchase 250,000 shares of Enzon common stock when and if any of the warrants obtained pursuant to the private placements are exercised. LBC has claimed \$3,000,000 in compensatory damages, plus punitive damages, counsel fees and costs for the alleged breach of the Letter Agreement. The Company believes that no such commission was due under the Letter Agreement and denies any liability under the Letter Agreement. The Company intends to defend this lawsuit vigorously and

believes the ultimate resolution of this matter will not have a material adverse effect on the financial position of the Company.

In the course of normal operations, the Company is subject to the marketing and manufacturing regulations as established by the Food and Drug Administration ("FDA"). During the year ended June 30, 1999, the Company and the FDA agreed to temporary labeling and distribution modifications for ONCASPAR due to increased levels of particulates in certain batches of ONCASPAR, which were manufactured by the Company. The Company, rather than its marketing partner, Rhone-Poulenc Rorer ("RPR"), will temporarily distribute ONCASPAR directly to patients, on an as needed basis, and will conduct the additional inspection and labeling procedures prior to distribution. During May 1999, the FDA placed additional restrictions on ONCASPAR, which specified ONCASPAR was to be distributed only to those patients who are hypersensitive to native L-asparaginase.

The Company has been able to manufacture several batches of ONCASPAR which contain acceptable levels of particulates and anticipates a final resolution of the problem during fiscal 2000. It is expected that RPR will resume distribution of ONCASPAR at that time. There can be no assurance that this solution will be acceptable to the FDA. If the Company is unable to resolve this problem it is possible that the FDA may not permit the Company to continue to distribute this product. An extended disruption in the marketing and distribution of ONCASPAR could have a material adverse impact on future ONCASPAR sales.

F-18

ENZON, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements, Continued

The Company maintains a separate supply agreement with RPR, under which RPR purchases from Enzon all of RPR's requirements for ONCASPAR at a price defined in the supply agreement. The Company and RPR are currently in discussions related to a disagreement over the purchase price of ONCASPAR under the supply agreement between the two companies. RPR has asserted that the Company has overcharged RPR under the supply agreement in the amount of \$2,329,000. The Company believes its costing and pricing of ONCASPAR to RPR complies with the supply agreement.

RPR has also asserted that the Company should be responsible for its lost profits while ONCASPAR is under the temporary labeling and distribution modifications. RPR contends that its lost profits through June 30, 1999 were \$2,968,000. The Company does not agree with RPR's claim for these two issues. The Company does not believe the ultimate resolution of these matters will have a material adverse effect on the financial results or operations of the Company.

The Company has agreements with certain members of its upper management which provide for payments following a termination of employment occurring after a change in control of the Company. The Company also has a 3-year employment agreement, dated April 5, 1997, with its Chief Executive Officer which provides for severance payments in addition to the change in control provisions discussed above.

# (11) Leases

The Company has several leases for office, warehouse, production and research facilities and equipment.

Future minimum lease payments, net of subleases, for noncancelable operating leases with initial or remaining lease terms in excess of one year as of June 30, 1999 are:

Year ending June 30,	Operating leases
2000	979,000
2001	952 <b>,</b> 000

2002	819,000
2003	765 <b>,</b> 000
2004	765 <b>,</b> 000
Later years, through 2007	2,752,000
Total minimum lease payments	\$7,032,000
	========

Rent expense amounted to \$1,394,000, \$1,768,000 and \$1,608,000 for the years ended June 30, 1999, 1998 and 1997, respectively.

For the years ended June 30, 1999, 1998 and 1997, rent expense is net of subrental income of \$110,000, \$221,000 and \$233,000, respectively. As of June 30, 1999, the Company no longer subleases a portion of its facilities.

#### (12) Retirement Plans

The Company maintains a defined contribution, 401(k) pension plan for substantially all its employees. The Company currently matches 50% of the employee's contribution of up to 6% of compensation, as defined. The Company's match is invested solely in a fund which purchases the Company's Common Stock in the open market. Total company contributions for the years ended June 30, 1999, 1998 and 1997 were \$115,000, \$100,000 and \$105,000, respectively.

F-19

# ENZON, INC. AND SUBSIDIARIES Notes to Consolidated Financial Statements, Continued

#### (13) Accrued Expenses

Accrued expenses consist of:

	June 30,	
	1999	1998
Accrued wages and vacation	\$1,074,000	\$695,000
Accrued Medicaid rebates	1,114,000	1,083,000
Current portion of royalty		
Advance - RPR	200,000	1,006,000
Contract and legal accrual	3,328,000	1,000,000
Other	546,000	592 <b>,</b> 000
	\$6,262,000	\$4,376,000
	========	========

### (14) Business and Geographical Segments

Effective July 1, 1998, the Company adopted SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information". The Company manages its business in one business segment in one location.

During the years ended June 30, 1999, 1998 and 1997, the Company had export sales of \$3,075,000, \$2,641,000 and \$2,377,000 respectively. Of these amounts, sales to Europe represented \$2,559,000, \$2,117,000 and \$1,937,000 during the years ended June 30, 1999, 1998 and 1997, respectively. Included as a component of European sales are sales to France which were \$1,108,000, \$994,000 and \$663,000; and sales to Italy which were \$1,201,000, \$879,000 and \$441,000 for the years ended June 30, 1999, 1998 and 1997.

ADAGEN sales represent approximately 90% of the Company's total net sales for the year ended June 30, 1999. ADAGEN's Orphan Drug designation under the Orphan Drug Act expired in March 1997. The Company believes the expiration of ADAGEN's Orphan Drug designation will not have a material impact on the sales of ADAGEN. Approximately 49%, 48% and 54% of the Company's ADAGEN sales for the years ended June 30, 1999, 1998 and 1997,

F-20

# EXHIBIT INDEX

Exhibit Numbers	Description	Page Number
21.0	Subsidiaries of Registrant	E1
23.0	Consent of KPMG LLP	E2
27.0	Financial Data Schedule	E3

## SUBSIDIARIES OF REGISTRANT

Symvex Inc. is a wholly-owned subsidiary of the Registrant incorporated in the State of Delaware. Symvex Inc. did business under its own name.

SCA Ventures Inc., (formerly Enzon Labs Inc.) is a wholly-owned subsidiary of the Registrant incorporated in the State of Delaware. SCA Ventures does business under its own name.

Enzon Pharm. B.V. is a wholly-owned subsidiary of the Registrant incorporated in the Netherlands.

Enzon  $\operatorname{GmbH}$  is a wholly-owned subsidiary of the Registrant incorporated in  $\operatorname{Germany}$ .

### INDEPENDENT AUDITORS' CONSENT

The Board of Directors Enzon, Inc.:

We consent to incorporation by reference in the Registration Statement Nos. 333-18051 and 33-50904 on Form S-8 and Registration Statement Nos. 333-58269, 333-46117, 333-32093 and 333-1535 on Form S-3 of Enzon, Inc. of our report dated September 8, 1999, relating to the consolidated balance sheets of Enzon, Inc. and subsidiaries as of June 30, 1999 and 1998, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended June 30, 1999, which report appears in the June 30, 1999 annual report on Form 10-K of Enzon, Inc.

/s/ KPMG LLP KPMG LLP

Short Hills, New Jersey September 28, 1999

## <ARTICLE> 5 <LEGEND>

This schedule contains summary financial information extracted from the Enzon, Inc. and Subsidiaries Consolidated Balance Sheet as of June 30, 1999 and the Consolidated Statement of Operations for the year ended June 30, 1999 and is qualified in its entirety by reference to such financial statements. </LEGEND>

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