FLEMINGTON PHARMACEUTICAL CORP
Form 10KSB
November 13, 2001

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended July 31, 2001

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [NO FEE REQUIRED]
For the transition period from to

Commission file No. 000-23399

FLEMINGTON PHARMACEUTICAL CORPORATION
(Exact name of registrant as specified in its charter)

| Delaware | 22-2407152 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 31 State Highway 12 Flemington, New Jersey | 08822 |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (908) 782-3431

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $.001 per share
Redeemable Class A Common Stock Purchase Warrants expiring November 18, 2002.

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 [ ]

Check if there is no disclosure of delinquent filings pursuant to Item 405 of Regulation S-K contained herein, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. [X]

State the issuer's revenues for its most recent fiscal year: $323,000

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant at November 8, 2001 was approximately $3,970,994 based upon the closing sale price of $0.65 for the Registrant's Common Stock, $.001 par value, as reported by the National Association of Securities Dealers OTC Bulletin Board on November 8, 2001.

As of November 8, 2001 the Registrant had 7,724,900 shares of Common Stock, $.001 par value, outstanding.

FLEMINGTON PHARMACEUTICAL CORPORATION

Annual Report on Form 10-KSB
For the Fiscal Year Ended July 31, 2001

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PART I

ITEM 1. BUSINESS.

General

Flemington Pharmaceutical Corporation, a Delaware corporation (the "Company" or the "Registrant"), is engaged in consulting activities and the development of novel application drug delivery systems for presently marketed prescription and over-the-counter ("OTC") drugs. The Company's (both patented and patent-pending) delivery systems are lingual sprays and soft gelatin bite capsules, enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. The Company's proprietary oral dosage delivery systems enhance and greatly accelerate the onset of the therapeutic benefits which the drugs are intended to produce. The Company refers to its delivery systems as Immediate -Immediate Release (I2R TM) because its delivery systems are designed to provide therapeutic benefits within minutes of administration. The Company's development efforts for its novel drug delivery systems are concentrated on drugs which are already available and proven in the marketplace. In addition to increasing bioavailability by avoiding metabolism by the liver before entry into the bloodstream, the Company believes that its proprietary delivery systems offer the following significant advantages: (i) improved drug safety profile by reducing the required dosage, including possible reduction of side -effects; (ii) improved dosage reliability; (iii) allowing medication to be taken without water; and (iv) improved patient convenience and compliance.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, the Company will continue to seek to develop such products through collaborative arrangements with major pharmaceutical companies, which will fund that development. The Company is presently a party to one such development agreement with a pharmaceutical company. Due to the Company's small revenue base, low level of working capital and inability to increase the number of development agreements with pharmaceutical companies, the Company has been unable to aggressively pursue its product development strategy. The Company will require significant additional financing and/or a strategic alliance with a well-funded development partner to undertake its business plan. See "Management Discussion and Analysis."

Since its inception in 1982, the Company has been a consultant to the pharmaceutical industry, focusing on product development activities of various European pharmaceutical companies, and since 1992 has used its consulting revenues to fund its own product development activities. The Company's recent focus on developing its own products evolved naturally out of its consulting experience for other pharmaceutical companies. Substantially all of the Company's revenues have been derived from its consulting activities. In 1998, the Company changed the name under which it performs its consulting activities from Pharmaconsult to FPC Consulting. The Company's principal business address is 31 State Highway 12, Flemington, New Jersey, 08822, and its telephone number is (908) 782-3431.

Forward Looking Statements

When used in this report, the words "may," "will," "expect," "anticipate," "continue," "estimate," "project," "intend" and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 regarding events, conditions and financial trends that may affect the Company's future plans of operations, business strategy, operating results and financial position. Current stockholders and prospective investors are cautioned that any forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties and that actual results may differ materially from those included within the forward-looking statements as a result of various factors. Such factors are described under the headings

"Business-Certain Considerations", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Financial Statements and Notes thereto.

Recent Developments

Filing of two Estradiol INDs and initiation of Phase II Studies

In mid-1999, as part of its joint development agreement with Nace Resources, (see Development Agreements, below), the Company completed its open label clinical pilot study of its Estradiol lingual spray product. In the opinion of the Company, the results of the study were favorable. The Company believes that the product would be appropriate for premenstrual migraine, for treatment of hot flashes in post- and perimenopausal women and as a long-term, low-dose, low side-effect treatment of post-menopausal symptoms. A Pre-IND meeting with FDA was held in the third quarter of 2000 and, based on the results of that meeting, a plan for further development was prepared. Two INDs were subsequently filed - one for vasomotor symptoms and a second for treatment of menstrual migraines. Both INDs were approved in 2000. Under the vasomotor IND a pilot study was started to see if rapid relief of hot flushes could be obtained with the lingual spray. The study, due to the small number of subjects and/or the study design, was not able clearly to demonstrate an advantage for the rapid relief of vasomotor symptoms. At this time a study large enough to demonstrate this rapid relief and/or to demonstrate the utility of the Lingual Spray for maintenance therapy has been delayed pending identification of a partner to fund the studies. A pilot study under the second IND was planned to start in the fourth quarter 2000, but has been delayed until a partner has been identified to fund the study. The Company is presently engaged in discussions with potential partners which would fund the further development of the product and the necessary regulatory filings.

Progesterone Lingual Spray

This product is being developed as part of the agreement with CLL and is intended to treat the symptoms of progesterone deficiency. The formulation work was completed, which was carried out by the Company and CLL, and stability and clinical supplies were manufactured in fourth quarter 1999. The pilot clinical study was carried out in early 2000. The results of this pilot clinical study supported the concept of fast and efficient relief of the symptoms associated with progesterone deficiency. A Pre-IND meeting with FDA was held in the third quarter of 2000 and based on the results of that meeting a plan for further development was prepared. CLL and the Company are seeking development partners to finance the further work associate with filing an NDA and bringing this product to market.

Doxylamine Succinate Lingual Spray

The Company has developed a formulation and performed stability studies for doxylamine succinate as a sleep-inducing agent. The Company has conducted a pilot clinical study. The study did not support the use of the product as a fast-onset OTC sleep inducer so reformulation is necessary. The earliest time that the Company could reasonably expect to have a commercially salable product in this category is early 2003.

Loratadine Lingual Spray

A loratadine lingual spray formulation has been developed and successfully undergone stability testing. A Pre-IND meeting with FDA was held in the third quarter of 2000 and based on the results of that meeting a plan for further development was prepared. An IND was filed and a pharmacokinetic

study was carried out under this IND to compare the plasma levels following administration of a 5.0 mg and a 2.5 mg lingual spray to those after administration of a 10 mg tablet. Both lingual spray doses resulted in higher plasma levels concentrations than the 10 mg tablet. In the case of the 5.0 mg dose the peak plasma levels were greater than twice those of the tablet and those after the 2.5 mg dose were about 50% higher. Therapeutic plasma levels based on the claimed start of antihistaminic effect for the Claritin(r) tablet (1-3 hours) were achieved between 24 and thirty minutes. The company is presently seeking a partner to develop this product.

Clemastine Lingual Spray

The formulation of clemastine lingual spray that was terminated by Novartis in 1998 was revised and a Pre-IND meeting with FDA was held in the third quarter of 2000. Based on the results of that meeting a plan for further development was prepared and an IND was filed. A pilot nasal challenge efficacy study was initiated in the second quarter of 2000. This study tested the relative response of subjects challenged with allergy producing substances to an OTC tablet (1.34 mg) and a lingual spray dose of 0.68 mg. The antihistamine was administered 15 minutes prior to the challenge. The results showed that the spray had the same antihistaminic effect when compared to placebo at 45 minutes after dosing as the tablet even though the dose was only half that of the tablet. Eight of the parameters measured in the study showed a clear trend that the spray was better than the tablet and the tablet was better than placebo. Even though the study was only a pilot study, the results appear to support the concept that a clemastine lingual spray could be the first OTC non-sedating antihistamine product in that there were two cases of drowsiness when the tablet was given and one with the placebo but none when the lingual spray was administered. A larger confirmatory study as well as other pilot studies are planned. The company is seeking a partner to develop this product.

Insulin Lingual Spray

Pursuant to an agreement with PolyMASC, a subsidiary of Valentis (see Agreements below), formulation development was started in the third quarter of 2000 to formulate their proprietary modified insulin molecule into the Company's lingual spray. The modified insulin has a polyethylene glycol molecule attached in a way that the insulin activity is maintained but the product should be more slowly degraded by enzymes in the blood. Due to restructuring at Valentis and a lack of funding on the part of the Company the project is presently on hold.

Replacement Lingual Spray

Pursuant to an agreement with Innovex, a partner of Novartis (see Agreements below), formulation development was started in the third quarter of 2000 to formulate a replacement lingual spray for one of their products. Formulation work has been completed and the samples for the planned pharmacokinetic study have been manufactured and tested for stability. The company has been informed that Innovex is no longer a party to the agreement but that Norvartis plans to develop this product with the Company. Discussions are ongoing to set up a coordination committee to manage the work being carried by the Company and Novartis.

Lavipharm Lingual Spray

Pursuant to an agreement with Lavipharm Laboratories a formulation development company (see Agreements below), formulation development was started in the second quarter of 2001 to formulate a compound of their choice as a lingual spray. Lavipharm had been unsuccessful in formulating the drug in their drug delivery systems to achieve a rapid increase in blood levels and

faster onset of action. It is contemplated that after confirmation of the ability of the Company's lingual spray formulation to deliver a rapid increase in plasma levels is demonstrated in a pilot pharmacokinetic study that a program will be developed to further develop the product. Lavipharm is paying the costs of the formulation development and the pilot pharmacokinetic study. Formulation development is completed and the results of the pharmacokinetic study are expected in the last quarter of 2001.

Loan to Chief Executive Officer

In April 1998, the Company made a $60,000 loan to its president and CEO in exchange for a 7% demand promissory note (the "Executive Note"). Accrued interest (which totaled $4,200 for fiscal 2001) is to be paid quarterly. In October 2001, the President and CEO indicated this loan would be repaid in full before year-end 2001.

Development Agreements

In November 1996, the Company entered into an Agreement with Altana Inc. ("Altana"), a U.S. subsidiary of Altana GmbH, under which the Company agreed to prepare for Altana an Abbreviated New Drug Application ("ANDA") for the Company's patent-pending lingual spray for treatment of angina. Under the terms of the Agreement, Altana will, upon approval of the product by the FDA, market the product in the U.S., and source all of its related product requirements from the Company. The Company was paid a consulting fee for preparation of the ANDA. In March 1998, the FDA refused to accept the ANDA for filing. Subsequently, the Company and Altana met with representatives of FDA and agreed upon a plan for the Company to file an NDA under Section 505(1)(b)(2) of the Act, together with two agreed-upon small clinical trials. Altana has agreed to fund those trials and to pay the Company a consulting fee in connection with its preparation of the NDA and its oversight of the trials. The Company is about to begin the manufacturing of clinical supplies for those trials during the fourth quarter of 2001.

In February 1998, the Company entered into two joint development agreements with CLL Pharmaceuticals, of Nice, France ("CLL") and Nace Resources, Inc. (now Nace Pharma) of Highland Park, Illinois ("Nace") for the development of various products using the Company's delivery technologies. Under the terms of such agreements, the Company, CLL and Nace, respectively, will conduct a series of pilot studies (at the parties' joint expense) to validate the efficacy of the various products being tested. If the Company and its partners are satisfied with the results of a particular pilot study, the parties will seek a license to fund further trials to support applications with the FDA and foreign regulatory agencies. Under such agreements, the Company will conduct the clinical trials and file all approval applications, and the Company and its partners will share equally in the expenses and profits (if any) arising from such arrangements. The first products identified for development studies are progesterone and estradiol for CLL and Nace, respectively.

During 1999 the estradiol clinical study was completed to the satisfaction of the Company and Nace. During 2000 two INDs were filed, one for Vasomotor relief (hot flushes) and one for abortive treatment of migraines associated with the menses. A phase II study was conducted under the Vasomotor IND to investigate the possibility of rapid relief of hot flush symptoms on administration of the lingual spray. Additional work is dependent on obtaining a partner firm to finance the development.

During 2000, laboratory development of the clinical supplies for the progesterone product and the pilot clinical study were completed with results satisfactory to the Company and CLL. Further development is on hold pending identification of a partner firm to finance the development.

In February 2000, the Company entered into a joint development agreements with PolyMASC, a subsidiary of Valentis, to formulate their proprietary modified insulin molecule into the Company's lingual spray. The modified insulin has a polyethylene glycol molecule attached in a way that the insulin activity is maintained but enzymes in the blood more slowly degrade the product. Formulation development was started in the third quarter of 2000. This project presently is on hold.

In 2000, the company entered into a joint development agreement with Innovex, which is marketing certain of the Novartis products, to develop a lingual spray formulation of one of those products. Formulation work has been completed and the samples for the initial pilot pharmacokinetic study have undergone stability testing.

In 2000, the company entered into a joint development agreement with Lavipharm Laboratories to develop a lingual spray formulation of a product of its choice. Formulation work has been completed and the samples for the initial pilot pharmacokinetic study are being prepared for stability testing. Following stability testing a pharmacokinetic study comparing plasma levels of the drug after administration of the spray at low dose levels and the standard tablet is planned. Lavipharm is financing the project.

Business Strategy

The Company's strategy is to concentrate its product development activities primarily on those pharmaceuticals for which there already are significant prescription and OTC sales, where the use of the Company's innovative delivery systems will greatly enhance speed of onset of therapeutic effect, reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect, and improve patient convenience or compliance.

In light of the material expense and delays associated with independently developing and obtaining approval of pharmaceutical products, the Company will continue to seek to develop such products through collaborative arrangements with major pharmaceutical companies, which will fund that development. The Company is presently a party to such a development agreement with Altana. The Company's lack of working capital has impaired its ability to pursue its strategy. See "Management Discussion and Analysis."

Patented and Patent Pending Delivery Systems

The Company has patent applications pending for two oral dosage delivery systems, the Lingual (Oral) Spray and the Soft Gelatin Bite Capsule, for which FDA approval is not a prerequisite for patent approval (See "Patents and Protection of Proprietary Information" below). The expected year of marketability will vary depending upon the specific drug product with which the delivery system will be utilized. Each individual use of the delivery system will require registration and/or approval with the FDA prior to marketability, and the amount of regulatory oversight required by the FDA will also depend on the specific type of drug product for which the delivery system is implemented. The following are descriptions of the two oral dosage delivery systems for which patent applications are either granted or pending:

Lingual (Oral) Spray. The Company's aerosol and pump spray formulations release the drug in the form of a fine mist into the mouth for immediate absorption into the bloodstream via the mucosal membranes. The Company believes that this delivery system offers certain advantages, including improving the safety profile of certain drugs by lowering the required dosage, improving dose reliability, and allowing medication to be taken without water. Drug absorption through the mucosal membranes of the m

outh is rapid and minimizes the first-pass metabolism effect (i.e., total or partial inactivation of a drug as it passes through the gastrointestinal tract and liver).

Soft Gelatin Bite Capsule. The Company's soft gelatin bite capsule formulation consists of a seamless gelatin shell surrounding a core substance (usually a liquid solution). When crushed or chewed, the soft gelatin bite capsule releases medication into the mouth, thereby allowing absorption through the oral mucosa. The portion of the dose that is eventually swallowed is introduced to the stomach in a solution ready for immediate absorption, thereby maximizing absorption from the gastrointestinal tract into the bloodstream. The result is rapid onset of the desired therapeutic effect.

Proposed Products

The Company's proposed products described below are subjected to laboratory testing and stability studies and tested for therapeutic comparison to the originators' products by qualified laboratories and clinics. To the extent that two drug products with the same active ingredients are substantially identical in terms of their rate and extent of absorption in the human body (bioavailability), they are considered bioequivalent. If the accumulated data demonstrates bioequivalency, submission is then made to the FDA (through the filing of an ANDA) for its review and approval to manufacture and market. If the accumulated data demonstrates that there are differences in the two drugs' rate and extent of absorption into the human body, or if it is intended to make additional or different claims regarding therapeutic effect for the newly developed product, submission is made to the FDA via a NDA for its review and approval under Section 505(1)(b)(2) or Section 505(b)(2) of the FDC Act. An NDA submitted under these sections of the FDC Act are generally less complex than an ordinary NDA and are usually acted upon by FDA in a shorter period of time. It is the Company's expectation that the majority of its products in development will require the filing of these shorter versions of an NDA because the products are known chemical entities, but the Company or its licensees will be making new claims as to therapeutic effects or lessened side effects, or both.

The Company estimates that development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes three to five years for the ANDA process. Development of products requiring additional clinical studies under Section 505(b)(2) NDAs, may take four to seven years. There can be no assurance that the Company's determinations will prove to be accurate or that pre-marketing approval relating to its proposed products will be obtained on a timely basis, or at all. See "Government Regulation."

The Company's initial proposed products fall into the following therapeutic classes:

* Estradiol Lingual Spray

Several new "non-estrogen" products have recently been introduced to treat osteoporosis without the associated side effects of estrogens. Due to the non-estrogen nature of these products, the Company believes that patients often experience "hot-flashes" and find it difficult to maintain the required dosage regimen. The lingual spray is intended to relieve the "hot-flashes" within minutes, which, the Company believes, will allow such patients to maintain the required dosage regimen more easily. The Company has completed preformulation development of this product, and has manufactured and packaged supplies for stability and clinical studies. The pilot clinical study was completed in mid-1999 and the Company considers the results of that study to be favorable. A Pre-IND meeting with FDA was held in the third quarter of 2000 and based on the results of that meeting a plan for further development was

prepared. Two INDs were subsequently filed - one for vasomotor symptoms and a second for treatment of menstrual migraines. Both INDs were approved in 2000. Under the vasomotor IND a pilot study was started to see if rapid relief of hot flushes could be obtained with the lingual spray. The study results have been received. A pilot study under the second IND is planned for fiscal 2001.

* Progesterone Lingual Spray

This product is being developed as part of the agreement with CLL and is intended to treat the symptoms of progesterone deficiency. The formulation work was completed, which was carried out by the Company and CLL, and stability and clinical supplies were manufactured in second quarter 1999. The pilot clinical study was carried out in early 2000. The results of this pilot clinical study supported the concept of fast relief of the symptoms associated with progesterone deficiency. A Pre-IND meeting with FDA was held in the third quarter of 2000 and based on the results of that meeting a plan for further development was prepared. CLL and the Company are seeking development partners to finance the further work associated with filing an NDA and bringing this product to market.

* Doxylamine Succinate Lingual Spray

The Company has developed a formulation and performed stability studies for doxylamine succinate as a sleep-inducing agent. The Company has conducted a pilot pharmacokinetic study comparing two doses of the lingual spray to those obtained after administration of the tablet. The results did not show any advantage for the lingual spray except possible ease of administration for those such as phagic patients, the elderly or children who cannot take or do not like to take tablets. It is believed that the very water soluble nature of the succinate salt was the cause of these results. Re-formulation was started to make the product less water soluble and more suitable for fast onset. These efforts are on hold pending identification of a partner to finance the further development.

* Cardiovascular (Nitroglycerin)

The Company's Nitroglycerin product has been formulated and stability testing has been completed. A United States patent was issued in 1999. This product is subject to a license agreement with Altana. See " -- Recent Developments." A pre-IND meeting has been held with the FDA and a program for clinical trials has been tentatively agreed upon with the FDA. The company is presently manufacturing clinical samples to be used in the two studies required. After stability studies an IND is planned for the fourth quarter of 2001 and an NDA the second quarter of 2002.

* Loratadine Lingual Spray

A loratadine lingual spray formulation has been developed and successfully undergone stability testing. A Pre-IND meeting with FDA was held in the third quarter of 2000 and based on the results of that meeting a plan for further development was prepared. An IND was filed in the fourth quarter of 2000 and a pharmacokinetic study was completed in the second quarter of 2001.

* Clemastine Lingual Spray

The formulation of clemastine lingual spray that was terminated by Novartis in 1998 was revised and a Pre-IND meeting with FDA was held in the third quarter of 2000. Based on the results of that meeting a plan for further development was prepared and an IND was filed. A pilot nasal challenge efficacy study was initiated in the second quarter of 2000. and was

completed in the fourth quarter of 2000. This study tested the relative response of subjects challenged with allergy producing substances to an OTC tablet (1.34 mg) and a lingual spray dose of 0.68 mg. The antihistamine was administered 15 minutes prior to the challenge. The results showed that the spray had the same antihistaminic effect when compared to placebo at 45 minutes after dosing as the tablet even though the dose was only half that of the tablet. Eight of the parameters measured in the study showed a clear trend that the spray was better than the tablet and the tablet was better than placebo. Even though the study was only a pilot study, the results support the concept that a clemastine lingual spray could be the first OTC non-sedating antihistamine product in that there were two cases of drowsiness when the tablet was given and one with the placebo but none when the lingual spray was administered. A larger confirmatory study, as well as other pilot studies, is planned. The Company is seeking a partner to develop this product.

* Insulin Lingual Spray

Subsequent to an agreement with PolyMASC, a subsidiary of Valentis, formulation development was started in the third quarter of 2000 to formulate their proprietary modified insulin molecule into the Companies lingual spray. The modified insulin has a polyethylene glycol molecule attached in a way that the insulin activity is maintained but the product is more slowly degraded by enzymes in the blood. Due to restructuring at Valentis and a lack of funding on the part of the Company the project is presently on hold.

Marketing and Distribution

The Company intends, generally, to license products developed with its technology to drug companies already selling such drug substances under their own brand names, or to market its products to pharmaceutical wholesalers, drug distributors, drugstore chains, hospitals, United States governmental agencies, health maintenance organizations and other drug companies. It is anticipated that promotion of the Company's proposed products will be characterized by an emphasis on their distinguishing characteristics, such as dosage form and packaging, as well as possible therapeutic advantages of such products. The Company will seek to position its proposed products as alternatives or as line extensions to brand-name products. The Company believes that to the extent that the Company's formulated products are patent-protected, such formulations may offer brand-name manufacturers the opportunity to expand their product lines. Alternatively, products which are not patented may be offered to brand-name manufacturers as substitute products after patent protection on existing products expire.

Inasmuch as the Company does not have the financial or other resources to undertake extensive marketing activities, the Company generally intends to seek to enter into marketing arrangements, including possible joint ventures or license or distribution arrangements, with third parties. The Company believes that such third-party arrangements will permit the Company to maximize the promotion and distribution of its products while minimizing the Company's direct marketing and distribution costs. Other than the Company's aforementioned agreements for the Company's proposed lingual spray products for angina, the Company has not entered into any agreements or arrangements with respect to the marketing of its proposed products and there can be no assurance that it will do so in the future. There can be no assurance that the Company's proposed products can be successfully marketed.

Strategies relating to marketing of the Company's other proposed formulated products have not yet been determined; these will be formulated in advance of anticipated completion of development activities relating to the particular formulated product. The Company has no experience in marketing or distribution of its proposed proprietary products, and the Company's ability to fund such marketing activities will require the Company to raise additional

funds and/or consummate a strategic alliance or combination with a well-funded business partner.

Manufacturing

The Company had entered into agreements with various European pharmaceutical manufacturers, regarding the manufacture of certain of the Company's products in spray and gelatin bite capsule dosage forms. These contracts have been canceled by the European manufacturers to the Company's detriment. New arrangements have been established for the manufacture of aerosol products for clinical supplies with a contract manufacturer in Pennsylvania. The Company will manufacture all of its pump spray products for clinical studies at its facility. Within the next year the company will have to locate contract manufacturers who can manufacture commercial requirements for its proposed products, at a price to be negotiated by the parties.

It is anticipated that the Company will arrange with third-party suppliers for supplies of active and inactive pharmaceutical ingredients and packaging materials used in the manufacture of the Company's proposed products. It is the Company's present intent to seek to enter into similar manufacturing arrangements for other products to be developed by it in the future.

The manufacture of the Company's pharmaceutical products will be subject to current Good Manufacturing Processes ("cGMP") prescribed by the FDA, and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See "Government Regulation" and "Raw Materials and Suppliers."

In addition, the raw materials necessary for the manufacture of the Company's products will, in all likelihood, be purchased by the Company from suppliers in the United States, Europe and Japan and delivered to its manufacturers' facilities by such suppliers. Accordingly, the Company and its manufacturers may be subject to various import duties applicable to both finished products and raw materials and may be affected by various other import and export restrictions as well as other developments impacting upon international trade. These international trade factors will, under certain circumstances, have an impact both on the manufacturing cost (which will, in turn, have an impact on the cost to the Company of the manufactured product) and the wholesale and retail prices of the products to be manufactured abroad. To the extent that transactions relating to the foreign manufacture of the Company's proposed products and purchase of raw materials involve currencies other than United States dollars (e.g., Swiss francs and German marks), the operating results of the Company will be affected by fluctuations in foreign currency exchange rates.

Raw Materials and Suppliers

The Company believes that the active ingredients used in the manufacture of its proposed pharmaceutical products are presently available from numerous suppliers located in the United States, Europe and Japan. Generally, certain raw materials, including inactive ingredients, are available from a limited number of suppliers and certain packaging materials intended for use in connection with the Company's lingual spray products that may only be available from sole source suppliers. Although the Company believes that it will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of its products, there can be no assurance that the Company or its manufacturers will be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. The failure to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies could have a material adverse effect on the ability to manufacture

formulated products.

Development and regulatory approval of the Company's pharmaceutical products are dependent upon the Company's ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the specified supplier, which could result in manufacturing delays. Accordingly, the Company will seek to locate alternative FDA approved suppliers.

Government Regulation

The development, manufacture and commercialization of pharmaceutical products are generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations, pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures.

Under the FDC Act, a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA. The FDA approval process relating to a new drug differs, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a NDA, including complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND pursuant to which permission is sought to begin preliminary clinical testing of the new drug. An NDA based on published safety and efficacy studies conducted by others may also be required to be submitted for a drug product with a previously approved active ingredient, if the method of delivery, strength or dosage is changed. Alternatively, a drug having the same active ingredients as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process.

While the ANDA process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the NDA for the previously approved drug.

The NDA approval process generally requires between four to seven years from NDA submission to pre-marketing approval, although in the case of an NDA submitted pursuant to Section 505(1)(b)(2) of the Act this time frame may be significantly shorter. By contrast, the ANDA process permits an expedited FDA review pursuant to which pre-marketing regulatory approval can generally be obtained in three to five years. The ANDA process is available for drugs with the same active ingredients, dosage form, strength and method of delivery as a product which has previously received FDA approval pursuant to the NDA process. Manufacturing information, including a review of chemical and physical data, stability data, facilities and processes, must also be evaluated by FDA before approval.

The Company believes that products developed in lingual spray and soft gelatin bite capsule delivery systems (dosage forms) usually will require

submission of an NDA.

The Company estimates that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes three to five years for the ANDA process and four to seven years for the NDA process, although NDAs submitted under Section 505(1)(b)(2) or Section 505(b)(2) are generally less complex than an ordinary NDA and are usually acted upon by the FDA in a shorter period of time. There can be no assurance that the Company's determinations will prove to be accurate or that pre-marketing approval relating to its proposed products will be obtained on a timely basis, or at all. The FDA application procedure has become more rigorous and costly and the FDA currently performs pre-approval and periodic inspections of each finished dosage form and each active ingredient.

The manufacture of the Company's pharmaceutical products will be subject to cGMP prescribed by the FDA, pre-approval inspection by the FDA and foreign authorities prior to the commercial manufacture of such products and periodic cGMP compliance inspection by the FDA. The Company's European manufacturers will be required to be in compliance with cGMP with respect to the manufacture of the Company's products. There can be no assurance that the Company's manufacturers will be deemed to be in compliance with cGMP with respect to any particular product. To the extent that the Company's manufacturers are deemed not to be in compliance with cGMP, there can be no assurance that the Company will be able to enter into other suitable manufacturing arrangements with third parties which are in compliance with cGMP.

Competition

The markets which the Company intends to enter are characterized by intense competition. The Company will be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those the Company intends to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with the Company's proposed products. The Company expects that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which the Company has targeted for development are intensely competitive, involving numerous competitors and products. The Company will seek to enhance its competitive position by focusing its efforts on its novel dosage forms.

Patents and Protection of Proprietary Information

The Company has applied for United States and foreign patent protection for the delivery systems which are the primary focus of its development activities as well as the delayed contact allergy topical formulations. Three United States patents have been issued and other applications are pending. There can be no assurance, however, that any additional patent applications will be granted, or, if granted, will provide any adequate protection to the Company. The Company also intends to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patent or similar rights with respect thereto.

Although the Company believes that its technology has been developed independently and does not infringe on the patents of others, there can be no assurance that the technology does not and will not infringe on the patents of others. In the event of infringement, the Company or its manufacturers could,

under certain circumstances, be required to modify the infringing process or obtain a license. There can be no assurance that the Company or its manufacturers would be able to do either of those things in a timely manner or at all, and failure to do so could have a material adverse effect on the Company and its business. In addition, there can be no assurance that the Company will have the financial or other resources necessary to enforce or defend a patent infringement or proprietary rights violation action. If any of the products developed by the Company infringe upon the patent or proprietary rights of others, the Company could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on the Company.

The Company also relies on confidentiality and nondisclosure arrangements with its licensees and potential development candidates. There can be no assurance that other companies will not acquire information which the Company considers to be proprietary. Moreover, there can be no assurance that other companies will not independently develop know-how comparable to or superior to that of the Company.

Buccal Nonpolar Spray or Capsule. On April 12, 1996 the Company filed an application with the United States Patent and Trademark Office ("PTO") for protection of this subject matter. On September 1, 1998 the PTO allowed the claims directed to sprays, but rejected the claims directed to the capsules. In October 1998 the Company dropped the capsule claims from this application, to pursue allowance and issuance of a patent directed to the spray claims. On October 21, 1999 the PTO issued a patent (5955098) to the Company on the spray claims.

On February 21, 1997, the Company filed an application under the Patent Cooperation Treaty ("PCT") for the above-subject matter. The International Preliminary Examination Authority has issued an opinion in which the PCT examiner determined that the subject matter of the invention while novel is not inventive for obviousness. This opinion, with which the Company disagrees, is not dispositive, however, it may be highly persuasive in subsequent proceedings in the European and individual national patent offices should the Company decide to proceed in these jurisdictions.

In October 1998, the Company filed a patent application in the European Patent Office and in Canada for the buccal nonpolar spray claims. The former has not yet been acted on, the latter is not yet due for examination.

Buccal Polar Spray or Capsule. On April 12, 1996 the Company filed an application with the United States Patent and Trademark Office ("PTO") for protection of this subject matter, no claims were allowed. On November 25, 1998, the Company filed the application in the PTO directed to the method of use of the spray and subsequently the PTO issued a patent (6110486) to the Company on these claims.

On February 21, 1997, the Company filed an application under the Patent Cooperation Treaty ("PCT") for the above-subject matter. The International Preliminary Examination Authority has issued an opinion in which the PCT examiner determined that the subject matter of the invention while novel is not inventive for obviousness. This opinion, with which the Company disagrees, is not dispositive, however, it may be highly persuasive in subsequent proceedings in the European and individual national patent offices should the Company decide to proceed in these jurisdictions.

In October and November 1998, the Company filed patent applications in Europe and Canada for the buccal polar spray claims. In the former case an Official action has been received and responded to. The latter is not ripe for examination yet.

Buccal Nonpolar Spray for Nitroglycerin. On April 12, 1996, the Company filed an application in the PTO directed to the above subject matter. On August 5, 1998 the PTO allowed claims to the above subject matter, and a patent (5869082) was issued in February 1999. On February 21, 1997 the Company filed a PCT application directed to the above subject matter. The application was rejected for lack of inventive step on the ground that the manner in which the claims differed from the prior art was required by legislation. European and Canadian counterpart applications have been filed. The Canadian application is not yet ripe for examination.

Buccal/Polar/Nonpolar Sprays or Capsule (Different Medicaments as Above). An application was filed with the PCT on October 1, 1997 designating a large number of possible countries including the United States. This application differs from the first two applications above in that it utilizes different ingredients. The PCT Examiner allowed two rather limited (but not commercially insignificant) claims, and rejected the remaining claims for lack of inventive step and lack of unity.

The Company has made individual filings for patent protection in USA, Japan, Canada, and Europe.

In the United States, the original application has been refiled as a CIP (008) directed only to pump spray compositions. An initial Official Action has been received and responded to. No examination is yet due in Japan and Canada.

Upon advice of our European Associate, the original application was filed as three separate divisional applications. While some new references have been cited no Official Action has been received in any of these cases.

Antihistamine Syrup and Ointment. On November 10, 1997 the Company filed an application with the U.S. PTO for protection of its antihistamine syrup and ointments, a technology to be utilized in the company's proposed poison ivy product. In October 1998, the PTO initially rejected the application for this product. The application was refiled in May 2000 with claims directed solely to method of protection claims. An Official Action has been received and a response has been filed to the patent examiner's comments. The Company is awaiting a reply.

General Comment with Respect to the Foregoing PCT Applications. The Company is interested in obtaining patent protection in Europe and Canada. It is to be expected that the same examiner who examined these applications in Europe as a PCT examiner will be the examiner who will handle applications in the European "National" Phase. Hence, the Company anticipates it may be necessary to appeal to the Board of Appeals in Munich. At the present time, it is not possible to accurately predict the expenses involved in pursuing the foregoing applications. However, expenses may exceed $100,000 (in the aggregate for all three applications) before a final disposition is obtained. The Company expects this process to take between two and four years.

Product Liability

The Company may be exposed to potential product liability claims by consumers. The Company does not presently maintain product liability insurance coverage. Although the Company will seek to obtain product liability insurance prior to the commercialization of any products, there can be no assurance that the Company will obtain such insurance or, if obtained, that any such insurance will be sufficient to cover all possible liabilities. In the event of a successful suit against the Company, insufficiency of insurance coverage could have a material adverse effect on the Company. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Failure to satisfy such insurance requirements could impede

the ability of the Company or its distributors to achieve broad retail distribution of its proposed products, which would have a material adverse effect upon the business and financial condition of the Company.

Customer Dependence

Since inception, substantially all of the Company's revenues have been derived from consulting activities primarily in connection with product development for various pharmaceutical companies. Among other things, the Company works with its European clients to obtain regulatory approvals for new drug formulations in the United States. For the year ended July 31, 2001, consulting activities relating to the Company's two (2) largest clients accounted for approximately 40% and 18% respectively, of the Company's revenue. For the year ended July 31, 2000, consulting activities relating to the Company's two largest clients accounted for approximately 27% and 18% respectively, of the Company's revenue. For the year ended July 31, 1999 consulting activities relating to the Company's three largest clients accounted for approximately 19%, 14% and 10% respectively, of the Company's revenue.

Employees

The Company currently has eight (8) full-time employees, three (3) of whom are executive officers of the Company, and two (2) of whom are engaged in administrative functions. The success of the Company will be dependent in part, upon its ability to hire and retain additional qualified sales and distribution personnel, however, there can be no assurance that the Company will be able to hire or retain such necessary personnel.

CERTAIN CONSIDERATIONS

This Form 10-KSB, the Company's Proxy Statement, other documents of the Company and statements made by members of management of the Company, in each case, may contain forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in such forward-looking statements. Factors that might cause such a difference include the following:

Accumulated Deficit and Operating Losses; Anticipated Continuing Losses; Limited Working Capital. The Company had an accumulated deficit at July 31, 2001 of approximately $5,523,000. The Company incurred operating losses in six of the last seven fiscal, years ended July 31 including a net loss of approximately $1,109,000 for the year ended July 31, 2001. Because the Company increased its product development activities, the Company anticipates that it will incur substantial operating expenses in connection with continued development, testing and approval of its proposed products, and expects these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that the Company is able to achieve adequate product sales levels.

Dependence on Principal Clients. [RFS3] To date, substantially all of the Company's revenues have been derived from consulting services rendered to a limited number of clients, the loss of certain of which would have an adverse effect on the Company. For the year ended July 31, 2001, consulting activities relating to the Company's two (2) largest clients, with which the Company has written agreements, accounted for approximately 40%, and 18% respectively, of the Company's revenues. There can be no assurance that the Company's clients will continue to seek consulting services from the Company or that the Company will continue to provide consulting services to the industry. See "---Customer Dependence."

Evolving Nature of Business; Entry into Product-Based Business. Although the Company has received revenue from its own product development activities, these revenues are insignificant as compared to the Company's revenues from product development consultation work done for its clients. The nature of the Company's revenue received from its own product development consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials, and similar milestone-related payments. Subject to additional funding, the Company expects to continue its consulting activities despite increasing its product development activities. The future growth and profitability of the Company will be dependent upon the Company's ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for, and license out or market, its own proposed products. Accordingly, the Company's prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. The Company anticipates that it will incur substantial operating expenses in connection with the development, testing and approval of its proposed products and expects these expenses to result in continuing and, perhaps, significant operating losses until such time, if ever, that the Company is able to achieve adequate levels of sales or license revenues. There can be no assurance that the Company will be able to raise additional financing, increase revenues significantly, or achieve profitable operations.

Significant Capital Requirements for Product Development and Commercialization. The Company has a significant capital requirement necessary to fund planned expenditures in connection with the research, development, testing and approval of its proposed products. The Company anticipates, based on its current proposed plans and assumptions relating to its operations (including the timetable of, and costs associated with, new product development), that the proceeds of the November 1997 public offering ("Public Offering"), its 2000 Private Placement, its 2001 Private Placement and projected cash flow from operations will be sufficient to satisfy its contemplated cash requirements for approximately four months from the date hereof. Due to the Company's small revenue base, low level of working capital and inability to increase the number of development agreements with pharmaceutical companies, the Company has been unable to pursue its product development strategy. The Company will require significant additional financing and/or a strategic alliance with a well-funded development partner to undertake its business plan. The Company has no current arrangements with respect to, or sources of, additional financing, and there can be no assurance that additional financing will be available to the Company on acceptable terms, if at all. In view of the Company's very limited resources, its anticipated expenses and the competitive environment in which the Company operates, any inability to obtain additional financing could severely limit the Company's ability to complete development and commercialization of its proposed products. See "Management's Discussion and Analysis Of Financial Condition And Results Of Operations."

No Commercially Available Products. The Company's principal efforts are the development of, and obtaining regulatory approvals for, its proposed products. The Company anticipates that marketing activities for its proprietary products, whether by the Company or one or more licensees will not begin until 2003 at the earliest. Accordingly, it is not anticipated that the Company will generate any revenues from royalties or sales of proprietary products until regulatory approvals are obtained and marketing activities begin. There can be no assurance that any of the Company's proposed proprietary products will prove to be commercially viable, or if viable, that they will reach the marketplace on the timetables desired by the Company. The failure or the delay of these products to achieve commercial viability would have a material adverse effect on the Company. See "- - Proposed Products" and " - Government Regulation."

Product Development and Acceptance Risks. The development of the Company's proposed products has not been completed and the Company will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such products must be obtained before the proposed products will become available for commercial sale. The Company does not anticipate generating material revenue from product sales until perhaps 2003 or thereafter. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems, and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. There can be no assurance that any of the Company's proposed products will be successfully developed, be developed on a timely basis or be commercially accepted once developed. The inability to successfully complete development, or a determination by the Company, for financial or other reasons, not to undertake to complete development of any product, particularly in instances in which the Company has made significant capital expenditures, could have a material adverse effect on the Company. See "- - Proposed Products."

Lack of Direct Consumer Marketing Experience; Dependence on Joint Marketing Arrangements. The Company has no experience in marketing or distribution at the consumer level of its proposed proprietary products. Moreover, the Company does not have the financial or other resources to undertake extensive marketing and advertising activities. Accordingly, the Company intends generally to rely on marketing arrangements, including possible joint ventures or license or distribution arrangements with third parties. The Company has not entered into any significant agreements or arrangements with respect to the marketing of its proposed products, and there can be no assurance that it will do so in the future or that any such products can be successfully marketed. The Company's strategy to rely on third party marketing arrangements could adversely affect its profit margins. See " - Marketing and Distribution."

Dependence on Contract Manufacturing. The Company's agreements with respect to the manufacture of its initially proposed products with its European contract manufacturers have been canceled Alternative arrangements will have to be made. The Company's dependence upon third parties for the manufacture of its products could have an adverse effect on the Company's profit margins and its ability to deliver its products on a timely and competitive basis.

Compliance with Good Manufacturing Practices. The Company currently intends to rely on third-party arrangements for the manufacture of its proposed products. The manufacture of the Company's pharmaceutical products will be subject to current Good Manufacturing Practices ("cGMP") prescribed by the FDA, pre-approval inspections by the FDA or foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. There can be no assurance that the Company's European manufacturers will be able to comply with cGMP or satisfy pre- or post-approval inspections in connection with the manufacture of the Company's proposed products. Failure or delay by any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on the Company. See "-- Manufacturing."

Supplier Dependence. The Company believes that the active ingredients used in the manufacture of its proposed pharmaceutical products are presently available from numerous suppliers located in the United States, Europe India and Japan. The Company believes that certain raw materials, including

inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with its spray products currently are available only from sole source suppliers. Although the Company does not believe it will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of its products, there can be no assurance that the Company will be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. The Company has a written supply agreement with Dynamit Nobel for certain raw materials for the nitroglycerin lingual spray product. With respect to other suppliers, the Company operates primarily on a purchase order basis beyond which there is no contract memorializing the Company's purchasing arrangements. The failure to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies could have a material adverse effect on the Company's ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of the Company's products are dependent upon the Company's ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which could result in manufacturing delays. See "- - Raw Materials and Suppliers."

Competition. The markets which the Company intends to enter are characterized by intense competition. The Company or its licensees may be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those the Company intends to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with the Company's proposed products. The Company expects that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which the Company has targeted for development are intensely competitive, involving numerous competitors and products. Most of the Company's prospective competitors possess substantially greater financial, technical and other resources than the Company. Moreover, many of these companies possess greater marketing capabilities than the Company, including the resources necessary to enable them to implement extensive advertising campaigns. There can be no assurance that the Company will have the ability to compete successfully. See "- - Competition."

Absence of Product Liability Insurance Coverage. The Company may be exposed to potential product liability claims by consumers. The Company presently maintains no product liability insurance coverage. Although the Company will seek to obtain product liability insurance before the commercialization of any proprietary products, there can be no assurance that the Company will be able to obtain such insurance or, if obtained, that any such insurance will be sufficient to cover all possible liabilities to which the Company may be exposed. In the event of a successful suit against the Company, insufficiency of insurance coverage could have a material adverse effect on the Company. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Failure to satisfy such insurance requirements could impede the ability of the Company or its distributors to achieve broad retail distribution of its proposed products, which could have a material adverse effect on the Company. None of the Company's European manufacturers have made any representations as to the

safety or efficacy of the products covered by their agreements or as to any products which may be marketed or used under rights granted under any such agreements, other than compliance with cGMP and product specifications. See "- - Product Liability."

Extensive Government Regulation. The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal United States regulatory authority, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations, pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug and Cosmetic Act (the "FDC Act"), a new drug may not be commercialized or otherwise distributed in the United States without the prior approval of the FDA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a new drug application ("NDA"), including complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. The NDA process generally requires, before the submission of the NDA, submission of an IND pursuant to which permission is sought to begin preliminary clinical testing of the new drug. An NDA, based on published safety and efficacy studies conducted by others, may also be required to be submitted for a drug product with a previously approved active ingredient if the method of delivery, strength or dosage form is changed. Alternatively, a drug having the same active ingredient as a drug previously approved by the FDA may be eligible to be submitted under an ANDA, which is significantly less stringent than the NDA approval process. While the ANDA process requires a manufacturer to establish bioequivalence to the previously approved drug, it permits the manufacturer to rely on the safety and efficacy studies contained in the DNA for the previously approved drug. The Company believes that some of its drug products developed in capsule form will be substantially similar to products which have previously obtained FDA approval and, accordingly, that approvals for such products can be obtained by submitting an ANDA. The Company, however, may be required, before submitting an ANDA, to submit a suitability petition, the purpose of which is to permit the FDA to evaluate whether a change in strength, dosage form or method of delivery is significant enough to require clinical trials and, therefore, an NDA filing. There can be no assurance that the FDA will not require the Company to conduct clinical trials for such products and otherwise comply with the NDA approval process. The Company believes that products developed in spray dosage form will require submission of an NDA. The Company estimates that the development of new formulations of pharmaceutical products, including formulation, testing and obtaining FDA approval, generally takes three to five years for the ANDA process and four to seven years for the NDA process. There can be no assurance that the Company's determinations will prove to be accurate or that pre-marketing approval relating to its proposed products will be obtained on a timely basis, or at all. The failure by the Company to obtain necessary regulatory approvals, whether on a timely basis, or at all, would have a material adverse effect on the Company.

Dependence on Existing Management. The success of the Company is substantially dependent on the efforts and abilities of its founder, President and Chief Executive Officer, Harry A. Dugger, III, Ph.D., the Company's Chairman, John J. Moroney, and the Company's Chief Financial Officer, Donald Deitman. Mr. Moroney is not required to devote full time to the Company. Decisions concerning the Company's business and its management are and will continue to be made or significantly influenced by these individuals. The

loss or interruption of their continued services would have a materially adverse effect on the Company's business operations and prospects. See "- Marketing and Distribution" and "DIRECTORS AND OFFICERS."

Control by Current Stockholders, Officers and Directors. Management and affiliates of the Company currently beneficially own (including shares they have the right to acquire) approximately 36.23[RFS4]% of the outstanding Common Stock. These persons are and will continue to be able to exercise control over the election of the Company's directors and the appointment of officers, increase the authorized capital, dissolve, merge or engage the Company in other fundamental corporate transactions.

Dividend Policy. The Company has never declared or paid a dividend on its Common Stock, and management expects that a substantial portion of the Company's future earnings will be retained for expansion or development of the Company's business. The decision to pay dividends, if any, in the future is within the discretion of the Board of Directors and will depend upon the Company's earnings, capital requirements, financial condition and other relevant factors such as contractual obligations. Management, therefore, does not contemplate that the Company will pay dividends on the Common Stock in the foreseeable future.

Limited Public Market. There has been a very limited public market for the Units, the Common Stock and Warrants. Although the Units, Common Stock and Warrants have been approved for inclusion on the OTC Bulletin Board, the securities have been thinly traded, and there can be no assurance that a more fluid trading market for the securities will develop or that, if developed, it will be sustained. The OTC Bulletin Board is an unorganized, inter-dealer, over-the-counter market which provides significantly less liquidity than the Nasdaq Stock market, and quotes for stocks included on the OTC Bulletin Board are not listed in the financial sections of newspapers as are those for the Nasdaq Stock Market. Therefore, prices for securities traded solely on the OTC Bulletin Board may be difficult to obtain and purchasers of the Units may be unable to resell the securities offered hereby at or near their original offering price or at any price. See "Possible Adverse Effect of "Penny Stock" Rules in Liquidity for the Company's Securities."

Outstanding Options and Warrants. The Company has reserved up to 3,405,472 shares of its Common Stock for issuance upon exercise of stock options and warrants. Of the reserved shares, a total of 1,500,000 shares have been reserved and evenly divided among each of the Company's 1992, 1997 and 1998 Stock Option Plans, of which options to purchase an aggregate of 500,000, 500,000 and 500,000 shares have been issued under the respective Plans. Another 800,000 shares are reserved for issuance and available for the options granted pursuant to the terms of the employment agreements of Mr. Moroney, and Drs. Dugger, Cox and Cleaver.(The Cox and Cleaver Employment Agreement options expired in August 2001). Further, shares of Common Stock are reserved for issuance to cover warrants to purchase an aggregate of 100,000 shares of Common Stock issued to Creative Technologies, Inc. in December 1996. In connection with the Public Offering, the Company issued 680,000 Class A common stock purchase warrants (the "Class A Warrants"). Also in connection with the Public Offering, the Company issued to the Underwriters an option to purchase 68,000 Units exercisable at $9.74 (165% of the respective public offering price of the Units) which expire in November, 2001 (the "Underwriters' Options"). In early 2000, the Company, in connection with the renewal of its financial consulting services contract with Saggi Capital granted it Warrants to purchase up to 200,000 shares of the Company's common stock at an exercise price of $1.00 per share. In May 2001, in connection with the 2001 Private Placement, the Company issued to the companies handling such placement Warrants to purchase an aggregate of 257,472 shares of the Company's common stock at an exercise price of $0.75 per share.

In connection with the 2001 Private Placement, the Company agreed, under certain circumstances, to register the Shares for distribution to the public. Exercise of these registration rights could involve a substantial expense to the Company and could prove a hindrance to future financings.

Exercise of the Underwriters' Options, the Class A Warrants, the outstanding warrants and stock options, and those which may be granted under the Stock Option Plans (collectively, the "Convertible Securities"), will reduce the percentage of Common Stock held by the public stockholders. Further, the terms on which the Company could obtain additional capital during the life of the Convertible Securities may be adversely affected, and it should be expected that the holders of the Convertible Securities would exercise them at a time when the Company would be able to obtain equity capital on terms more favorable than those provided for by such Convertible Securities.

Potential Adverse Effect of Redemption of Warrants. The Warrants issued in connection with the Company's Public Offering may be redeemed by the Company commencing May 1999 (eighteen months from the date of the Public Offering), or earlier with the consent of the Representative, at a redemption price of $.10 per Warrant upon not less then thirty days prior written notice provided the last sale price of the Common Stock on the NASD OTC Bulletin Board, Nasdaq (or another national securities exchange) for twenty consecutive trading days ending within three days of the notice of redemption, equals or exceeds 200% of the current Warrant exercise price, subject to adjustment. Redemption of the Warrants could force the holders thereof to exercise the Warrants and pay the exercise price at a time when it may be disadvantageous for the holders to do so, to sell the Warrants at the then current market price when they might otherwise wish to hold the Warrants, or to accept the redemption price, which is likely to be substantially less than the market value of the Warrants at the time of redemption.

Possible Resales Under Rule 144. Of the 7,724,900 shares of Common Stock held by the Company's present stockholders, 7,144,900 shares of Common Stock have not been registered under the Securities Act of 1933, as amended (the "Act"). Under certain circumstances, the unregistered shares may be available for public sale by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Act, subject to certain limitations. In general, under Rule 144, a person (or persons whose shares are aggregated) who has satisfied a one-year holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of Common Stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by a person who is not an affiliate of the Company and who has satisfied a two-year holding period. Of the unregistered shares, 3,197,003 shares have been held by present stockholders for more than two years.

The Company has reserved up to 3,405,472 shares of its Common Stock for issuance upon exercise of various stock options and warrants, of which 1,600,000 shares were registered under a Registration Statement on Form S-8 under the Act. Although all of the Company's officers and directors have executed lock-up agreements in which they agreed not to publicly offer, sell or otherwise dispose of directly or indirectly, any of the Company's securities owned by them, until July, 2002, any substantial sale of Common Stock pursuant to Rule 144 may have an adverse effect on the market price of the Shares or the component securities.

Future Unspecified Acquisitions. Although there are no such transactions contemplated at this time, the Company may, in the future, expand its business, in part, through the acquisition of compatible products or businesses. In attempting to locate and consummate such acquisitions, the Company may compete

with other prospective purchasers of the acquisition candidate, some of which may have greater resources than the Company. There can be no assurance that suitable acquisition candidates could be identified and acquired on terms favorable to the Company, or that the acquired product lines or operations could be profitably operated or integrated into the Company's operations. In addition, any internally generated growth experienced by the Company could place significant demands on the Company's management, thereby restricting or limiting its available time and opportunity to identify and evaluate potential acquisition candidates. The target entity of any such acquisition will not be subject to shareholder review and the Company's decision to pursue such transactions is not subject to shareholder approval.

Limitation on Directors' Liabilities under Delaware Law. Pursuant to the Company's Certificate of Incorporation and under Delaware law, directors of the Company are not liable to the Company or its stockholders for monetary damages for breach of fiduciary duty, except for liability in connection with a breach of duty of loyalty, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, for dividend payments or stock repurchases illegal under Delaware law or any transaction in which a director has derived an improper personal benefit.

Indemnification of Directors under Delaware Law. Pursuant to both the Company's Certificate of Incorporation and Delaware law, the Company's officers and directors are indemnified by the Company for monetary damages for breach of fiduciary duty, except for liability which arises in connection with (i) a breach of duty or loyalty, (ii) acts or omissions not made in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for dividend payments or stock repurchases illegal under Delaware law, or (iv) any transaction in which the officer or director derived an improper personal benefit. The Company's Certificate of Incorporation does not have any effect on the availability of equitable remedies (such as an injunction or rescissions) for breach of fiduciary duty. However, as a practical matter, equitable remedies may not be available in particular circumstances. The Company maintains director and officer liability coverage.

Authorization and Discretionary Issuance of Preferred Stock. The Company's Certificate of Incorporation authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined from time to time by the Board of Directors. Accordingly, the Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividends, liquidation, conversion, voting or other rights which could adversely affect the relative voting power or other rights of the holders of the Company's Common Stock. In the event of issuance, the preferred stock could be used, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company, which could have the effect of discouraging bids for the Company and thereby prevent stockholders from receiving the maximum value for their shares. Although the Company has no present intention to issue any shares of its preferred stock, there can be no assurance that the Company will not do so in the future. In the event the Company relocates under the Laws of the State of Delaware (as it proposes to do upon approval of the Company's shareholders) the rights, preferences and designations of the preferred stock will be substantially identical to those of the present.

## ITEM 2. PROPERTIES

The Company's executive offices are located at 31 State Highway 12, Flemington, New Jersey. The facility, constituting approximately 4,500 square feet is occupied under a five-year lease which expires during September 2005. Should this tenancy be terminated for any reason, there is ample comparable space available in the area for the Company to occupy. Since the manufacture

of the Company's products are conducted by outside vendors, the Company does not own or lease any production or manufacturing facilities. The Company believes the current Flemington facilities will adequately serve its needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

The Company is not involved in any legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

During the fourth quarter of the fiscal year covered by this report, no matters were submitted to a vote of security holders, through the solicitation of proxies or otherwise.

ITEM 4A. NON-DIRECTOR EXECUTIVE OFFICERS

The non-director executive officers of the Company and their positions with the Company are as follows:

Donald Deitman, Chief Financial Officer. Mr. Deitman joined the Company in 1998. From 1988 until joining the Company, Mr. Deitman was employed as a business consultant implementing multi-module MRP II software systems. From 1982 to 1988, Mr. Deitman was corporate controller for FCS Industries, Inc. of Flemington, New Jersey. From 1975 to 1982, he was manager of materials and systems for the Walworth Company operations located in Linden and Elizabeth, NJ and from 1966 to 1975, he was employed by Ortho Pharmaceuticals, Inc. and Ortho Diagnostics, Inc. Mr. Deitman received a BS in Accounting from Rutgers University in 1972.

PART II

ITEM 5. MARKET FOR COMMON STOCK AND RELATED SECURITY HOLDER MATTERS

(a) Private Placement. In July 2001, the Company successfully closed a placement of approximately 1,844,000 shares of its common stock, par value $.001 per share, at a per share price of $.75. The Company paid commissions, expenses, and legal fees of approximately $226,000 and received net proceeds of approximately $1,157,000.

(b) Market Information. Since the November 1997 closing of the Public Offering, the Company's Common Stock has traded in the over-the-counter market on the National Association of Securities Dealers, Inc. OTC Bulletin Board System ("OTCBB") under the symbol "FLEM". The following table sets forth the range of high and low closing bid quotations of the Common Stock as reported by the OTCBB for each fiscal quarter for the past two fiscal years or such shorter period that there has been a public trading market. High and low bid quotations represent prices between dealers without adjustment for retail mark-ups, mark-downs or commissions and may not necessarily represent actual transactions.

| | Bid Prices | |
|---|---|---|
| | High | Low |
| FISCAL 2001 | | |
| First Quarter (August 1, 2000 through October 31, 2000) | 2.125 | .969 |
| Second Quarter (November 1, 2000 through January 31, 2001) | 1.562 | .438 |
| Third Quarter (February 1, 2001 through April 30, 2001) | 1.094 | .550 |

| | | |
|---|---|---|
| Fourth Quarter (May 1, 2001 through July 31, 2001) | .950 | .510 |

FISCAL 2000

| | | |
|---|---|---|
| First Quarter (August 1, 1999 through October 25, 1999) | 1.687 | 0.875 |
| Second Quarter (November 1, 1999 through January 31, 2000) | 2.25 | .875 |
| Third Quarter (February 1, 2000 through April 30, 2000) | 3.375 | 1.00 |
| Fourth Quarter (May 1, 2000 through July 31, 2000) | 1.406 | .750 |

The closing bid price of the Company's Common Stock as reported by the OTCBB was $0.650 on November 8, 2001.

(b) Holders. As of November 8, 2001 there were approximately 93 record holders of the Company's Common Stock.

(c) Dividends. The Company has never declared or paid a dividend on its Common Stock, and management expects that all or a substantial portion of the Company's future earnings will be retained for expansion or development of the Company's business. The decision to pay dividends, if any, in the future is within the discretion of the Board of Directors and will depend upon the Company's earnings, capital requirements, financial condition and other relevant factors such as contractual obligations. Management does not anticipate that the Company will pay dividends on the Common Stock in the foreseeable future. Moreover, there can be no assurance that dividends can or will ever be paid.

## ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### General

Since its inception, substantially all of the Company's revenues have been derived from consulting activities, primarily in connection with product development for various pharmaceutical companies. In recent years, the Company has shifted its focus away from consulting for other companies to the development of its own products. The Company has had a history of recurring losses from operations, giving rise to an accumulated deficit at July 31, 2001 of approximately $5,523,000. Although substantially all of the Company's revenues to date have been derived from its consulting business, the future growth and profitability of the Company will be principally dependent upon its ability to successfully develop its products and to enter into license agreements with drug companies who will market and distribute the final products. The Company's revenues from consulting continued to decline during the two years ended July 31, 2001 and are likely to decline in the future as the Company continues to shift its emphasis away from consulting for clients and towards development of its own products.

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company incurred losses during the fiscal years ended July 31, 2001 (fiscal 2001) and 2000 (fiscal 2000) and had an accumulated deficit at July 31, 2001 of approximately $5,523,000.

The Company's continued existence is dependent upon its ability to achieve profitable operations or obtain additional financing. The Company is currently seeking collaborative arrangements with pharmaceutical companies for joint development of delivery systems and the successful marketing of these delivery systems. In order to pursue this strategy, the Company will be required to obtain financing and/or consummate a strategic alliance with a

well-funded business partner in the near future. In view of the Company's very limited resources, its anticipated expenses and the competitive environment in which the Company operates, there can be no assurance that the Company's operations will be sustained for the duration of its next fiscal year.

Results of Operations

Fiscal Year 2001 Compared to Fiscal Year 2000

Consulting Revenues for fiscal 2001 decreased approximately $67,000 or 65% to $36,000 from $103,000 for fiscal 2000. Product Development Revenues for fiscal 2001 increased approximately $85,000 or 47% to $264,000 from $179,000 for fiscal 2000. The decrease in Consulting Revenues and increase in Product Development Revenues was due to the Company's decision to concentrate additional efforts in the area of product development. Interest income for fiscal 2001 decreased approximately $21,000 or 48% to $23,000 from $44,000 for fiscal 2000. The interest income decrease was primarily attributable to significantly lower average cash balances for the 2001 year.

Total costs and expenses for fiscal 2001 decreased approximately $27,000 or 2% to approximately $1,478,000 from approximately $1,505,000 for fiscal 2000. Consulting costs and expenses for fiscal 2001 decreased approximately $117,000 or 70% to approximately $49,000 from approximately $166,000 for fiscal 2000. This decrease was primarily attributable to an approximate $112,000 decrease in payroll related expenses associated with consulting activities.

Product Development costs and expenses for fiscal 2001 increased approximately $242,000 or 61% to approximately $642,000 from approximately $400,000 for fiscal 2000. This increase was attributable to an approximate $194,000 increase in product development payroll expenses, an approximate $40,000 increase in rent expense allocated to product development due to the Company's expanded facilities occupied during October 2000, an approximate $18,000 increase in clinical studies expense and an approximate $12,000 increase in depreciation and amortization expense due to fixed assets acquisitions for laboratory activities. Expense decreases for product development were an approximate $28,000 decrease in legal fees related to intellectual property and an approximate $24,000 decrease in outside laboratory testing due to the Company establishing an internal laboratory.

Selling, General and Administrative costs and expenses for fiscal 2001 decreased approximately $152,000 or 16% to approximately $787,000 from approximately $939,000 for fiscal 2000. This decrease was primarily attributable to an approximate $134,000 decrease in payroll related expenses due to employee resignations and an approximate $47,000 decrease in legal fees due to the satisfaction of the Company's deductible for its D & O insurance policy. Expense increases for selling, general and administrative were an approximate $29,000 increase in outside consultant expenses due to the aforementioned employee resignations and an approximate $12,000 increase in the portion of rent expense allocated to SG&A due to more costly offices occupied during October 2000.

Liquidity and Capital Resources

From its inception, the Company's principal sources of capital have been provided by consulting revenues, private placements and a public offering of its securities, as well as loans and capital contributions from the Company's principal stockholders. At July 31, 2001 the Company had working capital of approximately $646,000 as compared to working capital of $667,000 at July 31, 2000 representing a net increase in working capital of approximately $18,000.

In July 2001, the Company successfully closed an offering of its securities ("Private Placement"). The Private Placement provided for the sale of approximately 1,844,000 shares of common stock, par value $.001 per share. The Company received proceeds, net of offering costs, of approximately $1,157,000.

Net cash used in operating activities was approximately $1,106,000 for fiscal 2001 compared to net cash used in operating activities of approximately $1,139,000 for fiscal 2000. Net cash used in operating activities for fiscal 2001 was primarily attributable to the net loss of $1,109,000. For fiscal 2001, $166,000 was used for investing activities. Therefore, notwithstanding a $1,109,000 net loss and $1,179,000 net loss for fiscal 2001 and 2000, respectively, total cash flow for fiscal 2001 increased approximately $994,000 as compared to a $1,015,000 increase for fiscal 2000.

The Company believes that its current cash levels together with revenues from operations, will be sufficient to satisfy its cash requirements for the next five (5) months and has substantial doubt about its ability to continue operations beyond such period without obtaining additional financing and/or consummating a strategic alliance with a well-funded business partner. No assurance can be given that future unforeseen events will not adversely affect the Company's ability to continue operations or to successfully obtain additional financing, which may not be available on terms acceptable to the Company, if at all.

Inflation

The Company does not believe that inflation has had a material effect on its results of operations during the past three fiscal years. There can be no assurance that the Company's business will not be affected by inflation in the future.

New Accounting Pronouncements

See Note 1 to the Financial Statements for a discussion of New Accounting Pronouncements affecting the Company.

## ITEM 7. FINANCIAL STATEMENTS

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

## ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

## PART III

## ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The name and age of each of the directors, his position with the Company, his principal occupation, and the period during which such person has served as a Director are set out below.

| Name of Nominee | Age | Position with the Company | Principal Occupation | Director Since |
|---|---|---|---|---|
| Harry A. Dugger, III, Ph.D. | 65 | President and Chief | President and | 1991 |

| | | | | |
|---|---|---|---|---|
| | | Executive Officer | Chief Executive Officer of the Company | |
| John J. Moroney | 47 | Chairman | President, Landmark Financial Corp. | 1991 |
| Robert F. Schaul, Esq. | 62 | Secretary and Director | Attorney | 1991 |
| Jack J. Kornreich | 62 | Director | Retired | 1996 |
| Robert C. Galler | 41 | Vice President, Corporate Development and Director | Financial Advisory Services | 2001 |

Harry A. Dugger, III, Ph.D., President and Director. Dr. Dugger is a founder of the Company and has been President and a director of the Company since its inception in May 1982. Prior to founding the Company, from June 1980 to November 1982, Dr. Dugger was employed as Vice President of Research and Development by Bauers-Krey Associates, a company engaged in the development of pharmaceutical products. From 1964 to 1980, Dr. Dugger was Associate Section Head for Research and Development at Sandoz Pharmaceuticals Corporation. Dr. Dugger received an MS in Chemistry from the University of Michigan in 1960 and received a Ph.D. in Chemistry from the University of Michigan in 1962.

John J. Moroney, Chairman of the Board. Mr. Moroney has been Chairman of the Company since May 1992. From May 1992 to November 1994, Mr. Moroney was also the Company's Chief Executive Officer. Mr. Moroney currently is President of Landmark Financial Corp., Harrington Park, New Jersey, a private financial consulting company. From 1985 to 1992, Mr. Moroney was a Managing Director of Corporate Finance for the investment banking firm of Ladenburg, Thalmann & Co., Inc., specializing in the pharmaceutical and health care industries. Mr. Moroney received a BS in 1975 and an MBA in 1977, both from Fordham University.

Robert F. Schaul, Esq., Secretary and Director. Mr. Schaul has been a Director of the Company since November 1991 and was Vice President, Secretary and General Counsel of the Company from November 1991 to February 1995. He has advised the Company since its formation. From 1995 to 1998, Mr. Schaul was Vice President and General Counsel of Landmark Financial Corp. From 1989 to 1991, Mr. Schaul was a partner with the law firm of Glynn, Byrnes and Schaul, and for twenty years prior thereto was an attorney and partner with the law firm Kerby, Cooper, English, Schaul & Garvin, specializing in business law and business related litigation. Mr. Schaul received a BA from New York University in 1961 and a JD from Harvard University in 1964.

Jack J. Kornreich, Director. Mr. Kornreich has been a director of the Company since 1996. He presently acts as an independent consultant. From 1989 to 1993, Mr. Kornreich was Executive Vice President and General Counsel of Bolar (formerly Circa Pharmaceuticals Corp. and now known as Watson Pharmaceutical Corp.). From 1984 to 1989, Mr. Kornreich practiced law as a partner in the firm of Baum & Kornreich (from 1980 to 1984 the firm was named Baum, Skigen & Kornreich). From 1975 to 1984, Mr. Kornreich was in private practice. Mr. Kornreich received a JD from Brooklyn Law School in 1963 and an LLM in Corporate Law from New York University in 1975.

Robert C. Galler, Vice President, Corporate Development and Director. Mr.

Galler has been an employee and Director of the Company since September, 2001. From 1992 to the present, Mr. Galler has been the President and Chairman of the Lois Joy Galler Foundation for Hemolytic Uremic Syndrome, a non-profit charity. From 1999 to 2001, Mr. Galler was Vice President, Corporate Development and Director of Select Therapeutics, Inc. From 1994 to 1998 Mr. Galler was a Director and advisor of Synsorb Biotech, Inc. From 1992 to 1994 Mr. Galler was an equity coordinator at Gallers Financial Group, Inc., and from 1984 to 1992 he was Vice President of Investments with Gruntal & Co. Mr. Galler attended Hofstra University, Hempstead, N. Y.

Board members are elected annually by the shareholders and the officers are appointed annually by the Board of Directors.

ITEM 10. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

The following table sets forth a summary for the fiscal years ended July 31, 2001, 2000 and 1999, respectively, of the cash and non-cash compensation awarded, paid or accrued by the Company to the Company's Chief Executive Officer ("CEO") and its two most highly compensated officers other than the CEO, who served in such capacities at the end of fiscal 2001 (collectively, the "Named Executive Officers"). No other executive officer of the Company earned in excess of $100,000 in total annual salary and bonus for, 2001, 2000 and 1999 in all capacities in which such person served the Company. There were no restricted stock awards, long-term incentive plan payouts or other compensation paid during fiscal 2001, 2000 and 1999 to the Named Executive Officers, except as set forth below:

SUMMARY COMPENSATION TABLE

| | | | | | Long-Term Compensation Awards | | Payouts | |
|---|---|---|---|---|---|---|---|---|
| Name and Principal Position | Fiscal Year | Salary ($) | Bonus ($) | Other Annual Compen-sation ($) | Restricted Stock Awards ($) | Securities Underlying Options/SAR (1) (#) | LTIP Payouts ($) | Al Oth Compe ($ |
| Harry A. Dugger, III, Ph.D. President and CEO | 2001 | 232,000(2) | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 | 226,000 | 0 | 0 | 0 | 95,000 | 0 | 0 |
| | 1999 | 210,000 | 0 | 0 | 0 | 0 | 0 | 0 |
| John J. Moroney Chairman | 2001 | 57,781 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 | 169,000 | 0 | 0 | 0 | 95,000 | 0 | 0 |
| | 1999 | 157,500 | 0 | 0 | 0 | 0 | 0 | 0 |
| Donald Deitman Chief Financial Officer | 2001 | 70,800 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2000 | 68,000 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1999 | 67,500 | 0 | 0 | 0 | 0 | 0 | 0 |

(1) No Stock Appreciation Rights have been issued.
(2) Includes $49,000 accrued, but unpaid, salary.

OPTION GRANTS IN LAST FISCAL YEAR
(individual grants)

There were no option grants during fiscal 2001.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR
AND FISCAL YEAR-END OPTION VALUES

The following table sets forth information with respect to the Named Executive Officers concerning the exercises of options during fiscal 2001 and the number and value of unexercised options held as of the end of fiscal 2001.

| Name of Executive Officer | Number of Shares Acquired on Exercise | Value Realized ($) | Number of Securities Underlying Unexercised Options at (Exercisable/ Unexercisable) | Value of Unexercised In-the-Money Options at Fiscal Year End ($) Exercisable/ Unexercisable) |
|---|---|---|---|---|
| Harry A. Dugger, III, Ph.D. | 0 | - | 645,000 / 0 | 0 / 0 |
| John J. Moroney | 0 | - | 645,000 / 0 | 0 / 0 |
| Donald Deitman | 0 | - | - | - |

Compensation of Directors

The Directors of the Company are elected annually and serve until the next annual meeting of stockholders and until a successor shall have been duly elected and qualified. Effective January 1999, Directors of the Company, who are not employees or consultants receive for each meeting attended directors fees of $500 for their services as members of the Board of Directors. Such Directors are also reimbursed for expenses incurred in connection with their attendance at meetings of the Board of Directors. Directors may be removed with or without cause by a vote of the majority of the stockholders then entitled to vote. There were no other arrangements pursuant to which any Director was compensated during fiscal 2001 for any services provided as a Director.

Stock Option Plans

The Company has three stock option plans, adopted in 1992, 1997 and 1998, respectively (collectively referred to as the "Plans"). Each Plan provides for the issuance of options to purchase 500,000 shares of Common Stock, for a total of 1,500,000 shares. The 1997 Stock Option Plan is administered by Harry A. Dugger, III, Ph.D. and John J. Moroney, who constitute the Compensation Committee of the Board of Directors ("Committee"), and the 1992 Stock Option Plan and 1998 Stock Option Plan are administered by the entire Board of Directors. For purposes of the following discussion, the term "Committee" will be used to reference the Committee with respect to the 1997 Stock Option Plan and the entire Board of Directors with respect to the 1992 Stock Option Plan and 1998 Stock Option Plan, as applicable. The Committee has sole discretion and authority, consistent with the provisions of the Plans, to select the Eligible Participants to whom options will be granted under the Plans, the number of shares which will be covered by each option and the form and terms of the agreement to be used. All employees and officers of the Company are eligible to participate in the Plans.

At September 30, 2001, eleven (11) persons were eligible to receive Incentive Stock Options ("ISOs") under the 1992, 1997 and 1998 Plans.

Options. The Committee is empowered to determine the exercise price of options granted under the Plans, but the exercise price of ISOs must be equal to or greater than the fair market value of a share of Common Stock on the date the option is granted (110% with respect to optionees who own at least 10% of the outstanding Common Stock). The Committee has the authority to determine the time or times at which options granted under the Plans become exercisable, but options expire no later than ten years from the date of grant (five years with respect to Optionees who own at least 10% of the outstanding Common Stock of the Company). Options are nontransferable, other than by will and the laws of descent, and generally may be exercised only by an employee while employed by the Company or within 90 days after termination of employment (one year from termination resulting from death or disability).

No ISO may be granted to an employee if, as the result of such grant, the aggregate fair market value (determined at the time each option was granted) of the shares with respect to which ISOs are exercisable for the first time by such Employee during any calendar year (under all such plans of the Company and any parent and subsidiary) exceeds $100,000. The Plans do not confer upon any employee any right with respect to the continuation of employment by the Company, nor do the Plans interfere in any way with the employee's right or the Company's right to terminate the employee's employment at any time.

Compensation Committee Interlocks and Insider Participation

Harry A. Dugger, III and John J. Moroney serve as the members of the Company's Compensation Committee, which reviews and makes recommendations with respect to compensation of officers, employees and consultants, including the granting of options under the Company's 1997 Stock Option Plan. The 1992 and 1998 Stock Option Plans are administered by the entire Board.

Mr. Moroney is also a Director and President of Landmark Financial Corp. ("Landmark"), serving as a member of Landmark's compensation committee. Robert F. Schaul, a Director and Secretary of the Company, earned legal fees from the Company during fiscal 2001 in the approximate amount of $85,000. See "Certain Transactions--Legal Fees," below.

Compensation Committee Report on Executive Compensation

Compensation of the Company's executives is intended to attract, retain and award persons who are essential to the enterprise. The fundamental policy of the Company's executive compensation program is to offer competitive compensation to executives that appropriately rewards the individual executive's contribution to corporate performance. The Board of Directors utilizes subjective criteria for evaluation of individual performance. The Board focuses on two primary components of the Company's executive compensation program, each of which is intended to reflect individual and corporate performance: base salary compensation and long-term incentive compensation. The Company has not paid cash incentive bonuses during fiscal 2001.

Except as set forth herein, the Company does not have any annuity, retirement, pension, deferred or incentive compensation plan or arrangement under which any executive officer is entitled to benefits, nor does the Company have any long-term incentive plan pursuant to which performance units or other forms of compensation are paid. Executive officers who qualify will be permitted to participate in the Company's 1992, 1997 and 1998 Stock Option Plans which were adopted in May 1992, February 1997 and June 1998, respectively. In September 1998 the Board of Directors adopted an investment

retirement account plan in which all employees of the Company are eligible to participate. Executive officers may participate in group life, health and hospitalization plans, if and when such plans are available generally to all employees. The Compensation Committee is satisfied that the compensation and stock option plans provided to the officers of the Company are structured and operated to create strong alignment with the long-term best interests of the Company and its stockholders.

The compensation of the Company's Chief Executive Officer, Dr. Dugger, for fiscal 2001 consisted of base salary of approximately $232,000. Because of an inadequacy of cash flow during the second and third quarters of fiscal 2001, Dr. Dugger and Mr. Moroney agreed to accrue all of their salaries until the cash flow situation resolved itself. In May 2001, Dr. Dugger's salary was resumed and one-half of his accrued salary was paid out. The remaining half ($49,000) continues as an accrual at this time. Also, in May 2001, Mr. Moroney resigned effective April 30, 2001, as an employee, although he continues as Chairman of the Board of Directors. At that time he forgave all of his accrued salary, approximately $72,000. At that same time, Mr. Moroney entered into a four month consulting arrangement with the Company for a one-time cash payment of $25,000 and a $6,500 per month fee. See Note 6 to the financial statements below. No bonuses or stock grants were awarded to Dr. Dugger during fiscal 2001. The determination by the Compensation Committee of Dr. Dugger's remuneration is based upon methods consistent with those used for other senior executives. The committee considers certain quantitative factors, including the Company's financial, strategic and operating performance for the year. The qualitative criteria include Dr. Dugger's leadership qualities and management skills, as exhibited by his innovations, time and effort devoted to the Company, and other general considerations. The Compensation Committee also takes note of comparable remuneration of other CEOs at similar companies. Based on the performance of the Company, the Compensation Committee believes that Mr. Dugger's compensation was appropriate.

Compensation Committee:

Harry A. Dugger, III, Ph.D
John J. Moroney

Stockholder Loans

In fiscal 1998, the Company lent the principal amount of $60,000 to Dr. Dugger in exchange for a 7% promissory note. The note is due on demand, with interest due quarterly. Interest approximated $4,200 for fiscal 2001. In October 2001, Dr. Dugger indicated this loan would be repaid in full before year-end 2001.

## STOCKHOLDER RETURN PERFORMANCE PRESENTATION

The comparative stock performance graph below compares the cumulative stockholder return on the Common Stock of the Company for the period from November 20, 1997 through the fiscal year ended July 31, 2001, with the cumulative total return on (i) the Total Return Index for the Nasdaq Stock market (U.S. Companies) (the "Nasdaq Composite Index"), and (ii) the American Stock Exchange, Inc. ("AMEX") Pharmaceutical Index (assuming the investment of $100 in the Company's Common Stock, the Nasdaq Composite Index and the AMEX Pharmaceutical Index on November 20, 1997 and reinvestment of all dividends). Measurement points are on the first full trading day after the Company's registration statement was declared effective by the SEC and the last trading day of the Company's fiscal year ended July 31. The Company cautions that the stock price performance shown in the graph below should not be considered indicative of potential future stock performance. Companies

included in the Nasdaq Composite Index and AMEX Pharmaceutical Index are generally larger and have greater capitalization than the Company.

[The following table represents a graphic chart which has been omitted]

| | 11/20/97 | 7/31/98 | 7/31/99 | 7/31/00 | 7/31/01 |
|---|---|---|---|---|---|
| AMEX Pharmaceutical Index (DRG) | $100.00 | $135.00 | $136.58 | $153.78 | $124.63 |
| Flemington Pharmaceutical Corporation (FLEM) | $100.00 | $ 24.00 | $ 15.57 | $ 13.25 | $ 5.64 |
| Nasdaq Composite Index | $100.00 | $118.75 | $162.25 | $231.59 | $156.82 |

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN BENEFICIAL OWNERS

As of November 8, 2001, there were 7,724,900 shares of Common Stock outstanding and entitled to vote at the Annual Meeting. Each share is entitled to one vote on each of the matters to be voted on at the Annual Meeting. The following table sets forth, as of October 18, 2001, certain information regarding the ownership of the Common Stock by (i) each person known by the Company to be the beneficial owner of more than 5% of the Common Stock, (ii) each of the Company's Directors and Named Executive Officers, as such term is defined under Item 402(a)(3) of Securities and Exchange Commission ("SEC") Regulation S-K, and (iii) all of the Company's Executive Officers and Directors as a group. Beneficial ownership has been determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Under Rule 13d-3 certain shares may be deemed to be beneficially owned by more than one person (such as where persons share voting power or investment power). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon the exercise of an option) within sixty (60) days of the date as of which the information is provided. In computing the ownership percentage of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in the following table does not necessarily reflect the person's actual ownership or voting power at any particular date.

| Title of Class | Name and address or Number in Group (1) | Amount and Nature of Beneficial Ownership (2) | Percentage of Class |
|---|---|---|---|
| Common Stock | Harry A. Dugger, III, Ph.D. | 1,829,003(3) | 21.9 |
| Common Stock | John J. Moroney | 1,018,080(4) | 12.2 |
| Common Stock | Donald Deitman | 0 | 0 |
| Common Stock | Robert F. Schaul, Esq. | 189,286(5) | 2.4 |
| Common Stock | Robert C. Galler | 0 | 0 |
| Common Stock | Jack J. Kornreich | 169,310(5) | 2.1 |
| Common Stock | All Executive Officers and Directors as a group (6 persons) | 3,205,679(3)(4)(5) | 36.23 |

(1) The address of all holders listed herein is c/o Flemington Pharmaceutical

Corporation, 31 State Highway 12, Flemington, New Jersey 08822.

(2) Except as otherwise indicated, each named holder has, to the Company's knowledge, sole voting and investment power with respect to the shares indicated.

(3) Includes options to purchase 200,000 shares of Common Stock issued under the 1992 Stock Option Plan; options to purchase 50,000 shares of Common Stock under the 1997 Stock Option Plan; options to purchase 95,000 shares of Common Stock issued under the 1998 Stock Option Plan, options to purchase 300,000 shares of Common Stock issued outside of the Plans; 108,000 shares owned by his daughter Christina Dugger Sommers; and 108,000 shares owned by his son Andrew Dugger. Dr. Dugger may be deemed to be a "parent" of the Company as such term is defined under the Federal securities laws.

(4) Includes options to purchase 200,000 shares of Common Stock issued under the 1992 Stock Option Plan; options to purchase 50,000 shares of Common Stock under the 1997 Stock Option Plan; options to purchase 95,000 shares of Common Stock issued under the 1998 Stock Option Plan, options to purchase 300,000 shares of Common Stock issued outside of the Plans; 208,080 shares owned jointly with his wife, and 60,000 shares owned by each of his three sons, Matthew, Timothy and Sean Moroney.

(5) Includes options to purchase 20,000 shares of Common Stock issued under the 1992 Stock Option Plan and options to purchase 25,000 shares of Commons Stock issued under the 1997 Stock Option Plan, options to purchase 105,000 shares of Common Stock issued under the 1998 Stock Option Plan.

Compliance with Section 16(a) of the Securities Exchange Act of 1934

Section 16(a) of the Exchange Act requires officers, directors and persons who own more than ten (10) percent of a class of equity securities registered pursuant to Section 12 of the Exchange Act to file reports of ownership and changes in ownership with both the SEC and the principal exchange upon which such securities are traded or quoted. Officers, directors and persons holding greater than ten (10) percent of the outstanding shares of a class of Section 12-registered equity securities ("Reporting Persons") are also required to furnish copies of any such reports filed pursuant to Section 16(a) of the Exchange Act with the Company. Based solely on a review of the copies of such forms furnished to the Company, the Company believes that from August 1, 2000 to September 30, 2001 all Section 16(a) filing requirements applicable to its Reporting Persons were complied with.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

CERTAIN TRANSACTIONS

Legal Fees

During fiscal 2001 the Company paid Mr. Schaul approximately $85,000 for legal services rendered to the Company.

PART IV

ITEM 13. EXHIBITS, LIST AND REPORTS ON FORM 8-K

List of Exhibits

The exhibits that are filed with this report or that are incorporated herein by reference are set forth in the Exhibit Index appearing on page E-1 hereof.

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the last quarter of fiscal 2001.

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of
Flemington Pharmaceutical Corporation

We have audited the balance sheet of Flemington Pharmaceutical Corporation as of July 31, 2001 and the related statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 financial statements referred to above present fairly, in all material respects, the financial position of Flemington Pharmaceutical Corporation at July 31, 2001, and the results of its operations and its cash flows for each of the two years in the period then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has had a history of recurring losses from operations, giving rise to a stockholders' deficiency through July 31, 2001 and is currently developing pharmaceutical products which will require substantial financing to fund anticipated product development costs. Resulting operating losses and negative cash flows from operations are likely to occur until, if ever, profitability can be achieved through successful marketing of newly developed products. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

WISS & COMPANY, LLP

Livingston, New Jersey
August 31, 2001

FLEMINGTON PHARMACEUTICAL CORPORATION

BALANCE SHEET
JULY 31, 2001

ASSETS

| | | |
|---|---|---|
| CURRENT ASSETS: | | |
| Cash | $585,000 | |
| Accounts receivable - trade, less allowance for doubtful accounts of $9,000 | 92,000 | |
| Prepaid expenses and other current assets | 57,000 | |
| Total Current Assets | | $734,000 |
| FURNITURE, FIXTURES, AND EQUIPMENT, LESS ACCUMULATED DEPRECIATION OF $95,000 | | 167,000 |
| DEMAND NOTE RECEIVABLE, SHAREHOLDER | | 60,000 |
| DUE FROM JOINT VENTURE PARTNER FOR REIMBURSABLE EXPENSES | | 6,000 |
| OTHER ASSETS | | 17,000 |
| | | $984,000 |

LIABILITIES AND STOCKHOLDERS' EQUITY

| | | |
|---|---|---|
| CURRENT LIABILITIES: | | |
| Accounts payable-trade | $ 11,000 | |
| Accrued expenses and other current liabilities | 77,000 | |
| Total Current Liabilities | | $ 88,000 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY : | | |
| Preferred stock, $.01 per value: Authorized 1,000,000 shares, none issued | | - |
| Common stock $.001 par value: Authorized - 50,000,000 shares. Issued and outstanding - 7,724,900 shares | 8,000 | |
| Additional paid-in capital | 6,411,000 | |
| Accumulated Deficit | (5,523,000) | |
| Total Stockholders' Equity | | 896,000 |
| | | $984,000 |

See accompanying notes to financial statements.

FLEMINGTON PHARMACEUTICAL CORPORATION

STATEMENTS OF OPERATIONS

| | Year Ended July 31, | |
|---|---|---|
| | 2001 | 2000 |
| REVENUES: | | |
| Consulting | $ 36,000 | $ 103,000 |
| Product Development | 264,000 | 179,000 |
| | 300,000 | 282,000 |
| COST AND EXPENSES: | | |
| Consulting | 49,000 | 166,000 |
| Product development | 642,000 | 400,000 |
| Selling, general and administrative expenses | 787,000 | 939,000 |
| | 1,478,000 | 1,505,000 |
| LOSS FROM OPERATIONS | (1,178,000) | (1,223,000) |
| INTEREST INCOME | 23,000 | 44,000 |
| NET LOSS BEFORE TAXES | (1,155,000) | (1,179,000) |
| Deferred Income Tax Benefit | 46,000 | - |
| NET LOSS | $(1,109,000) | $(1,179,000) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 6,326,000 | 4,447,000 |
| BASIC AND DILUTED LOSS PER COMMON SHARE: | | |
| Net Loss | $ (.18) | $ (.27) |

See accompanying notes to financial statements.

FLEMINGTON PHARMACEUTICAL CORPORATION

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

| | Common Stock | | Additional | | |
|---|---|---|---|---|---|
| | Shares | Par Value | Paid-in Capital | Accumulated Deficit | Stockholders' Equity |
| BALANCE, JULY 31, 1999 | 3,877,300 | $4,000 | $4,268,000 | $(3,235,000) | $ 1,037,000 |
| YEAR ENDED JULY 31, 2000 | | | | | |
| In connection with private placement, net of costs | 2,000,000 | 2,000 | 982,000 | - | 984,000 |
| Net Loss | - | - | - | (1,179,000) | (1,179,000) |

| | | | | | |
|---|---|---|---|---|---|
| BALANCE, JULY 31, 2000 | 5,877,300 | $6,000 | $5,250,000 | $(4,414,000) | $ 842,000 |
| YEAR ENDED JULY 31, 2001 | | | | | |
| Common Shares Issued for Services | 3,937 | - | 6,000 | - | 6,000 |
| In connection with private placement, net of costs | 1,843,663 | 2,000 | 1,155,000 | - | 1,157,000 |
| Net Loss | - | - | - | (1,109,000) | (1,109,000) |
| BALANCE, JULY 31, 2001 | 7,724,900 | $8,000 | $6,411,000 | $(5,523,000) | $ 896,000 |

See accompanying notes to financial statements.

FLEMINGTON PHARMACEUTICAL CORPORATION

STATEMENTS OF CASH FLOWS

| | Year Ended July 31, 2001 | 2000 |
|---|---|---|
| CASH FLOW FROM OPERATING ACTIVITIES: | | |
| Net loss | $(1,109,000) | $(1,179,000) |
| Adjustments to reconcile net loss to net cash flows from operating activities: | | |
| Shares issued for services | 6,000 | - |
| Options issued for services | - | 10,000 |
| Depreciation and amortization | 24,000 | 14,000 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (46,000) | 76,000 |
| Due from D&O Insurance Carrier | 86,000 | (86,000) |
| Prepaid expenses and other current assets | (5,000) | 6,000 |
| Due from Joint Venture partner for reimbursable expenses | 74,000 | (80,000) |
| Other Assets | (7,000) | 9,000 |
| Accounts payable - trade | (57,000) | 20,000 |
| Billings in excess of costs and estimated earnings on uncompleted contracts | (49,000) | 49,000 |
| Accrued expenses and other current liabilities | (23,000) | 22,000 |
| Net cash flows from operating activities | (1,106,000) | (1,139,000) |
| CASH FLOWS FROM INVESTING ACTIVITIES - | | |
| Purchase of property and equipment | (166,000) | (9,000) |
| Net cash flows from investing activities | (166,000) | (9,000) |

| | | |
|---|---|---|
| CASH FLOWS FROM FINANCING ACTIVITIES - | | |
| Private placement | 1,157,000 | 984,000 |
| Net cash flows from financing activities | 1,157,000 | 984,000 |
| NET CHANGE IN CASH | (115,000) | (164,000) |
| CASH, BEGINNING OF YEAR | 700,000 | 864,000 |
| CASH, END OF YEAR | $ 585,000 | $ 700,000 |
| SUPPLEMENTAL CASH FLOW INFORMATION: | | |
| Interest paid | $ - | $ - |
| Income taxes paid | $ - | $ - |

See accompanying notes to financial statements.

FLEMINGTON PHARMACEUTICAL CORPORATION

NOTES TO FINANCIAL STATEMENTS

Note 1 - Nature of the Business and Summary of Significant Accounting Policies:

Nature of the Business - Flemington Pharmaceutical Corporation (the "Company") , which was formerly incorporated under the laws of New Jersey was reincorporated in the State of Delaware in November 1998. The Company is engaged in domestic and international consulting activities and the development of novel pharmaceutical products combining presently marketed drugs with innovative patent-pending oral dosage delivery systems of the Company, designed to enhance and accelerate the onset of the therapeutic benefits which the drugs are intended to produce. Management intends to develop the products in collaboration with pharmaceutical companies having significant existing sales of the pharmaceutical compounds being incorporated into the Company's dosage delivery systems, thereby creating a more effective, and more attractive product.

Revenues and Costs - Revenues from contract clinical research are recognized as earned.

Contract costs normally consist of fees paid to outside clinics for studies and an allocable portion of the Company's operating expenses. General and administrative costs pertaining to contracts are charged to expense as incurred.

Financial Instruments - Financial instruments include cash, accounts receivable, amounts due from joint venture partner, loans to stockholders and employees, accounts payable, and accrued expenses. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values, based on market information available to management.

Furniture, Fixtures and Equipment - Furniture, fixtures and equipment are stated at cost. The Company provides for depreciation using accelerated methods, based upon estimated useful lives of 5 to 7 years for furniture, fixtures and equipment.

Income Taxes - Temporary differences between financial statement and income tax reporting result primarily from net operating losses and reporting on the cash basis of accounting for tax reporting purposes. As a result of these temporary differences, the Company has recorded a deferred tax asset with an offsetting valuation allowance for the same amount.

Defined Contribution Retirement Plans - The Company has a Simple IRA retirement plan providing for contributions at management's discretion. During the years ended July 2000 and July 2001, the Company made contributions to the new retirement plan of approximately $5,000 and approximately $15,000, respectively.

Risk Concentrations:

(a) Credit Risk - The Company maintains its cash balances in financial institutions that are insured by the Federal Deposit Insurance Corporation (FDIC) up to $100,000 each. Such balances, at times, may exceed the FDIC limits.

(b) Major Customers - During fiscal 2001, the Company had revenue from two customers located in the United States approximating 40% and 18%, respectively, of the Company's total revenue.

During fiscal 2000, the Company had revenue from two customers located in the United States approximating 27% and 18%, respectively, of the Company's total revenue.

(c) Accounts Receivable - At July 31, 2001, the Company had unsecured accounts receivable from one customer located in the United States of America and one customer located in France, approximating 55% and 30%, respectively, of the Company's total accounts receivable. At July 31, 2000, the Company had unsecured accounts receivable from one customer located in the United States, one customer located in France and one customer located in the United Arab Emirates, approximating 33%, 20% and 15%, respectively, of the Company's total accounts receivable. The Company has long-standing relationships with its principal customers and feels that credit risk associated with these customers is limited. With regard to new customers, the Company receives customer referrals through long-standing relationships.

(d) Supplier Dependence - The Company believes that certain raw materials, including inactive ingredients, are available only from a limited number of suppliers internationally and that certain packaging materials intended for use in connection with its spray products currently are available from limited supply sources. The Company does not believe it will encounter difficulties in obtaining inactive ingredients or packaging materials necessary for the manufacture of its products. However, there can be no assurance that the Company will be able to enter into satisfactory purchasing agreements or arrangements, thereby, causing a potential significant adverse effect on the Company's ability to arrange for the manufacture of formulated products.

Use of Estimates - 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 disclosures 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.

Earnings (Loss) per Share - Statement of Financial Accounting Standards (SFAS) No. 128, "Earnings Per Share" requires the disclosure of both diluted and basic earnings per share. Basic earnings per share is based on the weighted average of all common shares outstanding. The computation of diluted earnings per share does not assume the conversion, exercise or contingent issuance of securities that would have an antidilutive effect on earnings per share.

Recent Accounting Pronouncements - In July 2001, the FASB issued SFAS N. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 provides new guidance on the accounting for a business combination at the date a business combination is completed. Specifically, it requires use of the purchase method of accounting for all business combinations initiated after June 30, 2001, thereby eliminating use of the pooling-of-interests method. SFAS No. 142 establishes new guidance on how to account for goodwill and intangible assets after a business combination is completed. Among other things, it requires that goodwill and certain other intangible assets will no longer be amortized and will be tested for impairment at least annually and written down only when impaired. This statement will apply to existing goodwill and intangible assets, beginning with fiscal years starting after December 15, 2001. The Company is currently evaluating these statements but does not expect that they will have a material impact as the results of operations of financial position of the Company.

In December 1999, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements." The Company adopted SAB 101 as of August 1, 2000. The adoption of SAB 101 did not have an effect on the results of operations or financial portion of the Company.

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133 Accounting for Derivative Instruments and Hedging Activities which, as amended, will be effective for its fiscal year ending July 31, 2001. The Company does not expect any significant impact to its financial statements from SFAS No. 133.

Note 2 - Management's Plans to Overcome Operating and Liquidity Difficulties

The Company's financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company's continued existence is dependent upon its ability to achieve profitable operations or obtain additional financing. The Company is currently seeking collaborative arrangements with pharmaceutical companies for the joint development of delivery systems and the successful marketing of these delivery systems. The Company is exploring merger opportunities or other strategic alternatives to fund future operations.

In view of the Company's very limited resources, its anticipated expenses and the competitive environment in which the Company operates, there can be no assurance that its operations will be sustained for the duration of its next fiscal year.

Note 3 - Prepaid and Accrued expenses:

Prepaid expenses and other current assets - Approximately $38,000 of prepaid supplies and an approximate $5,000 employee loan (see note 6) are included in the $57,000 total. The remainder is prepaid expenses and other current assets.

Accrued expenses and other current liabilities - Approximately $49,000 of accrued salary and related payroll taxes due to the Company's president and CEO are included in the $77,000 total. The remainder is accrued expenses and other current liabilities.

Note 4 - Furniture, Fixtures and Equipment

Furniture, fixtures and equipment is summarized as follows:

| | July 31, 2001 |
|---|---|
| Equipment | $ 198,000 |
| Furniture and fixtures | 64,000 |
| | 262,000 |
| Less: Accumulated depreciation | 95,000 |
| | $ 167,000 |

Note 5 - Stockholders' equity:

Preferred Stock - The Company's Certificate of Incorporation authorizes the issuance of up to 1,000,000 shares of Preferred Stock. None of such Preferred Stock has been designated or issued to date. The Board is authorized to issue shares of Preferred Stock from time to time in one or more series and to establish and designate any such series and to fix the number of shares and the relative conversion rights, voting, terms of redemption and liquidation.

Note 6 - Related Party Transactions:

Employee Note Receivable - During June 2001, the company granted a six (6) months loan of approximately $5,000 to an employee. This loan provides for seven percent (7%) annual interest.

Forgiven Salary - During April 2001, the Company's chairman resigned as an employee and forgave approximately $72,000 of accrued and unpaid salary. The Company agreed to a four (4) months consulting contract with the chairman's consulting company for an immediate cash payment of $25,000 and a $6,500 per month fee.

Legal Fees - The Company has incurred legal fees with an officer and director of the Company. These fees approximated $85,000 and $66,000 for the years ended July 31, 2001 and 2000, respectively.

Stockholder's Note Receivable - In April 1998, the Company lent $60,000 to its President. The note is due on demand with interest at 7% due quarterly. Interest approximated $4,200 for each of the two years ended July 31, 2001.

Note 7 - Commitments and Contingencies:

Joint Venture - In December 1997, the Company entered into a joint venture agreement with a business development corporation (Nace) for the

purposes of developing products. For the year ended July 31, 2001, approximately $46,000 total costs had been recorded for this venture and approximately $23,000 had been invoiced to the joint venture partner. At July 31, 2001, approximately $6,000 was due from the joint venture partner.

Leases - In August 2000, the Company entered into a 5-year lease agreement, effective October 2000, for approximately 4,500 square feet of office, laboratory and manufacturing space. Annual rent is approximately $63,000, for each year, plus real estate taxes, currently estimated to be approximately $11,000 annually. Previously, the Company rented office space on a month to month basis. Rent expense for the Company totaled approximately $69,000 and $26,000 for the years ended July 31, 2001 and 2000, respectively.

Government Regulation - The development, manufacture and commercialization of pharmaceuticals are subject to extensive regulation by various federal and state government entities. The Company cannot determine the impact of government regulations on the development of its delivery systems.

Note 8 - Income Taxes:

No provision for current and deferred income taxes is required for the years ended July 31, 2001 and 2000.

The significant components of the Company's net deferred tax asset are summarized as follows:

| | July 31 | |
|---|---|---|
| | 2001 | 2000 |
| Differences between the cash basis of accounting for income tax reporting and the accrual basis for financial reporting purposes | $ (27,000) | $ (19,000) |
| Net operating loss carryforwards..... | 2,003,000 | 1,610,000 |
| | 1,976,000 | 1,591,000 |
| Valuation allowance | 1,976,000 | 1,591,000 |
| Net deferred tax asset..... | $ - | $ - |

The following is a reconciliation of income tax benefit computed at the 34% statutory rate to the provision for income taxes:

| | 2001 | 2000 |
|---|---|---|
| Tax at statutory rate..... | $ 377,000 | $ 401,000 |
| State Income Tax..... | 48,000 | 47,000 |
| Valuation allowance..... | (425,000) | (448,000) |
| | $ - | $ - |

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax asset will not be realized. The Company has determined, based on the Company's prior history of recurring losses, that a full valuation allowance is appropriate at July 31, 2001 and 2000.

At July 31, 2001, the Company has federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately $5,516,000 and $2,381,000, respectively, which can be used to offset current and future taxable income through the year 2021. During fiscal 2001 the Company sold a portion of its state net operating loss carryforwards realizing approximately $46,000. The Company has been informed that it is eligible to sell another portion of its state NOL during fiscal 2002.

Note 9 - Stock Options:

At July 31, 2001, the Company had three plans to allow for the issuance of stock options and other awards, the 1992 Stock Option Plan, the 1997 Stock Option Plan and the 1998 Stock Option Plan (the "Plans"). The total number of shares of common stock reserved for issuance, either as incentive stock options ("ISO's") under the Internal Revenue Code or as non-qualified options, under each of the Plans is 500,000 shares. ISOs may be granted to employees and officers of the Company and non-qualified may be granted to consultants, directors, employees and officers of the Company. Options to purchase Company's common stock could not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than ten years from the date of grant. ISOs granted to a 10% or more stockholder could not be for less than 110% of fair market value or for a term of more than 5 years.

The Company uses the intrinsic value method prescribed by APB Opinion No. 25 to measure compensation expense. If the fair value method had been used to measure compensation expense as prescribed by SFAS No. 123, net loss would have increased by $361,000 or $.08 per share to $1,540,000 or $.35 per share for fiscal 2000. There were no options granted in fiscal 2001.

The fair value of options granted in fiscal 2000 were estimated at the date of grant using a Black-Sholes option model with the following weighted-average assumptions, respectively: risk-free interest rates of 5.5% yield of 0.0% volatility factors of the expected market price of the Company's Common Stock of 10% to 174% and a weighted-average expected life of the options of five (5) to ten (10) years.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require input of highly subjective assumptions including the expected stock price volatility. When the Company shares were not traded publicly, the employee stock options had characteristics significantly different from those of publicly traded options. Because changes in the subjective input assumptions can materially affect fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single estimate of the fair value of its employee stock options.

Information with respect to stock option activity is as follows (in thousands, except exercise price amounts):

| | | Outstanding Options | |
|---|---|---|---|
| | Options Available for Grant | Number of Options | Weighted Average Exercise Price |
| Balance at August 1, 1999... | 400 | 1,900 | $1.66 |
| Grants..... | (400) | 400 | .93 |
| Exercises..... | - | - | - |
| Cancellations..... | - | - | - |

| | | | |
|---|---|---|---|
| Balance at July 31, 2000.... | - | 2,300 | 1.53 |
| Grants..... | - | - | - |
| Exercises..... | - | - | - |
| Cancellations..... | - | - | - |
| Balance at July 31, 2001.... | - | 2,300 | $1.53 |

Option price per share: $.88 - $2.00
Options exercisable: 2,300,000

The following table summarizes significant ranges of outstanding and exercisable options at July 31, 2001 (in thousands, except exercise price amounts):

| | Outstanding Options | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Options | Weighted Average Remaining Life in Years | Weighted Average Exercise Price | Options | Weighted Average Exercise Price |
| $0.51 - $1.00..... | 680 | 4.5 | $ .95 | 680 | $ .95 |
| $1.01 - $1.50..... | 120 | 2.5 | 1.11 | 120 | 1.11 |
| $1.51 - $2.00..... | 1,500 | 4.9 | 1.83 | 1,500 | 1.83 |
| | 2,300 | 4.7 | $ 1.53 | 2,300 | $ 1.53 |

In addition to stock options issued by the Company under the Plans, the Company has reserved 2,105,472 shares of common stock for non-plan options and warrants as detailed below.

Non-plan Options and Warrants - At July 31, 2001 there were outstanding the following classes and numbers of instruments exercisable for Common Stock:

A. 680,000 Class A Warrants, issued in connection with the Public Offering, exercisable until November 2002, to purchase a like number of shares of Common Stock at an exercise price of $5.80 per share.

B. 68,000 warrants, issued to the Underwriter in connection with the Public Offering, exercisable until November 2002, to purchase 68,000 units, each consisting of one share of Common Stock and one Class A Warrant at an exercise price of $9.74 per unit. Each Class A Warrant included in the units is exercisable on the same terms as is described above in paragraph A.

C. 800,000 stock options, not issued under any of the plans, as follows:

* 300,000 options each issued to the Company's President and Chairman of the Board of Directors, for a total of 600,000, having an exercise price of $1.84 per share, issued in connection with their respective employment agreements in June 1997, exercisable until November 2007.

* 100,000 options each issued to the Company's Vice President for Research and Development and Vice President for Product Development in May 1998, for a total of 200,000, in connection with their respective employment agreements, having an exercise price of $1.75 per share, exercisable until May 2008. These options expired in

August 2001.

D. 100,000 warrants issued to a consulting company exercisable until March 2003 at a price of $2.50.

E. 200,000 warrants issued to a consulting company exercisable until November 2010 at a price of $.75.

F. 257,472 warrants at $.75 per share issued to broker/dealers in connection with the fiscal year 2001 private placement. 50,000 warrants expire in October 2010, and remaining warrants of 207,472 shares expire in May 2011.

SIGNATURES

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

FLEMINGTON PHARMACEUTICAL CORPORATION

Date: November 13, 2001 By: /s/ Harry A. Dugger, III
---
Harry A. Dugger, III, President

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report is signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

| Signatures | Title | Date |
|---|---|---|
| /s/ Harry A. Dugger, III<br>Harry A. Dugger, III | President and Chief Executive Officer (Principal Executive Officer) | November 13, 2001 |
| /s/ Donald Deitman<br>Donald Deitman | Chief Financial Officer (Principal Financial Officer) | November 13, 2001 |
| /s/ John J. Moroney<br>John J. Moroney | Chairman of the Board and Director | November 13, 2001 |
| /s/ Robert F. Schaul<br>Robert F. Schaul | Secretary and Director | November 13, 2001 |
| /s/ Jack J. Kornreich<br>Jack J. Kornreich | Director | November 13, 2001 |

/s/ Robert C. Galler
---------- Director November 13, 2001
Robert C. Galler

| | Incorporated Documents | SEC Exhibit Reference |
|---|---|---|
| 2.1 | Agreement of Merger dated as of October 29, 1998 | As filed with the Registrant's Preliminary Proxy Statement on October 20, 1998, File No. 000-23399 |
| 3.1 | Certificate of Incorporation of the Registrant, as amended | As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201 |
| 3.2 | Bylaws of the Registrant, as amended | As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201 |
| 4.1 | Form of Warrant Agreement | As filed with the Registrant's Form SB-2, on October 31, 1997, File No. 333-33201 |
| 4.3 | Form of Class A Warrant Certificate | As filed with the Registrant's Form SB-2, on October 31, 1997, File No. 333-33201 |
| 4.4 | Form of Underwriters' Option Agreement | As filed with the Registrant's Form SB-2, on October 31, 1997, File No. 333-33201 |
| 10.1 | Employment Agreement with Harry A. Dugger III, Ph.D. | As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201 |
| 10.2 | Employment Agreement with John J. Moroney | As filed with the Registrant's Form SB-2, on October 3, 1997, File No. 333-33201 |
| 10.3 | Agreement dated December 7, 1996 between the Registrant and Altana, Inc. | As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201 |
| 10.4 | Registrant's 1992 Stock Option Plan | As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201 |
| 10.5 | Form of Option Agreement under the 1992 Stock Option Plan | As filed with the Registrant's Form SB-2, on October 3, 1997, File No. 333-33201 |
| 10.6 | Registrant's 1997 Stock Option Plan | As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201 |
| 10.7 | Form of Option Agreement under the 1997 Stock Option Plan | As filed with the Registrant's Form SB-2, on October 3, 1997, File No. 333-33201 |
| 10.8 | Agreement with Rapid Spray (Clemastine) dated June 2, 1992 | As filed with the Registrant's Form SB-2, on August 8, 1997, |

| | | |
|---|---|---|
| | | File No. 333-33201 |
| 10.9 | Agreement with Rapid Spray (Nitroglycerin) dated June 2, 1992 | As filed with the Registrant's Form SB-2, on August 8, 1997, File No. 333-33201 |
| 10.10 | Agreement with Creative Technologies, Inc. dated December 26, 1996 | As filed with the Registrant's Form SB-2, on October 3, 1997, File No. 333-33201 |
| 10.11 | Registrant's 1998 Stock Option Plan | As filed with the Registrant's Preliminary Proxy Statement on October 20, 1998, File No. 000-23399 |
| 10.12 | Employment Agreement with Donald P. Cox, Ph.D. | As filed with the Registrant's Form 10-KSB on October 28, 1999, File No. 000-23399 |
| 10.13 | Employment Agreement with Kenneth Cleaver, Ph.D. | As filed with the Registrant's Form 10-KSB on October 28, 1999, File No. 000-23399 |
| 10.14 | Amendment to Consulting Agreement with Saggi Capital Corp., dated March 25, 1998 | As filed with the Registrant's Form 10-KSB on October 28, 1999, File No. 000-23399 |
| 10.15 | Agreement with Altana, Inc., dated December 7, 1996 | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.16 | Agreement with CLL Pharma dated February 12, 1998 | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.17 | Agreement with Nace Resources, Inc., dated December 29, 1997, together with Amendment Number 1 dated February 9, 1998; Amendment Number 2 dated November 29, 1999; and Amendment 3, dated May 5, 2000 | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.18 | Agreement with PolyMASC Pharmaceuticals plc, dated July 25, 2000 | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| 10.19 | Authorization to proceed with Innovex, Inc. and Novartis Pharmaceuticals Corp., dated June 15, 2000 | As filed with the Registrant's Form 10-KSB/A on September 26, 2001, File No. 000-23399 |
| | Filed herewith | |
| 11.1 | Computation of earnings per share | |

EXHIBIT 11

FLEMINGTON PHARMACEUTICAL CORPORATION

EARNINGS PER SHARE COMPUTATION

| | YEAR ENDED JULY 31, 2001 |
|---|---|
| | BASIC |
| Weighted average shares outstanding | 6,326,000 |
| Dilutive effect of stock performance plans (1) | - |
| Total | 6,326,000 |
| Net Income (loss) | (1,109,000) |
| Earnings per share | (.18) |

| | YEAR ENDED JULY 31, 2000 |
|---|---|
| | BASIC |
| Weighted average shares outstanding | 4,447,000 |
| Dilutive effect of stock performance plans (1) | - |
| Total | 4,447,000 |
| Net Income (loss) | (1,179,000) |
| Earnings per share | (.27) |

(1) Since the company has reported a loss for each period, no potential shares from stock performance plans have been presented, as their effect would be anti-dilutive.