UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission file number 0-50680

BARRIER THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**22-3828030**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
600 College Road East, Suite 3200, Princeton, New Jersey	**08540**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(609) 945-1200**

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

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $.0001 per share	**NASDAQ National Market**

Indicate by check mark whether the registrant (1) has filed all reports 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 ☒ No

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No ☒

The aggregate market value of the voting Common Stock held by nonaffiliates of the registrant as of June 30, 2004 was approximately $88.6 million. Such aggregate market value was computed by reference to the closing price of the Common Stock as reported on the NASDAQ National Market on June 30, 2004. For purposes of making this calculation only, the registrant has defined affiliates as including all directors and executive officers.

The number of shares of the registrant's Common Stock outstanding as of March 23, 2005 was 23,945,519.

DOCUMENTS INCORPORATED BY REFERENCE.

Portions of the registrant's definitive proxy statement for its 2005 annual meeting of stockholders are incorporated by reference into Items 10, 11, 12, 13, and 14 of Part III of this Annual Report on Form 10-K.

BARRIER THERAPEUTICS, INC.

Form 10-K

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical facts or statements of current condition, this report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements contained in this report constitute our expectations or forecasts of future events as of the date this report was filed with the SEC and are not statements of historical fact. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "project," "intend," "should," "plan," "believe," "hope," and other words and terms of similar meaning. In particular, these forward-looking statements include, among others, statements about:

- the increasing trend of operating losses and the reasons for those losses;
- our spending on the clinical development of our later stage and earlier stage product candidates;
- our plans regarding the development or regulatory path for any of our product candidates;
- the timing of the initiation or completion of any clinical trials;
- the timing of filing for regulatory approvals with governmental agencies;
- the timing of the commercial launch of any of our product candidates, if approved;
- the commercialization of any of our product candidates, if approved; and
- other statements regarding matters that are not historical facts or statements of current condition.

Any or all of our forward-looking statements in this report may turn out to be wrong. We do not intend to update publicly any forward-looking statement, whether as a result of new information, future events or otherwise. These statements involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, level of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Therefore, you should not place undue reliance on any such forward-looking statements. The factors that could cause actual results to differ from those expressed or implied by our forward-looking statements include, in addition to those set forth in Part I, Item 7 under the heading "Risk Factors that May Affect Future Results," our ability to:

- obtain substantial additional funds;
- obtain and maintain all necessary patents or licenses;
- demonstrate the safety and efficacy of product candidates at each stage of development;
- meet applicable regulatory standards and file for or receive required regulatory approvals;
- meet obligations and required milestones under our license and other agreements;
- produce drug candidates in commercial quantities at reasonable costs and compete successfully against other products and companies; and
- market our products, if approved, and generate revenues.

PART I

ITEM 1. BUSINESS

Overview

We are a pharmaceutical company focused on the discovery, development and commercialization of pharmaceutical products in the field of dermatology. Our goal is to develop a portfolio of innovative products that address major medical needs in the treatment of dermatological diseases and disorders. We currently market Solagé® in the United States for the treatment of solar lentigines, a common condition also known as "age spots" or "liver spots", and for the broader indication including related hyperpigmented lesions in Canada. Our product pipeline includes eight product candidates in various stages of clinical development. We were incorporated in Delaware in September 2001 and commenced active operations in May 2002. Our principal offices are located at 600 College Road, Princeton, New Jersey 08540.

Recent Developments

In February, 2005, we completed a follow-on public offering of 4 million shares of our common stock at a price of $19.50 per share. Of the 4 million shares, two million were sold by existing stockholders of the Company and 2 million were sold by the Company, which resulted in net proceeds to the Company of approximately $36 million after payment of underwriting discounts and commissions and other expenses. Barrier did not receive any proceeds from the sale of the shares sold by the existing stockholders. None of Barrier's executive officers sold shares in this offering.

In February, 2005, we acquired the United States and Canadian rights to Solagé®, a product commonly used for depigmenting lesions, from Moreland Enterprises Limited. In the United States, Solagé® is indicated for the treatment of solar lentigines, commonly known as "age spots", while the Canadian indication also includes use for related hyperpigmented lesions. Under the terms of the agreement, we made an initial cash payment to Moreland of $3 million and may make future payments totaling up to an additional $2 million, depending upon future sales of the product. In addition, the agreement provides that in the event Moreland proposes to grant rights to a third party to distribute, license or otherwise divest its rights to the product outside the United States and Canada, subject to the terms of the agreement, we have a right of first refusal to acquire such rights. The agreement also provides for the assignment to us of all Solagé® United States and Canadian marketing authorizations, patents, patent applications and trademarks and the purchase by us of all existing inventory. The patent rights include United States and Canadian patents and patent applications covering Solagé®'s pharmaceutical composition and methods of use until at least 2010. We have also entered into a distribution agreement with Galderma Laboratories under which Galderma will provide us with distribution services and logistical support for Solagé® through December 2005.

Our Product Pipeline

Our four most advanced product candidates are:

- *Zimycan*: an ointment for the treatment of infants with diaper dermatitis complicated by candidiasis, an inflammatory disease characterized by diaper rash complicated with an infection by a yeast called *Candida*. On the basis of the positive Phase 3 pivotal clinical trial results that we announced in August 2004, we filed an amendment to a pending new drug application, or NDA, for Zimycan in the United States in November 2004. We expect to receive a first action letter from the FDA relating to the potential approval of Zimycan in the

United States during the first half of 2005. Zimycan has received marketing approval from the Belgian Health Authorities and is the subject of a mutual recognition procedure for approval in Europe.

- *Sebazole*: a gel for the treatment of seborrheic dermatitis, a type of eczema characterized by inflammation and scaling of the skin, principally of the scalp, face and chest. In December 2004, we announced positive results from a Phase 3 pivotal clinical trial for Sebazole. We expect to file an NDA for Sebazole in the United States during the third quarter of 2005.

- *Hyphanox*: an oral therapeutic for the treatment of fungal infections, including vaginal candidiasis, commonly known as vaginal yeast infection, and onychomycosis, commonly known as nail fungus. We are currently conducting a Phase 3 pivotal clinical trial for Hyphanox for the treatment of vaginal candidiasis to support applications for marketing approval in the United States and Europe. We expect to complete this trial during the second quarter of 2005. We expect to commence two Phase 3 clinical trials for Hyphanox for the treatment of onychomycosis during the second quarter of 2005.

- *Liarozole*: an oral therapeutic for the treatment of the group of conditions known as congenital ichthyosis, a rare genetic disease characterized by dryness and scaling of the skin. We expect to commence a Phase 2/3 clinical trial for Liarozole for the treatment of the lamellar form of congenital ichthyosis during 2005. Both the FDA and the Commission for the European Community have granted Liarozole orphan drug status for the treatment of congenital ichthyosis.

We have four other product candidates in earlier stages of clinical development for the treatment of a range of dermatological conditions, including acne, psoriasis and fungal infections. Our product pipeline also includes product candidates in preclinical development, as well as two other product candidates that are marketed by third parties in some countries outside the United States and Europe, which we would reformulate prior to initiating clinical trials. In addition, we have access to the classes of compounds claimed in the patents licensed to us under our license agreements with affiliates of Johnson & Johnson. We are currently conducting a screening program to search for new product candidates in the field of dermatology.

Our management team consists of a number of experienced pharmaceutical industry executives and recognized experts in dermatological drug discovery, development and commercialization. We were founded in 2001 by Geert Cauwenbergh, Ph.D., our Chief Executive Officer, who identified a portfolio of dermatological product candidates and intellectual property within the Johnson & Johnson family of companies that he believed could form the basis for an independent pharmaceutical company focused on dermatology. In May 2002, we acquired these assets through licenses from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., each a Johnson & Johnson company, in exchange for an equity interest in us. In this document, we sometimes refer to Janssen Pharmaceutica Products, L.P. and its affiliates as Janssen.

Dermatology Overview

Dermatology is the field of medicine concerned with the study and treatment of disorders and diseases of the skin. Skin is a vital organ of the human body. Skin functions as a barrier, protecting organs and tissues in the body from injury and invasion by foreign organisms that may cause infections or other damage. It helps regulate body temperature and sense external stimuli. The condition of one’s skin also has a significant impact on an individual’s overall health and appearance.

Skin is a complex system composed of three major layers:

- the epidermis is a protective layer and contains melanin, which is the pigment that gives skin its color and protects it against the harmful effects of the sun;
- the dermis contains nerves, blood vessels, hair follicles and many of the functional glands of the skin, including sweat glands and oil producing glands, known as sebaceous glands; and
- the subcutaneous tissue is a layer of fat that helps insulate the body from heat and cold.

Dermatological diseases and disorders may result from a number of factors, including aging, sun damage, immunological diseases, genetic background, viral, fungal or bacterial infections, allergic reactions and emotional or seasonal factors. These diseases and disorders can have a significant impact on an individual's physical and mental health and his or her social acceptance.

Despite the significant sales of prescription products for treatment of diseases of the skin, we believe that many limitations remain in the treatment of these diseases. Existing treatments are often inadequate for reasons of efficacy, toxicity or patient noncompliance. Many of the drugs currently used to treat dermatological diseases originally were developed to treat diseases of other parts of the body. For example, many of the oral antifungal drugs used today to treat dermatological infections first were developed as treatments for fungal infections of other parts of the anatomy. We believe that our focus on understanding the molecular basis for diseases of the skin may yield more convenient and effective drugs with fewer harmful side effects.

Our Business Strategy

Our strategy is to develop a portfolio of innovative products that address major medical needs in the treatment of dermatological diseases and disorders in order to become a global leader in the discovery, development and commercialization of prescription pharmaceutical products to treat these diseases and disorders. To achieve our goal, we intend to:

Aggressively pursue the development and regulatory approval of our product candidates. We are committing substantial resources towards completing development of, and obtaining regulatory approvals for, our product candidates in the United States and in other markets worldwide.

Commercialize our products directly through our own sales organization in the United States and Canada and through collaborations with third parties outside the United States and Canada. We plan to build our own sales force to market our products directly to dermatologists and other target physicians in the United States and Canada. To accelerate global market penetration of our products, we have entered into, and will continue to seek, collaborations with third parties outside the United States and Canada.

Maintain a diverse portfolio of product candidates. We are developing a product portfolio that includes product candidates at various stages of preclinical and clinical development and is not based on a single technology. We believe that the diversity in our product development pipeline increases the probability of our long-term commercial success.

Expand our product portfolio through a combination of internal development efforts and selective acquisitions of additional compounds and marketed products. We intend to continue expanding our product development pipeline by screening compounds to which we have access under our principal license agreements. We plan to supplement these efforts by licensing or otherwise acquiring additional compounds that we believe to be potentially superior to currently marketed products and by seeking to

selectively acquire marketed dermatological products that complement our development and commercialization strategy.

Product Development Pipeline

We have eight product candidates in various stages of clinical development. In addition, we have rights to other products, including two products that are marketed by third parties in some countries outside the United States and Europe which we would reformulate prior to initiating clinical trials. The FDA has not approved any of our product candidates.

We have based our assessment of the stage of development of our product candidates on our ongoing development efforts, for certain products, and on the clinical trials that were performed by or on behalf of Janssen Pharmaceutica Products, L.P. and its affiliates prior to our acquisition of these product candidates in May 2002. Depending upon the scope and adequacy of the data from these trials, directions or feedback we receive from regulatory agencies and our product development strategy, we may need to perform additional preclinical studies and clinical trials before proceeding to the next stage of clinical development or seeking regulatory approval. Many of the previously performed clinical trials and our currently ongoing Phase 2a trials were and are being conducted in Europe, where an investigational new drug application, or IND, or its foreign equivalent, was not a prerequisite to performing pilot studies or early stage clinical trials. In the United States, an IND must be filed with the FDA prior to performing clinical trials for each drug candidate and for each indication.

The following table summarizes our product candidates in clinical development, all of which we plan to develop as prescription drugs. The names listed below are our current designations for these programs and may not be the final approved trade name.

Product	Active Ingredients or Class of Molecule	Method of Administration	Indications	Stage of Development
Zimycan	miconazole	Topical	diaper dermatitis complicated by candidiasis	NDA filed MRP-Europe
Sebazole	ketoconazole	Topical	seborrheic dermatitis	Phase 3-complete
Hyphanox	itraconazole	Oral	vaginal candidiasis onychomycosis	Phase 3-ongoing Phase 3-planned
Liarozole	RAMBA class	Oral	congenital ichthyosis (lamellar)	Phase 2/3-planned
Rambazole	RAMBA class	Oral	psoriasis nodular acne	Phase 2a-ongoing Phase 2a-ongoing
Rambazole	RAMBA class	Topical	dermatological indications	Phase 2a-planned
Azoline	triazole antifungal	Oral	fungal infections	Phase 2a-complete
Hivenyl	H1 antihistamine	Oral	dermatological indications	Phase 2a-ongoing

Later Stage Product Candidates

Zimycan. Zimycan is a topical ointment with an active ingredient of 0.25% miconazole, an antifungal agent, in a zinc oxide and petrolatum base. We are developing Zimycan for use in the treatment of infants with diaper dermatitis complicated by candidiasis, which is an inflammatory disease in which an infant's diaper rash is complicated with an infection by a yeast called *Candida*. *Candida* yeasts thrive

in the warm, moist conditions typically found in an infant's diaper. Miconazole is an antifungal agent that treats fungal infections such as those caused by *Candida*. In the United States, there currently is no prescription drug specifically approved to treat diaper dermatitis complicated by candidiasis.

Product Background. Affiliates of Johnson & Johnson Consumer Companies, Inc. have received regulatory approval for this product for the treatment of diaper dermatitis and market it under the brand names Daktozin and Bebektin in some countries outside the United States.

In August 1998, an NDA for marketing approval for the broad indication of diaper dermatitis, without the restriction to diaper dermatitis complicated by candidiasis, was filed with the FDA. In connection with its review, the FDA issued not approvable letters for the broad indication of diaper dermatitis and requested an additional clinical trial focused specifically on infants with diaper dermatitis complicated by candidiasis. We have completed the additional Phase 3 clinical trial requested by the FDA and, based on the positive results described below, we filed an amendment to this NDA in November 2004.

Clinical Development. In August 2004, we announced results of a Phase 3 pivotal clinical trial conducted in the United States and Latin America for the use of Zimycan in the treatment of infants and children with proven diaper dermatitis complicated by candidiasis.

The double-blind, vehicle-controlled study, which was conducted at 20 sites in the United States and Latin America, included 236 children under the age of three years who were diagnosed with diaper dermatitis that was complicated by the presence of *Candida*. These children were treated for seven days with either the placebo vehicle, consisting of zinc oxide plus petrolatum, or with Zimycan. The vehicle used in this study is generally recognized as the standard of care for uncomplicated diaper dermatitis. The measurement used to assess the success of these trials, known as the primary efficacy endpoint, was overall cure at day 14, one week after the end of treatment. Overall cure was defined as eradication of the fungus and complete clearing of all signs and symptoms of the disease.

In the study, Zimycan achieved statistical significance compared to vehicle for all primary and secondary endpoints. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. A p-value of 0.05 or less for clinical trial results is generally considered by regulatory authorities as indicating statistically significant results for evidence of effectiveness.

The overall cure rates from this study are summarized in the table below:

	Overall Cure Rates at Day 14 (7 Days after the End of Treatment)
Zimycan.....	23%
Vehicle	10%
p-value.....	.005

As indicated in the table, the results of the study were statistically significant with a p-value of 0.005. More than twice the percentage of patients treated with Zimycan reached the primary endpoint as compared with patients treated with the vehicle. We also performed a subanalysis on the data from this trial that showed that at the end of the seven-day treatment period, the average reduction in the signs and symptoms score was 72% in infants treated with Zimycan compared to 25% in infants treated with the vehicle ointment.

In the study, both Zimycan and the vehicle were well tolerated. There were no serious adverse events in either group nor were there adverse events related to treatment in either group. The non-serious adverse events were evenly distributed between the groups and were considered typical of this patient population.

Regulatory Strategy. In November 2004, we filed with the FDA an amendment to the Zimycan NDA seeking marketing approval for Zimycan for the treatment of diaper dermatitis complicated by candidiasis in infants and children. We expect to receive a first action letter from the FDA relating to the approval of Zimycan during the first half of 2005.

Zimycan has received marketing approval from the Belgian Health Authorities and is the subject of a mutual recognition procedure in Europe. The mutual recognition procedure has been completed in the following eight countries: Austria, Denmark, Finland, Greece, Luxemburg, the Netherlands, Portugal and Sweden meaning that these countries have indicated they are prepared to grant marketing authorization. In the remaining European countries which we had included in our initial MRP filing, including the United Kingdom, Germany and Spain, we expect to make an additional MRP filing containing additional clinical data to address questions raised by the regulatory authorities in those countries.

Proprietary Rights. We have an exclusive, royalty-free license in the field of dermatology to an issued United States patent covering the formulation of the combination of miconazole and zinc oxide contained in Zimycan and methods of treating diaper dermatitis. The United States patent expires in 2007. We also have a license to corresponding patents in Europe, Japan and other foreign countries. The issued patents and any additional patents issuing from the patent applications in Europe, Japan and other foreign countries will expire in 2005. The active ingredient of Zimycan, miconazole, is off patent.

Sebazole. Sebazole is a topical formulation of 2.0% ketoconazole, an antifungal agent, in a waterless gel that we are developing as a once daily treatment for seborrheic dermatitis. Seborrheic dermatitis is a type of eczema that is characterized by a red, scaly, itchy rash primarily occurring on the face, scalp, behind the ears and in the middle of the chest. The condition often recurs, thereby requiring retreatment over time. Ketoconazole has potent pharmacological effects against the fungus known as P. ovale, which, when overcolonizing the skin, is considered to be one of the main causes of seborrheic dermatitis. Ketoconazole quickly suppresses this type of fungus and also exhibits anti-inflammatory effects that help to reduce redness in affected areas. We have designed Sebazole to deliver the benefits of ketoconazole with the advantages of our waterless gel.

Product Background. We are developing Sebazole as part of our program to develop a once daily treatment for seborrheic dermatitis using our waterless gel. The program initially focused primarily on the gel containing a combination of 2.0% ketoconazole and 0.05% of the steroid desonide in addition to Sebazole, which does not contain a steroid.

Clinical Development. In November 2003, we completed two Phase 3 clinical trials which enrolled more than 900 patients in approximately 50 locations in the United States and Europe. Each trial compared the safety and efficacy of Sebazole, the gel containing the combination of 2.0% ketoconazole and 0.05% desonide, the gel containing 0.05% of the steroid desonide and a placebo consisting of our gel with no active ingredients. Patients were treated once daily for a period of two weeks. The primary efficacy endpoint in these trials was the proportion of patients that were effectively treated at day 28, which was 14 days following the end of treatment. Effectively treated for the purpose of these Phase 3 clinical trials means a patient was cleared or almost cleared of seborrheic dermatitis. We initially designed the trials primarily for the product containing both ketoconazole and the steroid and, as a result, we conducted the trials following FDA regulations for combination product development. However, based on

the results of these clinical trials, we determined that Sebazole was the stronger product candidate. In both trials, Sebazole achieved the primary efficacy endpoint versus the vehicle gel with statistical significance. We found Sebazole to be comparable to our waterless gel containing desonide and to the combination of ketoconazole with desonide, suggesting that adding a steroid to the topical regimen does not provide additional benefit at 14 days following treatment. In these trials, Sebazole was well tolerated, with no serious drug-related adverse events reported.

Upon review of the results from these trials, the FDA requested that we perform one additional Phase 3 pivotal clinical trial of Sebazole. We completed this trial in December 2004. In this trial, we enrolled 459 patients in 24 locations in the United States. The trial compared the safety and efficacy of Sebazole to a placebo consisting of our gel with no active ingredient. Patients were treated once daily for a period of two weeks. The primary efficacy endpoint was the same as in on our two earlier Phase 3 trials — the proportion of patients that were effectively treated at day 28, which was 14 days following the end of treatment. In this trial, Sebazole was well tolerated, with no serious drug-related adverse events reported.

The results of the primary efficacy endpoint from all three Phase 3 trials of Sebazole are summarized in the table below:

	Percentage of Patients Effectively Treated at Day 28 (14 Days after the End of Treatment)		
Study (location)	**Sebazole**	**Vehicle**	**p-value**
Pivotal (United States).....	25%	14%	0.001
Supportive (United States)	28%	7%	<0.001
Supportive (Europe)	37%	22%	0.021

As indicated in the table, the results of each trial were statistically significant. In addition, in our pivotal trial, the results with respect to the secondary efficacy endpoint for mean change from baseline for scaling were statistically significant. The results with respect to the secondary efficacy endpoint for redness and itching were better as compared to vehicle alone but were not statistically significant. We also performed a cumulative irritation patch study in volunteers in which we observed that Sebazole was approximately five times less irritating than a ketoconazole cream.

Additionally, we are currently conducting a clinical study, for which enrollment is complete, to assess the long-term safety of Sebazole for up to one year of intermittent use. In January 2005, the FDA informed us that we should submit data for six months of intermittent use from this study at the time of the initial filing of our Sebazole NDA. The FDA also asked us to perform a study for Sebazole known as a percutaneous absorption study, which measures the amount of a drug's absorption, if any, into the bloodstream through the skin. The FDA requested that we submit data from this study at the time of the initial filing of our Sebazole NDA.

Regulatory Strategy. Based on the positive results of these three Phase 3 clinical trials, we expect to file an NDA with the FDA seeking marketing approval for Sebazole for the treatment of seborrheic dermatitis during the third quarter of 2005.

Proprietary Rights. We have an exclusive, royalty-free license in the field of dermatology to a United States patent application claiming specific formulations of ketoconazole in a waterless gel. Any patent issued in the United States from this application would expire in 2018. We also have an exclusive, royalty-free license to corresponding patent applications in Europe, Japan and other foreign countries.

Any patents issued from the patent applications in Europe, Japan and other foreign countries would expire in 2019. The active ingredient of Sebazole, ketoconazole, is off patent.

Hyphanox. Hyphanox is an oral formulation of itraconazole, an antifungal agent that we are developing for the treatment of various fungal infections, including vaginal candidiasis, and onychomycosis. Itraconazole is effective in treating these fungal infections. Janssen currently markets different formulations of itraconazole, under Sporanox and other brand names, in various countries. Sporanox is approved in the United States for the treatment of various disorders, including onychomycosis, but not for the treatment of vaginal candidiasis. Sporanox is approved for vaginal candidiasis and onychomycosis in Europe. A generic form of itraconazole has also been approved in the United States. A 100 mg capsule is the maximum strength in which oral Sporanox is currently available. We are developing Hyphanox as a 200 mg tablet. We believe this 200 mg formulation will allow for more convenient once daily dosing and provide for higher bioavailability and less inter-patient variability.

Product Background. In an effort to produce a more convenient dosing form of Sporanox, Janssen conducted a program to reformulate itraconazole into 200 mg tablets using a proprietary formulation of itraconazole requiring a manufacturing process known as melt extrusion. Melt extrusion is a manufacturing process that makes it possible to formulate itraconazole into tablets. We obtained the rights to Janssen's tablet formulation under our license agreements.

In the fourth quarter of 2003, we conducted a bioequivalence study of Hyphanox relative to Sporanox on 52 subjects. Bioequivalence between different formulations of a drug exists when the bioavailability of one formulation relative to the other formulation is within a specified regulatory range. Bioavailability is a measure of the degree to which a drug becomes available to the bloodstream after administration. Based on data from this study, the bioavailability of Hyphanox relative to Sporanox is slightly above the upper limit of the regulatory range to establish bioequivalence.

In addition, in this bioequivalence study, we observed that there was lower inter-patient variability in itraconazole plasma levels in subjects taking Hyphanox compared to subjects taking Sporanox. This may help us to differentiate Hyphanox, if approved, from other itraconazole products such as Sporanox, since decreased variability between subjects could result in greater consistency in the delivery of the active ingredient, itraconazole, in a patient's body.

Clinical Development. In the first quarter of 2004, we commenced a Phase 3 pivotal clinical trial in the United States for the use of a single day, single dose treatment of two 200 mg tablets of Hyphanox in the treatment of vaginal candidiasis. We expect to enroll approximately 1,200 women in the trial, approximately 800 of whom will be measured for clinical and mycological cure rates 25 days after treatment. In this trial, we will be required to demonstrate that Hyphanox is not clinically inferior to fluconazole, the active ingredient in Diflucan marketed by Pfizer. We established the trial design after discussions with the FDA. In the first half of 2005, we plan to initiate two Phase 3 pivotal clinical trials using pulse therapy designed to test a once daily dosage of two 200 mg tablets of Hyphanox for the treatment of onychomycosis.

Regulatory Strategy. If our ongoing Phase 3 clinical trial of Hyphanox in the treatment of vaginal candidiasis is successful, in the second half of 2005, we expect to file an NDA with the FDA seeking marketing approval for Hyphanox for the treatment of vaginal candidiasis. If our planned Phase 3 clinical trials of Hyphanox in the treatment of onychomycosis are successful, we expect to file an NDA with the FDA seeking marketing approval for Hyphanox for the treatment of onychomycosis.

Proprietary Rights. We have an exclusive license in the field of dermatology to a United States patent claiming the Hyphanox formulation and methods of using this formulation for treatment of fungal

infections. The United States patent claiming the formulation and methods of treatment expires in 2017. We also have an exclusive license to corresponding patents and patent applications in Europe, Japan and other foreign countries. The issued patent and any additional patents issuing from the patent applications in Europe, Japan and other foreign countries will expire in 2016 through 2017. The active ingredient of Hyphanox, itraconazole, is off patent.

Janssen Option. Janssen has an exclusive option to acquire the right to commercialize Hyphanox on a region-by-region basis. In order to permit Janssen to exercise this right, we are obligated to notify them if we are able to manufacture Hyphanox batches that are reproducible and bioequivalent to Janssen's melt extrusion formulation or Sporanox or if we prove clinical efficacy in subsequent Phase 3 clinical trials. Based on the data from the bioequivalence study described above, the bioavailability of Hyphanox relative to Sporanox is slightly above the upper limit of the regulatory range to establish bioequivalence. Accordingly, our study did not demonstrate bioequivalence between Hyphanox and Sporanox and thus did not trigger the Janssen option. However, this option would be triggered if any subsequent study demonstrates bioequivalence or if our Phase 3 clinical trials for Hyphanox demonstrate clinical efficacy. Please see "—Johnson & Johnson License Agreements—Additional Terms Applicable to Hyphanox" for a further description of Janssen's option.

Liarozole. Liarozole is our first product candidate based on a class of molecules known as retinoic acid metabolism blocking agents, or RAMBAs. We are developing Liarozole as an oral treatment for the group of conditions known as congenital ichthyosis. Congenital ichthyosis is a rare genetic disease, affecting one in 6,000 people in the United States. The disease is characterized by severe dryness and scaling of the skin, with the scaling often occurring over large areas of the body. There is no prescription drug currently approved in the United States that is indicated for the treatment of congenital ichthyosis.

RAMBAs work by blocking the intracellular metabolism of natural retinoic acid in cells. This blocking results in an increased accumulation of the body's own retinoic acid in the body's cells, which we believe may provide the same therapeutic benefits as synthetic retinoid therapy but potentially with less risk of adverse side effects. We believe that one of the potential advantages of Liarozole and other RAMBAs over synthetic retinoids may be the reduction or absence of long-term risk for birth defects. Because of the risk of birth defects arising from the tissue retention of synthetic retinoids, long-term contraception is strongly recommended in women after the use of these agents. Preclinical studies conducted in rats dosed with Liarozole showed no birth defects in pups conceived one week after completion of a one week treatment with Liarozole. In contrast, after treatment is completed with acitretin, the active ingredient in Soriatane, there is a risk of birth defects for several months.

Product Background. Liarozole was originally developed for the treatment of prostate cancer and was tested in clinical trials at various doses of up to 600 mg per day. In these clinical trials, subjects treated with higher levels of Liarozole experienced serious toxic side effects as is often the situation with anti-cancer therapies. However, because subjects in these trials exhibited retinoid-like effects in the skin, a development program was started to explore the therapeutic potential of Liarozole at lower doses in a variety of retinoid-responsive diseases, including congenital ichthyosis.

To date, Liarozole has been the subject of the Phase 2 and Phase 3 clinical trials described below. However, no assessment of the efficacy or safety of a product candidate can be considered definitive until all clinical trials needed to support a submission for marketing approval are complete. Success in earlier clinical trials does not mean that subsequent trials will confirm the earlier findings.

In a Phase 2 clinical trial of Liarozole for the treatment of congenital ichthyosis, that was conducted prior to our acquisition of rights to Liarozole, 11 of 12 subjects that were treated with a twice

daily 150 mg dosage of oral Liarozole showed marked improvement. The other subject showed moderate improvement. In addition, in a Phase 3 clinical trial of Liarozole and acitretin, 15 of the 32 subjects with severe ichthyosis were treated with a twice daily 75 mg dosage of Liarozole. In this trial, Liarozole demonstrated similar efficacy as acitretin and was well tolerated.

Clinical Development. We performed a retrospective review of the side effects observed in people treated with Liarozole at doses of up to 600 mg per day. The results of this review suggest that the serious side effects seen at higher doses are less likely to be encountered at our proposed 150 mg per day dose for dermatological use.

Regulatory Strategy. Both the FDA and the Commission for the European Community have granted Liarozole orphan drug status for the treatment of congenital ichthyosis. We have had discussions with the European Medicines Agency for the Evaluation of Medicinal Products, or EMEA, and the FDA concerning clinical requirements for us to obtain marketing approval for Liarozole for the treatment of congenital ichthyosis. In this regard, we plan to conduct a Phase 2/3 clinical trial in the United States, Europe and other countries to evaluate both the appropriate dose and efficacy of Liarozole. The specific type of congenital ichthyosis to be studied is expected to be lamellar ichthyosis. We expect to begin this trial in 2005. Because of its orphan drug status, if Liarozole is the first product candidate to receive FDA approval for congenital ichthyosis, it will be entitled to orphan drug exclusivity. This means that the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority or improved safety to the product with orphan exclusivity.

Proprietary Rights. We have an exclusive, royalty-free license in the field of dermatology to United States patents claiming the chemical compound Liarozole, pharmaceutical formulations containing Liarozole and methods of treatment with Liarozole. The United States patents claiming the chemical compound Liarozole and pharmaceutical formulations containing Liarozole expire in 2006. The United States patent claiming methods of treatment for congenital ichthyosis using Liarozole as a RAMBA expires in 2009. We also have an exclusive, royalty-free license to corresponding patents and patent applications in Europe, Japan and other foreign countries. The issued patent and any additional patents issuing from the patent applications in Europe, Japan and other foreign countries will expire in 2007 through 2009.

Earlier Stage Clinical Candidates

Our product development pipeline includes four product candidates that are in earlier stages of clinical development. All of these product candidates are based on intellectual property licensed by us under our principal license agreements. We are developing these product candidates as treatments for a wide range of dermatological diseases and disorders, including acne, psoriasis and fungal infections. We plan to advance the clinical development of these product candidates based on our assessment of their market potential, the results of pilot studies and Phase 1 clinical trials and our available resources. The preliminary observations of efficacy and safety from any of our preclinical or clinical trials for our earlier stage product candidates are not necessarily indicative of the results that may be demonstrated in future clinical trials. We will need to conduct significant additional preclinical or clinical trials prior to seeking marketing approval for our earlier stage product candidates.

Rambazole. Rambazole is our second product candidate based on the RAMBA class of molecules. We are developing an oral formulation of Rambazole for the treatment of psoriasis and severe acne and a topical formulation for dermatological indications, including common forms of acne and mild to moderate psoriasis. We believe that Rambazole may address some of the limitations of existing therapies, such as toxicity, or the degree to which existing therapies are harmful at certain levels of

treatment, and immune suppression, or the tendency of some existing therapies to compromise a patient's immune system.

Product Background — Oral Rambazole. Various preclinical and clinical studies were conducted on Rambazole prior to our acquisition of rights to this product candidate. In preclinical in vitro and animal studies, oral Rambazole demonstrated potential effectiveness in the treatment of psoriasis and acne. These studies also suggested that Rambazole is more selective and more active than first generation RAMBA-based product candidates, such as Liarozole. An oral formulation of Rambazole was tested in two Phase 1 clinical trials. One of these clinical trials was a single dose escalation study, and the other was a multiple dose escalation study. In the multiple dose escalation study, increased doses of Rambazole resulted in increased manifestation of skin effects typical for retinoid therapy, including dry lips and skin.

Product Background — Topical Rambazole. In preclinical *in vitro* and animal studies, topical Rambazole demonstrated potential effectiveness in the treatment of psoriasis, acne and photo-damage. In addition, animal studies conducted with RAMBAs indicate that topical RAMBA treatment may produce the same therapeutic results as retinoic acid treatments but potentially with less irritation. However, as with any study performed on animals, this data is not necessarily indicative of the results that may be demonstrated in future clinical trials. A Phase 2 clinical trial for acne compared 13 subjects treated with a topical formulation of Rambazole to 13 subjects treated with a placebo. Subjects were treated for 12 weeks. In this trial, subjects receiving topical Rambazole showed a greater percentage reduction of acne lesions than those receiving the placebo. In addition, topical Rambazole was well tolerated, with no serious drug-related adverse events reported.

Clinical Development. We are currently conducting two Phase 2a clinical trials in Europe using oral Rambazole, one in moderate to severe psoriasis and the other in moderate to severe nodular acne. Each study will enroll approximately 17 subjects. The goal of these studies is to determine safety and preliminary indications of effectiveness of oral Rambazole in the treatment of both psoriasis and severe or nodular acne. A review of initial Phase 2a trial data from 17 patients with moderate to severe psoriasis demonstrated a reduction in the psoriasis area severity index, commonly known as PASI score, by approximately 50% in patients treated with 1mg once daily for eight consecutive weeks. These PASI scores were measured at week 10, two weeks after stopping the treatment. There were no serious treatment-related adverse effects reported, while non-serious side effects experienced by this limited patient group included dryness of skin and lips.

Regulatory Strategy. Based on these data, in mid-2005, we plan to submit an IND or its European equivalent necessary for us to commence Phase 2b clinical trials of oral Rambazole for psoriasis. In addition, in 2005, we plan to initiate a Phase 2a clinical trial in Europe to evaluate the effectiveness of topical Rambazole in mild to moderate acne.

Azoline. Azoline is an antifungal agent that we are developing as an oral treatment for skin and mucosal fungal infections. Preclinical testing has shown Azoline to be more potent than itraconazole against dermatological fungal infections and less interactive than itraconazole with the metabolism of other drugs. We have completed a one week Phase 1 clinical trial for Azoline in two different dose strengths. The results of this trial indicate that at the doses tested, Azoline has a half-life in the body of approximately 81 hours, which is nearly three times longer than that of itraconazole. As a result, we believe that Azoline may be an effective short course oral treatment for fungal infections. In this trial, Azoline was well tolerated, with no serious drug- related adverse events reported.

We recently conducted Phase 2a clinical trials involving 67 patients with various fungal infections of the skin. These patients were treated with 200 mg of Azoline once daily for one, three or five days. The product candidate was studied in tinea pedis, commonly known as athlete's foot, tinea corporis,

commonly known as ring worm, tinea cruris, commonly known as jock itch, tinea versicolor and seborrheic dermatitis. In these trials, at day 28, more than three weeks after treatment, patients treated for one day demonstrated response rates of 60% and patients treated for three or five days demonstrated clinical response rates (percent reduction in overall signs and symptoms) of between 78% and 100%, depending on the skin condition treated. There were no serious treatment-related adverse effects reported. Based on this data, we plan to submit an IND to the FDA and commence Phase 2b clinical trials of Azoline in the United States during 2005.

Hivenyl. Hivenyl is an antihistamine that we are developing as an oral treatment for allergic reactions of the skin, such as the types of reactions associated with hives and those associated with poison ivy, which may not cause sedation typically associated with antihistamines. Patients experience sedation when an antihistamine crosses the blood-brain barrier. In preclinical studies in animal models, Hivenyl did not cross the blood-brain barrier. In addition, the results of two dose escalation Phase 1 clinical trials of Hivenyl suggest that Hivenyl inhibits allergic reactions, has a fast onset of action and does not cause sedation. In these trials, no cardiovascular side effects or sedation was experienced at doses of five to 15 times those that elicited an antihistamine response. We are currently conducting a Phase 2a clinical trial in Europe for Hivenyl.

Other Product Candidates

One of our clinical product candidates, Atopik, is currently undergoing reformulation and will require additional preclinical evaluation. In addition, we have rights to two other products, ketanserin and oxatomide, that are marketed by third parties in some countries outside the United States and Europe which we would reformulate prior to initiating clinical trials.

Atopik. Atopik is a PDE4 inhibitor meaning that it helps prevent the body's production of an enzyme known as PDE4 that is associated with some types of skin reactions. We are developing Atopik as a topical treatment for eczema, which is a group of inflammatory skin conditions. In a pilot clinical study, Atopik reduced inflammatory response to stimuli that cause dermatitis. A second study conducted by us during 2004 did not show the same results. We are working on an optimized topical formulation of Atopik that seeks to minimize systemic absorption while maintaining effectiveness. We plan to complete this reformulation prior to pursuing further clinical development of this product candidate.

Ketanserin. Ketanserin is a topical serotonin 2 antagonist that an affiliate of Janssen Pharmaceutica Products, L.P. developed and markets in some countries outside the United States and Europe as a wound healing agent for the treatment of chronic skin ulcers. We plan to reformulate ketanserin prior to pursuing further clinical development for the treatment of diabetic and arterial ulcers and serious cracking of the skin. We are currently conducting a placebo-controlled pilot clinical study with ketanserin for the treatment of anal fissures.

Oxatomide. Oxatomide is a topical histamine, serotonin and leukotriene antagonist that an affiliate of Janssen Pharmaceutica Products, L.P. developed and markets in some countries outside of the United States and Europe for the prevention and treatment of allergies. In preclinical studies, a topical formulation of oxatomide demonstrated early indications of effectiveness in the treatment of pain and itch. We plan to reformulate oxatomide as a topical ointment prior to pursuing further clinical development for the treatment of itch associated with various skin conditions. We have completed an open-label pilot clinical study with oxatomide for the treatment of atopic eczema in 2004. Based upon the encouraging results of this study, we are evaluating the next steps to take in the development of this product candidate.

Preclinical Development

Under our principal license agreements we have access to the classes of compounds claimed in the patents licensed to us in the field of dermatology. We are screening these compounds to determine if they are suitable product development candidates. Members of our management team have worked extensively with these compounds prior to the formation of our company. We also work with academic institutions and third-party laboratories to perform the screening on selected compounds.

We plan to supplement these efforts by licensing or otherwise acquiring additional compounds that we believe to be potentially superior to currently marketed products. In October 2002, we entered into an agreement with a third party to obtain an exclusive, worldwide license, with the right to grant sublicenses, under the patents and know-how related to Ecalcidene to research, develop and commercialize products containing Ecalcidene. In recent preclinical studies that we conducted, we were not able to replicate some of the results previously seen with Ecalcidene. As a result, we are likely to discontinue the development of Ecalcidene.

Johnson & Johnson License Agreements

In May 2002, we licensed our initial portfolio of product candidates, other than Ecalcidene, and the patents and other intellectual property and know-how, test data, marketing data and other tangible property associated with those product candidates, from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., under two similar but separate intellectual property transfer and license agreements. In September 2004, we amended these two intellectual property transfer and license agreements to provide for revised territories and exclusivity terms.

Under these license agreements, we obtained exclusive licenses to a portfolio of patents and non-exclusive licenses to related know-how to make, use and sell our initial product candidates in the field of dermatology. For purposes of the agreements, the field of dermatology includes applications for the treatment or prevention of diseases of human skin, hair, nails and oral and genital mucosa, but excludes treatments for skin cancer. We also have access to classes of compounds claimed in the patents licensed to us under the agreements, which we can screen in our search for new product candidates in the field of dermatology. If we or an affiliate of Johnson & Johnson advance one of these compounds to Phase 1 clinical development, the developing party must give notice to the other party when the developing party has initiated a Phase 1 clinical trial for the particular compound. At that point, the other party must discontinue any development or commercialization of that compound for any indication in any field for so long as the compound continues to be in active clinical development or commercialization by the developing party. In addition, neither Johnson & Johnson nor its affiliates may develop Liarozole, Rambazole, Azoline Hivenyl, Atopik and several specified preclinical candidates in any formulation for any indication in any field. In exchange for these licenses, we issued an aggregate of 8,333,333 shares of our series A convertible preferred stock to Johnson & Johnson Consumer Companies, Inc. and Janssen Pharmaceutica Products, L.P.

License Terms for Our Product Candidates

The following is a summary of the terms of the license agreements with respect to our existing product candidates and to any products that we may develop from the classes of compounds claimed in the patents licensed to us:

Royalties. The licenses are royalty free.

Territories and Exclusivity. The licenses are exclusive throughout most of the world, except that our right to sell the following products in the following territories is semi-exclusive with the Johnson & Johnson companies:

- Zimycan in Argentina, Australia, Belgium, Denmark, Germany, Indonesia, Luxembourg, Mexico, New Zealand, Peru and Venezuela; and

- Ketanserin in South America.

In addition, we have not been granted the right to sell oxatomide in Japan, Italy, Mexico and much of Central America or ketanserin in Mexico, Central America and the Caribbean.

Commercialization and Manufacturing Rights. We have the sole right to commercialize any product candidate covered by intellectual property licensed to us under the license agreements that we elect to commercialize ourselves or with the assistance of a contract sales organization. In other circumstances, however, Johnson & Johnson, through any of its affiliates, has a right of first negotiation for the commercialization of our product candidates based on such intellectual property. The rights of first negotiation for the commercialization of our product candidates can be exercised on a territory-by-territory basis. The material elements of these rights are as follows:

- If we intend to commercialize any product through a third party, other than a contract sales organization, in a particular territory, we must provide notice of this intention in accordance with the provisions of the license agreements. Johnson & Johnson has 90 days after the provision of this notice to advise us if it desires to enter into a commercialization agreement for that product in that territory.

- If, prior to the expiration of the 90-day offer period we do not receive that notice, we may enter into a commercialization agreement with a third party for that product without further restrictions or obligations under these rights of first negotiation.

- If, prior to the expiration of the 90-day offer period we do receive that notice, we must negotiate exclusively for 90 days to execute a commercialization agreement.

- If we do not agree on a definitive agreement within the 90-day negotiation period, we may, at any time within a specified period of time after the end of the 90-day negotiation period, enter into a commercialization agreement for that product with a third party so long as the terms are not, taken as a whole, materially less favorable to us than those proposed by the Johnson & Johnson affiliate with which we were negotiating.

- If within the specified negotiation period, we intend to enter into a commercialization agreement with a third party with terms materially less favorable to us than those proposed by the Johnson & Johnson affiliate or, if after the specified negotiation period, we intend to enter into a commercialization agreement with a third party on any terms, then Johnson & Johnson, through any of its affiliates, is entitled to an additional 45-day offer period to express an interest in commercializing that product. If, prior to the termination of the additional 45-day offer period, Johnson & Johnson notifies us of its interest in commercializing the product, we must negotiate exclusively for 60 days to execute a commercialization agreement.

- If we enter into a commercialization agreement with an affiliate of Johnson & Johnson, it will have the right to negotiate a manufacturing agreement with us relating to that particular

product in the territory covered by the commercialization agreement. The terms of the right of first negotiation for a manufacturing agreement are the same as the terms of the right of first negotiation for a commercialization agreement.

We triggered this right of first negotiation with respect to Sebazole, Liarozole and ketanserin by indicating our intention to commercialize these product candidates outside the United States through third-party arrangements. The 90-day offer period for these product candidates in this territory has expired. Therefore, if we receive marketing approvals, we have the exclusive right to commercialize Sebazole, Liarozole and ketanserin outside the United States, either by ourselves or with a third party, in the territories in which we hold these licenses under the license agreements. In addition, because we intend to commercialize these four product candidates in the United States ourselves, the rights of first negotiation do not apply to these product candidates in the United States. If we later decide to commercialize any of these product candidates in the United States through a third party, other than a contract sales organization, we will trigger the right of first negotiation with respect to that product candidate. In addition, we triggered this right of first negotiation with respect to Zimycan by indicating our intention to commercialize this product candidate through third-party arrangements in all territories in which we hold commercialization rights, including the United States. The 90-day offer period for Zimycan has expired. Therefore, if we receive marketing approvals, we have the exclusive right to commercialize Zimycan, either by ourselves or with a third party, in all such territories.

Term and Termination. The license agreements expire on a country-by-country basis and product-by-product basis after the later of 10 years from the execution date or the expiration of the last patent included in the license agreement in the particular country. Following expiration of the license agreements with respect to a product, we receive a fully paid, royalty-free license applicable to that product in the particular country. These licenses may be terminated on a product-by-product basis, if, by dates specified in the license agreements, we are not conducting active clinical trials of the particular product or if we do not obtain regulatory approval for that product. Either of the license agreements may be terminated if we breach that agreement and do not cure the breach within 90 days or in the event of our bankruptcy or liquidation.

Additional Terms Applicable to Hyphanox

The following is a summary of agreement terms that are unique to Hyphanox:

Royalties. The license is royalty free unless we decide to use a third party to commercialize Hyphanox, in which case we will owe a royalty based on our net sales of Hyphanox. This royalty would also apply to sales by a successor company in the event of a change of control.

Territories and Exclusivity. The license is exclusive and worldwide.

Janssen Option. Janssen has an exclusive option to acquire the right to commercialize Hyphanox on a geographic region-by-region basis. We are obligated to notify Janssen if we are able to manufacture Hyphanox batches that are reproducible and bioequivalent with the Janssen melt extrusion formulation or Sporanox or if we prove clinical efficacy in subsequent Phase 3 clinical trials. Janssen has 90 days following its receipt of this notice to inform us if it wishes to exercise its option and, if so, for which territories. If Janssen exercises its option, we will enter into a license agreement in a form that we have already negotiated pursuant to which Janssen will become obligated to:

- pay us an up-front license fee and a regulatory milestone payment;
- reimburse us for our reasonable development costs related to Hyphanox; and

- pay us a royalty on net sales of Hyphanox, including a provision for minimum royalties by territory.

As described elsewhere in this document, because the data from our bioequivalence study of Hyphanox relative to Sporanox indicate that the bioavailability of Hyphanox relative to Sporanox is slightly above the upper limit of the regulatory range for bioequivalence, the study did not demonstrate their bioequivalence. As a result, our bioequivalence study did not trigger this option. However, this option may be triggered if any other study we conduct demonstrates bioequivalence or if our Phase 3 clinical trials for Hyphanox demonstrate clinical efficacy.

We retain the right to commercialize Hyphanox in each of the territories of the world for which Janssen does not exercise its option. If we commercialize Hyphanox through a licensee or sublicense in any country in which we retain commercialization rights, we are obligated to pay Janssen a royalty on our net sales of Hyphanox. If we distribute Hyphanox ourselves or use a contract marketing or sales organization to distribute Hyphanox in any country in which we retain commercialization rights, we are not required to pay Janssen a royalty. If we do not enter into a commercialization agreement with a third party during a specified period following the 90-day period after we provide the notice to Janssen described above, Janssen is entitled to specified rights of first negotiation.

Abbott Development and Supply Agreement

In May 2002, we entered into a development and supply agreement with Abbott GmbH & Co. KG under which Abbott agreed to assist us in developing an itraconazole product using Abbott's proprietary melt extrusion manufacturing process. Pursuant to the agreement, we are required to pay agreed upon development costs and fees to Abbott. In addition, the agreement provides that as soon as reasonably possible after we submit an NDA for Hyphanox, we will enter into a supply agreement with Abbott under which Abbott will be our sole supplier and manufacturer of Hyphanox. Under the terms of the supply agreement, Abbott will be required to manufacture the itraconazole melt extrudate used in the manufacture of Hyphanox exclusively for us or our designee.

Grupo Ferrer Distribution and License Agreement

In November 2004, we entered into a distribution and license agreement with Grupo Ferrer Internacional, S.A. The agreement provides for Grupo Ferrer to be our exclusive marketer and distributor of our Zimycan, Sebazole, Liarozole and ketanserin product candidates in several countries throughout Europe, Latin America and Africa. In addition to marketing and distributing the products, Grupo Ferrer will assist us in obtaining regulatory approvals for the products in the territories.

Under the agreement, we will receive our primary revenues from the sale of finished products to Grupo Ferrer. The agreement also provides for an initial fee of €500,000, or approximately $650,000, which we received in January 2005, and we may receive up to an additional €600,000, or approximately $780,000, based on the achievement of certain regulatory and sales milestones.

The distribution and license agreement expires on a country-by-country basis and product-by-product basis after the later of 10 years from the date of the first commercial sale with respect to a product or the expiration of the last patent covering the product in the particular country. Following the expiration of the agreement with respect to a product in a particular country, Grupo Ferrer's right to distribute and manufacture the product will become non-exclusive and royalty-free. If, following expiration, Grupo Ferrer desires to continue to utilize any of our trademarks; it could do so for a nominal royalty.

Patent Protection and Intellectual Property; Orphan Drug; Hatch-Waxman Act; Pediatric Treatment Exclusivity

We are pursuing a number of methods to establish and maintain market exclusivity for our product candidates, including seeking patent protection for our product candidates, the use of statutory market exclusivity provisions and otherwise protecting our intellectual property.

Patents and Intellectual Property Protection

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Our patent portfolio includes patents and patent applications with claims directed to the active ingredients, pharmaceutical formulations, methods of use and methods of manufacturing of a number of our product candidates. We include a discussion of our proprietary rights related to each of our later stage products and the applicable limitations to our rights in the discussion of those products elsewhere in this "Business" section and in the "Risk Factors" section.

United States patents issuing from patent applications filed on or after June 8, 1995 have a term of twenty years from the earliest claimed priority date. For United States patents in force on or after December 8, 1994 that issued from applications filed before June 8, 1995, the term is the greater of twenty years from the earliest claimed priority date or seventeen years from the date of issue.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Orphan Drug Designation

Some jurisdictions, including Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. The FDA and the Commission for the European Community have granted Liarozole orphan drug status for the treatment of congenital ichthyosis. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.

Under European Union medicines laws, criteria for designation as an “orphan medicine” are similar but somewhat different from those in the United States. Orphan medicines are entitled to ten years of market exclusivity, except under certain limited circumstances comparable to United States law. During this period of market exclusivity, no “similar” product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits.

The Hatch-Waxman Act

Under the United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active ingredient. Hatch-Waxman prohibits an abbreviated new drug application, an ANDA, or an NDA where the applicant does not own or have a legal right of reference to all the data required for approval, to be submitted by another company for another version of such drug during the five year exclusive period. Protection under Hatch-Waxman will not prevent the filing or approval of another full NDA, however, the applicant would be required to conduct its own adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new NDAs with new clinical trials for previously approved drugs and supplemental NDAs, for example, for new indications, dosages, or strengths of an existing drug, if new clinical investigations are essential to the approval. This three year exclusivity covers only the new changes associated with the supplemental NDA and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient.

The Hatch-Waxman Act also permits a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that

application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We are considering applying for patent term extensions for some of our current patents, to add patent life beyond the expiration date, depending on the expected length of clinical trials and other factors involved in the filing of a new drug application.

Pediatric Treatment Exclusivity

The Best Pharmaceuticals for Children Act signed into law January 4, 2002, provides an additional six months of marketing exclusivity for new or marketed drugs for specific pediatric studies conducted at the written request of the FDA. On December 3, 2003, President Bush signed the Pediatric Research Equity Act of 2003, or PREA, into law, authorizing the FDA to require pediatric studies for drugs to ensure the drugs' safety and efficacy in children. PREA requires that new NDAs or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from PREA. Unless otherwise required by regulation, PREA does not apply to any drug for an indication with orphan designation.

Manufacturing

We have no experience in, and we do not own any facilities for, manufacturing products or our product candidates. We have relied and will continue to rely on third-party contract manufacturers to produce sufficient quantities of our product candidates for use in our preclinical studies and clinical trials. Except as described below, we are not obligated to obtain our product candidates from any particular third-party contract manufacturer, and we believe that we would be able to obtain our product candidates from a number of third-party manufacturers at comparable cost.

If any of our product candidates are approved, we plan to rely on third-party contract manufacturers to produce sufficient quantities for large scale commercialization. Johnson & Johnson and its affiliates has a right of first negotiation for the manufacture of our product candidates in some circumstances, the terms of which are described above under the caption "—Johnson & Johnson License Agreements." If we do enter into manufacturing arrangements with third parties, these contract manufacturers will be subject to extensive governmental regulation. Regulatory authorities in the markets which we intend to serve require that drugs be manufactured, packaged and labeled in conformity with current Good Manufacturing Practices, or cGMPs. In this regard, we plan to engage only contract manufacturers who have the capability to manufacture drug products in compliance with cGMPs in bulk quantities for commercialization.

Our product candidates include both oral and topical formulations and are produced through a variety of manufacturing processes of varying degrees of difficulty. For example, Zimycan is produced through a fairly common process, which combines miconazole in a zinc oxide and petrolatum base, while Hyphanox is manufactured as a tablet using a proprietary melt extrusion process that is currently only available through our development agreement with a contract manufacturer. The active pharmaceutical ingredients of three of our later stage product candidates are generic and are currently available from a number of suppliers. The active pharmaceutical ingredient of Liarozole and a number of our earlier stage clinical candidates are proprietary. We are currently in the process of negotiating contracts with third

parties to develop and supply us with these active pharmaceutical ingredients as well as finished products on commercial scale.

Marketing and Sales

We currently have no sales or distribution capabilities and limited marketing capabilities. However, we have a Chief Commercial Officer with significant experience in sales and marketing roles at large pharmaceutical companies. We have also hired, and plan to continue to hire, additional experienced, qualified employees to our commercial team. In addition, we contracted with a third party for logistics and distribution services. In order to commercialize any of our product candidates, we must either continue to internally develop or acquire sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services for us.

In the United States and Canada, we plan to build our own sales force to market our product candidates that receive marketing approval directly to dermatologists and other target physicians. The dermatological medical communities in the United States and Canada are relatively small. We believe that we can best serve this discrete target physician market with a focused, specialty sales force. We believe that by developing our own sales force, we can control marketing efforts more effectively and obtain better access to the physicians that we target. We are, however, engaged in discussions with parties who could provide sales and distribution services for us as a contract sales organization until we are able to build our sales force or until we have sufficient products to market in the United States. If we initially use a contract sales organization, we may transition the contract sales organization into a proprietary sales force. In general, should we decide to enter into third-party distribution arrangements and marketing alliances for the marketing and sale of any of our later stage product candidates in the United States, we would first need to trigger the right of first negotiation with respect to any such product as further described under the caption "—Johnson & Johnson License Agreements." In addition, we have entered into an agreement with a third party to distribute, if approved, our Zimycan product candidate to health care institutions in the United States and Canada.

We intend to market our products globally. We have entered into third-party distribution arrangements and marketing alliances for some of our later stage product candidates with potential collaborators and distributors for the major countries outside the United States and Canada in addition to less significant markets. In addition to the agreement with Grupo Ferrer described above, we have distribution agreements for Zimycan for the United Kingdom, Ireland, Israel, Turkey, the territories administered by the Palestinian Authority and Scandinavia. We plan to enter into similar third-party distribution arrangements and marketing alliances for our other products when and if we determine that these products have progressed to later stages of development.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, and import and export of our proposed products. All of our product candidates will require regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. Various federal, state, local, and foreign statutes and regulations also govern testing, manufacturing, safety, labeling, storage and record-keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent substantial compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations. If we fail to comply with the applicable requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

The steps required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- execution of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication for which approval is sought;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP; and
- FDA review and approval of the NDA.

Preclinical studies generally are conducted in laboratory animals to evaluate the potential safety and activity of a product. Violation of the FDA's good laboratory practices regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. In the United States, drug developers submit the results of preclinical trials, together with manufacturing information and analytical and stability data, to the FDA as part of the IND, which must become effective before clinical trials can begin in the United States. An IND becomes effective 30 days after receipt by the FDA unless before that time the FDA raises concerns or questions about issues such as the proposed clinical trials outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. If these concerns or questions are unresolved, the FDA may not allow the clinical trials to commence.

Pilot studies generally are conducted in a limited patient population to determine whether the product candidate warrants further clinical trials based on preliminary indications of efficacy. These pilot studies may be performed in the United States after an IND has become effective or outside of the United States prior to the filing of an IND in the United States in accordance with government regulations and institutional procedures in the country in which the trials are conducted.

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in assessing the safety and the effectiveness of the drug. Each protocol must be submitted to the FDA as part of the IND prior to beginning the trial.

Typically, clinical evaluation involves a time-consuming and costly three-phase sequential process, but the phases may overlap. Each trial must be reviewed, approved and conducted under the auspices of an independent institutional review board, and each trial must include the patient's informed consent.

Phase 1 Refers typically to closely monitored clinical trials and includes the initial introduction of an investigational new drug into human patients or healthy volunteer subjects. Phase 1 clinical trials are designed to determine the safety, metabolism and pharmacologic actions of a drug in humans, the potential side effects associated with increasing doses of the product candidate and, if possible, to gain early evidence of the product candidate's effectiveness. Phase 1 trials also include the study of structure-activity relationships, drug metabolism and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. During Phase 1 clinical trials, sufficient information about a drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid Phase 2 studies. The total number of subjects and patients included in Phase 1 clinical trials varies, but are generally in the range of 20 to 80 people.

Phase 2 Refers to controlled clinical trials conducted to evaluate appropriate dosage and the effectiveness of a drug for a particular indication or indications in patients with a disease or condition under study and to determine the common short-term side effects and risks associated with the drug. These clinical trials are typically well controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Although the FDA regulations do not do so, it is common practice in the pharmaceutical industry to sometimes distinguish Phase 2 clinical trials as Phase 2a and Phase 2b. In general, we believe that the common understanding in the industry of Phase 2a and Phase 2b is as follows:

- Phase 2a refers to a clinical trial in a targeted patient population to evaluate preliminary efficacy and/or further safety of a drug candidate. One or more of the following properties may be evaluated: dose response, duration of effect and kinetic/dynamic relationship.

- Phase 2b refers to a controlled dose ranging clinical trial to evaluate further the efficacy and safety of a candidate drug in a targeted patient population and to attempt to define an appropriate dosing regimen.

Phase 3 Refers to expanded controlled and uncontrolled clinical trials. These clinical trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained. Phase 3 clinicals are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 trials usually include from several hundred to several thousand subjects.

Phase 1, 2 and 3 testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the United States and may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. A clinical program is designed after assessing the causes of the disease, the mechanism of action of the active pharmaceutical ingredient of the product candidate and all clinical and preclinical data of previous trials performed. Typically, the trial design protocols and efficacy endpoints are established in consultation

with the FDA. Upon request through a special protocol assessment, the FDA can also provide specific guidance on the acceptability of protocol design for clinical trials. The FDA, an institutional review board, or we may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug.

Assuming successful completion of the required clinical trials, drug developers submit the results of preclinical studies and clinical trials, together with other detailed information including information on the manufacture and composition of the product, to the FDA, in the form of an NDA, requesting approval to market the product for one or more indications. In most cases, the NDA must be accompanied by a substantial user fee. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use.

Before approving an application, the FDA will inspect the facility or facilities at which the product is manufactured. The FDA will not approve the application unless cGMP compliance is satisfactory. The FDA will issue an approval letter if it determines that the application, manufacturing process and manufacturing facilities are acceptable. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a not approvable letter.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. Furthermore, the FDA may prevent a drug developer from marketing a product under a label for its desired indications or place other conditions on distribution as a condition of any approvals, which may impair commercialization of the product. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Similar regulatory procedures must also be complied with in countries outside the United States.

If the FDA approves the new drug application, the drug becomes available for physicians to prescribe in the United States. After approval, the drug developer must comply with a number of post-approval requirements, including delivering periodic reports to the FDA, submitting descriptions of any adverse reactions reported, and complying with drug sampling and distribution requirements. The holder of an approved NDA is required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Also, quality control and manufacturing procedures must continue to conform to cGMPs after approval. Drug manufacturers and their subcontractors are required to register their facilities and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMPs which imposes certain procedural and documentation requirements relating to quality assurance and quality control. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance. The FDA may require post market testing and surveillance to monitor the product’s safety or efficacy, including additional studies, known as Phase 4 trials, to evaluate long-term effects.

In addition to studies requested by the FDA after approval, a drug developer may conduct other trials and studies to explore use of the approved compound for treatment of new indications, which require FDA approval. The purpose of these trials and studies is to broaden the application and use of the drug and its acceptance in the medical community.

We use, and will continue to use, third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered with the three-phase sequential process that is discussed above under "— United States Governmental Regulation."

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. This authorization is a marketing authorization approval, or MAA. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

Competition

The pharmaceutical industry and the dermatology segment in particular, is highly competitive and include a number of established, large and mid-sized pharmaceutical companies, as well as smaller emerging companies, whose activities are directly focused on our target markets and areas of expertise. If approved, our product candidates will compete with a large number of products that include over-the-counter treatments, prescription drugs specifically indicated for a dermatological condition and prescription drugs that are prescribed off-label. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the

pharmaceutical industry at a rapid pace. These developments may render our product candidates or technologies obsolete or noncompetitive.

Our recently acquired Solagé® product faces competition in the treatment of solar lentigenes from Triluma from Galderma S.A., Avage from Allergan, Inc., EpiQuin Micro from SkinMedica, Inc. and other prescription 4% hydroquinone formulations as well as over-the-counter 2% hydroquinone products, Retin-A from Neutrogena and other tretinoin containing topical formulations.

If approved, each of our product candidates will compete for a share of the existing market with numerous products that have become standard treatments recommended or prescribed by physicians. For example, we believe the primary competition for our product candidates are:

- For Zimycan, in the treatment of diaper dermatitis complicated by candidiasis, ointments and creams containing nystatin, Mycolog II from Bristol-Myers Squibb Company, clotrimazole containing creams from Bayer AG and from generic manufacturers and topical miconazole creams.

- For Sebazole, in the treatment of seborrheic dermatitis, Nizoral from Janssen, Desowen from Galderma S.A., Loprox from Medicis Pharmaceutical Corporation and the generic equivalents of each.

- For Hyphanox, in the treatment of vaginal candidiasis, Diflucan from Pfizer Inc., generic fluconazole tablets, Sporanox from Janssen and generic itraconazole capsules. For Hyphanox, in the treatment of onychomycosis, Sporanox from Janssen, Lamisil from Novartis AG and Penlac from Dermik Laboratories.

- For Liarozole, in the treatment of congenital ichthyosis, Soriatane from Hoffmann-La Roche Inc. and Connetics Corporation and over-the-counter topical moisturizers and emollients.

- For oral Rambazole, in the treatment of acne, Accutane from Hoffman-La Roche and generic manufacturers. For oral Rambazole, in the treatment of psoriasis, Soriatane from Hoffman-La Roche and Connetics, biologic agents such as Amevive from Biogen Idec Inc. and Raptiva from Genentech, Inc., methotrexate from generic manufacturers.

We also believe that many of the competitive products for our later stage product candidates and Rambazole will similarly compete with our earlier stage product candidates because of the indications for these product candidates.

We expect to compete on, among other things, the efficacy of our products, the reduction in adverse side effects experienced and more desirable treatment regimens, combined with the effectiveness of our experienced management team. Competing successfully will depend on our continued ability to attract and retain skilled and experienced personnel, to identify, secure the rights to and develop pharmaceutical products and compounds and to exploit these products and compounds commercially before others are able to develop competitive products. In addition, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of generic products making branded products less attractive, from a cost perspective, to buyers.

Although we believe that, if approved, our product candidates will have favorable features for the treatment of their intended indications, existing treatments or treatments currently under clinical development that also receive regulatory approval may possess advantages in competing for market share.

Third-Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Employees

As of December 31, 2004, we had 64 employees, all of whom were full-time employees. Fourteen of our employees hold Ph.D., M.D. or equivalent degrees. Of the total 64 employees, 43 are located at our corporate headquarters in Princeton, New Jersey, 20 are located at the facility of our subsidiary, Barrier Therapeutics, N.V. in Geel, Belgium and one is located in Canada. None of our employees is represented by a collective bargaining arrangement, and we believe our relationship with our employees is good.

Trademarks

We are seeking United States trademark registrations for our proposed trademarks Barrier Therapeutics™, Sebazole™, Zimycan™, Hyphanox™, Rambazole™ and Hivenyl™. Liarozole, Azoline and Atopik are temporary designations. We are developing commercial names for Liarozole, Azoline and Atopik product candidates. In connection with our acquisition of the Solagé® product, we acquired the rights to the United States and Canadian trademark registrations for Solagé® Topical Solution.

Available Information

We maintain a website at www.barriertherapeutics.com. We make available free of charge through the Investor Relations section of our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. We include our website address in this Annual Report on Form 10-K only as an inactive textural reference and do not intend it to be an active link to our website. The material on our website is not part of our Annual Report on Form 10-K. You may also obtain a free copy of these reports and amendments by contacting our General Counsel at Barrier Therapeutics, Inc., 600 College Road, Suite 3200, Princeton, NJ 08540.

ITEM 2. PROPERTIES

We lease approximately 20,300 square feet of administrative offices at our corporate headquarters, which is located in Princeton, New Jersey. We also lease approximately 10,600 square feet of administrative offices in Geel, Belgium. Our Princeton, New Jersey lease expires in 2010 if not renewed by September 30, 2010, and our lease in Belgium is short-term and renewable. We believe that our current facilities are adequate for our present purposes.

ITEM 3. LEGAL PROCEEDINGS

We are currently not a party to any material legal proceedings.

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

We did not submit any matters to the vote of security holders during the fourth quarter of fiscal 2004.

OUR EXECUTIVE OFFICERS

The following table identifies our current executive officers:

Name	Age	Position
Geert Cauwenbergh, Ph.D	51	Chairman of the Board, Chief Executive Officer and Director
Charles T. Nomides	48	Chief Operating Officer
Marcel Borgers, Ph.D	65	Chief Scientific Officer
Alfred Altomari.....	46	Chief Commercial Officer
Anne M. VanLent	57	Executive Vice President, Chief Financial Officer and Treasurer
Albert C. Bristow.....	35	General Counsel and Secretary

Geert Cauwenbergh, Ph.D. is the founder of our company and has been our Chairman of the Board and Chief Executive Officer since our inception in September 2001. Prior to joining us, Dr. Cauwenbergh was at Johnson & Johnson Consumer and Personal Care Products Companies from 2000 to 2002 where he served in various capacities, most recently as Vice President of Technology. From 1994 to 2000, Dr. Cauwenbergh was at Johnson & Johnson Consumer Companies Worldwide where he served in various capacities, most recently as Vice President of Research & Development. He received his Ph.D. in Medical Sciences from the Catholic University of Leuven, Faculty of Medicine, Belgium where he also completed his Masters and undergraduate work.

Charles T. Nomides has been our Chief Operating Officer since July 2002. Prior to joining us, Mr. Nomides was at Johnson & Johnson Consumer Products Worldwide from 1997 to 2002 where he most recently served as Director of Research and Development in charge of the Ortho Neutrogena prescription drug development group. Mr. Nomides received a bachelor's degree in Biology from Clarion State University and received graduate training from Temple University and The Milton S. Hershey Medical Center.

Marcel Borgers, Ph.D. has been our Chief Scientific Officer and Chairman of our Scientific Advisory Board since May 2002. Prior to joining us, from September 1969 to April 2000, Dr. Borgers was the Vice President of Life Sciences for the Janssen Research Foundation. Dr. Borgers held the Dr. Paul Janssen Chair in Cell Biology at the University of Antwerp from 1992 to 2002. Dr. Borgers also has

served as a professor at the Faculty of Medicine and Pharmaceutical Sciences of the Free University of Brussels since 1994 and as a Professor of Cell Biology, Faculty of Medicine, University of Maastricht, the Netherlands since 1991. He received his doctorate in sciences from the University of Paris, Faculty of Sciences.

Alfred Altomari has been our Chief Commercial Officer since August 2003. Prior to joining us, Mr. Altomari was at affiliates of Johnson & Johnson from 1982 to 2003 where he most recently served as General Manager of the Ortho Neutrogena prescription drug development group. Mr. Altomari also serves as a director of Agile Therapeutics, Inc. Mr. Altomari received a bachelor's degree in Science with a dual major in finance and accounting from Drexel University and received his M.B.A. from Rider University.

Anne M. VanLent has been our Executive Vice President, Chief Financial Officer and Treasurer since May 2002. Prior to joining us, Ms. VanLent served as a principal of the Technology Compass Group, LLC, a healthcare/technology consulting firm, since she founded it in October 2001. From July 1997 to October 2001, she was the Executive Vice President—Portfolio Management for Sarnoff Corporation, a multidisciplinary research and development firm. Ms. VanLent also currently serves as a director of Penwest Pharmaceuticals Co. and Integra Lifesciences Holdings Corp. She received a bachelor's degree in Physics from Mount Holyoke College and did graduate work in biophysics.

Albert C. Bristow has been our General Counsel since October 2003. Mr. Bristow was an attorney with Morgan, Lewis & Bockius LLP, Princeton, New Jersey, from January 2000 until joining us, and an attorney with Archer & Greiner, Haddonfield, New Jersey, from September 1995 until January 2000. Mr. Bristow received a bachelor's degree in the Arts from Lafayette College and a J.D. from the University of Pennsylvania.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is quoted on the NASDAQ National Market under the symbol "BTRX." We began trading on the NASDAQ National Market on April 29, 2004. The following table sets forth the range of high and low sale prices for the common stock as reported on the NASDAQ National Market for the periods indicated below.

	High	Low
2004		
Second Quarter (Commencing April 29, 2004)	$15.75	$10.86
Third Quarter	$15.00	$8.50
Fourth Quarter	$18.11	$11.70

As of March 23, 2005 there were 34 holders of record of our Common Stock. On March 23, 2005, the last reported sale price of our common stock as reported on the NASDAQ National Market was $15.46 per share.

We have not paid any dividends on our common stock since our inception and do not anticipate paying any dividends on our Common Stock in the foreseeable future.

Recent Sales of Unregistered Securities

In the preceding three years, we have issued the following securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act") (the option, share and price numbers below give effect, where applicable, to the one-for-two reverse stock split of our common stock, which was completed prior to the closing of our initial public offering, or IPO):

Since our inception in September 2001, we have issued an aggregate of 837,750 shares of common stock, par value $0.0001 per share. These shares include a total of 712,500 shares of common stock issued between October 31, 2001 and February 20, 2002, at a purchase price per share of $0.002, for a total of $1,425 in cash, a total of 110,000 shares of common stock issued between August 1, 2002 and October 24, 2002, at an average purchase price per share of $0.60, for a total of $66,000 in cash. In addition, we issued a total of 15,250 shares of common stock issued upon the exercise of outstanding options between February 4, 2004 and the IPO, at an average purchase price per share of $2.29, for a total of $34,850 in cash.

Since our inception, we have also issued an aggregate of 31,921,809 shares of preferred stock, par value of $0.0001 per share. These shares include 8,333,333 shares of series A convertible preferred stock issued on May 7, 2002 in exchange for intellectual property, patent applications and licenses valued at approximately $25,000,000, 7,716,670 and 7,666,666 shares of series B convertible preferred stock issued on May 3, 2002 and May 7, 2003, respectively, at a purchase price per share of $3.00, for a total of approximately $46,150,008, and 8,205,140 shares of series C convertible preferred stock issued on October 23, 2003 at a purchase price per share of $3.90, for a total of approximately $32,000,046. In connection with our IPO, all shares of preferred stock were converted into common stock on a 2 shares of preferred for 1 share of common basis.

No underwriters were involved in the foregoing sales of securities. The securities described in this Item 5 were issued to United States investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Rule 506 of Regulation D promulgated thereunder relative to sales by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of our convertible preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration.

The issuance of stock options and the common stock issuable upon the exercise of such options as described in this Item 5 were issued pursuant to written compensatory plans or arrangements with the Registrant's employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about the Registrant or had access, through employment or other relationships, to such information.

Use of Proceeds from Sales of Registered Securities

On May 4, 2004, we closed the sale of 5,000,000 shares of our common stock in our initial public offering (the "Offering"). The Registration Statement on Form S-1 (Reg. No. 333-112539) (the "Registration Statement") we filed to register our common stock in the Offering was declared effective by the Securities and Exchange Commission on April 29, 2004. The Offering commenced as of April 29, 2004 and did not terminate before any securities were sold. The offering was completed and all shares

were sold at an initial price per share of $15.00. The aggregate purchase price of the Offering amount registered was $75,000,000.

The managing underwriters for the Offering were Morgan Stanley & Co. Incorporated, Banc of America Securities LLC and J.P. Morgan Securities Inc. We incurred expenses in connection with the Offering of $7.05 million, which consisted of direct payments of: (i) $1.5 million in legal, accounting and printing fees; (ii) $5.25 million in underwriters' discounts, fees and commissions; and (iii) $0.3 million in miscellaneous expenses.

After deducting expenses of the Offering, we received net offering proceeds of approximately $68 million. As of December 31, 2004, we held the $68 million proceeds, all of which are invested in marketable securities. We intend to use these remaining proceeds to advance our product candidates through preclinical and clinical trials, for commercialization of our products, for general corporate purposes including acquisition or in-licensing of products or product candidates, and for working capital. We regularly assess the specific uses and allocations for these funds.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data presented below for, and as of the end of, each of our last four fiscal years has been derived from and is qualified by reference to our consolidated financial statements. Our consolidated financial statements for the fiscal years ended December 31, 2004, 2003 and 2002 and for the period beginning on our inception and ending on December 31, 2001 have been audited by Ernst & Young LLP, independent certified public accountants.

This information should be read in conjunction with our consolidated financial statements and the related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" which is Item 7 of Part II of this annual report on Form 10-K.

We have not paid any cash dividends on our shares of Common Stock during the periods presented.

	Year Ended December 31,				Period From September 17, 2001 (inception) to December 31,
	2004	2003	2002	2001	2004
	(in thousands, except share and per share data)				
Consolidated Statement of Operations Data:					
Revenues:					
Contract revenue	$ 100	$ —	$ —	$ —	$ 100
Grant revenue	797	367	—	—	1,163
Total revenues	897	367	—	—	1,263
Operating expenses:					
Research and development	30,905	17,485	3,542	—	51,931
Sales and marketing	4,310	—	—	—	4,310
General and administrative	7,164	3,730	1,532	20	12,446
In-process research and development	—	—	25,000	—	25,000
Total operating expenses	42,379	21,215	30,074	20	93,687
Loss from operations	(41,482)	(20,848)	(30,074)	(20)	(92,424)
Interest income	1,409	419	275	—	2,102
Interest expense	(37)	(3)	(5)	(1)	(45)
Loss before income tax benefit	(40,110)	(20,432)	(29,804)	(21)	(90,367)
Income tax benefit	367	217	—	—	584
Net loss	(39,743)	(20,215)	(29,804)	(21)	(89,783)
Preferred stock accretion	(4,592)	(8,432)	(3,392)	—	(16,417)
Net loss attributable to common stockholders	$ (44,335)	$ (28,647)	$ (33,196)	$ (21)	$ (106,200)
Basic and diluted net loss per share	$ (3.02)	$ (83.95)	$ (240.75)		
Weighted average shares used in computing basic and diluted net loss per share	14,677,710	341,256	137,889		

	December 31,			
	2004	2003	2002	2001
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash, cash equivalents and marketable securities	$ 89,081	$ 53,776	$ 18,144	$ 89
Working capital	82,847	51,682	17,475	62
Total assets	92,784	56,971	19,296	107
Deficit accumulated during the development stage	(106,200)	(61,865)	(33,217)	(21)
Total stockholders' equity (deficit)	83,570	(61,534)	(33,198)	(20)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a pharmaceutical company focused on the discovery, development and commercialization of pharmaceutical products in the field of dermatology. Our goal is to develop a portfolio of innovative products that address major medical needs in the treatment of dermatological diseases and disorders. We currently market Solagé® in the U.S. for the treatment of solar lentigines, a common condition also known as "age spots" or "liver spots," and for the broader indication including related hyperpigmented lesions in Canada. Our product pipeline includes eight product candidates in various stages of clinical development. Our four most advanced product candidates are the following:

- *Zimycan:* an ointment for the treatment of infants with diaper dermatitis complicated by candidiasis, an inflammatory disease characterized by diaper rash complicated with an infection by a yeast called *Candida.*

- *Sebazole:* a gel for the treatment of seborrheic dermatitis, a type of eczema characterized by inflammation and scaling of the skin, principally of the scalp, face and chest.

- *Hyphanox:* an oral therapeutic for the treatment of fungal infections, including vaginal candidiasis, commonly known as vaginal yeast infection, and onychomycosis, commonly known as nail fungus.

- *Liarozole:* an oral therapeutic for the treatment of the group of conditions known as congenital ichthyosis, a rare genetic disease characterized by dryness and scaling of the skin.

We were incorporated in September 2001 and commenced active operations in May 2002. We have not generated any revenues from our product candidates. We have financed our operations and internal growth almost entirely through proceeds from private placements of preferred stock, our initial public offering in the second quarter of 2004 and our follow-on public offering in the first quarter of 2005. Through December 31, 2004 we were a development stage enterprise. We have incurred significant losses since our inception in 2001, as we have devoted substantially all of our efforts to research and development activities, including clinical trials. As of December 31, 2004, we had a deficit accumulated during the development stage of $106.2 million. Our deficit accumulated during the development stage has resulted primarily from our acquisition of the rights to our product candidates, our research and development activities and preferred stock accretion. We expect our operating losses to continue to increase as we do not expect to generate significant revenues in the near future, we expect to continue to increase our research and development costs, our costs of commercial operations are expected to increase, and we will continue to incur the costs of being a public company.

We expect to continue to spend significant amounts, including clinical trial costs, on the development of our product candidates. We plan to seek marketing approvals for our products in various countries throughout the world, particularly in the United States, Canada and Europe. We expect our costs to increase significantly as we continue to develop and ultimately commercialize our product candidates and acquired products, such as Solagé® . While we will be focusing on the clinical development of our later stage product candidates in the near term, we expect to increase our spending on earlier stage clinical candidates as well. We also plan to identify and develop, either internally or through collaborative agreements, additional product candidates that address major needs in dermatology through acquisitions or licenses of marketed dermatological products or rights to potential new products and product candidates that would fit within our growth strategy. Accordingly, we will need to generate significant revenues to achieve, and then maintain, profitability.

Drug development in the United States and most countries throughout the world is a process that includes several steps defined by the FDA and similar regulatory authorities in foreign countries. In the United States, the FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an investigational new drug application, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant expenses associated with clinical development are the Phase 3 clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a new drug application, or NDA, may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In order to commence clinical trials or marketing of a product outside the United States, we must obtain approval of the applicable foreign regulatory authorities. Although governed by the laws and regulations of the applicable country, clinical trials conducted outside the United States typically are administered with a similar three-phase sequential process.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, any of our product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- future clinical trial results;
- the expense of clinical trials for additional indications;
- the expense and timing of regulatory approvals;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Research and development expenses and purchased in-process research and development expense, in the aggregate, represented approximately 73% of our total operating expense for the year ended December 31, 2004, 82% of our total operating expenses for the year ended December 31, 2003 and 95% of our total operating expenses for the year ended December 31, 2002. Research and development expenses consist primarily of costs incurred for the conduct of our clinical trials, manufacturing development costs related to our clinical product candidates, personnel and related costs related to our research and product development activities and outside professional fees related to clinical development and regulatory matters.

Purchased in-process research and development expense represents costs incurred for the acquisition of our product candidates. During 2002, we expensed $25.0 million for in-process research and development solely as a result of our entering into our principal license agreements. Pursuant to these agreements, we obtained exclusive licenses to a portfolio of patents and non-exclusive licenses to related know-how, to make, use and sell our initial product candidates in the field of dermatology in many countries throughout the world. This transaction was accounted for as an acquisition of assets and consisted of several projects at various stages of development as well as access to the classes of compounds claimed in the patents licensed to us, which we can screen in our search for new product candidates in the field of dermatology. We acquired these assets under licenses from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., in exchange for the issuance of 8,333,333 shares of our series A convertible preferred stock, which were converted into 4,166,666 shares of our common stock in connection with our initial public offering.

During 2004, we incurred sales and marketing costs as we started to prepare for the launch of our first product, subject to obtaining requisite marketing approvals. Sales and marketing costs represented approximately 10% of our total operating expenses for the year ended December 31, 2004. We had no sales and marketing expenses in 2003. We expect these costs to increase as we launch acquired products and our product candidates which are subject to receiving regulatory approval. As a result of our acquisition of Solagé® , we expect to incur sales and marketing costs related to Solagé® . In addition, if we were to acquire or in-license other products, we would then incur sales and marketing costs related to such products. We expect these costs to include marketing expenses to prepare for the launch of our product candidates and acquired products, expenses related to a sales organization for those regions in which we decide to market our products ourselves and costs for marketing efforts to support third parties with whom we may collaborate in the future in regions where we do not market directly.

General and administrative expenses consist primarily of salaries and related expenses and costs of general corporate activities, including legal and accounting fees, insurance and consulting costs. General and administrative costs represented approximately 17% of our operating expenses for the year ended December 31 2004, 18% of our total operating expenses for the year ended December 31, 2003 and 5% of our total operating expenses for the year ended December 31, 2002.

We expect to continue to incur net losses over the next several years as we continue our clinical development, apply for regulatory approvals, enter into arrangements with third parties for manufacturing and distribution services and, if approved, market our products. We have a limited history of operations and anticipate that our quarterly results of operations will fluctuate for several reasons, including:

- the timing and extent of our research and development efforts;
- the timing and extent of our adding new employees and infrastructure;

- the timing of any contract, license fee or royalty payments that we may receive or be required to make; and

- the timing and outcome of our applications for regulatory approvals.

- the timing and extent of recognition of product and other revenue.

- the timing and extent of marketing and selling expenses.

Recent Developments

On February 15, 2005 we completed a follow-on offering of 2,000,000 shares of our common stock which resulted in net proceeds to the Company of approximately $36 million, after payment of underwriter's discounts, commissions and other fees.

In February 2005, we acquired the United States and Canadian rights to Solagé® (mequinol 2%, tretinoin 0.01%) Topical Solution. Under the terms of the acquisition, Barrier made an initial cash payment of $3 million and will make future payments totaling up to an additional $2 million, if certain sales targets are met. We were assigned all U.S. and Canadian marketing authorizations, patents, and trademarks for the product. The patent rights include U.S. and Canadian patents covering Solagé® 's pharmaceutical composition and methods of use until 2010.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and assumptions. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing at the end of this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

Contract revenues include license fees and other payments associated with collaborations with third parties. Revenue is generally recognized when there is persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectibility is reasonably assured.

Revenue from non-refundable, upfront license fees where we have a continuing involvement is recognized ratably over the performance period. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured. We periodically re-evaluate our estimates of the

performance period and revise our assumptions as appropriate. These changes in assumptions may affect the amount of revenue recorded in our financial statements in future periods.

We use revenue recognition criteria in Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements" and Emerging Issues Task Force ("EITF") Issue 00-21 "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). Revenue arrangements that include multiple deliverables, are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.

Grant revenues are recognized as the Company provides the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

In-process Research and Development

The amount of any in-process research and development expense is generally determined based on an analysis using risk-adjusted cash flows expected to be generated by products that may result from in-process technologies that have been acquired. We review the project rights that we acquire to determine the stage of their development, the probability of demonstrating in clinical trials sufficient safety and efficacy for FDA approval and product risk factors inherent in the drug development process. The product specific risk factors include the type of drug under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile and development plans. The valuation used to estimate in-process research and development expense requires us to use significant estimates and assumptions that, if changed, may result in a different valuation for in-process technology.

In connection with our license agreements with Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., each a Johnson & Johnson company, we reviewed the project rights that we acquired to determine the stage of their development, the probability of demonstrating in our clinical trials sufficient safety and efficacy for FDA approval and the technical milestones needed to be reached before commercialization is possible. We determined as of the acquisition date that for each project there was significant risk that our clinical trials may not demonstrate the levels of safety and efficacy needed for FDA approval and that each project had significant milestones to reach before commercialization. We also determined that all of the projects had no alternative future uses if they were not successful. Accordingly, we classified each product as in-process research and development and expensed their acquisition costs immediately.

We valued the assets acquired based on the value of the consideration that Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc. received in the transaction. Concurrent with the transaction, we issued for cash 15,333,336 shares of our series B convertible preferred stock, with similar characteristics to our series A convertible preferred stock, to investors not related to us or these companies. Based on the value of our series B convertible preferred stock, we valued the in-process research and development at $25.0 million.

Stock-based Compensation

Stock-based compensation charges represent the difference between the exercise price of options granted to employees and the fair value of our common stock on the date of grant for financial statement

purposes in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. We recognize this compensation charge over the vesting periods of the shares purchasable upon exercise of options. Should our assumptions of fair value change, the amount recorded as intrinsic value may increase or decrease in the future.

We recorded deferred stock-based compensation of $3.0 million and related amortization of $2.0 million during the year ended December 31, 2004. To date, we have recorded stock-based compensation of $3.7 million and related amortization expense of $2.2 million. We are applying a graded vesting amortization policy for our deferred compensation. This accelerated vesting method provides for vesting of portions of the overall award at interim dates and results in higher compensation expense in earlier years than straight-line amortization. Had we chosen to apply the straight line method of amortization of deferred compensation, our stock compensation charge would have been $1.1 million lower for the year ended December 31, 2004.

Stock-based compensation charges also include the periodic revaluation of stock options that we have granted to non-employees, in accordance with the provisions of Statement of Financial Accounting Standards No. 123 and Emerging Issues Task Force No. 96-18. Pursuant to this accounting literature, equity instruments, such as options, are required to be recorded at the fair value of the consideration received, or the fair value of the equity instrument issued, whichever may be more readily measured. For grants to our non-employees, the fair value of the equity instrument issued is more readily measured and we assign value to the options using a Black-Scholes methodology. As required, we revalue these options over the period when earned in accordance with their respective terms. Should our input assumptions change, for example, fair value of common stock at the measurement date, the fair value of our non-employee consultant compensation will change.

We recorded stock-based compensation expense totaling $756,000 for the year ended December 31, 2004, $107,000 for the year ended December 31, 2003 and $17,000 for the year ended December 31, 2002 in connection with the grant of stock options to our non-employees.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 123 (revised 2004) *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes Accounting Principal Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and amends FASB No. 95, *Statement of Cash Flows*. Generally, the approach to accounting in Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements as based on their fair values. Currently we account for these payments under the intrinsic value provisions of APB No. 25. Statement 123(R) is effective for us beginning July 1, 2005. The Statement offers several alternatives for implementation. At this time, our management has not made a decision as to the alternative it may select. We are in the process of determining how the new method of valuing stock-based compensation as prescribed by Statement 123(R) will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of additional non-cash compensation expense related to such awards will have on our financial statements.

Results of Operations

Years Ended December 31, 2004 and December 31, 2003

Revenue. To date, our revenue has consisted primarily of grant revenue. This represents income that we received under a grant from a Belgian governmental agency promoting technology in the Flemish

region of Belgium through research grants. Pursuant to the terms of the grant, we will receive €1.8 million, or approximately $2.0 million, over a three-year period, to fund research on early-stage, preclinical programs and compound screening. We are recognizing revenue as we perform qualifying work under this grant.

In addition, during the latter half of 2004, we recognized revenue related to a commercial contract. We expect to continue to recognize revenue from certain contracts during the first half of 2005. We expect that our revenue will fluctuate from year-to-year and quarter-to-quarter.

We recognized grant revenue of $797,000 for the year ended December 31, 2004 and grant revenue of $367,000 for the year ended December 31, 2003. Additionally, during the year December 31, 2004, we recognized $100,000 from a collaboration agreement which is being ratably recognized over the performance period.

Research and Development Expenses. Below is a summary of our research and development expenses for the years December 31, 2004 and 2003.

	Year ended December 31	
	2004	2003
	(in thousands)	
Sebazole	$ 5,750	$5,016
Hyphanox	8,391	4,864
Zimycan	1,778	1,774
Liarozole	1,249	334
Other clinical stage products	3,589	671
Research and preclinical stage products costs	1,896	713
Internal costs	8,251	4,112
Total research and development expenses	$ 30,904	$ 17,484

In the preceding table, research and development expenses are set forth in the following seven categories:

- *Sebazole*—third-party direct project expenses relating to the development of Sebazole and our former product candidate, Seboride.
- *Hyphanox*—third-party direct project expenses relating to the development of Hyphanox.
- *Zimycan*—third-party direct project expenses relating to the development of Zimycan.
- *Liarozole*—third-party direct project expenses relating to the development of Liarozole.
- *Other clinical stage products*—direct project expenses relating to the development of our other clinical stage product candidates and products in reformulation.
- *Research and preclinical stage product costs*—direct expenses relating to the development of our research and preclinical product candidates and the screening of molecules to identify new product candidates.
- *Internal costs*—costs related primarily to personnel, as well as consulting, overhead and other expenses related to our research and development activities. We do not allocate these costs to specific projects as these costs relate to all research and development activities.

Projects may be reclassified from a prior presentation according to its current stage of development.

Total research and development expenses for the year December 31, 2004 compared to the year December 31, 2003 increased $13.4 million. During the year December 31, 2004 our research and development costs related to Sebazole were comparatively flat with the two Phase 3 clinical trials in the United States and Europe in 2003, compared with costs related to a confirmatory Phase 3 clinical trial for Sebazole, which commenced in the second quarter of 2004 and our long-term safety study which commenced in the third quarter of 2004. Our costs for Hyphanox in the year December 31, 2004 are related to a Phase 3 pivotal clinical trial for the treatment of vaginal candidiasis, which commenced in January 2004 and costs related to manufacturing. Our costs in the year December 31, 2003 for Hyphanox were primarily for the purchase of raw materials and related manufacturing, as well as the costs of conducting a pilot bioequivalence study. Our costs related to Zimycan for the year ended December 31, 2004 increased slightly due to the cost of our Phase 3 pivotal clinical trial, which began enrolling patients in the first half of 2003 and was completed during the third quarter of 2004, and the costs incurred in connection with the preparation of regulatory filings and filing fees. Our costs for Liarozole in 2004 are related to the cost of the review of clinical data, clinical supplies and manufacturing of the active ingredient, and in 2003 for the manufacturing of drug substance for clinical supplies.

Internal costs in the year December 31, 2004 increased $4.1 million compared to the year December 31, 2003. Personnel and related costs totaled $6.2 million for the year December 31, 2004, an increase of $3.1 million over the corresponding period in 2003. This increase includes amortization of deferred compensation of $730,000, which was $82,000 at December 31, 2003. Additionally, headcount grew to 36 employees at December 31, 2004 from 24 employees at December 31, 2003. Other costs, which include consultants, overhead and other expenses, totaled $2.1 million, an increase of $1.0 million compared to the corresponding period in 2003.

We anticipate that research and development expenses will continue to increase as we further advance our late stage product candidates through clinical development, including the higher cost of Phase 3 clinical trials, and including long-term safety trials. In addition, we will begin to incur additional expenses for our mid-stage pipeline as we move toward larger Phase 2 trials and to devote additional resources to our earlier stage research and preclinical projects. We also expect our personnel and related expenses for research and development to increase.

Sales and Marketing Expenses. Sales and marketing expenses totaled $4.3 million for the year December 31, 2004. We recorded no sales and marketing expenses in 2003. These costs include personnel and related expenses of $1.8 million and marketing and market research expense of $1.1 million for the year December 31, 2004. We expect these costs to continue to increase as we prepare for the possible launch of our product candidates, subject to obtaining the requisite marketing approvals, as well as the launch of any acquired products or in-licensed products. We have also added employees during the fourth quarter of 2004 and early 2005, and expect to add staff during 2005, which will comparatively increase our costs for the full year of 2005. During the latter half of 2005, we expect to incur costs related to the sales of Solagé® and Zimycan, if and when approved by the FDA, which may include costs related to our own sales force, utilizing a contract sales organization, or entering into a co-promotion arrangement.

General and Administrative Expenses. General and administrative expenses totaled $7.2 million for the year December 31, 2004, an increase of $3.4 million over the corresponding period in 2003. Personnel and related costs totaled $3.4 million for the year December 31, 2004, an increase of $1.8 million over the corresponding period in 2003. These costs include amortization of deferred compensation expense of $975,000 in 2004, which was $116,000 for the year December 31, 2003. Additionally, general

and administrative headcount grew to 19 employees at December 31, 2004 from 14 employees at December 31, 2003. General and administrative costs also increased due to increased stock-based compensation expense related to non-employees of $756,000, an increase of $648,000 over the corresponding period in 2003, and due to the costs related to our becoming a public company in the second quarter of 2004.

We expect general and administrative costs to continue to increase as we add more personnel and expand our infrastructure. The costs associated with being a public company will also increase our general and administrative expenses.

Interest income, net of interest expense. Interest income, net of expense totaled $1.4 million for the year December 31, 2004, an increase of $957,000 as compared to the corresponding period in 2003. The increase was primarily due to our higher balances of cash and cash equivalents and marketable securities in 2004 compared to 2003 and slightly higher interest rates.

Years Ended December 31, 2003 and 2002 and Period From Inception Through December 31, 2001

We began operations in May 2002 following the closing of our sale of our series A and series B convertible preferred stock. This comparison of results of operations for the years ended December 31, 2003 and December 31, 2002, is therefore a comparison of a full year of operations for 2003 to the initial eight-month period of our operations in 2002 and to no operations in 2001.

Revenue. We did not recognize any revenue in 2002. We recognized grant revenue of $0.4 million in 2003. This represents income that we received under our grant from a Belgian governmental agency promoting technology in the Flemish region of Belgium through research grants.

Research and Development Expenses. Below is a summary of our research and development expenses for 2002 and 2003. There were no research and development expenses in 2001.

	2003	2002
	(in thousands)	
Sebazole	$ 5,016	$ 883
Hyphanox	4,864	1,192
Zimycan	1,774	345
Other clinical stage products	997	—
Research and preclinical stage product costs	721	49
Internal costs	4,112	1,074
Total research and development expenses	$ 17,484	$ 3,543

In the preceding table, research and development expenses are set forth in the following six categories:

- *Sebazole*—third-party direct project expenses relating to the development of Sebazole and Seboride.
- *Hyphanox*—third-party direct project expenses relating to the development of Hyphanox.
- *Zimycan*—third-party direct project expenses relating to the development of Zimycan.
- *Other clinical stage products*—direct project expenses relating to the development of our other clinical stage product candidates, the products in reformulation and the screening of molecules to identify new product candidates.

- *Research and preclinical stage product costs*—direct expenses relating to the development of our research and preclinical product candidates.

- *Internal costs*—costs related primarily to personnel, as well as consulting, overhead and other expenses related to our research and development activities. We do not allocate these costs to specific projects as these costs relate to all research and development activities.

Total research and development expenses in 2003 increased primarily from the conduct and completion of our two Phase 3 clinical trials for Seboride, which clinical program is focused on Sebazole, the process development, scale-up, manufacturing and bioequivalence testing of Hyphanox, which began in the third quarter of 2002 and continued throughout 2003, and the costs related to our Zimycan Phase 3 clinical trial, which was partially enrolled as of December 31, 2003. We incurred initial direct program expenses in 2003 on our other clinical stage product candidates, which include Liarozole, Azoline, Rambazole and Atopik.

Included in research and internal costs are expenses incurred in connection with our research grant and other discovery activities, which increased $0.7 million in 2003. Internal costs include personnel, consultant, overhead and other expenses. Personnel costs increased $2.3 million in 2003 as we added ten people to our research and development staff in 2003, and we incurred a full year of payroll and related costs. Other costs which include consultants, overhead and other expenses increased $0.7 million during 2003.

In-process Research and Development Expense. During 2002, we expensed $25.0 million for in-process research and development solely as a result of our entering into our principal license agreements.

General and Administrative Expenses. General and administrative expenses increased from $1.5 million in 2002 to $3.7 million in 2003. The increase in 2002 resulted primarily from the commencement of operations and the costs related to doing so, including adding personnel and incurring professional fees and occupancy and other facility costs. The increase in 2003 resulted primarily from increased personnel and related expenses of $1.1 million, due to incurring a full year of expense during 2003 and an increase in the number of our employees. In 2003, we hired nine additional administrative employees in areas such as finance, business development and information technology. The increase also reflects increased occupancy costs of $0.3 million and professional fees of $0.2 million necessary for the expansion of our operations.

Sales and Marketing Expenses. We had not incurred any sales and marketing expenses through 2003.

Interest Income. Interest income increased from $275,000 in 2002 to $419,000 in 2003. We had no interest income in 2001. The increase was due to our higher balances of cash and cash equivalents in 2003 compared to 2002, resulting from the $22.4 million in net cash proceeds that we received from our issuance of series B convertible preferred stock in May 2002, the $23.0 million in net cash proceeds that we received from our issuance of series B convertible preferred stock in May 2003 and the $31.9 million in net cash proceeds that we received from our issuance of series C convertible preferred stock in October 2003.

Liquidity and Capital Resources

We have funded our operations principally from issuances of our convertible preferred stock and convertible promissory notes, the proceeds from our initial public offering and our follow-on public offering. Since our inception, we raised approximately $36 million from our follow-on public offering in

February 2005, net of expenses, $67.9 million from our initial public offering in May 2004, net of expenses, and we have issued preferred stock for aggregate net cash proceeds of approximately $77.3 million, $31.9 million of which was raised through our sale of series C convertible preferred stock in October 2003, $23.0 million of which was raised through our sale of series B convertible preferred stock in May 2003 and $22.4 million of which was raised through our sale of series B convertible preferred stock in May 2002. Issuances of convertible promissory notes resulted in proceeds of $100,000 in 2001 and $50,000 in 2002. These notes were subsequently converted into shares of our series B convertible preferred stock in accordance with their terms. All of the preferred stock that we issued converted to common stock in connection with our initial public offering.

In September 2003, we entered into a $750,000 financing arrangement to fund the purchase of office furniture, computer equipment and software. The original note for approximately $267,000 had an interest rate of 6.4% plus a fluctuating mark-up based on market rates that is set at the time of funding. The fixed portion was reduced to 6.15% in August 2004 in connection with a new note for approximately $407,000. We entered into an additional promissory note in December 2004 to fund $148,000 at 9.37%. We expect to enter into additional promissory notes to fund most of our fixed asset purchases.

At December 31, 2004, we had cash, cash equivalents and marketable securities totaling $89.1 million and working capital of $82.8 million.

We used cash in operations for the year ended December 31, 2004 of $32.2 million. Cash used in operations for the year ended December 31, 2003 was $18.8 million. The increase was attributable to the increased working capital requirements to fund our operations, including our operating losses.

Cash used in investing activities for the year ended December 31, 2004 was $35.7 million. We used cash in investing activities for the year ended December 31, 2003 of $31.0 million and $12.4 million for the year ended December 31, 2002. Our investing activities reflect investments in marketable securities and purchases of fixed assets necessary for operations. We plan to utilize third parties to manufacture our products and to conduct laboratory-based research. Therefore, we do not expect to make significant capital expenditures in 2005.

Net cash provided by financing activities was $68.3 million during the year ended December 31, 2004, compared to $55.2 million during the year ended December 31, 2003. The source of cash provided by financing activities during the year ended December 31, 2004 was related primarily to proceeds from the sale of common stock in our initial public offering. The source of cash provided by financing activities for the year ended December 31, 2003 was related primarily from our receipt of $23.0 million in May 2003 upon the second closing of the series B convertible preferred stock financing and $31.9 million in October 2003 upon the closing of the series C convertible preferred stock financing. Cash provided by financing activities for the year ended December 31, 2002 was $22.4 million, primarily from the receipt of net cash proceeds of $22.4 million in May 2002 through our first issuance of series B convertible preferred stock. Cash provided by financing activities for the year ended December 31, 2001 was $100,000 as a result of the issuance of convertible promissory notes in the fourth quarter of 2001.

We expect that our existing cash at December 31, 2004, together with the proceeds to us from our follow-on public offering, will be sufficient to fund our anticipated operating expenses, debt obligations and capital requirements through the end of 2006. Our future capital requirements will depend on many factors, including:

- the success of our development and commercialization of our product candidates;
- the scope and results of our clinical trials;

- advancement of other product candidates into clinical development;
- potential acquisition or in-licensing of other products or technologies;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the costs of manufacturing activities;
- the costs of commercialization activities, including product marketing, sales and distribution and related working capital needs;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property-related costs, including any possible litigation costs; and
- our ability to establish and maintain collaborative and other strategic arrangements.

Our capital requirements are likely to increase. As a result, we may require additional funds and may attempt to raise additional funds through public or private equity offerings or debt financings, collaborative agreements with corporate partners or from other sources.

The following table summarizes our material contractual commitments as of December 31, 2004:

	Payments Due by Period			
Contractual Obligation	**Total**	**One to Three Years**	**Four to Five Years**	**After Five Years**
Lease obligations	$ 3,401,000	$1,733,000	$1,207,000	$461,000
Other contractual obligations	12,200,000	10,700,000	1,500,000	—
Total	$15,601,000	$12,433,000	$2,707,000	$461,000

The other contractual obligations reflected in the table include obligations to purchase product candidate materials contingent on the delivery of the materials and to fund various clinical trials contingent on the performance of services. These obligations also include long-term obligations, including milestone payments that may arise under agreements that we may terminate prior to the milestone payments being due. The table excludes contingent royalty payments that we may be obligated to pay in the future.

Net Operating Loss Carryforwards

We incurred net operating losses for all the periods since inception and consequently did not pay federal, state or foreign income taxes. As of December 31, 2004, we had federal net operating loss carryforwards of $58.1 million and state net operating loss carryforwards of $50.1 million. Pursuant to Section 382 of the Internal Revenue Code of 1986, the annual utilization of a company's net operating loss carryforwards may be limited if the company experiences a change in ownership of more than 50% within a three-year period. As a result of our equity offerings, we may have experienced such an ownership change. However, we have not performed a detailed analysis of any ownership change. Accordingly, our net operating loss carryforwards available to offset future federal taxable income arising before such ownership changes may be limited. For financial reporting purposes, we have recorded a valuation allowance to fully offset the deferred tax asset related to these carryforwards because realization of the benefit was uncertain.

During 2004 and 2003, the Company sold a portion of its unused New Jersey State operating loss carryforwards, through a program sponsored by the State of New Jersey and the New Jersey Economic Development Authority. We received cash proceeds of approximately $367,000 in 2004 and $217,000 in 2003.

Quantitative and Qualitative Disclosures about Market Risks

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities. We invest in high-quality financial instruments, primarily money market funds, federal agency notes, corporate debt securities and United States treasury notes, with the effective duration of the portfolio less than one year, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

Most of our transactions are conducted in United States dollars, although we do have some agreements with vendors located outside the United States. Transactions under some of these agreements are conducted in United States dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under other of these agreements are conducted in the local foreign currency. We have a wholly-owned subsidiary, Barrier Therapeutics, N.V., which is located in Geel, Belgium. Except for funding being received under our grant from a Belgian governmental agency, which is denominated in Euros and locally earned interest income, all research costs incurred by Barrier Therapeutics, N.V. are funded under a service agreement with Barrier Therapeutics, Inc. from investments denominated in dollars. Therefore, we are subject to currency fluctuations and exchange rate gains and losses on these transactions. If the exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

Risks Related to Our Business

Risks Related to Our Financial Results and Need for Additional Financing

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future.

Since our inception in September 2001, we have incurred significant operating losses and, as of December 31, 2004, we had a deficit accumulated during the development stage of $106.2 million. We have not yet completed the development of any of our product candidates, and none are ready for commercialization, except for Zimycan in Belgium. As a result, prior to our acquisition of Solagé® which we are marketing in the United States and Canada, we had generated no revenues from the sale of our products. We expect to continue to incur significant operating expenses and anticipate that our expenses may increase substantially in the foreseeable future as we:

- conduct clinical trials;
- conduct research and development on existing and new product candidates;
- seek regulatory approvals for our product candidates;
- commercialize our product candidates, if approved;
- hire additional clinical, scientific, sales and marketing and management personnel;

- add operational, financial and management information systems; and

- identify and in-license additional compounds or product candidates.

We need to generate significant revenue to achieve profitability. Even if we succeed in developing and commercializing one or more of our product candidates, we may never generate sufficient sales revenue to achieve and then maintain profitability. We expect to incur operating losses for the foreseeable future.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

As of December 31, 2004, we had cash, cash equivalents and marketable securities of $89.1 million. In February 2005, we raised net proceeds of approximately $36 million from the sale of 2 million shares of our common stock. We believe that our existing cash resources and our interest on these funds will be sufficient to meet our projected operating requirements through the end of 2006. We currently have no additional commitments or arrangements for any additional financing to fund the research and development and commercial launch of our product candidates. We will require additional funding in order to continue our research and development programs, including preclinical studies and clinical trials of our product candidates, pursue regulatory approvals for our product candidates; pursue the commercial launch of our product candidates and for general corporate purposes. Our future capital requirements will depend on many factors, including:

- the success of our development and commercialization of our product candidates;

- the scope and results of our clinical trials;

- advancement of other product candidates into clinical development;

- potential acquisition or in-licensing of other products or technologies;

- the timing of, and the costs involved in, obtaining regulatory approvals;

- the costs of manufacturing activities;

- the costs of commercialization activities, including product marketing, sales and distribution and related working capital needs;

- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property-related costs, including any possible litigation costs; and

- our ability to establish and maintain collaborative and other strategic arrangements.

Adequate financing may not be available on terms acceptable to us, if at all. We may continue to seek additional capital through public or private equity offerings, debt financings or collaborative arrangements and licensing agreements.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing that we raise or additional equity we may sell

may contain terms that are not favorable to us or our common stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it will be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us.

Lack of funding could adversely affect our ability to pursue our business. For example, if adequate funds are not available, we may be required to curtail significantly or eliminate one or more of our product development programs.

Risks Related to Development of Product Candidates

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or if our clinical trials do not demonstrate safety and efficacy in humans.

We are currently not authorized to market any of our product candidates in any jurisdiction. We can market Solagé® in the United States and Canada and Zimycan in Belgium. We intend to market our products in the United States and in various other countries, and as a result, we will need to obtain separate regulatory approvals in most jurisdictions. Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Preclinical studies and clinical trials are expensive, can take many years and have uncertain outcomes. In addition, the regulatory approval procedures vary among countries and additional testing may be required in some jurisdictions. Our success will depend on the success of our currently ongoing clinical trials and subsequent clinical trials that have not yet begun. It may take several years to complete the clinical trials of a product, and a failure of one or more of our clinical trials can occur at any stage of testing. We believe that the development of each of our product candidates involves significant risks at each stage of testing. If clinical trial difficulties and failures arise, our product candidates may never be approved for sale or become commercially viable. We do not believe that any of our product candidates have alternative uses if our current development activities are unsuccessful.

There are a number of difficulties and risks associated with clinical trials. These difficulties and risks may result in the failure to receive regulatory approval to sell our product candidates or the inability to commercialize any of our product candidates. The possibility exists that:

- we may discover that a product candidate does not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved;

- the results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;

- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

- subjects may drop out of our clinical trials;

- our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials; and

- the cost of our clinical trials may be greater than we currently anticipate.

For example, in November 2003, we completed two Phase 3 clinical trials that were designed primarily to analyze the use of one of our proposed product candidates, Seboride, for the treatment of seborrheic dermatitis. We decided not to seek regulatory approval for Seboride because the results of these clinical trials did not exhibit the expected therapeutic results for that product candidate. Similarly, because our preclinical studies of Ecalcidene did not replicate the results of earlier third-party studies, the development of Ecalcidene is likely to be discontinued. Furthermore, the costs of our Phase 3 clinical trial for Hyphanox in the treatment of vaginal candidiasis were higher than expected principally because of the need to recruit additional patients, to add additional sites and to hire an additional contract research organization to assist in the management of the trial.

With respect to a number of our product candidates, we expect to rely on the results of clinical trials that were performed by or on behalf of Janssen Pharmaceutica Products, L.P. and its affiliates prior to our acquisition of these product candidates. It is possible that these trial results may not be predictive of the results of the clinical trials that we conduct for our product candidates. In addition, the results of these prior clinical trials may not be acceptable to the FDA or similar foreign regulatory authorities because the data may be incomplete, outdated or not otherwise acceptable for inclusion in our submissions for regulatory approval. For example, although our product candidates ketanserin and oxatomide are marketed by other companies in some countries outside the United States and Europe, the data used to support the current regulatory approvals for these products do not meet current regulatory guidelines in the United States and Europe. As a result, we must repeat most of the clinical work already completed prior to filing for marketing approval in the United States and Europe for these product candidates.

If we do not receive regulatory approval to sell our product candidates or cannot successfully commercialize our product candidates, we would not be able to generate any initial revenues or grow revenues in future periods, which would result in significant harm to our financial position and adversely impact our stock price.

If our clinical trials for our product candidates are delayed, we would be unable to commercialize our product candidates on a timely basis, which would materially harm our business.

Planned clinical trials may not begin on time or may need to be restructured after they have begun. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining an effective investigational new drug application, or IND, or regulatory approval to commence a clinical trial;

- negotiating acceptable clinical trial agreement terms with prospective trial sites;

- obtaining institutional review board approval to conduct a clinical trial at a prospective site;

- recruiting qualified subjects to participate in clinical trials;

- competition in recruiting clinical investigators;

- shortage or lack of availability of supplies of drugs for clinical trials;
- the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;
- the placement of a clinical hold on a study;
- the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and
- exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

For example, we completed enrollment of our Phase 3 clinical trial for Zimycan later than expected due to difficulties enrolling infants with proven diaper dermatitis complicated by candidiasis. In addition, in January 2005, the FDA informed us that we should submit the six-month data for a total of 300 patients from our ongoing long-term safety study of our Sebazole product candidate at the time of the initial filing of the NDA. We expect that the request from the FDA to include this data will delay the filing of our Sebazole NDA until the third quarter of 2005 due to the time we expect it will take us to analyze data from the required number of patients. In January 2005, the FDA also asked us to perform a study for Sebazole known as a percutaneous absorption study, which measures the amount of a drug's absorption, if any, into the bloodstream through the skin. The FDA requested that we submit data from this study at the time of the initial filing of the NDA. If satisfying either the long-term safety data or percutaneous absorption data requirements takes longer than we currently expect, the initial filing of our NDA for Sebazole could be delayed.

We believe that our product candidates have significant milestones to reach, including, other than Zimycan, the successful completion of clinical trials, before commercialization. If we have significant delays in or termination of clinical trials, our financial results and the commercial prospects for our product candidates or any other products that we may develop will be adversely impacted. In addition, our product development costs would increase and our ability to generate revenue could be impaired.

If we are wrong in our assessment of the stages of clinical development of our initial product candidates, we may need to perform preclinical studies or clinical trials that we did not anticipate, which would result in additional product development costs for us and delays in filing for regulatory approval for our product candidates.

We acquired the rights to our initial product candidates from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., each a Johnson & Johnson company. Prior to this acquisition, they had conducted preclinical studies and clinical trials on several of our product candidates. For our product candidates for which we are not currently conducting a clinical trial, we have made an assessment as to whether the next clinical trial that we will perform will be a Phase 1, Phase 2 or Phase 3 clinical trial based on the results of these preclinical studies and clinical trials. We may be wrong in our assessment of the stages of clinical development of our initial product candidates for several reasons, including that the data we obtained from the previous trials may be outdated or otherwise no longer acceptable for our purposes or to the FDA or similar regulatory authorities in connection with applications that we may file for regulatory approval. If our current assessments prove to be inaccurate, we will likely have to perform additional preclinical studies or clinical trials, which will require us to expend additional resources and may delay filing for regulatory approval for that product.

We may acquire additional products or product candidates in the future and any difficulties from integrating such acquisitions could damage our ability to attain profitability.

We have acquired our entire current product pipeline by licensing intellectual property from third parties, and we may acquire additional products or product candidates that complement or augment our existing product development pipeline. However, because we acquired substantially all of our existing product candidates in the same transaction, we have limited experience integrating products or product candidates into our existing operations. Integrating any newly acquired product or product candidate could be expensive and time-consuming. We may not be able to integrate any acquired product or product candidate successfully. For example, we recently acquired the United States and Canadian rights to Solagé®. Solagé® is our first marketed product. As a result, we may have difficulty integrating it with our existing product candidates as we expand our resources dedicated to marketing. In addition, we have no experience with a commercial product and cannot assure you that our marketing efforts we will be successful. Moreover, we may need to raise additional funds through public or private debt or equity financing to make these acquisitions, which may result in dilution for stockholders and the incurrence of indebtedness.

Risks Related to Our Dependence on Third Parties for Manufacturing, Research and Development and Marketing and Distribution Activities

Because we have no manufacturing capabilities, we will contract with third-party contract manufacturers whose performance may be substandard or not in compliance with regulatory requirements, which could increase the risk that we will not have adequate supplies of our product candidates and harm our ability to commercialize our product candidates.

We do not have any manufacturing experience or facilities. We rely on third-party contract manufacturers to produce the product candidates that we use in our clinical trials. We expect to continue to rely on third parties to manufacture any products that we commercialize. If we are unable to retain our current, or engage additional, contract manufacturers, we will not be able to conduct our clinical trials or sell any products for which we receive regulatory approval. The risks associated with our reliance on contract manufacturers include the following:

- Contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical development schedules or adequately manufacture our products in commercial quantities when required.

- Changing manufacturers may be difficult because the number of potential manufacturers for some of our product candidates may be limited and, in one case, there is only a single source of supply. Specifically, the intermediate for our product candidate Hyphanox is manufactured using a process that is proprietary to our contract manufacturer. We do not have a license to the technology used by our contract manufacturer to make the intermediate needed for the Hyphanox tablets. If this manufacturer cannot provide adequate supplies of the intermediate for Hyphanox, we cannot sublicense this technology to a third party to act as our supplier. As a result, it may be difficult or impossible for us to find a qualified replacement manufacturer quickly or on terms acceptable to us, the FDA and corresponding foreign regulatory agencies, or at all.

- With the exception of Hyphanox, each of our product candidates can be produced by multiple manufacturers. However, if we need to change manufacturers, the FDA and

corresponding foreign regulatory agencies must approve these manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards. For instance, for Zimycan, we have used one contract manufacturer in connection with the marketing authorization application that we filed in Europe and we intend to use a separate contract manufacturer for commercial supply of the product in the United States. If we decide to have our United States manufacturer supply us with Zimycan for sale in Europe, it is likely that many of the applicable foreign regulatory agencies will need to approve our United States manufacturer prior to making that transition.

- Our contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current Good Manufacturing Practices, or cGMPs, and other governmental regulations and corresponding foreign standards. Other than through contract, we do not have control over compliance by our contract manufacturers with these regulations and standards. Our present or future contract manufacturers may not be able to comply with cGMPs and other FDA requirements or similar regulatory requirements outside the United States. Failure of our contract manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

- Our contract manufacturers may breach our manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

We may compete with other drug developers for access to manufacturing facilities for our current and future product candidates. If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Dependence upon third parties for the manufacture of our product candidates may reduce our profit margins, if any, and may limit our ability to develop and deliver products on a timely and competitive basis.

If third parties on whom we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products and product candidates.

We depend on independent clinical investigators and contract research organizations to conduct our clinical trials. Contract research organizations also assist us in the collection and analysis of trial data. We also depend on third parties to perform services related to our adverse event reporting requirements. The investigators, contract research organizations and other contractors are not our employees, and we cannot control, other than by contract, the amount of resources, including time, that they devote to our product candidates. However, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial that have been approved by regulatory agencies and for ensuring that we report product-related adverse events in accordance with applicable regulations. Furthermore, the FDA and European regulatory authorities require us to comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

In connection with our reliance on our independent clinical investigators and contract research organizations, our clinical trials may be extended, delayed, suspended or terminated, including as a result of:

- the failure of these investigators and research organizations to comply with good clinical practice or to meet their contractual duties;
- the failure of our independent investigators to devote sufficient resources to the development of our product candidates or to perform their responsibilities at a sufficiently high level;
- our need to replace these third parties for any reason, including for performance reasons or if these third parties go out of business; or
- the existence of problems in the quality or accuracy of the data they obtain due to the failure to adhere to clinical protocols or regulatory requirements or for other reasons.

Extensions, delays, suspensions or terminations of our clinical trials as a result of the performance of our independent clinical investigators and contract research organizations will delay, and make more costly, regulatory approval for any product candidates that we may develop.

In addition, although we have used a number of contract research organizations to conduct our clinical trials, there are many other qualified contract research organizations available. Any change in a contract research organization during an ongoing clinical trial could seriously delay that trial and potentially compromise the results of the trial.

We are dependent upon distribution arrangements and marketing alliances to commercialize our product candidates outside the United States and Canada. These distribution arrangements and marketing alliances place the marketing and sale of our product candidates in these regions outside our control.

We have entered into distribution arrangements and marketing alliances relating to the commercialization of some of our product candidates. Dependence on these arrangements and alliances subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our distributors may devote to the commercialization of our product candidates;
- our distributors may experience financial difficulties;
- business combinations or significant changes in a distributor's business strategy may also adversely affect a distributor's willingness or ability to complete its obligations under any arrangement; and
- these arrangements are often terminated or allowed to expire, which could interrupt the marketing and sales of a product and decrease our revenue.

We may not be successful in entering into additional distribution arrangements and marketing alliances with third parties for our earlier stage products. Our failure to enter into these arrangements on favorable terms could delay or impair our ability to commercialize our product candidates outside the United States and Canada and could increase our costs of commercialization. In addition, we may be at a competitive disadvantage in negotiating these agreements with third parties because under our license agreements, Johnson & Johnson, through any of its affiliates, has a right of first negotiation for the

commercialization of our product candidates that are based on the licensed intellectual property. Because this first right of negotiation may only be triggered after Phase 2 clinical trials and could extend for up to 180 days, it may hinder our ability to enter into distribution agreements and marketing alliances. It may also delay our receipt of any milestone payments or reimbursement of development costs.

Risks Related to Intellectual Property

There are limitations on our patent rights relating to our product candidates that may affect our ability to exclude third parties from competing against us if we receive approval to market these product candidates.

The patent rights that we own or have licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we receive regulatory approval to market these product candidates. In particular:

- We do not hold composition of matter patents covering the active pharmaceutical ingredients of three of our later stage product candidates. Composition of matter patents on active pharmaceutical ingredients are the strongest form of intellectual property protection for pharmaceutical products as they apply without regard to any method of use or other type of limitation. The active ingredients of most of these product candidates are off patent. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredients as our products so long as the competitors do not infringe any method of use or formulation patents that we may hold. Examples include Solagé®, Zimycan, Sebazole and Hyphanox, for which the active pharmaceutical ingredients, mequinol, trentinoin, miconazole, ketoconazole and itraconazole, are all off patent. The United States patent covering the active ingredient in Liarozole expires in 2006.

- We do not hold composition of matter patents covering the formulations of some of our later stage product candidates. Composition of matter patents on formulations can provide protection for pharmaceutical products to the extent that the specifically covered formulations are important. For our product candidates for which we do not hold composition of matter patents covering the formulation, competitors who obtain the requisite regulatory approval can offer products with the same formulations as our products so long as the competitors do not infringe any active pharmaceutical ingredient or method of use patents that we may hold. The United States patent covering the formulation of miconazole and zinc oxide in Zimycan expires in 2007. The United States patent covering the composition of Solagé® expires in 2010.

- For some of our product candidates, the principal patent protection that covers, or that we expect will cover, our product candidate is a method of use patent. This type of patent only protects the product when used or sold for the specified method. However, this type of patent does not limit a competitor from making and marketing a product that is identical to our product for an indication that is outside of the patented method. Moreover, physicians may prescribe such a competitive identical product for off-label indications that are covered by the applicable patents. Although such off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

- Our patent licenses from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc. are limited to the field of dermatology. As a result, with some exceptions, Johnson & Johnson, its affiliates or its

licensees could manufacture and market products similar to our products outside of this field. This also could result in off-label use of these competitive products for dermatological indications.

These limitations on our patent rights may result in competitors taking product sales away from us, which would reduce our revenues and harm our business.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.

All of our eight current product candidates in clinical development are based on intellectual property that we have licensed from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc. We depend, and will continue to depend, on these license agreements. The terms of these licenses are set out in two license agreements. These license agreements may be terminated on a product-by-product basis, if, by dates specified in the license agreements, we are not conducting active clinical development of the particular product or if we do not obtain regulatory approval for that product. Either of the license agreements may also be terminated if we breach that license agreement and do not cure the breach within 90 days or in the event of our bankruptcy or liquidation.

Disputes may arise with respect to our licensing agreements regarding manufacturing, development and commercialization of any products relating to this intellectual property. These disputes could lead to delays in or termination of the development, manufacture and commercialization of our product candidates or to litigation.

Various aspects of our Johnson & Johnson license agreements may adversely affect our business.

Under our principal license agreements, neither Johnson & Johnson nor any of its affiliates is restricted from developing or acquiring products that may address similar indications as our products or otherwise compete with our products. We have the sole right to commercialize any product candidate based on intellectual property licensed to us under these agreements that we elect to commercialize ourselves or with the assistance of a contract sales organization. In other circumstances, however, Johnson & Johnson and any of its affiliates has a right of first negotiation for the commercialization of our product candidates based on such intellectual property. The rights of first negotiation for the commercialization of our product candidates can be exercised on a territory-by-territory basis. This negotiation may extend for up to 180 days, which may delay our commercialization efforts or hinder our ability to enter into distribution agreements.

Under the license agreements, Janssen has an exclusive option to acquire the right to commercialize Hyphanox on a geographic region-by-region basis. Janssen has 90 days to exercise this option from the date that we provide notice that we are able to manufacture Hyphanox batches that are reproducible and bioequivalent to Janssen's Sporanox product or a similar itraconazole product previously developed by Janssen. We also must provide this notice if we can demonstrate clinical efficacy in a Phase 3 clinical trial performed by us. We expect Janssen's right to exercise this option will be triggered if the results of our ongoing Phase 3 clinical trial of Hyphanox in vaginal candidiasis are positive. Depending on whether or not Janssen exercises its option and the regions for which it chooses to exercise its option, our business may be either favorably or adversely affected.

The license agreements also permit each of Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., to abandon its maintenance of any patents or the prosecution of any patent applications included in the licensed intellectual property for any reason. If any of these companies abandon these activities, we have the option to undertake their maintenance and prosecution if we decide to prevent their abandonment. To date, we have assumed the maintenance and prosecution for all of the patents and patent applications relating to our Sebazole and Zimycan product candidates. If we are required to undertake these activities for any additional product candidates, our operating costs will increase.

In addition, our license agreements limit our use of our product candidates to the specific field of dermatology as defined in the license agreements. As so defined, dermatology consists of applications for the treatment or prevention of diseases of human skin, hair, nails and oral and genital mucosa, but excludes treatments for skin cancer. We have not been granted the right to sell oxatomide in Japan, Italy, Mexico and much of Central America or to sell ketanserin in Mexico, Central America and the Caribbean. Our right to sell the following products in the following countries is semi-exclusive with the Johnson & Johnson companies:

- Zimycan in Argentina, Australia, Belgium, Denmark, Germany, Indonesia, Luxembourg, Mexico, New Zealand, Peru and Venezuela; and

- Ketanserin in South America.

This field of use and geographic restrictions limit our ability to market our products worldwide and, therefore, limit the potential market size for our products.

If we are unable to obtain and maintain patent protection for our intellectual property, our competitors could develop and market products similar or identical to ours, which may reduce demand for our product candidates.

Our success will depend in part on our ability to obtain and maintain patent protection for our proprietary technologies and product candidates and our ability to prevent third parties from infringing our proprietary rights. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on patent protection for new technologies, products and processes. Accordingly, we expect to seek patent protection for our new proprietary technologies and some of our product candidates. The risk exists, however, that new patents may be unobtainable and that the breadth of the claims in a patent, if obtained, may not provide adequate protection for our proprietary technologies or product candidates.

Although we own or otherwise have rights to a number of patents, these patents may not effectively exclude competitors, the issuance of a patent is not conclusive as to its validity or enforceability and third parties may challenge the validity or enforceability of our patents. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18

months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued United States patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in the foreign patents or patent applications. It is possible that a competitor may successfully challenge our patents or that challenges will result in the elimination or narrowing of patent claims and, therefore, reduce our patent protection.

Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement lawsuits, which are expensive and time-consuming. In addition, because of the size of our patent portfolio, we may not be able to prevent infringement or unauthorized use of all of our patents due to the associated expense and time commitment of monitoring these activities. If there is an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, may narrow our patent claims or may refuse to stop the other party from using the technology at issue on the ground that our patents do not cover its technology. Interference proceedings brought in the United States Patent and Trademark Office may be necessary to determine whether our patent applications or those of our collaborators are entitled to priority of invention relative to third parties. Litigation, interference or opposition proceedings may result in adverse rulings and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our respective proprietary rights, particularly in countries where the laws may not protect our rights as fully as in the United States.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology may be adversely affected.

In addition to patent protection, we rely upon trade secrets relating to unpatented know-how and technological innovations to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and consultants. We also have confidentiality and invention or patent assignment agreements with our employees and our consultants. If our employees or consultants breach these agreements, we may not have adequate remedies for any of these breaches. In addition, our trade secrets may otherwise become known to or be independently developed by our competitors.

If the development of our product candidates infringes the intellectual property of our competitors or other third parties, we may be required to pay license fees or cease our development activities and pay damages, which could significantly harm our business.

Even if we have our own patents which protect our products, our product candidates may nonetheless infringe the patents or violate the proprietary rights of third parties. In these cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to develop and commercialize our product candidates. We may not, however, be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property.

Third parties may assert patent or other intellectual property infringement claims against us, or our collaborators, with respect to technologies used in potential product candidates. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. In addition, any patent claims brought against our collaborators could affect their ability to carry out their obligations to us.

Furthermore, as a result of a patent infringement suit brought against us, or our collaborators, the development, manufacture or potential sale of product candidates claimed to infringe a third party's intellectual property may have to stop or be delayed. Ultimately, we may be unable to commercialize some of our product candidates or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Risks Related to Regulatory Approval of Our Product Candidates

We may not receive regulatory approvals for our product candidates or approvals may be delayed, either of which could materially harm our business.

Government authorities in the United States and foreign countries extensively regulate the development, testing, manufacture, distribution, marketing and sale of our product candidates and our ongoing research and development activities. All of our product candidates are in various stages of development, and we are currently not authorized to market any of our product candidates. We believe that our product candidates have significant milestones to reach, including the receipt of regulatory approvals, before commercialization.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. According to the FDA, a Phase 1 clinical trial typically takes several months to complete, a Phase 2 clinical trial typically takes several months to two years to complete and a Phase 3 clinical trial typically takes one to four years to complete. Industry sources report that the preparation and submission of new drug applications, or NDAs, which are required for regulatory approval, generally take six months to one year to complete after completion of a pivotal clinical trial. Industry sources also report that approximately 10 to 15% of all NDAs accepted for filing by the FDA are rejected and that FDA approval, if granted, usually takes approximately one year after submission, although it may take longer if additional information is required by the FDA. Accordingly, we cannot assure you that the FDA will approve any NDA that we may file, including our recently filed Zimycan NDA amendment and our Sebazole NDA that we expect to file during the third quarter of 2005. In addition, the Pharmaceutical Research and Manufacturers of America reports that only one out of five product candidates that enter clinical trials will ultimately be approved by the FDA for commercial sale.

In particular, human therapeutic products are subject to rigorous preclinical studies, clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. For example, the FDA has previously issued three not approvable letters for Zimycan in 1986, 1999 and 2000. Changes in the FDA approval process during the development period or changes in regulatory review for each submitted product application may also cause delays in the approval or result in rejection of an application. In addition, recent withdrawals of approved products by major pharmaceutical companies may result in a renewed focus on safety at the FDA which may result in delays in the approval process. The FDA has substantial discretion in the approval process and may reject our data or disagree with our interpretations of our clinical trial data, which also could cause delays of an approval or the rejection of an application. The FDA may also determine that there is no substantial benefit over the products currently marketed to justify approval. The approval process may take many years to complete and may involve ongoing requirements for post-

marketing studies. For example, in January 2005, the FDA informed us that we should submit the six-month data on all 300 patients from our ongoing long-term safety study of our Sebazole product candidate at the time of the initial filing of the NDA. We expect that the FDA's request to include this data will delay the filing of our Sebazole NDA until the third quarter of 2005.

Any FDA or other regulatory approval of our product candidates, once obtained, may be withdrawn, including for failure to comply with regulatory requirements or if clinical or manufacturing problems follow initial marketing. If our product candidates are marketed abroad, they will also be subject to extensive regulation by foreign governments.

Any failure to receive the regulatory approvals necessary to commercialize our product candidates would severely harm our business. The process of obtaining these approvals and the subsequent compliance with appropriate domestic and foreign statutes and regulations require spending substantial time and financial resources. If we fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any product candidate we develop, our ability to receive product or royalty revenues and our liquidity and capital resources.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates for the treatment of rare dermatological diseases, and our competitors may obtain orphan drug exclusivity prior to us, which could significantly harm our business.

Some jurisdictions, including Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. The Commission for the European Community and the FDA have granted Liarozole orphan drug status for its use in the treatment of congenital ichthyosis. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity and specific tax credits in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that another application to market the same drug for the same indication may not be approved, except in limited circumstances, for a period of up to ten years in Europe and for a period of seven years in the United States. Obtaining orphan drug designations and orphan drug exclusivity for our product candidates for the treatment of rare dermatological diseases may be critical to the success of these product candidates. Our competitors may obtain orphan drug exclusivity for products competitive with our product candidates before we do, in which case we would be excluded from that market. Even if we obtain orphan drug exclusivity for any of our product candidates, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product, any orphan drug exclusivity we have obtained will not block the approval of such competitive product.

If we fail to comply with regulatory requirements, regulatory agencies may take action against us, which could significantly harm our business.

Any products for which we obtain marketing approval including our marketed product Solagé®, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, will be subject to continual requirements and review by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

In addition, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, cGMP regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements. The cGMP regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. If we engage contract manufacturers, we will rely on their compliance with cGMP regulations and other regulatory requirements relating to the manufacture of products, if any. We also will be subject to state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies. We may be slow to adapt or may not be able to adapt to these changes or new requirements. Because many of our products contain ingredients that also are marketed in over-the-counter drug products, there is a risk that the FDA or an outside third party at some point would propose that our products be distributed over-the-counter rather than by prescription potentially affecting third-party and government reimbursement for our products.

Later discovery of previously unknown problems with our products, manufacturing processes or failure to comply with regulatory requirements, may result in any of the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

We have only limited experience in regulatory affairs, which may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing the applications necessary to gain regulatory approvals. Moreover, some of the products that are likely to result from our product development, licensing and acquisition programs may be based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any products that we develop, license or acquire.

If we fail to obtain regulatory approval in foreign jurisdictions, we would not be able to market our products abroad, and the growth of our revenues, if any, would be limited.

We intend to have our products marketed outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

Risks Related to Commercialization

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community and reimbursement of them by third-party payors, including government payors. Safety, efficacy, convenience and cost-effectiveness, particularly as compared to competitive products, are the primary factors that affect market acceptance. Even if a potential product displays a favorable efficacy and safety profile in clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

If we are unable to establish a domestic sales and marketing infrastructure or enter into agreements with third parties to perform these functions in territories outside the United States and Canada, we will not be able to commercialize our product candidates.

We currently have only limited internal sales, distribution and marketing capabilities. In order to commercialize any of our product candidates, we must either acquire or internally develop sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services for us.

In the United States and Canada, we plan to build our own sales force to market our products directly to dermatologists and other target physicians. The acquisition or development of a sales and distribution infrastructure for our domestic operations will require substantial resources, which may divert the attention of our management and key personnel and negatively impact our product development efforts. Moreover, we may not be able to hire a sales force that is sufficient in size or adequate in expertise.

Risks Related to Employees and Growth

If we are not able to retain our current senior management team or attract and retain qualified scientific, technical and business personnel, our business will suffer.

We are dependent on the members of our senior management team, in particular, our Chief Executive Officer, Dr. Geert Cauwenbergh, our Chief Operating Officer, Charles Nomides and our Chief Commercial Officer, Alfred Altomari, for our business success. Dr. Cauwenbergh and Mr. Nomides have a long history and association with our current product candidates and intellectual property. Our employment agreements with these and our other executive officers are terminable on short notice or no notice. The loss of any one of these individuals would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and approval of our product candidates. We do not carry key man life insurance on the lives of any of our personnel.

We will need to hire additional employees as we grow. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.

Our growth will require us to hire a significant number of qualified scientific, commercial and administrative personnel. There is intense competition for human resources, including management in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates. The inability to attract new employees when needed and retain existing employees as we grow could severely harm our business.

Future growth will impose significant added responsibilities on members of our management, including the need to identify, recruit, retain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to manage any future growth effectively.

Changes in the expensing of stock options could result in unfavorable accounting charges or require us to change our compensation practices.

We rely heavily on stock options to compensate existing employees and attract new employees. We currently are not required to record stock-based compensation charges if the employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. On December 16, 2004, the Financial Accounting Standards Board issued Statement No. 123 (revised 2004) which requires all share-based payment to employees to be recognized in the statement of operations based on their fair values. During 2005 we will change our accounting policy to record expense for the fair value of the stock options granted, therefore our operating expenses will increase. We will continue to include stock options in our compensation arrangements.

Risk Related to Our Industry

If third-party payors do not reimburse customers for any of our product candidates that are approved for marketing, they might not be used or purchased, and our revenues and profits will not develop or grow.

Our revenues and profits depend heavily upon the availability of reimbursement for the use of our product candidates that are approved for marketing from third-party health care and government payors,

both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Since reimbursement approval for a product is required from each third-party and government payor individually, seeking this approval is a time-consuming and costly process. Third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of any product we might bring to market. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any drug product incorporating new technology. In addition, as a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

New federal legislation will increase the pressure to reduce the price of pharmaceutical products paid for by Medicare, which will adversely affect our revenues, if any.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse for pharmaceutical products. The legislation expands Medicare coverage for drug purchases by the elderly and eventually will introduce a new reimbursement methodology based on average sales prices for drugs. In addition, the new legislation provides authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of the new legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These costs initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could seriously harm our business.

Foreign governments tend to impose strict price controls, which may adversely affect our revenues, if any.

In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability for a product and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of products that expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend

ourselves against these claims, we may incur substantial losses or expenses, be required to limit the commercialization of our product candidates and face adverse publicity. We have obtained limited product liability insurance coverage for our clinical trials with a $10 million annual aggregate coverage limit, and our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash.

If our competitors develop and market products faster than we do or if the products of our competitors are considered more desirable than ours, revenues for any of our product candidates that are approved for marketing will not develop or grow.

The pharmaceutical industry, and the dermatology segment in particular, is highly competitive and includes a number of established, large and mid-sized pharmaceutical companies, as well as smaller emerging companies, whose activities are directly focused on our target markets and areas of expertise. We face and will continue to face competition in the discovery, in-licensing, development and commercialization of our product candidates, which could severely impact our ability to generate revenue or achieve significant market acceptance of our product candidates. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates or technologies obsolete or noncompetitive.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical trial experience; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than us. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or technologies. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than us in manufacturing and marketing their products.

Our recently acquired Solagé® product faces competition in the treatment of solar lentigeness from Triluma from Galderma S.A., Avage from Allergan, Inc., EpiQuin Micro from SkinMedica, Inc. and other prescription 4% hydroquinone formulations as well as over-the-counter 2% hydroquinone products, Retin-A from Neutrogena and other tretinoin containing topical formulations. If approved, each of our product candidates will compete for a share of the existing market with numerous products that have

become standard treatments recommended or prescribed by physicians. For example, we believe the primary competition for our product candidates are:

- For Zimycan, in the treatment of diaper dermatitis complicated by candidiasis, ointments and creams containing nystatin, Mycolog II from Bristol-Myers Squibb Company, clotrimazole containing creams from Bayer AG and from generic manufacturers and topical miconazole creams.

- For Sebazole, in the treatment of seborrheic dermatitis, Nizoral from Janssen, ketoconazole creams from generic manufacturers, Desowen from Galderma S.A. and Loprox from Medicis Pharmaceutical Corporation.

- For Hyphanox, in the treatment of vaginal candidiasis, Diflucan from Pfizer Inc., generic fluconazole tablets, Sporanox from Janssen and generic itraconazole capsules. For Hyphanox, in the treatment of onychomycosis, Sporanox from Janssen, Lamisil from Novartis AG and Penlac from Dermik Laboratories.

- For Liarozole, in the treatment of congenital ichthyosis, Soriatane from Hoffmann-La Roche Inc. and Connetics and over-the-counter topical moisturizers and emollients.

- For oral Rambazole, in the treatment of acne, Accutane from Hoffman-La Roche and generic manufacturers. For oral Rambazole, in the treatment of psoriasis, Soriatane from Hoffman-La Roche and Connetics, biologic agents such as Amevive from Biogen Idec Inc. and Raptiva from Genentech, Inc. and methotrexate from generic manufacturers.

We also believe that many of the competitive products for our later stage product candidates and Rambazole will similarly compete with our earlier stage product candidates because of the indications for which we are developing these product candidates.

Risks Related to Our Common Stock

Our stock price is volatile, and the market price of our common stock may drop below the price you pay.

Market prices for securities of biopharmaceutical and specialty pharmaceutical companies have been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of our clinical trials or those of our competitors;

- the regulatory status of our product candidates;

- whether or not Janssen exercises its option to commercialize Hyphanox;

- failure of any of our product candidates, if approved, to achieve commercial success;

- developments concerning our competitors and their products;

- success of competitive products and technologies;

- regulatory developments in the United States and foreign countries;

- developments or disputes concerning our patents or other proprietary rights;
- our ability to manufacture any products to commercial standards;
- public concern over our drugs;
- litigation involving our company or our general industry or both;
- future sales of our common stock;
- changes in the structure of health care payment systems, including developments in price control legislation;
- departure of key personnel;
- period-to-period fluctuations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates of our financial results or recommendations by securities analysts;
- investors' general perception of us; and
- general economic, industry and market conditions.

If any of these risks occurs, it could cause our stock price to fall and may expose us to class action lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Provisions in our certificate of incorporation and bylaws and under Delaware law may prevent or frustrate a change in control or a change in management that stockholders believe is desirable.

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- a classified board of directors;
- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could be used to institute a rights plan, or a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors.

The affirmative vote of the holders of at least two-thirds of our shares of capital stock entitled to vote is necessary to amend or repeal the above provisions of our certificate of incorporation. In addition,

absent approval of our board of directors, our bylaws may only be amended or repealed by the affirmative vote of the holders of at least two-thirds of our shares of capital stock entitled to vote.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of our company.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities. We invest in high-quality financial instruments, primarily money market funds, federal agency notes, corporate debt securities and United States treasury notes, with the effective duration of the portfolio of approximately one year, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

Most of our transactions are conducted in United States dollars, although we do have some agreements with vendors located outside the United States. Transactions under some of these agreements are conducted in United States dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under other of these agreements are conducted in the local foreign currency. We have a wholly-owned subsidiary, Barrier Therapeutics, N.V., which is located in Geel, Belgium. Except for funding being received under our grant from a Belgian governmental agency, which is denominated in Euros and locally earned interest income, all research costs incurred by Barrier Therapeutics, N.V. are funded under a service agreement with us from investments denominated in dollars. Therefore, we are subject to currency fluctuations and exchange rate gains and losses on these transactions. If the exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements are annexed to this Annual Report on Form 10-K beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report.. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including our

Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure. We believe that a controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Directors

The information concerning our directors required by Item 10 is incorporated by reference to the information contained under the heading "Election of Directors" in our definitive proxy statement for the 2005 annual meeting of stockholders.

Our Executive Officers

The information concerning our executive officers required by Item 10 included herein at the end of Part 1 under the heading "Our Executive Officers".

Audit Committee Financial Expert

The information concerning our audit committee financial expert required by Item 10 is incorporated by reference to the information contained under the heading "Meetings and Committees of the Board of Directors" in our definitive proxy statement for the 2005 annual meeting of stockholders.

Identification of the Audit Committee

The information concerning our audit committee required by Item 10 is incorporated by reference to the information contained under the heading "Meetings and Committees of the Board of Directors" in our definitive proxy statement for the 2005 annual meeting of stockholders.

Compliance with Section 16(a) of the Exchange Act

The information concerning our compliance with Section 16(a) of the Exchange Act by our directors and executive officers required by Item 10 is incorporated by reference to the information contained under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for the 2005 annual meeting of stockholders.

Code of Ethics

The information concerning our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller required by Item 10 is incorporated by reference to the information contained under the heading "Corporate Governance" in our definitive proxy statement for the 2005 annual meeting of stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is incorporated by reference to the information contained under the headings "Executive Compensation" and "Director Compensation" in our definitive proxy statement for the 2005 annual meeting of stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is incorporated by reference to the information contained under the headings "Ownership of Common Stock" and "Equity Compensation Plan Information" in our definitive proxy statement for the 2005 annual meeting of stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 13 is incorporated by reference to the information contained under the headings "Executive Compensation" in our definitive proxy statement for the 2005 annual meeting of stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is incorporated by reference to the information contained under the heading "Independent Public Auditor" in our definitive proxy statement for the 2005 annual meeting of stockholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) DOCUMENTS FILED AS PART OF THIS REPORT

The following is a list of our consolidated financial statements and our subsidiaries and supplementary data included in this report under Item 8 of Part II hereof:

1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

Report of Independent Auditors.

Consolidated Balance Sheets as of December 31, 2004 and 2003.

Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002.

Consolidated Statements of Stockholders' Equity (Deficiency) for the years ended December 31, 2004, 2003 and 2002.

Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002.

Notes to Consolidated Financial Statements.

2. FINANCIAL STATEMENT SCHEDULES

Schedules are omitted because they are not applicable or are not required, or because the required information is included in the consolidated financial statements or notes thereto.

Exhibits

The following is a list of exhibits filed as part of this annual report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation, filed as Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
3.2	Amended and Restated Bylaws of the Registrant, filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
4.1	Specimen copy of stock certificate for shares of Common Stock of the Registrant, filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
4.2	Amended and Restated Investors Rights Agreement, dated as of April 20, 2004, by and among the Registrant and the Investors listed therein, filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.1†	2002 Equity Compensation Plan, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.2*(1)*	Intellectual Property Transfer and License Agreement, dated as of May 6, 2002, by and between the Registrant and Johnson & Johnson Consumer Companies, Inc., filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.3	Amendment No. 1 to the Intellectual Property Transfer and License Agreement dated as of September 7, 2004, by and between Barrier Therapeutics, Inc. and Johnson & Johnson Consumer Companies, Inc., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 10, 2004
10.4*(1)*	Intellectual Property Transfer and License Agreement, dated as of May 6, 2002, by and among the Registrant and Janssen Pharmaceutica Products, L.P. and Ortho-McNeil Pharmaceutical, Inc., filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-112539)

Exhibit No.	Description
10.5	Amendment No. 1 to the Intellectual Property Transfer and License Agreement, dated as of September 7, 2004, by and between Barrier Therapeutics, Inc. and Janssen Pharmaceutica Products, L.P. , filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 10, 2004
10.6†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.7†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Charles Nomides, filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.8†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
*10.9†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Alfred Altomari
*10.10†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Albert Bristow
10.11†	Restricted Stock Purchase Agreement, dated as of October 31, 2001, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.12†	Amendment No. 1 to Restricted Stock Purchase Agreement, dated as of May 7, 2002, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.13†	Amendment No. 2 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.14†	Restricted Stock Purchase Agreement, dated as of February 20, 2002, by and between the Registrant and Charles Nomides, filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.15†	Amendment No. 1 to Restricted Stock Purchase Agreement, dated May 7, 2002, by and between the Registrant and Charles Nomides, filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.16†	Amendment No. 2 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Charles Nomides, filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-112539)

Exhibit No.	Description
10.17†	Restricted Stock Purchase Agreement, dated as of August 1, 2002, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.18†	Amendment No. 1 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.19	Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.20	Amendment No. 1 dated November 6, 2003, to Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.21	Master Security Agreement, dated as of August 21, 2003 and Amendment, dated as of September 3, 2003, between the Registrant and General Electric Capital Corporation, filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.22*(1)*	Development and Supply Agreement, dated as of May 16, 2002, between the Registrant and Abbott GmbH & Co. KG, filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.23†	2004 Stock Incentive Plan, filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.24†	Employee Stock Purchase Plan, filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.25	Amendment No. 2 dated May 13, 2004, to Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2004.
10.26*(1)*	Distribution and License Agreement dated November 4, 2004 between the Registrant and Grupo Ferrer Internacional, S.A., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 9, 2004
10.27	Finished Product Supply Agreement, dated July 14, 2004, between Janssen Pharmaceutica, NV and the Registrant
10.28	Product Acquisition Agreement, dated as of February 5, 2005, by and between the Registrant and Moreland Enterprises Limited

Exhibit No.	Description
*21	List of Subsidiaries
*23.1	Consent of Ernst & Young LLP
*23.2	Power of Attorney (included on signature page)
*31.1	Certification of principal executive officer required by Rule 13a-14(a)
*31.2	Certification of principal financial officer required by Rule 13a-14(a)
*32.1	Section 1350 Certification of principal executive officer
*32.2	Section 1350 Certification of principal financial officer

* Filed herewith.

† Compensation plans and arrangements for executives and others.

(1) Portions of the Exhibit have been omitted and have been filed separately pursuant to an application for confidential treatment granted by the Securities and Exchange Commission.

SIGNATURES

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

March 25, 2005

BARRIER THERAPEUTICS, INC.
(Registrant)

By: GEERT CAUWENBERGH
Geert Cauwenbergh, Ph.D.
Chairman And Chief Executive Officer
(Principal Executive Officer)

By: ANNE M. VANLENT
Anne M. VanLent
Executive Vice President, Chief Financial Officer & Treasurer
(Principal Financial Officer)

POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated. Each person whose signature appears below in so signing also makes, constitutes and appoints Geert Cauwenbergh, Ph.D. and Anne M. VanLent and each of them acting alone, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to execute and cause to be filed with the Securities and Exchange Commission any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, and hereby ratifies and confirms all that said attorney-in-fact or his substitute or substitutes may do or cause to be done by virtue hereof.

Signature	Title	Date
GEERT CAUWENBERGH Geert Cauwenbergh, Ph.D.	Chairman and Chief Executive Officer (Principal executive officer)	March 25, 2005
ANNE M. VANLENT Anne M. VanLent	Executive Vice President, Chief Financial Officer and Treasurer (Principal financial officer)	March 25, 2005
SRINIVAS AKKARAJU Srinivas Akkaraju, M.D., Ph.D.	Director	March 25, 2005

ROBERT CAMPBELL		
Robert Campbell	Director	March 25, 2005
CARL EHMANN		
Carl Ehmann, M.D.	Director	March 25, 2005
PETER ERNSTER		
Peter Ernster	Director	March 25, 2005
CHARLES F. JACEY, JR.		
Charles F. Jacey, Jr.	Director	March 25, 2005
ANDREW N. SCHIFF		
Andrew N. Schiff, M.D.	Director	March 25, 2005
NICHOLAS SIMON		
Nicholas Simon	Director	March 25, 2005

BARRIER THERAPEUTICS, INC.
(a development stage company)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Barrier Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Barrier Therapeutics, Inc. and Subsidiary (a development stage company) as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for each of the three years in the period ended December 31, 2004 and for the period from September 17, 2001 (inception) to December 31, 2004. 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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 consolidated financial position of Barrier Therapeutics, Inc. at December 31, 2004 and 2003 and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, and for the period from September 17, 2001 (inception) to December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Metro Park, New Jersey
February 24, 2005

BARRIER THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2004	2003
Assets		
Current assets:		
Cash and cash equivalents	$ 11,907,632	$ 11,471,652
Marketable securities	77,173,505	42,304,660
Interest receivable	925,643	716,226
Prepaid expenses and other current assets	1,610,427	1,239,712
Total current assets	91,617,207	55,732,250
Property and equipment, net	1,124,291	844,741
Security deposits	42,290	38,579
Deferred financing costs	—	355,000
Total assets	$ 92,783,788	$ 56,970,570
Liabilities, redeemable preferred stock and stockholders' equity (deficiency)		
Current liabilities:		
Notes payable, current portion	$ 261,131	$ 253,541
Accounts payable	3,147,628	1,358,576
Accrued expenses	4,687,054	1,952,065
Deferred revenue	650,000	453,482
Other current liabilities	24,889	32,543
Total current liabilities	8,770,702	4,050,207
Notes payable, long-term portion	443,315	193,379
Commitments and Contingencies		
Series A redeemable convertible preferred stock, $.0001 par value; 4,166,666 shares authorized, 0 shares issued and outstanding at December 31, 2004, 4,166,666 shares, issued and outstanding at December 31, 2003	—	29,689,482
Series B redeemable convertible preferred stock, $.0001 par value; 7,691,667 shares authorized, 0 shares issued and outstanding at December 31, 2004, 7,691,667 shares issued and outstanding at December 31, 2003	—	51,832,740
Series C redeemable convertible preferred stock $.0001 par value; 4,102,565 shares authorized, 0 shares issued and outstanding at December 31, 2004, 4,102,565 issued and outstanding at December 31, 2003	—	32,738,346
Stockholders' deficiency:		
Common stock, $.0001 par value; 80,000,000 authorized, 21,894,830 issued and outstanding at December 31, 2004; and 40,000,000 shares authorized; 822,500 issued and outstanding at December 31, 2003	2,190	83
Additional paid-in capital	191,567,857	887,268
Deficit accumulated during development stage	(106,199,976)	(61,864,753)
Deferred compensation	(1,510,114)	(527,652)
Accumulated other comprehensive loss	(290,186)	(28,530)
Total stockholders' equity (deficiency)	83,569,771	(61,533,584)
Total liabilities and stockholders' equity	$ 92,783,788	$ 56,970,570

See accompanying notes.

BARRIER THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,			Period from September 17, 2001 (inception) to December 31,
	2004	2003	2002	2004
Revenues:				
Contract	$ 100,000	$ —	$ —	$ 100,000
Grant	796,593	366,751	—	1,163,344
Total revenues	896,593	366,751	—	1,263,344
Operating expenses:				
Research and development	30,904,344	17,484,410	3,542,638	51,931,392
Sales and marketing	4,309,745	—	—	4,309,745
General and administrative	7,164,493	3,730,258	1,531,347	12,446,195
In-process research and development	—	—	25,000,000	25,000,000
Total operating expenses	42,378,582	21,214,668	30,073,985	93,687,332
Loss from operations	(41,481,989)	(20,847,917)	(30,073,985)	(92,423,988)
Interest income	1,408,634	418,906	274,636	2,102,191
Interest expense	(36,313)	(3,289)	(4,586)	(45,373)
Loss before income tax benefit	(40,109,668)	(20,432,300)	(29,803,935)	(90,367,170)
Income tax benefit	366,789	217,027	—	583,816
Net loss	(39,742,879)	(20,215,273)	(29,803,935)	(89,783,354)
Preferred stock accretion	(4,592,344)	(8,432,174)	(3,392,104)	(16,416,622)
Net loss attributable to common stockholders	$(44,335,223)	$ (28,647,447)	$(33,196,039)	$(106,199,976)
Basic and diluted net loss attributable to common stockholders per share	$ (3.02)	$ (83.95)	$ (240.75)	
Weighted-average shares outstanding—basic and diluted	14,677,710	341,256	137,889	

See accompanying notes.

BARRIER THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)

Period from September 17, 2001 (inception) to December 31, 2001, and the years ended December 31, 2002, 2003, and 2004

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During Development Stage	Notes Receivable From Officer	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficiency)
	Shares	Amount						
Initial incorporation on September 17, 2001 (inception)	637,500	$ 64	$ 1,212	$ —	$ —	$ —	$ —	$ 1,276
Net loss				(21,267)				(21,267)
Balance at December 31, 2001	637,500	64	1,212	(21,267)	—	—	—	(19,991)
Net loss				(29,803,935)				(29,803,935)
Unrealized gain on available for sale securities							30,992	30,992
Foreign currency translation							9,147	9,147
Total comprehensive loss								(29,763,796)
Issuance of common stock	185,000	19	20,880					20,899
Compensation expense related to options issued to non-employees			17,467					17,467
Loan to officer					(59,980)			(59,980)
Preferred stock accretion				(3,392,104)				(3,392,104)
Balance at December 31, 2002	822,500	83	39,559	(33,217,306)	(59,980)	—	40,139	(33,197,505)
Net loss				(20,215,273)				(20,215,273)
Unrealized loss on available for sale securities							(42,816)	(42,816)
Foreign currency translation							(25,853)	(25,853)
Total comprehensive loss								(20,283,942)
Compensation expense related to options issued to non-employees			107,448					107,448
Restricted stock no longer subject to repurchase			14,511					14,511
Deferred compensation relating to stock options			725,750			(725,750)		—
Amortization of deferred compensation						198,098		198,098
Repayment of notes receivable					59,980			59,980
Preferred stock accretion				(8,432,174)				(8,432,174)
Balance at December 31, 2003	822,500	83	887,268	(61,864,753)	—	(527,652)	(28,530)	(61,533,584)
Net loss				(39,742,879)				(39,742,879)
Unrealized loss on available for sale securities							(179,383)	(179,383)
Foreign currency translation							(82,273)	(82,273)
Total comprehensive loss								(40,004,535)
Conversion of preferred stock to common stock	15,960,898	1,596	118,835,127					118,836,723
Issuance of common stock	5,000,000	500	67,940,862					67,941,362
Stock issued upon exercise of stock options	107,382	11	116,964					116,975
Stock issued under employee stock purchase plan	4,050	—	36,215					36,215
Compensation expense related to options issued to non-employees			755,909					755,909
Restricted stock no longer subject to repurchase			11,702					11,702
Deferred compensation relating to stock options			2,994,626			(2,994,626)		—
Amortization of deferred compensation						2,001,348		2,001,348
Reversal of deferred compensation due to employee terminations			(10,816)			10,816		—
Preferred stock accretion				(4,592,344)				(4,592,344)
Balance at December 31, 2004	21,894,830	$2,190	$191,567,857	$ (106,199,976)	$ —	$ (1,510,114)	$ (290,186)	$ 83,569,771

See accompanying notes.

BARRIER THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Period from September 17, 2001 (inception) to December 31,
	2004	2003	2002	2004
Operating activities				
Net loss	$ (39,742,879)	$ (20,215,273)	$(29,803,935)	$ (89,783,354)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	380,555	143,779	38,462	562,796
Amortization of deferred compensation	2,001,348	198,098	—	2,199,446
Purchased in-process research and development	—	—	25,000,000	25,000,000
Non-cash compensation expense related to the issuance of options to non-employees	755,909	107,448	17,467	880,824
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(370,715)	(384,450)	(669,668)	(1,424,833)
Interest receivable	(209,417)	(472,206)	(244,020)	(925,643)
Accounts payable and accrued expenses	4,879,041	1,419,682	1,528,340	7,834,682
Deferred revenue	196,518	453,482	—	650,000
Other, net	(78,821)	(29,831)	1,009	(77,019)
Net cash used in operating activities	(32,188,461)	(18,779,271)	(4,132,345)	(55,083,101)
Investing activities				
Purchase of fixed assets	(660,105)	(751,039)	(275,943)	(1,687,087)
Security deposits	(3,711)	(38,579)	—	(42,290)
Purchase of marketable securities	(104,323,663)	(52,592,578)	(13,034,384)	(169,950,625)
Maturities of marketable securities	69,275,435	22,354,667	955,811	92,585,912
Net cash used in investing activities	(35,712,044)	(31,027,529)	(12,354,516)	(79,094,090)
Financing activities				
Issuance of convertible promissory notes	—	—	50,000	150,000
Repayment of loan to officer	—	59,980	—	59,980
Borrowings under notes payable	555,193	267,851	—	823,044
Repayment of notes payable	(297,667)	(6,525)	—	(304,192)
Proceeds from issuance of preferred stock	(16,189)	54,918,631	22,367,659	77,270,101
Proceeds from issuance of common stock, net	67,941,362	—	171	67,942,809
Proceeds from exercise of stock options and other benefit plans	153,190	—	6,000	159,190
Net cash provided by financing activities	68,335,889	55,239,937	22,423,830	146,100,932
Effect of exchange rate on cash and cash equivalents	596	3,585	9,147	(16,110)
Net increase in cash and cash equivalents	435,980	5,436,723	5,946,116	11,907,632
Cash and cash equivalents, beginning of period	11,471,652	6,034,929	88,813	—
Cash and cash equivalents, end of period	$ 11,907,632	$ 11,471,652	$ 6,034,929	$ 11,907,632
Supplemental disclosures of cash flow information				
Cash paid during the period for interest	$ 36,313	$ 3,289	$ 5,671	$ 45,273
Non-cash investing and financing activities				
Issuance of common stock in exchange for notes payable	$ —	$ —	$ 59,980	$ 59,980
Preferred stock issued for convertible promissory note	$ —	$ —	$ 150,000	$ 150,000
Release of formerly restricted stock	$ 11,702	$ 14,511	$ —	$ 26,213
Issuance of note payable in exchange for prepaid insurance	$ —	$ 185,594	$ —	$ 185,594
Issuance of Series A redeemable convertible preferred stock in exchange for purchased in-process research and development	$ —	$ —	$ 25,000,000	$ 25,000,000
Conversion of preferred stock	$ 118,836,723	$ —	$ —	$ 118,836,723
Initial public offering expenses reclassified to Additional Paid-in Capital	$ 1,808,638	$ —	$ —	$ 1,808,638

See accompanying notes.

BARRIER THERAPEUTICS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2004

1. Summary of Significant Accounting Policies

Organization, Description of Business and Basis of Presentation

Barrier Therapeutics, Inc. (the "Company") was incorporated in Delaware on September 17, 2001 but commenced active operations in May 2002. The Company was formed to develop and market products that address medical needs in the treatment of dermatological diseases and disorders initially based on intellectual property in-licensed from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., each a Johnson & Johnson company. The Company's activities since inception have consisted principally of raising capital, performing research and development, hiring personnel and establishing facilities. Accordingly, the Company is considered to be in the development stage. The Company has offices in Princeton, New Jersey and Geel, Belgium.

Since inception, the Company has relied primarily upon the sale of equity securities to fund operations, most recently through the Company's initial public offering in April 2004 and follow-on public offering in February 2005. The Company believes that its existing resources should be sufficient to meet its capital and liquidity requirements through at least the end of 2006. However, the Company's capital requirements will depend on many factors, including the success of its development and commercialization of the Company's product candidates. Even if the Company succeeds in developing and commercializing one or more of its product candidates, it may never achieve sufficient sales revenue to achieve or maintain profitability. There can be no assurance that the Company will be able to obtain additional capital when needed on acceptable terms, if at all.

Initial Public Offering

On May 4, 2004, the Company completed an initial public offering ("IPO") of 5,000,000 shares of the Company's common stock which resulted in net proceeds of approximately $67.9 million after payment of underwriting discounts and commissions and other expenses aggregating $7.1 million.

Reverse Stock Split

On April 28, 2004, the Company completed a one-for-two reverse stock split of its common stock pursuant to which every two shares of the Company's common stock were replaced with one share of the Company's common stock and the conversion ratio of each share of preferred stock was adjusted accordingly to reflect the reverse stock split. As a result, in connection with the IPO, on April 28, 2004, the 31,921,809 outstanding shares of the Company's redeemable convertible preferred stock converted into 15,960,898 shares of the Company's common stock.

All references to common stock, common shares outstanding, average number of common shares outstanding and per share amounts in these consolidated financial statements and condensed notes to consolidated financial statements prior to the effective date of the reverse stock split have been restated to reflect the one-for-two reverse stock split on a retroactive basis.

Redeemable Convertible Preferred Stock

The carrying value of redeemable preferred stock was increased by periodic accretions through the date of its conversion at the IPO. These increases were effected through charges to deficit accumulated during the development stage.

Consolidation

The financial statements include the accounts of Barrier Therapeutics, Inc. and its wholly-owned subsidiary, Barrier Therapeutics, NV. Intercompany transactions and balances are eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2004, the Company has substantially all of its cash and cash equivalents deposited with one financial institution.

Marketable Securities

Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income.

Fair Value of Financial Instruments

The carrying amounts of the Company’s financial instruments, which include cash and cash equivalents, marketable securities, accounts payable, accrued expenses, and notes payable approximate their fair values.

Fixed Assets

Fixed assets include furniture and fixtures, computer and office equipment and software. Fixed assets are stated at cost, less accumulated depreciation. Depreciation is provided over the estimated useful lives of the respective assets, generally three to seven years, using the straight-line method. Leasehold improvements are amortized over the estimated useful lives of the assets or related initial lease terms, whichever is shorter.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including fixed assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is assessed using discounted cash flows. Through December 31, 2004, no impairment has occurred.

Revenue Recognition

The Company uses revenue recognition criteria in Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements" and Emerging Issues Task Force ("EITF") Issue 00-21 "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into license fees in the statement of operations over the terms of the performance obligation.

Contract revenues include license fees and other payments associated with collaborations with third parties. Revenue from non-refundable, upfront license fees where the Company has continuing involvement is recognized ratably over the performance period. Royalties from licensees are based on third-party sales of licensed products and will be recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured.

Grant revenues are recognized as the Company provides the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

Research and Development Costs

Costs to develop the Company's products are expensed as incurred. Assets acquired that are used for research and development and have no future alternative use are expensed as in-process research and development.

Concentration of Credit Risk

The Company's financial instruments that are exposed to concentration of credit risks consist primarily of cash and cash equivalents, and marketable securities. The Company maintains its cash and cash equivalents in bank accounts which, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to significant credit risk on cash and cash equivalents and marketable securities.

Income Taxes

The Company accounts for income taxes under the asset and liability method whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Foreign Currency Translation

Assets and liabilities are translated into U.S. dollars at year-end exchange rates and equity accounts are translated at historical exchange rates. The Company translates income and expense accounts at weighted average rates for each month and records gains and losses from the translation of financial statements in foreign currencies into U.S. dollars in other comprehensive income.

Comprehensive Loss

Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income*, requires components of other comprehensive loss, including unrealized gains and losses on available-for-sale securities and foreign currency translation, to be included as part of total comprehensive loss. The components of comprehensive loss are included in the statements of stockholders' equity.

Stock-Based Compensation

As allowed by SFAS 123, the Company had elected to continue to apply the intrinsic value-based method of accounting prescribed in APB Opinion 25 and, accordingly, does not recognize compensation expense for stock option grants made at an exercise price equal to or in excess of the fair market value of the stock at the date of grant.

Had compensation cost for the Company's outstanding employee stock options been determined based on the fair value at the grant dates for those options consistent with SFAS 123, the Company's net loss and basic and diluted net loss per share, would have been changed to the following pro forma amounts:

	Year Ended December 31,		
	2004	2003	2002
Net loss attributable to common stockholders	$ (44,335,223)	$(28,647,447)	$ (33,196,039)
Add noncash employee compensation as reported	2,001,348	198,098	
Deduct total stock-based employee compensation expense determined under fair value based method for all awards	(3,618,458)	(600,483)	(69,156)
SFAS 123 pro forma net loss	$ (45,952,333)	$(29,049,832)	$ (33,265,195)
Basic and diluted loss attributable per common share	$ (3.02)	$ (83.95)	$ (240.75)
Basic and diluted loss attributable to common stockholders per share, SFAS 123 pro forma	$ (3.13)	$ (85.13)	$ (241.25)

SFAS 123 pro forma information regarding net loss is required by SFAS 123, and has been determined as if the Company had accounted for its stock-based employee compensation under the fair value method prescribed in SFAS 123. The fair value of the options was estimated using the Black-Scholes pricing model with the following assumptions:

	Year Ended December 31,		
	2004	2003	2002
Risk-free interest rate	3.0%	2.8-3%	4.0-4.5%
Dividend yield	0%	0%	0%
Expected life	8.5 years	9.0 years	9.5 years
Volatility	65%	75%	75%

The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. Stock option grants are expensed over their respective vesting periods.

The Company accounts for options issued to nonemployees under SFAS 123 and EITF Issue 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services* ("EITF 96-18"). As such, the value of such options is periodically remeasured during their vesting terms.

Deferred Stock Compensation

During the year ended December 31, 2004, in connection with the grant of stock options to employees and directors, the Company recorded deferred stock compensation totaling $2,994,626, representing the difference between the fair value of common stock on the date such options were granted, determined in accordance with GAAP, and the exercise price. These amounts are included as a reduction of stockholders' equity and are being amortized over the vesting period of the individual options, generally four years, using an accelerated vesting method. The accelerated vesting method provides for vesting of portions of the overall award at interim dates and results in higher vesting in earlier years than straight-line vesting. During the year ended December 31, 2004, the Company recorded amortization of deferred stock compensation of $2,001,348.

Net Loss Per Common Share

The Company computes basic net loss per common share ("Basic EPS") by dividing net loss by the weighted-average number of common shares outstanding. Diluted net loss per common share ("Diluted EPS") is computed by dividing net loss by the weighted-average number of common shares and dilutive common shares equivalents then outstanding. Common equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, and the shares issuable upon the exercise of stock options. Diluted EPS is identical to Basic EPS since common equivalent shares are excluded from the calculations, as their effect is anti-dilutive. The following table summarizes the Company's calculation of net loss per common share:

	Year Ended December 31,		
	2004	2003	2002
Net loss attributable to common stockholders	$(44,335,223)	$ (28,647,447)	$ (33,196,039)
Basic and diluted:			
Weighted-average shares of common stock outstanding	14,988,799	822,500	735,288
Less: weighted-average shares subject to repurchase	(311,089)	(481,244)	(597,399)
Shares used in computing basic and diluted net loss per common share	14,677,710	341,256	137,889
Basic and diluted net loss per common share	$ (3.02)	$ (83.95)	$ (240.75)

Recently Issued Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 123 (revised 2004) *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes Accounting Principal Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and amends FASB No. 95, *Statement of Cash Flows*. Generally, the approach to accounting in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Currently the Company accounts for these payments under the intrinsic value provisions of APB No. 25. Statement 123(R) must be adopted no later than July 1, 2005. The Statement offers several alternatives for implementation. At this time, the Company's management has not made a decision as to the alternative it may select. The Company is in the process of determining how the new method of valuing stock-based compensation as prescribed by Statement 123(R) will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of additional non-cash compensation expense related to such awards will have on its financial statements.

2. Available for Sale Investments

The following is a summary of available for sale investments as of December 31, 2004 and December 31, 2003:

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2003				
Maturities within one year:				
Corporate notes	$ 32,063,659	$ —	$ (26,919)	$ 32,036,740
Maturities between one to five years:				
Corporate notes	10,252,825	15,095		10,267,920
Total	$ 42,316,484	$ 15,095	$ (26,919)	$ 42,304,660
December 31, 2004				
Maturities within one year:				
Corporate notes	$ 56,244,826	$ —	$(172,622)	$ 56,072,204
Federal agency notes	16,431,651	—	(12,287)	16,419,364
Asset-backed securities	4,688,235	—	(6,298)	4,681,937
Total	$ 77,364,712	$ —	$(191,207)	$ 77,173,505

Unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and discounts from the date of purchase to maturity. Such amortization is included in interest income as an addition to or deduction from the coupon interest earned on the investments. There are no realized gains or losses on marketable securities as the Company has not sold any marketable securities during the periods presented and cost has approximated fair value at the maturity dates.

Unrealized losses in the Company's portfolio relate primarily to fixed income debt securities and the majority of the unrealized losses are one year or less. For these securities, the unrealized losses are due to increases in interest rates and not changes in credit risk. The gross unrealized losses in the portfolio of investments represent less than one percent of the total fair value of the portfolio. The Company has concluded that the unrealized losses in its marketable securities are not other-than-temporary and the Company has the ability to hold the securities to maturity or a planned forecasted recovery.

3. Fixed Assets

Fixed assets consist of the following:

	December 31, 2004	December 31, 2003
Furniture and fixtures	$ 470,832	$ 298,151
Computer, laboratory and office equipment	702,999	426,605
Computer software	468,277	279,721
Leasehold improvements	44,979	22,505
	1,687,087	1,026,982
Less accumulated depreciation	(562,796)	(182,241)
	$ 1,124,291	$ 844,741

Depreciation expense was $380,555 and $143,779 for the years ended December 31, 2004 and 2003, respectively.

4. Balance Sheet Detail

Accrued liabilities consist of the following as of December 31:

	December 31, 2004	December 31, 2003
Accrued product costs	$ 2,316,224	$ 906,112
Accrued compensation and benefits	1,697,883	411,507
Accrued other	672,947	634,446
	$ 4,687,054	$ 1,952,065

5. Notes Payable

In September 2003, the company entered into an equipment and furniture financing arrangement with a third party for up to $750,000 which was increased to $1,500,000 in 2004, with an interest rate of 6.15% plus the three year Treasury Constant Maturities rates at the time of funding. Each time it receives funding, the Company will enter into a promissory note with a term of 3 years, collateralized by the related equipment and furniture.

In November 2003, the Company entered into a promissory note for $267,851, payable in 35 monthly installments of $8,498, including interest at 8.84%. In August 2004, the Company entered into a promissory note for $407,179, payable in 35 monthly installments of $12,939, including interest at 8.95%. In December 2004, the Company entered into a promissory note for $148,014, payable in 35 monthly installments of $4,732, including interest at 9.37%.

In December 2003, the Company financed $185,593 of its clinical trial insurance, to an unrelated third party. The balance due was paid in full in October 2004.

Commitments under notes payable are as follows:

2005	$ 261,131
2006	277,085
2007	166,230
	$ 704,446

6. Income Taxes

There is no tax provision for federal income taxes as the Company has incurred operating losses since inception. At December 31, 2004, the Company has net operating loss carryforwards for federal income tax purposes of approximately $58,109,000, which begin to expire in 2021. The Company has research tax credit carryovers for federal income tax purposes at December 31, 2004 of approximately $2,161,000, which begin to expire in 2021.

During 2004 and 2003, the Company sold a portion of its unused New Jersey State operating loss carryforwards, through a program sponsored by the State of New Jersey and the New Jersey Economic Development Authority. Cash proceeds of approximately $367,000 and $217,000, net of fees of $49,317 and $35,330, respectively, were received by the Company resulting in the recognition of a tax benefit.

The benefit for income taxes is as follows:

	Year Ended December 31,		
	2004	2003	2002
Federal income taxes:			
Current expense	$ –	$ –	$ –
Deferred expense	–	–	–
State income taxes:			
Current benefit	(366,789)	(217,027)	–
Deferred expense	–	–	–
Foreign income taxes:			
Current expense	–	–	–
Deferred expense	–	–	–
Income tax benefit	$(366,789)	$(217,027)	$ –

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change under Section 382 of the Internal Revenue Code occurred. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards attributable to periods before the change.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards. At December 31, 2004 and December 31, 2003, a valuation allowance was recorded to fully offset the net deferred tax asset. The change in the valuation allowance for the years ended December 31, 2004 and 2003 was approximately $17,835,000 and $8,034,000, respectively. Significant components of the Company's deferred tax assets at December 31, 2004 and 2003 are as follows:

	Year Ended December 31, 2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$22,760,000	$ 9,675,000
Stock-based compensation	1,232,000	129,000
Research tax credits	3,242,000	180,000
Deferred revenue	260,000	-
Other	407,000	42,000
Total deferred tax asset	27,901,000	10,026,000
Deferred tax liabilities:		
Depreciation	(102,000)	(62,000)
Total gross deferred tax liabilities	(102,000)	(62,000)
Less valuation allowance	(27,799,000)	(9,964,000)
Net deferred tax asset	$ —	$ —

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2004 and 2003 is as follows:

	Year Ended December 31, 2004	2003
Statutory rate	(34)%	(34)%
State income tax	(7)%	(6)%
Research tax credits	(5)%	-
Change in valuation allowance	45	39
Benefit for income tax	(1)%	(1)%

7. Stockholders' Equity and Capital Structure

Redeemable Convertible Preferred Stock

On April 28, 2004, in connection with the IPO and as a result of the adjustment to the conversion ratio effected by the one-for-two reverse stock split of the Company's common stock every two shares of the Company's Series A, Series B, and Series C redeemable convertible preferred stock were converted into one share of common stock. Fractional shares were redeemed for cash.

Series A Redeemable Convertible Preferred Stock

Series A redeemable convertible preferred stock ("Series A") was issued in exchange for licenses, intellectual property, patents and patent applications valued at $25,000,000 during 2002. The holders of Series A were Janssen Pharmaceutica Products L.P. and Johnson & Johnson Consumer Companies, Inc.

A total of 8,333,333 shares were converted and exchanged into 4,166,666 shares of common stock.

Series B Redeemable Convertible Preferred Stock

The Company received an aggregate of $46,150,008 in exchange for the issuance of the Series B redeemable convertible preferred stock ("Series B")at $3.00 per share. As a result of the initial closing of 7,716,670 shares during May 2002, the Company received $23,000,010 cash, and $150,000 of debt was converted to Series B during 2002. On May 7, 2003 (the second closing), the Company issued 7,666,666 shares for an aggregate purchase price of $22,999,998. Offering costs of approximately $632,000 were netted against gross proceeds.

A total of 15,383,336 shares were converted and exchanged into 7,691,667 shares of common stock.

Series C Redeemable Convertible Preferred Stock

The Company received an aggregate of $32,000,046 in exchange for the issuance of the Series C redeemable convertible preferred stock ("Series C") during 2003. Offering costs of approximately $97,000 were netted against gross proceeds.

A total of 8,205,140 shares were converted and exchanged into 4,102,565 shares of common stock.

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance at January 1, 2003	4,166,666	26,750,330	3,858,335	24,159,433	—	—
Issuance of Series B Redeemable Convertible Preferred Stock	—	—	3,833,332	22,999,998	—	—
Accretion to redemption value	—	2,939,152	—	4,673,309	—	—
Issuance of Series C Redeemable Convertible Preferred Stock	—	—	—	—	4,102,565	31,918,633
Accretion to redemption price	—	—	—	—	—	819,713
Balance at December 31, 2003	4,166,666	29,689,482	7,691,667	51,832,740	4,102,565	32,738,346
Accretion to redemption value	—	1,052,130	—	2,035,630	—	1,504,584
Financing expenses	—	—	—	—	—	(16,189)
Conversion into common stock	(4,166,666)	(30,741,612)	(7,691,667)	(53,868,370)	(4,102,565)	(34,226,741)
Balance at December 31, 2004	—	$ —	—	$ —	—	$ —

Preferred Stock

Pursuant to the Company's Amended and Restated Certificate of Incorporation filed on May 3, 2004, the Company has 5,000,000 shares of authorized "blank-check" preferred stock. The Board of Directors is authorized to issue these shares in one or more series without stockholder approval. The Board of Directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock.

Common Stock

The Company is authorized to issue 80,000,000 shares of common stock. The Company is required to, at all times, reserve and keep available out of its authorized but unissued shares of common stock sufficient shares to effect the conversion of the shares of the redeemable convertible preferred stock and stock options.

Restricted Stock Purchase Agreements

On October 31, 2001, the Company entered into restricted stock purchase agreements with three individuals who were founders of the Company, for an aggregate of 637,500 shares at a price of $.002 per share. Additionally, in February 2002, 75,000 shares were issued to another individual considered to be a founder of the Company, under a restricted stock purchase agreement. On August 1, 2002, the Company issued 100,000 shares of common stock under a restricted stock purchase agreement to one of the officers of the Company for $20 cash and a full-recourse note for $59,980. The note and accrued interest were repaid in full during 2003.

The restricted shares generally vest as follows: (a) 25% on the common stock shall vest on the date each founder commences employment with the Company, (b) 18.75% shall vest on the first anniversary of the date of employment, (c) the remaining 56.25% shall vest in equal installments over a three year period beginning the month following the first anniversary.

Employee Stock Purchase Plan

The Company established an Employee Stock Purchase Plan (the "ESPP") in February 2004 which was approved by the stockholders in March 2004. The ESPP became effective on April 28, 2004 in connection with the Company's initial public offering. The plan allows eligible employees the opportunity to acquire shares of Barrier's common stock (the "Common Stock") at periodic intervals through accumulated payroll deductions. These deductions will be applied at semi-annual intervals to purchase shares of Common Stock at a discount from the then current market price. The purchase price per share will be equal to 85% of the fair market value per share on the date in which the participant is enrolled, or, if lower, 85% of the fair market value per share on the semi-annual purchase date. Semi-annual purchase dates are the last business day of January and July each year.

Initially 200,000 shares were reserved for issuance. The number of shares reserved for the plan will be automatically increased each year on the first trading day in January by an amount equal to .5% of the total number of outstanding shares of common stock on the last trading day of December in the prior year, not to exceed 150,000 shares. There is a 1,500 share purchase limitation per participant and 7,500 aggregate purchase limitation per purchase date.

As of December 31, 2004, a total of 4,050 shares of common stock were purchased at $8.94 per share.

Stock Options

On April 26, 2002, the Company's Board of Directors and stockholders approved the Company's 2002 Equity Compensation Plan (the "2002 Plan"). In March 2004, the Company's Board of Directors and stockholders approved the Company's 2004 Equity Compensation Plan (the "2004" Plan). The 2004 Plan became effective concurrent with the initial public offering. On that date, the outstanding options

under the 2002 Plan were transferred to the 2004 Plan, and no further options may be granted under the 2002 Plan. The 2002 Plan options will continue to be governed by their existing terms, unless the Board or its committee elects to extend one or more features of the 2004 Plan to these options. The options granted under the 2002 Plan have substantially the same terms as the options granted under the 2004 Plan.

The 2004 Plan provides for the granting of options to purchase shares of the Company's common stock to key employees, advisors and consultants at a price not less than the fair market value at the date of grant, or stock appreciation rights tied to the value of such common stock. The number of shares of common stock reserved for issuance under the 2004 Plan will automatically increase each year on the first trading day in January of each calendar year by an amount equal to 5% of the total number of shares of common stock outstanding on the last trading day in December, not in excess of 1,000,000 shares.

The 2004 Plan is intended to encourage ownership of stock by employees and consultants of the Company and to provide additional incentives for them to promote the success of the Company's business and is administered by the Board of Directors or committee consisting of members of the Board. Options granted pursuant to the 2004 Plan generally vest 25% after the first year, and the remaining 75% vest monthly over the next three years.

The following table summarizes information about stock options outstanding at December 31, 2004:

		Options Outstanding		
	Shares Available for Grant	Number of Shares	Option Price Per Share Range	Weighted-Average Exercise Price
Balance at December 31, 2001	—	—	$ —	$ —
Shares authorized	1,037,500	—	—	—
Options granted	(367,500)	367,500	.60	.60
Options exercised	—	(10,000)	.60	.60
Options forfeited	—	—	—	—
Restricted shares granted	(100,000)	—	—	—
Balance at December 31, 2002	570,000	357,500	.60	.60
Shares authorized	500,000	—	—	—
Options granted	(521,083)	521,083	.80-3.00	.88
Options exercised	—	—	—	—
Options forfeited	—	—	—	—
Balance at December 31, 2003	548,917	878,583	.60-3.00	.88
Shares authorized	500,000	—	—	—
Options granted	(691,050)	691,050	3.50-17.70	8.50
Options exercised	—	(107,382)	.60-4.00	1.09
Options forfeited	23,314	(23,314)	.60-3.50	.94
Balance at December 31, 2004	381,181	1,438,937	$ .60-17.70	$ 4.52

The following table summarizes information about vested stock options outstanding:

	December 31,	
	2004	2003
Vested stock options	383,586	159,404
Weighted-average exercise price	$ 1.09	$ .68

The following table summarizes information about stock options outstanding at December 31, 2004:

Exercise Price	Options Outstanding	Options Vested	Weighted-Average Remaining Contractual Life
$.60 – $1.50	758,473	345,647	8.1
3.00 – 4.00	190,864	37,939	9.1
8.00 – 10.00	220,000	—	9.2
10.00 – 14.00	243,000	—	9.6
14.00 – 18.00	26,600	—	9.9
	1,438,937	383,586	8.7

The weighted-average fair value of options issued during 2004 was $10.70.

Compensation expense of $755,909 and $107,448 has been recognized in 2004 and 2003, respectively, for non-employee options granted.

8. In-Process Research and Development

In 2002, the Company licensed its initial portfolio of product candidates, other than Ecalcidene, and the patents and other intellectual property and know-how, test data, marketing data and other tangible property associated with those product candidates, from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc., and Ortho-McNeil Pharmaceutical, Inc. under two similar but separate intellectual property transfer and license agreements for use in the field of dermatology. Under the license agreements, the Company also has access to the classes of compounds claimed in the patents licensed to the Company under the license agreements, which the Company can screen in its search for new product candidates in the field of dermatology. This transaction was accounted for as an acquisition of assets.

The status of the most advanced of these product candidates at the time of acquisition are described below:

Seboride, a once-a-day dose topical gel based on the combination of ketoconazole and desonide for the treatment of seborrheic dermatitis that combines the long-lasting effect of the antifungal agent with the fast-acting, mid-potency steroid. As of the date acquired, Phase 2 clinical trials were completed for Seboride, and two Phase 3 clinical trials needed to be initiated and successfully completed prior to a new drug application filing.

Zimycan, an ointment with an active ingredient of 0.25% miconazole, an antifungal agent in a zinc oxide and petrolatum base for the treatment of infants with *Candida*-associated diaper dermatitis. When acquired, the Company needed to design, initiate and successfully complete an additional Phase 3 clinical trial in *Candida*-associated diaper dermatitis and file an amendment to the Company's new drug application that was assigned to the Company under the license agreements.

Hyphanox, formerly referred to by the Company as Sporamelt, an oral formulation of itraconazole, an antifungal agent, that the Company is developing for the treatment of various fungal infections. Bioequivalence studies and two Phase 3 clinical trials with an initial melt extrusion formulation of the drug were performed prior to the Company's acquisition of rights to the product candidate. As part of the license agreements, Janssen Pharmaceutica Products, L.P., retained an exclusive option to acquire the right to commercialize Hyphanox on a geographic region-by-region basis.

Liarozole, the Company's first product candidate based on a class of molecules known as retinoic acid metabolism blocking agents, or RAMBAs. The Company is developing Liarozole as an oral treatment for congenital ichthyosis. As of the acquisition date, topical Liarozole had undergone initial Phase 2 and Phase 3 clinical trials for ichthyosis.

The project rights were reviewed to determine the stage of their development, the achievement of technological feasibility and the technical milestones needed to be reached before commercialization is possible. It was determined as of the acquisition date that each project had significant technical risk associated with achieving the technological feasibility needed for FDA approval and each project had significant milestones to reach before commercialization. It was also determined that all of the projects had no alternative future uses if they were not successful. Accordingly, each product was classified as in-process research and development and expensed immediately.

The Company valued the assets acquired based on the value of the consideration that Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc., and Ortho-McNeil Pharmaceutical, Inc. received in the transaction. Concurrent with the transaction the Company issued for cash 15,333,336 shares of its series B redeemable convertible preferred stock, with similar characteristics to its series A redeemable convertible preferred stock, to investors not related to the Company or Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc., or Ortho-McNeil Pharmaceutical, Inc.. Based on the value of the Company's series B redeemable convertible preferred stock, the Company valued the in-process research and development at $25,000,000.

9. Loss Per Share

The following table set forth the computation of basic and diluted net loss attributed to common stockholders per share:

	Year Ended December 31,		
	2004	2003	2002
Numerator			
Net loss	$(39,742,879)	$ (20,215,273)	$ (29,803,935)
Preferred stock accretion	(4,592,344)	(8,432,174)	(3,392,104)
Numerator for basic and diluted net loss attributable to common stockholders per share—net loss attributable to common stockholders	$(44,335,223)	$ (28,647,447)	$ (33,196,039)
Denominator			
Denominator for basic and diluted net loss attributable to common stockholders per share—weighted-average shares	14,677,710	341,256	137,889
Basic and diluted net loss attributable to common stockholders per share	$ (3.02)	$ (83.95)	$ (240.75)

The following table shows dilutive common share equivalents outstanding, which are not included in the above historical calculation, as the effect of their inclusion is anti-dilutive during each period.

	Year Ended December 31,		
	2004	2003	2002
Preferred stock	—	31,921,809	16,050,003
Options	1,438,937	878,583	357,500

10. Commitments and Contingencies

Johnson & Johnson

In addition to the Series A exchanged for the acquisition of in-process research and development, Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc., and Ortho-McNeil Pharmaceutical, Inc., received certain rights of first negotiation for the marketing and sales of those drugs which the Company successfully develops from that portfolio. The most significant terms of the license provide the following:

(a) the licenses are subject to a right of first negotiation for the marketing and sale of those drugs which the Company elects not to market itself or through contract sales organizations on a territory-by- territory basis,

(b) the licenses are royalty-free, except for the so-called “itraconazole melt extrusion,” Hyphanox, which will require the payment of a royalty with respect to those sales not effectuated directly by the Company or through contract sales organizations on a territory-by-territory basis, and

(c) as to the "itraconazole melt extrusion" only, Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc., and Ortho-McNeil Pharmaceutical, Inc., has an option to acquire the marketing and sales rights on a territory-by-territory basis subject to payment to the Company of: fees as specified in the contract; all of the Company's development costs on such project; and a royalty on sales, as stated in the contract, depending on the duration from the date of delivery of materials until the Company's first major market filing for drug approval (NDA or equivalent).

Other Significant Agreements

The Company enters into agreements for clinical trials management, contract manufacturing and testing of its compounds. At December 31, 2004, the Company has aggregate commitments of approximately $12.2 million under such contracts.

Additionally, the Company has entered into one development and supply agreement which provides for a future royalty payment equal to a stated percentage of the weighted average market price of sales of certain finished products which incorporate the product developed under the same contract.

11. Related Party Transactions

In July 2004, the Company entered into an agreement with Janssen Pharmaceutica, NV under which the Company committed to purchase € 1,000,000 (approximately $1,365,000) of inventory within the two-year period ending July 2006.

The Company expensed $20,788 and $1,607,209 for the purchase of raw materials and clinical supplies from a company related to a preferred stockholder during 2004 and 2003, respectively.

The Company accrued interest of $4,586 to a preferred stockholder on the convertible promissory notes during 2002.

During 2002, the Company entered into an agreement with an officer to loan $59,980 for the purchase of 100,000 shares of restricted stock. At December 31, 2002, interest of $1,150 was accrued and included in interest receivable. During 2003, the principal amount of $59,980 and $3,024 of interest was paid in full.

12. Leases

The Company leases its U.S. corporate facilities in Princeton, New Jersey under a lease which expires in September 2010. The Company leases space in Geel, Belgium under a short-term service agreement with a monthly fee of approximately $17,000. Future minimum lease commitments, net of sublease income, are as follows:

2005	$ 594,443
2006	553,881
2007	584,416
2008	592,041
2009	614,917
Thereafter	461,188
	$ 3,400,886

Total rent expense was $425,068 in 2004, $282,662 in 2003, and $115,757 in 2002.

13. Benefit Plan

In July 2002, the Company established a 401(k) plan (the "Plan") covering all eligible employees. As of December 31, 2004, the Company has not elected to match any of the employee's contributions to the Plan.

14. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2003				
Net loss	$ (4,104,126)	$(4,604,222)	$ (4,633,692)	$ (6,873,233)
Net loss attributable to common stockholders	(5,474,186)	(6,435,977)	(6,808,201)	(9,929,083)
Basic and diluted net loss per common share(1)	$ (24.60)	$ (20.94)	$ (17.33)	$ (22.45)
2004				
Net loss	$ (7,523,698)	$(8,756,113)	$ (10,150,160)	$ (13,312,908)
Net loss attributable to common stockholders	(10,942,050)	(9,930,105)	(10,150,160)	(13,312,908)
Basic and diluted net loss per common share(1)	$ (22.62)	$ (0.66)	$ (0.47)	$ (0.62)

(1) Per common share amounts for the quarters and full years have been calculated separately. Accordingly, quarterly amounts do not add to the annual amount because of differences in the weighted-average common shares outstanding during each period principally due to the effect of the Company's issuing shares of its common stock during the year.

Diluted EPS is identical to Basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

15. Subsequent Events (Unaudited)

On February 10, 2005 the Company sold 2,000,000 shares of common stock in a follow-on public offering. The Company raised approximately $36 million, net of offering costs.

On February 7, 2005, the Company acquired all U.S. and Canadian marketing rights for a dermatology product and is purchasing all existing inventory, in exchange for an initial cash payment of approximately $3.1 million and up to $2 million in additional payments if certain sales targets are met. The acquisition will be accounted for under the purchase method of accounting as an asset acquisition, and total purchase price will be allocated to identifiable intangible assets and inventory during the first quarter of 2005.

INDEX OF EXHIBITS

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation, filed as Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
3.2	Amended and Restated Bylaws of the Registrant, filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
4.1	Specimen copy of stock certificate for shares of Common Stock of the Registrant, filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
4.2	Amended and Restated Investors Rights Agreement, dated as of October 23, 2003, by and among the Registrant and the Investors listed therein, filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.1†	2002 Equity Compensation Plan, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.2*(1)*	Intellectual Property Transfer and License Agreement, dated as of May 6, 2002, by and between the Registrant and Johnson & Johnson Consumer Companies, Inc., filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.3	Amendment No. 1 to the Intellectual Property Transfer and License Agreement dated as of September 7, 2004, by and between Barrier Therapeutics, Inc. and Johnson & Johnson Consumer Companies, Inc., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 10, 2004
10.4*(1)*	Intellectual Property Transfer and License Agreement, dated as of May 6, 2002, by and among the Registrant and Janssen Pharmaceutica Products, L.P. and Ortho-McNeil Pharmaceutical, Inc., filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.5	Amendment No. 1 to the Intellectual Property Transfer and License Agreement, dated as of September 7, 2004, by and between Barrier Therapeutics, Inc. and Janssen Pharmaceutica Products, L.P. , filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 10, 2004
10.6†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.7†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Charles Nomides, filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-112539)

Exhibit No.	Description
10.8†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
*10.9†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Alfred Altomari
*10.10†	Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Albert Bristow
10.11†	Restricted Stock Purchase Agreement, dated as of October 31, 2001, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.12†	Amendment No. 1 to Restricted Stock Purchase Agreement, dated as of May 7, 2002, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.13†	Amendment No. 2 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.14†	Restricted Stock Purchase Agreement, dated as of February 20, 2002, by and between the Registrant and Charles Nomides, filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.15†	Amendment No. 1 to Restricted Stock Purchase Agreement, dated May 7, 2002, by and between the Registrant and Charles Nomides, filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.16†	Amendment No. 2 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Charles Nomides, filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.17†	Restricted Stock Purchase Agreement, dated as of August 1, 2002, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.18†	Amendment No. 1 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.19	Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-112539)

Exhibit No.	Description
10.20	Amendment No. 1 dated November 6, 2003, to Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.21	Master Security Agreement, dated as of August 21, 2003 and Amendment, dated as of September 3, 2003, between the Registrant and General Electric Capital Corporation, filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.22*(1)*	Development and Supply Agreement, dated as of May 16, 2002, between the Registrant and Abbott GmbH & Co. KG, filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.23†	2004 Stock Incentive Plan, filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.24†	Employee Stock Purchase Plan, filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-112539)
10.25	Amendment No. 2 dated May 13, 2004, to Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2004.
10.26*(1)*	Distribution and License Agreement dated November 4, 2004 between the Registrant and Grupo Ferrer Internacional, S.A., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 9, 2004
*21	List of Subsidiaries
*23.1	Consent of Ernst & Young LLP
*23.2	Power of Attorney (included on signature page)
*31.1	Certification of principal executive officer required by Rule 13a-14(a)
*31.2	Certification of principal financial officer required by Rule 13a-14(a)
*32.1	Section 1350 Certification of principal executive officer
*32.2	Section 1350 Certification of principal financial officer

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* Filed herewith.

† Compensation plans and arrangements for executives and others.

(1) Portions of the Exhibit have been omitted and have been filed separately pursuant to an application for confidential treatment granted by the Securities and Exchange Commission.

EXHIBIT 31.1

CERTIFICATIONS

I, Geert Cauwenbergh, certify that:

1. I have reviewed this annual report on Form 10-K of Barrier Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2005

GEERT CAUWENBERGH

Geert Cauwenbergh, Ph.D.
Chairman and Chief Executive Officer
(Principal executive officer)

EXHIBIT 31.2

CERTIFICATIONS

I, Anne M. VanLent, certify that:

1. I have reviewed this annual report on Form 10-K of Barrier Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (d) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(e) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2005

ANNE M. VANLENT

Anne M. VanLent
Executive Vice President, Chief Financial Officer and Treasurer
(Principal financial officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Barrier Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Geert Cauwenbergh, Chairman and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, based on my knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

GEERT CAUWENBERGH

Geert Cauwenbergh, Ph.D.
Chairman and Chief Executive Officer
(Principal executive officer)

March 25, 2005

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Barrier Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anne M. VanLent, Executive Vice president, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, based on my knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

ANNE M. VANLENT

Anne M. VanLent
Executive Vice President, Chief Financial Officer and
Treasurer
(Principal financial officer)

March 25, 2005