DUSA PHARMACEUTICALS INC
Form 10-K
March 15, 2002

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, 2001

DUSA Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

NEW JERSEY	22-3103129
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer)
25 Upton Drive Wilmington, Massachusetts	01887
(Address of principal executive offices)	(Zip Code)

Commission File Number: 0-19777
Registrant's telephone number, including area code: (978) 657-7500
Securities registered pursuant to Section 12(b) of the Act: None

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

Common Stock
(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No
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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 or Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

The aggregate market value of the voting stock held by non-affiliates of the registrant computed by reference to the closing price of such stock as of March 11, 2002 was $43,292,825.

The number of shares of common stock outstanding of the Registrant as of March 11, 2002 was 13,865,390.

DOCUMENTS INCORPORATED BY REFERENCE

Document incorporated by reference to this Report is:

(1) Proxy Statement for the 2002 Annual Meeting of Shareholders. Part III, Items 10 through 13.

PART I

This Annual Report on Form 10-K and certain written and oral statements incorporated herein by reference of DUSA Pharmaceuticals, Inc. (referred to as "DUSA," "we," and "us") contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about DUSA's industry, management's beliefs and certain assumptions made by our management. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," or variations of such words and similar expressions, are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict particularly in the highly regulated pharmaceutical industry in which we operate. Therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include those set forth herein under "Risk Factors" on pages 24 through 35, as well as those noted in the documents incorporated herein by reference. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. However, readers should carefully review the statements set forth in other reports or documents we file from time to time with the Securities and Exchange Commission, particularly the Quarterly Reports on Form 10-Q and any Current Reports on Form 8-K.

ITEM 1. BUSINESS

GENERAL

We are a pharmaceutical company developing drugs in combination with light devices to treat or detect a variety of conditions in processes known as photodynamic therapy or photodetection. We are engaged primarily in the research and development of our first drug, the Levulan(R) brand of aminolevulinic acid HCl, or ALA, with light, for use in a broad range of medical conditions. When we use Levulan(R) and follow it with exposure to light to treat a medical condition, it is known as Levulan(R) photodynamic therapy, or Levulan(R) PDT. When we use Levulan(R) and follow it with exposure to light to detect medical conditions it is known as Levulan(R) photodetection, or Levulan(R) PD.

Our first products, the Levulan(R) Kerastick(R) 20% Topical Solution with PDT and the BLU-U(R) brand light source were launched in the United States in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. Schering AG, our worldwide dermatology marketing partner (except Canada), has made regulatory filings for approval of our therapy outside of the United States including filings in Austria, Australia, and Brazil. We have brought the BLU-U(R) into compliance with CE marking and ISO 9001 requirements in order to be ready to supply these markets upon regulatory approval. The Levulan(R) Kerastick(R) with PDT for AKs of the face or scalp has also been approved by the Health Protection Branch - Canada. Our former Canadian affiliate, Draxis Health, Inc., retained the marketing rights

for Canada, and we are working to establish a supply arrangement with Draxis for the Canadian market. We will also be entitled to royalties on any sales in that country.

In November 1999, we signed a marketing, development and supply agreement with Schering AG, a German corporation, for our dermatology products.

We granted to Schering AG the right to promote, market, sell, and distribute our Levulan(R) Kerastick(R) with PDT for AKs of the face or scalp on a worldwide basis (with the exception of Canada). In the United States, Schering AG's United States affiliate, Berlex Laboratories, Inc., is marketing these products. Schering AG also promotes the BLU-U(R); however, we are responsible for distributing the units, as well as for repairs and maintenance. We lease or rent the BLU-U(R) to physicians, medical institutions and academic centers throughout the country. We are also co-developing and will commercialize with Schering AG additional Levulan(R) products for other dermatology disorders. Under the agreement, Schering AG has the exclusive right to market, promote, sell and distribute the products which are developed in the co-development program. Schering AG has agreed to fund two-thirds of our co-development program for dermatology in an amount up to $3,000,000 in 2002, subject to the results of dermatology feasibility studies currently ongoing and further decisions by the development committee, which meets quarterly. The parties may agree to continue to fund the co-development program beyond this date. Under the terms of the agreement, we have also received $30,000,000, including $23,750,000 in cash milestones and unrestricted research payments and $6,250,000 for which a Schering AG affiliate received 340,458 shares of our common stock. See "Business -- Strategic Partners."

For 2002, we have decided, in co-operation with Schering AG, to continue funding development of Levulan(R) PDT to treat warts and onychomycosis, more commonly known as nail fungus, and have begun development on broader labeling for the AK indication. In 2001, we started trials in warts and onychomycosis and had completed patient enrollment in both trials at the end of the year. We also completed an acne trial during 2001 but have decided not to fund further trials in acne during 2002. See "Business -- Dermatology Indications."

We are also carrying out two trials for the treatment of Barrett's esophagus dysplasia, a precancerous condition of the esophagus. In addition, we continue to support independent investigator trials to advance research in the use of Levulan(R) PDT in indications such as colorectal cancers, gastrointestinal tumors, prevention of restenosis and other internal disorders.

We are developing Levulan(R) PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, Levulan(R), Kerastick(R) and BLU-U(R) are registered trademarks. These trademarks are also registered in Europe and applications are pending in other parts of the world. See "Business -- Licenses; and -- Patents and Trademarks."

We were incorporated on February 21, 1991, under the laws of the State of New Jersey. Our principal executive offices are currently located at 25 Upton Drive, Wilmington, Massachusetts 01887 (telephone: (978) 657-7500). On March 3, 1994, we formed DUSA Pharmaceuticals New York, Inc., a wholly owned subsidiary located in Valhalla, New York, to coordinate our research

and development efforts. We financed our development stage operations, prior to the market launch of our first products, primarily from sales of securities in public offerings, and in private and offshore transactions that are exempt from registration under the Securities Act of 1933, as amended, (the "Act"). See "Management's Discussion and Analysis of Financial Condition -- Overview; -- Results of Operations; and -- Liquidity and Capital Resources."

BUSINESS STRATEGY

The following are the key elements of our strategy:

- Support the Marketing of our First Products. We are working with our dermatology marketing partner, Schering AG, to optimize the marketing efforts of the Berlex team in the United States for our first PDT system, the Levulan(R) Kerastick(R) 20% Topical Solution with our BLU-U(R) for the treatment of AKs of the face or scalp. We are also working on plans for the future launch of our products in Europe, Australia, Canada and elsewhere.

- Leveraging our Levulan(R) PDT/PD Platform to Develop Additional Products. In dermatology, we intend, together with Schering AG, to co-develop and commercialize additional Levulan(R) products for other skin conditions. Outside dermatology, we intend to (i) develop new drug formulations and light devices to target large markets with unmet medical needs, such as the treatment of Barrett's esophagus dysplasia, (ii) explore collaborations relating to the detection of brain cancer and bladder cancer, and (iii) explore cost-effective approaches to the detection and/or treatment of a number of gynecological conditions.

- Enter into Additional Strategic Alliances. When we believe that the development program for a non-dermatology indication may be beyond our own resources or may be advanced to market more rapidly with the use of resources of a corporate partner, we may seek opportunities to license, market or co-promote our products. We have already decided to seek a marketing partner for Barrett's esophagus dysplasia, commencing later this year, after we have data from our current clinical trials.

- Use the Results of Independent Researchers to Identify New Applications. We will continue to support independent investigators' research so that we have the benefit of human data when we evaluate potential indications for corporate development. We will also continue to monitor independent research in order to identify potential new indications.

- Pursue the Addition of Complimentary Products and/or Businesses. We have been evaluating and pursuing various licensing and acquisition opportunities for complementary products and/or businesses which may include drugs, devices, technologies or related businesses.

PDT/PD OVERVIEW

In general, both photodynamic therapy and photodetection are two-step processes:

- The first step is the application of a drug known as a "photosensitizer," which collects in specific cells.

- The second step is activation of the photosensitizer by controlled exposure to a selective light source.

During this process, energy from the light activates the photosensitizer. In PDT, the activated photosensitizer transfers energy to oxygen molecules found in cells, converting the oxygen into a highly energized form known as "singlet oxygen," which destroys or alters the sensitized cells. In PD, the activated photosensitizer emits energy in the form of light, making the sensitized cells fluoresce, or "glow."

The longer the wavelength of visible light, the deeper into tissue it penetrates. Different wavelengths, or colors, of light, including red and blue light, may be used to activate photosensitizers. The selection of the appropriate color of light for a given indication is primarily based on two criteria:

- the desired depth of penetration of the light into the target tissue, and

- the efficiency of the light in activating the photosensitizer.

Blue light does not penetrate deeply into tissues and is better suited for treating superficial lesions. It is generally a potent activator of photosensitizers. Red light penetrates more deeply into the skin. Therefore, it is better suited for treating cancers and deeper tissues, but it is generally not as strong an activator of photosensitizers. Different photosensitizers do not absorb all colors of visible light in the same manner. For any given photosensitizer, some colors are more strongly absorbed than others.

Another consideration in selecting a light source is the location of the target tissue. Lesions on the skin which are easily accessible can generally be treated with a non-laser light source. Internal indications, which are often more difficult to access, may require a laser in order to focus the light into a small fiber optic delivery system which may be passed through an endoscope or into a hollow organ.

PDT can be a highly selective treatment that targets specific tissue while minimizing damage to normal surrounding tissue. It allows for multiple courses of therapy. Generally, the photosensitizer and the light separately have no PDT/PD effect. The most common side effect of photosensitizers that are taken systemically is temporary skin sensitivity to bright light. Patients undergoing PDT and PD treatments are usually advised to avoid direct sunlight and/or to wear protective clothing during this period. Patients' indoor activities are unrestricted except that they are told to avoid bright lights. The degree of selectivity and period of skin photosensitivity varies among different photosensitizers and is also related to the drug dose given.

OUR LEVULAN(R) PDT/PD PLATFORM

OUR LEVULAN(R) BRAND OF ALA

We have a unique approach to PDT and PD, using the human cell's own natural processes. Levulan(R) PDT takes advantage of the fact that ALA is the first product in a natural biosynthetic pathway present in virtually all living human cells. In normal cells, the production of ALA is tightly regulated through a feedback inhibition process. In our PDT/PD system, excess ALA, as Levulan(R), is added from outside the cell, bypassing this normal feedback inhibition. The ALA is then converted through a number of steps into a potent natural photosensitizer named protoporphyrin IX, or PpIX. This is the compound that is activated by light during Levulan(R) PDT/PD, especially in fast growing cells. Any PpIX that remains after treatment is eliminated naturally by the same biosynthetic pathway.

We believe that Levulan(R) is unique among PDT/PD agents. It has the following features:

- Naturally Occurring. ALA is a naturally occurring substance found in virtually all human cells.

- Small Molecule. Levulan(R) is a small molecule that is easily absorbed whether delivered topically, orally, or intravenously.

- Highly Selective. Levulan(R) is not itself a photosensitizer, but is a pro-drug that is converted through a cell-based process into the photosensitizer PpIX. The combination of topical application, tissue specific uptake and conversion into PpIX and targeted light delivery make this a highly selective process. Therefore, we can achieve clinical effects in targeted tissue with minimal effects to normal surrounding and underlying tissue.

- Controlled Activation. Levulan(R) has no PDT effect without exposure to light at specific wavelengths, so the therapy is easily controlled.

Scientists believe that the accumulation of PpIX following the application of Levulan(R) is more pronounced in:

- rapidly growing diseased tissues, such as precancerous and cancerous lesions,

- conditions characterized by rapidly proliferating cells and certain microbes (i.e., fungus), such as onychomycosis and psoriasis, and

- in certain normally fast-growing tissues, such as esophageal mucosa and the lining of the uterus.

OUR KERASTICK(R) BRAND APPLICATOR

We designed our proprietary Kerastick(R) specifically for use with Levulan(R). It is a single-use, disposable applicator, which allows for the rapid preparation and uniform application of Levulan(R) topical solution in standardized doses. The Kerastick(R) has two separate glass ampules,

one containing Levulan(R) powder and one containing a liquid vehicle, enclosed within a plastic tube and an outer cardboard sleeve. There is a filter and a metered dosing tip at one end. Prior to application, the doctor or nurse crushes and shakes the Kerastick(R) according to directions to mix the contents into a solution. The Kerastick(R) tip is then dabbed on to the individual AK lesions, releasing a predetermined amount of Levulan(R) 20% topical solution.

OUR LIGHT SOURCES

Customized light sources are critical to successful Levulan(R) PDT/PD because the effectiveness of Levulan(R) therapy depends on delivering light at the appropriate wavelengths and intensities. We intend to continue to develop integrated drug and light device systems, in which the light sources:

- are compact and tailored to fit specific medical needs,

- are pre-programmed and easy to use, and

- provide cost-effective therapy.

Our proprietary BLU-U(R) is a fluorescent light source that can treat the entire face or scalp at one time, which has been specifically designed for use with Levulan(R). The light source is compact and portable. It can be used in a physician's office, requires minimal floor space, and plugs into a standard electrical outlet. The BLU-U(R) also incorporates a proprietary regulator that controls the optical power of the light source to within specified limits. It has a simple control panel consisting of an on-off key switch and digital timer which turns off the light automatically at the end of the treatment. The BLU-U(R) is also compliant with CE marking and ISO 9001 requirements.

We are using non-laser light sources whenever feasible because, compared to lasers, they are:

- safer,

- simpler to use,

- more reliable, and

- far less expensive.

For treatment of AKs, our BLU-U(R) uses blue light which penetrates superficial skin lesions and is a potent activator of PpIX. Longer red wavelengths penetrate more deeply into tissue but are not as potent activators of PpIX. Therefore, for treatment of superficial lesions of the skin, such as AKs, we are using relatively low intensity, non-laser blue light sources, which are designed to treat large areas, such as the entire face or body. For treatment of diseases which have lesions which may penetrate several millimeters into the skin or other tissue, e.g. for most forms of cancer, high-powered red light is often preferable. We have United States and foreign patents and patent applications pending which relate to devices and methods of using light devices for use in Levulan(R) PDT and PD. See "Business -- Patents and Trademarks."

Our Levulan(R) PDT/PD research and development team has experience in the development and regulatory approval process of both drugs and devices for use in clinical PDT/PD.

OUR PRODUCTS

The following table outlines our products and product candidates. Our research and development expenses for the last three years were $10,789,906 in 2001, $8,163,419 in 2000 and $4,194,532 in 1999.

PRODUCT/INDICATION	REGULATORY STATUS
DERMATOLOGY	
Levulan(R) Kerastick(R) and BLU-U(R) for PDT of AKs	Approved; Phase IV
Levulan(R) PDT for Onychomycosis (Nail Fungus)	Phase I/II

Levulan(R) PDT for Persistent Hand and Foot Wart Removal	Phase I/II
Levulan(R) PDT for Broader Labeling of AK Indication	Phase II2
Levulan(R) PDT for Acne	Investigator Study

OTHER INDICATIONS

Levulan(R) PDT for Barrett's Esophagus Dysplasia	Phase I/II
Levulan(R)-induced Fluorescence-guided Resection for Brain Cancer	Investigator Study(2)
Levulan(R) PDT for Prevention of Restenosis	Investigator Study

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1 Draxis Health, Inc., our former parent, holds a license to PARTEQ's ALA patents for Canada.

2 To commence in 2002.

DERMATOLOGY INDICATIONS

Actinic Keratoses (AKs). AKs are superficial precancerous skin lesions usually appearing as rough, scaly patches of skin with some underlying redness. The traditional methods of treating AKs are cryotherapy, or the freezing of skin, using liquid nitrogen, and 5-fluorouracil cream, or 5-FU. Although both methods can be effective, each has limitations and can result in significant side effects. Cryotherapy is non-selective, is usually painful at the site of freezing and can cause blistering and loss of skin pigmentation, leaving white spots. In addition, because there is no standardized treatment protocol, results are not uniform. 5-FU can be highly irritating and requires twice-a-day application by the patient for approximately two to four weeks, resulting in inflammation, redness and erosion or rawness of the skin. Following the treatment an additional one to two weeks of healing is required. Our approved treatment method involves applying Levulan(R) 20% topical solution using the Kerastick(R) to the AK lesions, followed 14 to 18 hours later with exposure to our BLU-U(R) for approximately 17 minutes. In 2001, we successfully completed the first of two Phase IV trials required by the Food and Drug Administrations, or FDA, testing for allergic skin reactions to our therapy. We expect to start the second trial, to evaluate the long-term effects of our therapy, shortly. Together with Schering AG, we have also started development activities to broaden the labeling for the AK indication to enhance the Levulan(R) product line.

As of January 1, 2002, the national reimbursement code for the BLU-U(R) application procedure, along with a "J-code" that reimburses physicians for the costs of the Levulan(R) Kerastick(R), became effective. Doctors can also bill for any applicable visit fees. The codes will also facilitate electronic billing for our therapy, eliminating paperwork involved with the previous manual billing method. We believe that these changes, along with Berlex's ongoing education and marketing programs, will help make Levulan(R) PDT a common therapy for AKs.

Onychomycosis. This condition is more commonly known as nail fungus. Current topical therapies are only effective in a small percentage of patients. Oral prescription medications are more effective but must be taken over 12 weeks or more, and pose risks of systemic side effects such as liver disease and

adverse interactions with other medications. In an unpublished investigator study, 12 patients received a single treatment of Levulan(R) to their infected nail, which was then exposed to a non-laser red light source. Three patients showed a complete response to the Levulan(R) PDT. They lost their nail after one week and regrew a new nail which was free of nail fungus. DUSA and Schering AG commenced a vehicle-controlled, randomized, multicenter clinical feasibility trial for this indication in 2001. Levulan(R) 20% topical solution or vehicle was applied to infected toenails, followed in three to six hours by exposure to broadband red light. Infected toenails are being evaluated for efficacy, and will be retreated with Levulan(R) PDT, if necessary, at follow-up visits for up to three months. Aggressive recruitment for the Phase I/II trial led to completion of patient enrollment by year-end, with initial results expected in the third quarter of this year.

Persistent Hand and Foot Warts. Warts, which are characterized by abnormal epidermal skin cell growth, are a common skin condition caused by the human papilloma virus. Warts are usually treated first with over-the-counter salicylic acid preparations. Often, these treatments are successful. However, in cases where the warts do not clear, patients normally consult a physician. The physician's next line of therapy is usually cryotherapy with liquid nitrogen, which is applied by the doctor for anywhere from weeks to months to years in rare cases. This treatment is painful and can occasionally leave scars. Some dermatologists use lasers to treat warts, although this process can also take many treatments with no guarantee of success. Sometimes warts still persist despite all attempts at treatment. Warts that have been present for a year or more, despite therapy, are termed recalcitrant warts.

In a 1999 independent Danish randomized clinical trial using ALA PDT on 30 patients with 250 recalcitrant warts, the investigator reported that one of the treatment groups showed a 70% elimination of recalcitrant warts through a 12-month period. In 2001, together with Schering AG, we began a vehicle-controlled, randomized, multicenter clinical feasibility trial, to enroll 64 patients with plantar warts persisting after a single standard treatment. The trial involves applying Levulan(R) to the warts followed either three to six or 16 to 24 hours later by light treatment using a broadband red light. Patients receive up to three retreatments of partially responding and non-responding warts at two-week intervals. Patient enrollment in the study was completed at the end of 2001 and initial results are expected in the first half of this year.

Acne. Acne is a common skin condition caused by the blockage and/or inflammation of sebaceous (oil) glands. Traditional treatments for mild to moderate facial inflammatory acne include over-the-counter topical medications for mild cases, and prescription topical medications or oral

antibiotics for mild to moderate cases. An oral retinoid drug called Accutane(R)(1) is the treatment of choice for cystic acne and can be used for moderate to severe inflammatory acne. Over-the-counter treatments are often not effective and can result in side effects, including drying, flaking and redness. Prescription antibiotics lead to improvement in many cases, but patients must often take them on a long-term basis. Accutane(R) can have a variety of side effects, from dryness of the lips and joint pains, to birth defects, and elevated levels of triglycerides and liver enzymes. With Levulan(R) PDT therapy for acne we are seeking to improve or clear patients' acne without the need for long-term oral therapy and with fewer side effects than current therapies.

As part of the co-development program with Schering AG, a dose-ranging clinical trial was completed in 2001. The specific low dose protocol tested was not able to replicate the clinical results seen in previous independent research using higher drug doses but which caused significant side effects. Further

development activity to better optimize the therapy is under consideration.

INTERNAL INDICATIONS

Barrett's Esophagus Dysplasia. Barrett's esophagus is an acquired condition in which the normal tissue lining of the esophagus is replaced by abnormal tissue in response to chronic exposure to stomach acid. Over time, the area of the esophagus affected can develop dysplastic (precancerous) cells. As the dysplasia progresses from low-grade to high-grade, the risk of esophageal cancer increases significantly such that patients with confirmed high-grade dysplasia often undergo major surgery to remove the affected portion of the esophagus. The condition is often undetected until the disease reaches later stages.

There is currently no approved therapy to halt or reverse Barrett's esophagus dysplasia, or to slow its progression to esophageal cancer. Current medical treatment of the condition commonly includes lifelong anti-reflux therapy with drugs called proton pump inhibitors to reduce stomach acid. A current treatment for more advanced, precancerous, Barrett's esophagus involves surgery to remove affected areas of the esophagus. At least one company has filed an NDA seeking approval of a PDT therapy for Barrett's esophagus. The role of anti-reflux surgery is also being evaluated by the medical community.

Independent European studies have reported that in late-stage Barrett's esophagus the high-grade dysplasia can be destroyed by ALA PDT. In a randomized, controlled European investigator study supported by DUSA, Levulan(R) PDT has been shown to allow the conversion of early-stage Barrett's esophagus with low-grade dysplasia and portions of Barrett's esophageal lining back to normal esophageal lining. During 2001, patient accrual was completed in a DUSA-supported randomized investigator study of the effects of differing Levulan(R) doses with red laser light for the treatment of early-stage Barrett's esophagus. Also, during the second half of 2001, we started two Phase I/II studies using systemic Levulan(R) and red laser light in varying light doses for the treatment of early and late-stage Barrett's esophagus dysplasia, respectively. Patients are randomized to receive various light doses, may be retreated, and will be followed for 24 months after the initial treatment. We plan to do a preliminary analysis of the data after treating approximately 10 patients in each study.

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1 Accutane(R)is a registered trademark of Hoffmann La-Roche.

Bladder Cancer Detection. Bladder cancer is most often treated by surgical removal of the tumor, but in many of these cases tumors recur within two to three years. Doctors screen high-risk patients regularly for bladder cancer, because of the risk of recurrence. One of the standard methods for bladder cancer detection involves using a cystoscope to view the bladder with white light.

We concluded our own Phase I/II multi-center clinical trial for enhancement of bladder cancer detection during 1999 using Levulan(R) PD and an endoscope light source provided by Richard Wolf Medical Instruments Corp.

The results suggested that significant further study would be necessary to develop a commercially viable product to optimize bladder cancer detection using Levulan(R) PD. We are currently exploring possible collaborations for the development of Levulan(R)-induced fluorescence-guided resection for the detection of bladder cancer.

Prevention of Restenosis Following Balloon Angioplasty. Restenosis is the re-narrowing of an artery after balloon angioplasty due to the rapid growth of smooth muscle cells at the site of the angioplasty. Many patients who undergo balloon angioplasty suffer restenosis within six months of the procedure. Current forms of treatment for restenosis involve repeated angioplasty procedures, stenting or by-pass surgery. Animal studies have shown that Levulan(R) PDT prevents the rapid growth of smooth muscle cells within the artery after balloon angioplasty. In October 1999, results were published in the British Journal of Surgery from an investigator study using Levulan(R) PDT to reduce restenosis after balloon angioplasty. The seven patients studied had been selected because they each had developed restenosis within two to six months following angioplasty in the past. After treatment with balloon angioplasty followed by Levulan(R) PDT, all of the patients had symptomatic relief and, during the six-month follow-up period, none of the patients had any recurrence of symptoms. In June 2001, the investigators reported the long-term follow-up results on these same seven patients. After following the treated patients for over two years, six of the seven remained asymptomatic and only one had to undergo another angioplasty procedure.

In 2001, we began supporting a randomized controlled investigator study for this indication. However, based on recent reports of significant progress in the prevention of restenosis following balloon angioplasty using drug-coated stents, we have reduced our support of the study. We intend to continue to monitor the progress of the patients in the investigator study but we have decided not to begin our own development program for this indication at this time. We intend to follow the results of the drug-coated stent clinical trials and reassess the market potential for the use of Levulan(R) PDT in the prevention of restenosis following balloon angioplasty in the non-stentable patient population after those results are available.

OTHER POTENTIAL DERMATOLOGY INDICATIONS

Facial Photodamaged Skin. Photodamaged skin, which is skin damaged by the sun, occurs primarily in fair-skinned individuals after many years of sun exposure. Signs of photodamaged skin include roughness, wrinkles and brown spots. AKs also tend to occur in areas of photodamaged skin. There are numerous consumer cosmetic and herbal products which claim to lessen or relieve

the symptoms of photodamaged skin. In most cases, there is little scientific data to support these claims. The FDA has approved only one prescription drug, Renova(R)(2), to treat this common skin condition. Patients generally use the product for between six and 24 weeks before improvement may be seen.

As part of our AK clinical trials, we conducted a Phase II safety and efficacy study, testing 64 patients with three to seven AK lesions of the face or scalp within an area of photodamaged skin. The physician investigators applied Levulan(R) 20% topical solution over the entire area including the photodamaged skin. After 14 to 18 hours, the patients were treated with blue light at differing light doses. Investigators noted marked improvement in skin roughness in two-thirds of the patients after treatment with Levulan(R) PDT as well as some degree of improvement of wrinkles and brown spots. However, ten of the 64 patients found that the burning and stinging of the PDT therapy was too uncomfortable and as a result the treatment was either terminated early or the light power was reduced. No patients reported a serious treatment-related adverse event. Based on this data, we believe that this is a future potential indication for Levulan(R) PDT.

OTHER POTENTIAL INTERNAL INDICATIONS

Cervical Intraepitheleal Neoplasia. Cervical intraepitheleal neoplasia,

or CIN, is a common precancerous condition of the cervix. The pap smear (cervical cytology specimens) is the test commonly used to screen for this and other conditions of the cervix. Each year, millions of pap smear procedures are performed in the United States. Approximately one-third of the test results reveal some abnormality of the cervical tissue, and in many of these cases the results are suspicious but not conclusive and therefore cannot be definitively diagnosed. We believe that Levulan(R) PD could help doctors to locate and biopsy the abnormal cervical tissue.

A DUSA supported investigator study using topical application of Levulan(R) to the cervix showed that Levulan(R)-induced fluorescence could be highly selective for detecting CIN tissue. We have delayed support of any new investigator-sponsored studies while we consider the cost-effectiveness of developing various approaches to the use of Levulan(R) PD for CIN, including an in vivo topical or systemic use of Levulan(R) for the fluorescence detection of CIN visually on the cervix and/or an ex vivo use of Levulan(R) as an adjunct to pap smears for microscopic examination.

Brain Cancer. Despite standard therapies which include surgical tumor removal, radiation therapy, and chemotherapy, adult patients with the most aggressive high-grade malignant brain tumor type (glioblastoma multiforme) generally survive only one year. Independent European investigators have reported that systemic ALA dosing before surgical resection of tumors resulted in selective fluorescence of only the tumors. The normal white matter of the brain showed no fluorescence. These investigators have used ALA-induced fluorescence in a study involving 52 patients with glioblastoma multiforme as a guide for the more complete removal of tumors than would be possible using white light alone. During 2002, we intend to support an investigator study to confirm the European investigators' results and will also be examining the possibility of collaborating with other companies on development of this indication.

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2 Renova(R)is a registered trademark of Johnson & Johnson.

There may be numerous other potential therapeutic and cancer detection uses for Levulan(R) PDT/PD, and we may support research in several of these areas, as appropriate, with pilot trials, and/or investigator-sponsored studies, based on pre-clinical, clinical, regulatory and marketing criteria we have established through our strategic planning processes. Some of these potential uses in dermatology include treatment of skin cancers, such as squamous cell carcinomas and cutaneous T-cell lymphomas, psoriasis, and genital warts; and non-dermatology indications include detection and/or treatment gastro-intestinal tumors, and oral cavity cancer.

STRATEGIC PARTNERS

In November 1999, we signed a marketing, development and supply agreement with Schering AG for the use of our Levulan(R) products to treat or detect dermatology disorders. Schering AG is a large multi-national pharmaceutical company which has significant dermatology sales outside the United States. Under the agreement we granted to Schering AG the exclusive worldwide right, except for Canada, to promote, market, sell and distribute our Levulan(R) Kerastick(R) with PDT for AKs, and any additional dermatology products developed under the co-development program. The parties have agreed to jointly fund the dermatology co-development program through 2002, with Schering AG contributing two-thirds of the joint committee-approved budget, up to $3,000,000, while we contribute the remaining one-third, up to $1,500,000, subject to the results of dermatology feasibility studies currently ongoing and

further decisions by development committee, which meets quarterly. Schering AG also has limited rights to negotiate with us for rights to any non-dermatology products that we intend to develop with corporate partners.

We have received $30,000,000 from Schering AG, including $23,750,000 in cash milestones and unrestricted research payments and $6,250,000 for which a Schering AG affiliate received 340,458 shares of our common stock. No further milestone payments are due for this first indication.

We are responsible for the manufacture and supply of the Kerastick(R) to Schering AG. Schering AG pays a supply price to us for the drug products, as well as a royalty on drug sales. Schering AG also promotes the BLU-U(R), while we have agreed to distribute, maintain and repair the BLU-U(R) units under rental or lease/maintenance agreements. Initially, we leased the BLU-U(R) units to dermatologists and other physicians, medical institutions and academic centers throughout the United States and engaged a leasing company to complete the leasing transactions. In September 2001, DUSA and Berlex began a new program to rent the BLU-Us(R) to physicians for 36 months, with costs deferred for the first six months, while Berlex provides physicians with a supply of Kerastick(R) units at its cost. We are negotiating with a new leasing company to have them manage the rental program. DUSA, Berlex and the current leasing company will continue to support customers that remain on the initial program; however, the majority of such customers have converted to the new rental program. Under the initial program, customers have the right to cancel their leases after periods of up to one year. Under the new program, customers may terminate the BLU-U(R) rental at any time.

On September 26, 2001, we reached agreement with Schering AG to amend the marketing, development and supply agreement. With the execution of this amendment, Schering and its United

States affiliate, Berlex Laboratories, Inc., agreed to reimburse DUSA $1,000,000 for costs DUSA incurred to modify its manufacturing agreement with North Safety Products, Inc. ("North"). See "Business -- Supply Partners." In consideration for this amendment, we agreed to be responsible for certain additional liabilities in the event of our failure to supply Schering AG's requirements of finished product as defined in the original agreement. In addition, we agreed to use our best efforts to qualify DUSA as the primary manufacturer and supplier of the Kerastick(R) within six months following the date that North ceases production. The amendment also terminated the guaranty by Schering AG to us of BLU-U(R) lease payments by physicians, and the secured line of credit promissory note from Schering to DUSA for up to $1,000,000 to finance inventory of BLU-U(R) units.

The marketing, development and supply agreement terminates on a product-by-product basis in each country in the territory on the later of (a) 12-1/2 years after the first commercial sale of a respective product in such country, or (b) the expiration of patents pertaining to the manufacture, sale or use of such product in such country. It terminates in its entirety upon the expiration of the agreement with respect to all products in all countries covered by the agreement. Subject to various terms and conditions, the parties may terminate the agreement earlier.

SUPPLY PARTNERS

National Biological Corporation. In November 1998, we entered into a purchase and supply agreement with National Biological Corporation ("NBC") for the manufacture of some of our light sources, including the BLU-U(R). We have agreed to order from NBC all of our supply needs of these light sources for the United States and Canada and NBC has agreed to supply us with the quantities we

order. If an opportunity arises, the parties have agreed to negotiate the terms under which NBC would supply us with light sources for sale in countries other than the current territories.

NBC has granted to us a license to manufacture the light sources if NBC fails to meet our supply needs. Under these circumstances, we would also have a worldwide license to import, use, sell or dispose of the light sources under NBC's technology within the field of PDT. Also, NBC has agreed that it will not supply light sources that may be used to compete with our business. In early 2001, we prepaid NBC for raw material costs in the amount of $400,000 associated with our then current order. This amount will be credited against the final purchase price which will be due on delivery of finished units at a rate of $1,000 per unit. In addition, we agreed that if we did not order a certain number of BLU-U(R) brand units by January 2, 2002 for delivery in 2002, we would pay NBC $100,000 to cover certain overhead costs. In consideration for this payment, NBC agreed to maintain its BLU-U(R) manufacturing capabilities in a state of readiness during 2002 with the capability of producing BLU-U(R) units in accordance with established procedures. The payment was made in January 2002.

The agreement has a 10-year term, subject to earlier termination for breach or insolvency or for convenience. However, a termination for convenience requires 12 months' prior written notice.

North Safety Products. In September 1999, we entered into a purchase and supply agreement with North Safety Products, Inc. ("North"), a unit of Norcross Safety Products, LLC, for

the manufacture and supply of our Kerastick(R) brand applicator. We have agreed to purchase from North a significant portion of our total commercial requirements for supply of the Kerastick(R) for sale in the United States and Canada. Prices for the product are based on the quantities of Kerastick(R) ordered which are subject to change depending on various product costs and competitive market conditions.

In February 2001, we agreed to compensate North for certain overhead expenses associated with the manufacture of the Kerastick(R) to cover underutilization of North's facilities in accordance with an amendment to the purchase and supply agreement, since actual orders were below certain previously anticipated levels. In July 2001, we revised this agreement with North and paid $1,000,000 in up-front underutilization fees and agreed to make additional payments totaling $400,000 covering the period through December 31, 2002. Of these amounts, $1,000,000 of the underutilized fees were reimbursed through an amendment to DUSA's agreement with Schering AG. See "Business -- Strategic Partners." In consideration for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures. In addition, North is obligated to provide us with manufacturing records, personnel support, and a list of consultants and suppliers that have supported the development and manufacturing of the Kerastick(R).

The term of the purchase and supply agreement was also amended and will end on December 31, 2002 unless DUSA exercises an option to extend the term through June 30, 2003. If DUSA should decide to extend the term, North will be entitled to payment of additional underutilization fees of up to $500,000, prorated based on the level of Kerastick(R) units produced from July 1, 2001 through June 30, 2003. We also continue to have the right to terminate for stated breaches of the agreement. Also see "Business -- Manufacturing."

Sochinaz SA. Under an agreement dated December 24, 1993, Sochinaz SA

("Sochinaz") manufactures and supplies all of our requirements of Levulan(R) worldwide from its FDA approved facility in Switzerland. In June 2000, we amended the agreement to include an option to allow us to extend the term for an additional three (3) years until December 3, 2007. As consideration for the amendment, we agreed to reimburse Sochinaz for a portion of its costs to bring its manufacturing facilities into compliance with the FDA current good manufacturing practices, or cGMPs. We paid $250,000 in cash and issued 26,666.66 shares of our common stock having a fair market value of $750,000. While we can obtain alternative supply sources in certain circumstances, any new supplier would have to be inspected and qualified by the FDA.

LICENSES

PARTEQ Research and Development Innovations. We license the patents underlying our Levulan(R) PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations ("PARTEQ"), the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, which became effective August 27, 1991, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ's method patent rights, to make, have made, use and sell products which are precursors of PpIX, including ALA. The agreement also covers any improvements discovered, developed or acquired by or for PARTEQ, or Queen's

University, to which PARTEQ has the right to grant a license. A non-exclusive right is reserved to Queen's University to use the subject matter of the agreement for non-commercial educational and research purposes. A right is reserved to the Department of National Defense Canada to use the licensed rights for defense purposes including defense procurement but excluding sales to third-parties.

When we are selling our products directly, we have agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where we have a sublicensee, such as Schering AG, we will pay 6% and 4% when patent rights do and do not exist, respectively, on our net selling price less the cost of goods for products sold to the sublicensee, and 6% of royalty payments we receive on sales of products by the sublicensee. We are also obligated to pay 5% of any lump sum sublicense fees paid to us, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts. The agreement is effective for the life of the latest United States patents and becomes perpetual and royalty-free when no United States patent subsists. See Note 11a to the Company's Notes to the Consolidated Financial Statements. We have the right to terminate the PARTEQ agreement with or without cause upon 90 days notice.

For 2000 and going forward, annual minimum royalties to PARTEQ on sales of products must total at least CDN $100,000. See Note 11a to the Company's Notes to the Consolidated Financial Statements.

Together with PARTEQ and Draxis Health, Inc., our former parent, we entered into an agreement (the "ALA Assignment Agreement") effective October 7, 1991. According to the terms of this agreement we assigned to Draxis our rights and obligations under the license agreement to the extent they relate to Canada. In addition, we have agreed to disclose to Draxis on an ongoing basis, any technology which is available to us relating to the subject matter of the license agreement which would assist Draxis in developing the Canadian market under the assigned rights. Draxis is responsible for royalties which would otherwise be payable by us in accordance with the license agreement for net Canadian sales of products and sublicensing revenues. Draxis has also agreed to pay us a royalty of 2% of net Canadian sales of products.

PATENTS AND TRADEMARKS

We actively seek, when appropriate, to protect our products and proprietary information through United States and foreign patents, trademarks and contractual arrangements. In addition, we rely on trade secrets and contractual arrangements to protect certain of our proprietary information and products.

Our ability to compete successfully depends, in part, on our ability to defend our patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We have no product patent protection for the compound ALA itself, as our basic patents are for methods of detecting and treating various diseased tissues using ALA or related compounds called precursors, in combination with light. Even where we have patent protection, there is no guarantee that we will be able to enforce our patents. Patent litigation is expensive, and

we may not be able to afford the costs. We own or exclusively license patents and patent applications related to the following:

- unique physical forms of ALA,

- methods of using ALA and its unique physical forms in combination with light, and

- compositions and apparatus for those methods.

These patents expire no earlier than 2009, and certain patents are entitled to terms beyond that date.

Under the license agreement with PARTEQ and Draxis, we hold an exclusive worldwide license to certain patent rights in the United States and a limited number of foreign countries. See "Business - Licenses." All United States patents and patent applications licensed from PARTEQ relating to ALA are method of treatment patents. Method of treatment patents limit direct infringement to users of the methods of treatment covered by the patents. We currently have patents and/or pending patent applications in the United States and in a number of foreign countries covering unique physical forms of ALA, compositions containing ALA, as well as ALA applicators, light sources for use with ALA, and other technology. We cannot guarantee that any pending patent applications will mature into issued patents.

We have limited patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counter-parts in only three foreign countries. Even with the issuance of additional patents, other parties are free to develop other uses of ALA, including medical uses, and to market ALA for such uses, assuming that they have obtained appropriate regulatory marketing approvals. Certain forms of ALA are commercially available chemical products. ALA in the chemical form commercially supplied for decades is not itself subject to patent protection. In fact, there are reports of several third-parties conducting clinical studies with ALA for the treatment of certain conditions in countries outside the United States where PARTEQ may not have patent protection. Additionally, enforcement of a given patent may not be practicable or an economically viable alternative.

We can give no assurance that a third-party or parties will not claim (with or without merit) that we have infringed or misappropriated their proprietary rights. A number of entities have obtained, and are attempting to

obtain patent protection for various uses of ALA. We can give no assurances as to whether any issued patents, or patents that may later issue to third-parties, may affect the uses on which we are working or whether such patents can be avoided, invalidated or licensed if they cannot be avoided or invalidated. If any third-party were to assert a claim for infringement, we can give no assurances that we would be successful in the litigation or that such litigation would not have a material adverse effect on our business, financial condition and results of operation. Furthermore, we may not be able to afford the expense of defending against such a claim.

Except for the opposition of Japanese Patent No. 273032, which we license from PARTEQ, we are not aware of any formal challenges to the validity of PARTEQ's or our patents. However, we cannot guarantee that other challenges or claims will not be asserted in the future. In 1999, Japanese Patent No. 273032, which relates to the basic method of using ALA, was opposed and, as

a result, the Japanese Patent Office Board of Appeals revoked the patent. With PARTEQ's assistance, we have been simultaneously pursuing an appeal at the Tokyo High Court and an amendment trial before the Japanese Patent Office. We can at this time give no assurance of the likelihood of success of either contest or any assurance that we will decide to spend the funds required to complete the contests. If our response does not allay the concerns of the Board, they may limit our patent protection or finalize the cancellation. Japan is a major pharmaceutical market and loss of this patent could adversely affect us in at least two ways. First, if we seek to enter the Japanese market, the lack of a patent would probably retard or diminish our market share. Second, even if we did not seek to market in Japan, third-parties might not be interested in licensing the product in Japan without patent protection, and this might limit our potential revenues from this market.

In addition, we cannot guarantee that our patents, whether owned or licensed, or any future patents that may issue, will prevent other companies from developing similar or functionally equivalent products. Further, we cannot guarantee that we will continue to develop our own patentable technologies or that our products or methods will not infringe upon the patents of third-parties. In addition, we cannot guarantee that any of the patents that may be issued to us will effectively protect our technology or provide a competitive advantage for our products or will not be challenged, invalidated, or circumvented in the future.

We also attempt to protect our proprietary information as trade secrets. Generally agreements with each employee, licensing partner, consultant, university, pharmaceutical company and agent contain provisions designed to protect the confidentiality of our proprietary information. However, we can give no assurances that these agreements will provide effective protection for our proprietary information in the event of unauthorized use or disclosure of such information. Furthermore, we can give no assurances that our competitors will not independently develop substantially equivalent proprietary information or otherwise gain access to our proprietary information, or that we can meaningfully protect our rights in unpatentable proprietary information.

Even in the absence of composition of matter patent protection for ALA, we may receive financial benefits from: (i) patents relating to the use of such product (like PARTEQ's patents); (ii) patents relating to special compositions and formulations; and (iii) limited marketing exclusivity that may be available as a patent term extension under the Hatch/Waxman Act and any counterpart protection available in foreign countries. See "Business -- Government Regulation." Effective patent protection also depends on many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the

active ingredient of the product and the requirements of the new drug provisions of the Food, Drug and Cosmetic Act, or similar laws and regulations in other countries.

We intend to seek registration of trademarks in the United States, and other countries where we may market our products when it is sufficiently close to commercialization so that appropriate brand names may be selected in light of the circumstances then existing. To date, we have been issued 10 trademark registrations, and other applications are pending.

MANUFACTURING

We do not currently operate any manufacturing facilities. Our drug, Levulan(R), the Kerastick(R) brand applicator and the BLU-U(R) brand light source are each manufactured by a single third-party supplier. See "Business -- Supply Partners." Under our agreement with Schering AG, we are obligated to maintain certain inventory levels of our Levulan(R) products until we qualify a second source of supply for ALA.

Contemporaneously with the amendment of our agreement with North, which provides for earlier termination of the current Kerastick(R) manufacturing arrangement, we decided to build a Kerastick(R) manufacturing line at our Wilmington facility. We believe that the development of our own manufacturing capabilities should enable us to better manage and control the costs of production; however, our unit cost per Kerastick(R) will increase, until product sales increase significantly. We have begun the construction process, with the initial build-out expected to take approximately six months, followed by the facility and drug stability testing required for FDA approval of the site. FDA inspection is expected to occur within approximately six months following the construction and testing stages.

MARKETING AND SALES

Under our agreement with Schering AG, marketing and sales of Levulan(R) PDT products for use in dermatology in the United States will be the responsibility of Schering AG's affiliate, Berlex Laboratories, Inc. Following receipt of marketing approval in the United States, Schering AG must select the country, countries or key territories in which it intends to seek regulatory approval and to sell our products on a product-by-product basis. If Schering AG elects not to market a product in a specific territory or country, we regain the right to market the product. To date, Schering AG has filed for regulatory approval of our first products in Austria (the initial step in obtaining approval throughout the European Union), Australia, and Brazil. We retain the rights to market and sell all future products for non-dermatology indications. Subject to Schering AG's limited right to negotiate, we can enter into marketing, co-promotional, distribution or similar type agreements with corporate partners for our non-dermatology indications.

Draxis has been granted the rights to market Levulan(R) PDT in Canada. See "Business -- Licenses." The Health Protection Branch - Canada has granted marketing approval for the Levulan(R) Kerastick(R) with PDT using the BLU-U(R) for AKs of the face or scalp and we are working with Draxis to establish a supply arrangement for the Canadian market.

COMPETITION

Commercial development of PDT agents other than Levulan(R) are currently being pursued by a number of companies. These include: QLT PhotoTherapeutics Inc. (Canada); Axcan, Inc. (U.S.); Miravant, Inc. (U.S.); Pharmacyclics, Inc. (U.S.); QuantaNova Canada Ltd. (formerly Scotia

Pharmaceuticals) (United Kingdom); and Photogen Technologies, Inc. (U.S.). We are also aware of several overseas companies doing research with ALA or ALA-related compounds, including: Medac GmbH (Germany) which is 25% owned by Schering AG; and Photocure ASA (Norway).

Photocure has received marketing approval of its ALA precursor (ALA methylester) compound with PDT for the treatment of AK's in the European Union, New Zealand, and countries in Scandinavia. Photocure has also filed for regulatory approvals in Australia and the United States. If Photocure receives approval from the FDA to market its ALA AK product in the U.S., its entry into the marketplace will represent direct competition for our products. We are also aware that Medac is developing ALA PD for fluorescence-guided resection of brain cancer and bladder cancer in Germany.

Our position in the PDT field could be adversely affected by product developments achieved by other companies. The pharmaceutical industry is highly competitive. Many of our competitors have substantially greater financial and technical and marketing resources than we have. In addition, several of these companies have had significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care. Our competitors may succeed in developing products that are safer or more effective than ours and in obtaining regulatory marketing approval of future products before we do. Our competitiveness may also be affected by our ability to manufacture and market our products and by the level of reimbursement for the cost of our drug and treatment by third-party payors, such as insurance companies, health maintenance organizations and government agencies.

We believe that comparisons of the properties of various photosensitizing PDT drugs will also highlight important competitive issues. We expect that our principal methods of competition with other PDT companies will be based upon such factors as the ease of administration of our photodynamic therapy; the degree of generalized skin sensitivity to light; the number of required doses; the selectivity of our drug for the target lesion or tissue of interest; and the type and cost of our light systems. New drugs or future developments in PDT or in other drug technologies may provide therapeutic or cost advantages for competitive products. No assurance can be given that developments by other parties will not render our products uncompetitive or obsolete.

Our current primary competitors for our first products are the existing therapies for treatment of AKs. See "Business -- Dermatology Indications, Actinic Keratoses." We expect that our principal methods of competition with these therapies will be cost and patient benefits including cosmetic results.

GOVERNMENT REGULATION

The manufacture and sale of pharmaceuticals and medical devices in the United States are governed by a variety of statutes and regulations. These laws require, among other things:

- approval of manufacturing facilities, including adherence to current good manufacturing, laboratory and clinical practices during production and storage known as cGMPs, GLPs and GCPs respectively,

- controlled research and testing of products,

- applications for marketing approval containing manufacturing, preclinical and clinical data to establish the safety and

efficacy of the product, and

- control of marketing activities, including advertising and labeling.

The marketing of pharmaceutical products requires the approval of the FDA in the United States, and similar agencies in other countries. The FDA has established regulations and safety standards, which apply to the preclinical evaluation, clinical testing, manufacture and marketing of pharmaceutical products. The process of obtaining marketing approval for a new drug normally takes several years and often involves significant costs. The steps required before a new drug can be produced and marketed for human use in the United States include:

- preclinical studies
- the filing of an Investigational New Drug, or IND, application,
- human clinical trials, and
- the approval of a New Drug Application, or NDA.

Preclinical studies are conducted in the laboratory and on animals to obtain preliminary information on a drug's efficacy and safety. The time required for conducting preclinical studies varies greatly depending on the nature of the drug, and the nature and outcome of the studies. Such studies can take many years to complete. The results of these studies are submitted to the FDA as part of the IND application. Human testing can begin if the FDA does not object to the IND application.

The human clinical testing program involves three phases. Each clinical study typically is conducted under the auspices of an Institutional Review Board or IRB at the institution where the study will be conducted. An IRB will consider among other things, ethical factors, the safety of human subjects and the possible liability of the institution. A clinical plan, or "protocol," must be submitted to the FDA prior to commencement of each clinical trial. All patients involved in the clinical trial must provide informed consent prior to their participation. The FDA may order the temporary or permanent discontinuance of a clinical trial at any time for a variety of reasons, particularly if safety concerns exist. These clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations.

In Phase I, studies are usually conducted on a small number of healthy human volunteers to determine the maximum tolerated dose and any product-related side effects of a product. Phase I studies generally require several months to complete, but can take longer, depending on the drug and the nature of the study. Phase II studies are conducted on a small number of patients having a specific disease to determine the most effective doses and schedules of administration. Phase II studies generally require from several months to two years to complete, but can take longer, depending on the drug and the nature of the study. Phase III involves wide scale studies on patients with the same disease in order to provide comparisons with currently available therapies. Phase III studies generally require from six months to four years to complete, but can take longer, depending on the drug and the nature of the study.

Data from Phase I, II and III trials are submitted to the FDA with the NDA. The NDA involves considerable data collection, verification and analysis, as well as the preparation of summaries of the manufacturing and testing processes and preclinical and clinical trials. Submission of an NDA does not

assure FDA approval for marketing. The application review process generally takes one to three years to complete, although reviews of treatments for AIDS, cancer and other life-threatening diseases may be accelerated, expedited or subject to fast track treatment. The process

may take substantially longer if, among other things, the FDA has questions or concerns about the safety and/or efficacy of a product. In general, the FDA requires properly conducted, adequate and well-controlled clinical studies demonstrating safety and efficacy with sufficient levels of statistical assurance. However, additional information may be required. For example, the FDA also may request long-term toxicity studies or other studies relating to product safety or efficacy. Even with the submission of such data, the FDA may decide that the application does not satisfy its regulatory criteria for approval and may disapprove the NDA. Finally, the FDA may require additional clinical tests following NDA approval to confirm safety and efficacy, often referred to as Phase IV clinical trials.

Upon approval, a prescription drug may only be marketed for the approved indications in the approved dosage forms and at the approved dosage with the approved labeling. Adverse experiences with the product must be reported to the FDA. In addition, the FDA may impose restrictions on the use of the drug that may be difficult and expensive to administer. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems occur or are discovered after the product reaches the market. After a product is approved for a given indication, subsequent new indications, dosage forms, or dosage levels for the same product are reviewed by the FDA after the filing and upon approval of a supplemental NDA. The supplement deals primarily with safety and effectiveness data related to the new indication or dosage. Finally, the FDA requires reporting of certain safety and other information, often referred to as "adverse events" that become known to a manufacturer of an approved drug. If an active ingredient of a drug product has been previously approved, drug applications can be filed that may be less time-consuming and costly.

On December 3, 1999, the FDA approved the marketing of our Levulan(R) Kerastick(R) 20% Topical Solution with PDT for treatment of AKs of the face or scalp. The commercial version of our BLU-U(R) was approved on September 26, 2000.

We are currently conducting Phase I/II studies on the use of ALA for the treatment of warts, onychomycosis, and Barrett's esophagus dysplasia. Other than the FDA-approved use of the Levulan(R) Kerastick(R) with PDT for treatment of AKs, our other products still require significant development, including additional preclinical and clinical testing, and regulatory marketing approval prior to commercialization. The process of obtaining required approvals can be costly and time consuming and there can be no guarantee that the use of Levulan(R) in any future products will be successfully developed, prove to be safe and effective in clinical trials, or receive applicable regulatory marketing approvals. Medical devices, such as our light source device, are also subject to the FDA's rules and regulations. These products are required to be tested, developed, manufactured and distributed in accordance with FDA regulations, including good manufacturing, laboratory and clinical practices. Under the Food, Drug & Cosmetic Act, all medical devices are classified as Class I, II or III devices. The classification of a device affects the degree and extent of the FDA's regulatory requirements, with Class III devices subject to the most stringent requirements and FDA review. Generally, Class I devices are subject to general controls (e.g., labeling and adherence to the cGMP requirement for medical devices), and Class II devices are subject to general controls and special controls (e.g., performance standards, postmarket surveillance, patient registries and FDA guidelines). Class III devices, which

typically are life-sustaining or life-supporting and implantable devices, or new devices that have been found not to be substantially equivalent to a legally marketed Class I or Class II "predicate device," are subject

to general controls and also require clinical testing to assure safety and effectiveness before FDA approval is obtained. The FDA also has the authority to require clinical testing of Class I and II devices. The BLU-U(R) has been classified as a Class III device. We anticipate that our other devices will also be classified as Class III and be subject to the highest level of FDA regulation. Approval of Class III devices require the filing of a PMA application supported by extensive data, including preclinical and clinical trial data, to demonstrate the safety and effectiveness of the device. If human clinical trials of a device are required and the device presents a "significant risk," the manufacturer of the device must file an investigational device exemption or "IDE" application and receive FDA approval prior to commencing human clinical trials. At present, our devices are being studied in preclinical and clinical trials under our INDs.

Following receipt of the PMA application, if the FDA determines that the application is sufficiently complete to permit a substantive review, the agency will accept it for filing and further review. Once the submission is filed, the FDA begins a review of the PMA application. Under the Food, Drug and Cosmetics Act, the FDA has 180 days to review a PMA application. The review of PMA applications more often occur over a significantly protracted time period, and the FDA may take up to two years or more from the date of filing to complete its review.

The PMA process can be expensive, uncertain and lengthy. A number of other companies have sought premarket approval for devices that have never been approved for marketing. The review time is often significantly extended by the FDA, which may require more information or clarification of information already provided in the submission. During the review period, an advisory committee likely will be convened to review and evaluate the PMA application and provide recommendations to the FDA as to whether the device should be approved for marketing. In addition, the FDA will inspect the manufacturing facility to ensure compliance with cGMP requirements for medical devices prior to approval of the PMA application. If granted, the premarket approval may include significant limitations on the indicated uses for which the product may be marketed, and the agency may require post-marketing studies of the device.

Medical products containing a combination of drugs, including biologic drugs, or devices may be regulated as "combination products" in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (drug/device, device/biologic, drug/biologic, etc.) Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, including a biologic drug, or device. Currently, PDT/PD treatments are defined as drug/device combination products. The main responsibility for review of PDT products (drugs and devices) is under the jurisdiction of the FDA's drug center, the Center for Drug Evaluation and Research, with support from the Center for Devices and Radiological Health. The FDA has not formally established the degree and extent of the regulatory requirements for the various components of PDT/PD.

In connection with our NDA for the Levulan(R) Kerastick(R) with PDT for AKs, a combination filing (including a PMA for the BLU-U(R) light source device and the NDA for the Levulan(R) Kerastick(R)) was submitted to the Center for Drug Evaluation and Research. The PMA was then separated from the NDA submission by the FDA and reviewed by the FDA's Center for Devices and Radiological Health. Based upon this experience, we anticipate that any future NDAs for Levulan(R)

PDT/PD will be a combination filing accompanied by PMAs. There is no guarantee that PDT products will continue to be regulated as combination products.

The United States Drug Price Competition and Patent Term Restoration Act of 1984 known as the Hatch-Waxman Act provides for the return of up to five years of patent term for a patent that covers a new product or its use, to compensate for time lost during the regulatory review process. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension, and there can be no guarantee that the application will be granted. We believe that the FDA's December 3, 1999 approval of our NDA for the Levulan(R) Kerastick(R) with PDT is the first marketing approval for a medical use of ALA. We therefore believe that this approval may form the basis for extending the term of one of our patents. However, there can be no assurance that we will receive a patent term extension.

The Hatch-Waxman Act also establishes a five-year period of marketing exclusivity from the date of NDA approval for new chemical entities approved after September 24, 1984. Levulan(R) is a new chemical entity and market exclusivity will expire on December 3, 2004. During this Hatch-Waxman marketing exclusivity period, no third-party may submit an "abbreviated NDA" or "paper NDA" to the FDA.

Finally, any abbreviated or paper NDA applicant will be subject to the notification provisions of the Hatch-Waxman Act, which should facilitate our notification about potential infringement of our patent rights. The abbreviated or paper NDA applicant must notify the NDA holder and the owner of any patent applicable to the abbreviated or paper NDA product, of the application and intent to market the drug that is the subject of the NDA.

We also intend to market our products outside of the United States. Prior to marketing a product in other countries, approval by that nation's regulatory authorities must be obtained. Our marketing partner, Schering AG, will be responsible for applying for marketing approvals outside the United States for Levulan(R) PDT for dermatology uses and has, to date, filed applications for approval in Austria, Australia and Brazil. Generally, we try to design our protocols for clinical studies so that the results can be used in all the countries where we hope to market the product. However, countries sometimes require additional studies to be conducted on patients located in their country.

With the enactment of the Drug Export Amendments Act of the United States in 1986, products not yet approved in the United States may be exported to certain foreign markets if the product is approved by the importing nation and approved for export by the United States government. We can give you no assurance that we will be able to get approval for any of our potential products from any importing nations' regulatory authorities or be able to participate in the foreign pharmaceutical market.

Our research and development activities have involved the controlled use of certain hazardous materials, such as mercury in fluorescent tubes. While we do not currently manufacture any products, we are subject to various laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products. We believe that

we are in material compliance with applicable environmental laws and regulations. For the present, we have not made any material capital expenditures for environmental control facilities. However, once we establish our own production line for the manufacture of the Kerastick(R), we expect that

environmental laws will govern our facility. We can give you no assurance that we will not have to make significant expenditures in order to comply with environmental laws and regulations in the future. Also, we cannot assure you that current or future environmental laws or regulations will not materially adversely effect our operations, business or assets. In addition, although we believe that our safety procedures for the handling and disposal of such materials comply with the standards prescribed by current environmental laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could exceed our resources.

PRODUCT LIABILITY AND INSURANCE

We are subject to the inherent business risk of product liability claims in the event that the use of our technology or any prospective product is alleged to have resulted in adverse effects during testing or following marketing approval of any such product for commercial sale. We maintain product liability insurance for coverage of our clinical trial activities and for our commercial supplies. There can be no assurance that such insurance will continue to be available on commercially reasonable terms or that it will provide adequate coverage against all potential claims.

EMPLOYEES

At the end of 2001, we had 55 full-time employees. We have employment agreements with our key executive officers. We have purchased, and are the named beneficiary of, a key man life insurance policy having a face value of CDN $2,000,000 on the life of our President. We also retain numerous independent consultants and the services of key researchers at leading university centers whose activities are coordinated by our employees. For example, in October 2001 the Company executed a master service agreement, effective June 15, 2001, with Therapeutics, Inc. to manage the clinical development of DUSA's products in the field of dermatology. We intend to hire other employees and consultants as needed.

RISK FACTORS

This section of our Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. We use words such as "anticipate," "believe," "expect," future" and "intend" and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the factors described below and elsewhere in this Annual Report. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report.

The following are among the risk factors we face related to our business, assets and operations. They are not the only ones we face. Additional risks and uncertainties that we are not aware of or that we currently deem immaterial also may impair our business. If any of the following risks actually occur, our business, financial condition and operating results could be materially adversely affected.

RISKS RELATED TO DUSA

WE ARE NOT CURRENTLY PROFITABLE AND MAY NOT BE PROFITABLE IN THE FUTURE UNLESS

WE CAN SUCCESSFULLY MARKET AND SELL OUR FIRST PRODUCT, THE LEVULAN(R) KERASTICK(R) WITH PDT FOR THE TREATMENT OF AKS OF THE FACE OR SCALP.

BECAUSE WE AND SCHERING AG, OUR MARKETING PARTNER FOR DERMATOLOGY PRODUCTS, HAVE ONLY LIMITED EXPERIENCE MARKETING OR SELLING DERMATOLOGY PRODUCTS IN THE UNITED STATES, OUR REVENUES FROM ROYALTIES AND PRODUCT SALES MAY SUFFER.

The commercial success of Levulan(R) Kerastick(R) with PDT for AKs of the face or scalp will partly depend on the effective marketing of our products in the United States by Schering AG through its affiliate, Berlex Laboratories, Inc. While Schering AG has experience marketing dermatology products in Europe, prior to the September 2000 launch of our first products, neither Schering AG, Berlex nor DUSA had any experience marketing dermatology products in the United States. Schering AG has 39 sales representatives and area managers who are dedicated to the marketing of the Levulan(R) PDT system. If Schering AG ceases to fund or fails to adequately fund marketing efforts or develop, train and manage a sufficiently large sales force, the demand for our product will be limited and our royalties from Schering AG on sales of the product, our income from our light device, and our revenue on supply fees on the Kerastick(R) will be adversely affected. Additionally, Schering AG has the right to terminate our agreement on 12-months written notice. If Schering AG were to decide to terminate our agreement early, we would have to establish a marketing capability at significant expense.

IF SCHERING AG DECIDES TO DISCONTINUE FUNDING THE DERMATOLOGY DEVELOPMENT PROGRAM, WE MAY NOT BE ABLE TO ADVANCE THE VARIOUS PROGRAMS AS QUICKLY WHICH WOULD DELAY THE APPROVAL PROCESS AND MARKETING OF NEW POTENTIAL PRODUCTS.

The development and commercialization process is costly and delays and/or unanticipated costs could adversely affect our financial condition. There can be no guarantee that Schering AG will continue to fund the dermatology co-development program beyond its current commitment for 2002. If Schering decides, for any reason, to cease funding the co-development program, continued development of our potential dermatology products would require DUSA to commit substantially greater capital to research and development of such dermatology products and we may not have sufficient funds to complete all of our programs.

SINCE WE RELY HEAVILY ON OUTSIDE CONTRACTORS AS SOLE SUPPLIERS AND MANUFACTURERS OF OUR LEVULAN(R) KERASTICK(R) AND BLU-U(R), OUR MARKETING EFFORTS AND SALES MAY SUFFER IF THESE THIRD-PARTIES FAIL IN ANY WAY TO ADEQUATELY SUPPLY US WITH THE QUALITY AND QUANTITY OF THE PRODUCTS WE NEED.

We do not currently have the capacity to manufacture any of our products on our own and rely on third-parties to manufacture our products. We have only one source for Levulan(R), one source for our Kerastick(R), and one for the BLU-U(R). So far, our manufacturers have not been

required to produce our products in large commercial quantities. Manufacturers often encounter difficulties when large quantities of new products are manufactured for the first time, including problems involving:

- product yields,
- quality control,
- component and service availability,

- compliance with FDA regulations, and

- the need for further FDA approval if manufacturers make material changes to manufacturing processes and/or facilities.

We cannot guarantee that problems will not arise with production yields, costs or quality as our manufacturers seek to increase production. Any manufacturing problems could delay or limit our supplies or prevent commercialization of our products. If any of these suppliers fail to meet our needs, our business, financial condition and results of operations would suffer.

If any facility or equipment in the facility of our manufacturers is damaged or destroyed, we will not be able to quickly or inexpensively replace it. If there are any quality or supply problems with any components supplied to our manufacturers for our products, we may not be able to quickly replace them.

Under the terms of our agreement with Schering AG, our continuing failure to supply Schering AG's requirements of Levulan(R), the Kerastick(R) and/or the BLU-U(R) would release Schering AG from its obligation to purchase supplies from us. The supply fees Schering AG is required to pay to us would be reduced by Schering AG's cost to manufacture and we would receive only a royalty payment on sales. Our business, financial condition and results of operations would be adversely affected.

IF WE ARE UNABLE TO COMPLETE THE CONSTRUCTION OF OUR MANUFACTURING SITE IN A TIMELY MANNER, ANY RESULTING INTERRUPTION IN THE SUPPLY OF KERASTICKS(R) COULD HAVE AN ADVERSE EFFECT ON OUR REVENUE.

Recently, we decided to build our own, commercial-scale, Kerastick(R) manufacturing capabilities at our Wilmington facility in order to replace our current third-party manufacturer. Our current supply agreement with North Safety Products, Inc. shall terminate, at our option, on the later of December 31, 2002 or June 30, 2003. We have begun the construction process, with the initial build-out expected to take approximately six months, followed by the facility and drug stability testing required for FDA approval of the site. FDA inspection is expected to occur within approximately six months following the construction and testing stages. If we encounter difficulties or delays in completing our manufacturing facility, obtaining FDA approval of the facility, or in manufacturing commercial quantities of the Kerastick(R), such difficulties or delays could adversely affect our business, financial condition or results of operations. Also, the cost to build and complete testing of such manufacturing capabilities, including equipment, will be approximately $2,700,000. If we do not have sufficient sales, the financing and other costs associated with the construction could have an adverse effect on our liquidity and financial situation.

ANY FAILURE TO COMPLY WITH ONGOING GOVERNMENTAL REGULATIONS IN THE UNITED STATES WILL LIMIT OUR ABILITY TO MARKET OUR FIRST PRODUCTS.

Our products are subject to continued and comprehensive regulation by the FDA and by state and local regulations. These laws require, among other things,

- approval of manufacturing facilities, including adherence to "good manufacturing and laboratory practices" during production and storage,

- controlled research and testing of products even after

approval, and

- control of marketing activities, including advertising and labeling.

Both the manufacture and marketing of our first products, the Levulan(R) Kerastick(R) and the BLU-U(R) are subject to continuing FDA review. Our manufacturers must continue to comply with the FDA's current Good Manufacturing Practices, commonly known as cGMP, and foreign regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. In complying with cGMP and foreign regulatory requirements, our third-party manufacturers will be obligated to expend time, money and effort in production, record keeping and quality control to assure that our products meet applicable specifications and other requirements. If our third-party manufacturers fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products.

As part of our approval from the FDA, we were required to conduct two Phase IV follow-up studies. We have successfully completed the first study; the second study, to evaluate the long-term recurrence rate of AKs after treatment with our new therapy, is scheduled to begin shortly. If we discover a previously unknown problem with the product, a manufacturer or its facility, changes in product labeling restrictions or withdrawal of the product from the market may occur. Manufacturing facilities are subject to ongoing periodic inspection by the FDA, including unannounced inspections. We cannot give you any assurance that our third-party sole sources will continue to meet all applicable FDA regulations in the future. If any of our manufacturers fail to maintain compliance with FDA regulatory requirements, it would be time consuming and costly to qualify other sources. These consequences could have an adverse effect on our financial condition and operations. If we fail to comply with applicable regulatory approval requirements, a regulatory agency may:

- send us warning letters,
- impose fines and other civil penalties on us,
- suspend our regulatory approvals,
- refuse to approve pending applications or supplements to approved applications filed by us,
- refuse to permit exports or our products from the United States,
- require us to recall products,
- require us to notify physicians of labeling changes and/or product related problems,
- impose restrictions on our operations, or
- criminally prosecute us.

ANY FAILURE TO FILE FOR OR OBTAIN FOREIGN REGULATORY APPROVALS COULD ADVERSELY AFFECT OUR REVENUES FROM FUTURE PRODUCT SALES.

As part of our collaboration agreement with Schering AG, we will be jointly seeking foreign regulatory approvals for Levulan(R) Kerastick(R) PDT for

AKs. To date, we have filed applications in Austria, Australia and Brazil. We cannot give you any assurances that we will receive foreign approvals on a timely basis, or at all, or that problems will not arise that could delay or prevent the commercialization of our products in foreign countries. The introduction of our products in foreign markets will subject us to foreign regulatory clearances, and reimbursement reviews, which may be unpredictable and uncertain, and which may impose substantial additional costs and burdens which Schering AG and/or DUSA may be unwilling or unable to pay. At present, applications for foreign marketing authorizations are made at the national level, although certain registration procedures are available within the European Union to companies wishing to market a product in more than one member country. A regulatory authority must be satisfied that adequate evidence of safety, quality, and efficacy of the product has been presented before marketing authorization is granted. In addition, electrical medical devices, such as the BLU-U(R), must be manufactured in compliance with the current requirements of ISO 9000. Our third-party manufacturer has brought the BLU-U(R) into compliance with CE marking and ISO 9001 requirements, but we can give you no assurance as to continued compliance with future requirements. The foreign regulatory approval process includes all of the risks associated with obtaining FDA marketing approval and approval by the FDA does not ensure approval by other countries. Failure to file for and/or obtain foreign regulatory approvals could adversely affect our financial condition and operations.

WE HAVE SIGNIFICANT LOSSES AND ANTICIPATE CONTINUED LOSSES FOR THE FORESEEABLE FUTURE.

We have a history of operating losses. We expect to have continued losses through 2002 as we expand research and development of new products and establish ourselves in the marketplace. As of December 31, 2001, our accumulated deficit was $49,845,445. We cannot predict whether any of our products will achieve significant market acceptance or generate sufficient revenues to become profitable. Our commercial success will depend on whether:

- our products are more effective therapies than currently available treatments,
- physicians receive sufficient reimbursement for our products, and
- we can, either together with partners or alone, successfully market our products.

WE HAVE ONLY ONE THERAPY THAT HAS RECEIVED REGULATORY APPROVAL AND WE CANNOT PREDICT WHETHER WE WILL EVER DEVELOP OR COMMERCIALIZE ANY OTHER PRODUCTS.

EXCEPT FOR THE LEVULAN(R) KERASTICK(R) WITH THE BLU-U(R) FOR PDT TO TREAT AKS, ALL OF OUR PRODUCTS ARE IN EARLY STAGES OF DEVELOPMENT AND MAY NEVER RESULT IN ANY COMMERCIALLY SUCCESSFUL PRODUCTS.

Currently, we are developing a single drug compound for a number of different medical conditions. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products. All of our products, except for the

Levulan(R) Kerastick(R) with the BLU-U(R) for PDT to treat AKs, are at an early stage of development. We cannot predict how long the development for these products will take or whether they will be medically effective. We cannot be sure that a successful market will ever develop for our new drug technology. We do not know if any of our products will ever be commercially successful.

WE MUST RECEIVE SEPARATE APPROVAL FOR EACH OF OUR POTENTIAL PRODUCTS BEFORE WE CAN SELL THEM COMMERCIALLY IN THE UNITED STATES OR ABROAD.

All of our other potential products will require the approval of the FDA before they can be marketed in the United States. If we fail to obtain the required approvals for other potential products our revenues will be limited. Before an NDA, which is an application to the FDA seeking approval to market a new drug, can be filed with the FDA, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually one to three years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan(R) PDT products are based on new technology. To the best of our knowledge, the FDA has approved only three drugs for use in photodynamic therapy, including Levulan(R). This factor may lengthen the approval process. We face much trial and error and we may fail at numerous stages along the way.

We cannot predict whether we will obtain approval for any of our potential products. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan(R) PDT or PD is safe and effective for any new use we are studying. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy. We must also obtain foreign regulatory clearances before we can market any potential products in foreign markets. The foreign regulatory approval process includes all of the risks associated with obtaining FDA marketing approval and may impose substantial additional costs.

OUR LACK OF SALES AND MARKETING EXPERIENCE COULD AFFECT OUR ABILITY TO MARKET OUR NON-DERMATOLOGY PRODUCTS, WHICH COULD ADVERSELY AFFECT OUR REVENUES FROM FUTURE PRODUCT SALES.

We are lacking the experience and capacity to market, sell and distribute our products. In order to market non-dermatology products and/or if Schering AG abandons its rights to any dermatology products, or terminates our agreement, and if we do not enter an agreement with a corporate partner who has the experience and resources to perform these roles, we would be required to hire our own staff and a sales force. We have no experience in developing, training or managing a sales force. We will incur substantial additional expenses if we have to develop, train and manage these business activities. We may be unable to build a sales force and the costs of establishing a sales force may exceed our product revenues. In addition, companies that may compete with us currently have extensive and well-funded marketing and sales operations. Any marketing and sales efforts we make may be unsuccessful.

IF WE ARE UNABLE TO OBTAIN THE NECESSARY CAPITAL TO FUND OUR OPERATIONS, WE WILL HAVE TO DELAY OUR DEVELOPMENT PROGRAMS AND MAY NOT BE ABLE TO COMPLETE OUR CLINICAL TRIALS.

If our sales goals for our first product are not met, we may need substantial additional funds to fully develop, manufacture, market and sell all of our other potential products. We cannot predict exactly if or when additional funds will be needed. We may obtain funds through a public or private financing, including equity financing, and/or through collaborative arrangements. We cannot predict whether any financing will be available on acceptable terms when we need it because investors may be unwilling to invest in DUSA if we have setbacks in

the development program or if the public fails to use our products.

If funding is insufficient, we will have to delay, reduce in scope or eliminate some or all of our research and development programs. We cannot predict which programs will be affected since it will depend upon the status of clinical trials at that time. We may license rights to third-parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own.

IF WE ARE UNABLE TO PROTECT OUR PROPRIETARY TECHNOLOGY, TRADE SECRETS OR KNOW-HOW, WE MAY NOT BE ABLE TO OPERATE OUR BUSINESS PROFITABLY.

WE HAVE LIMITED PATENT PROTECTION AND IF WE ARE UNABLE TO PROTECT OUR PROPRIETARY RIGHTS, COMPETITORS MIGHT BE ABLE TO DEVELOP SIMILAR PRODUCTS TO COMPETE WITH OUR PRODUCTS AND TECHNOLOGY.

Our ability to compete successfully depends, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We have no product patent protection for the compound ALA itself, as our basic patents are for methods of detecting and treating various diseased tissues using ALA or related compounds called precursors, in combination with light. Even where we have patent protection, there is no guarantee that we will be able to enforce our patents. We own or exclusively license patents and patent applications related to the following:

- unique physical forms of ALA,
- methods of using ALA and its unique physical forms in combination with light, and
- compositions and apparatus for those methods.

Some of the indications we are developing may not be covered by the claims in our existing patents. In addition, a number of third-parties are seeking patents for additional uses of ALA. These additional uses, whether patented or not, could limit the scope of our future operations because other ALA products might become available which would not infringe our patents. These products would compete with ours even though they are marketed for a different use.

We have limited patent protection outside the United States which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counter-

parts in only three foreign countries. Absent patent protection, third-parties may freely market ALA, subject to appropriate regulatory approval. There are reports of several third-parties conducting clinical studies using ALA, or ALA precursors, in countries where DUSA lacks patent protection. These studies could provide the clinical data necessary to gain regulatory approval, resulting in competition.

Our patent protection in Japan may be diminished or lost entirely. Japanese Patent No. 273032, which we have licensed from PARTEQ, has been opposed and the Japanese Patent Office Board of Appeals revoked this patent. With PARTEQ's assistance, we are simultaneously pursuing an appeal of the revocation before the Tokyo High Court and an amendment trial before the Japanese Patent Office. Japan is a major pharmaceutical market and loss of this patent could adversely affect DUSA in at least two ways. First, should DUSA seek to enter the

Japanese market, the lack of a patent would probably diminish our market share. Second, even if we did not seek to market in Japan, third-parties might not be interested in licensing the product in Japan without patent protection, and this might affect DUSA's revenues.

While we attempt to protect our proprietary information as trade secrets through agreements with each employee, licensing partner, consultant, university, pharmaceutical company and agent, we cannot guarantee that these agreements will provide effective protection for our proprietary information. It is possible that:

- these persons or entities might breach the agreements,
- we might not have adequate remedies for a breach, and/or
- our competitors will independently develop or otherwise discover our trade secrets.

PATENT LITIGATION IS EXPENSIVE, AND WE MAY NOT BE ABLE TO AFFORD THE COSTS.

The costs of litigation or any proceeding relating to our intellectual property rights could be substantial even if resolved in our favor. Some of our competitors have far greater resources than we do and may be better able to afford the costs of complex patent litigation. For example, third-party competitors may infringe one or more of our patents, and we could be required to spend significant resources to enforce our patent rights. Also, if we were to sue a third-party for infringement of one or more of our patents, that third-party could challenge the validity of our patent(s). Defending our patents could also result in the expenditure of significant resources. We cannot guarantee that a third-party or parties will not claim, with or without merit, that we have infringed their patent(s), or misappropriated their proprietary material. Defending this type of legal action could also involve considerable expense.

If a third-party were to file a United States patent application, or be issued a patent claiming technology also claimed by us in a pending United States application(s), we may be required to participate in interference proceedings in the United States Patent and Trademark Office to determine the priority of invention. A third-party also could request the declaration of a patent interference between one of our issued patents, and a third-party United States patent application. Any interference proceedings likely would require participation by us and/or PARTEQ, and could involve substantial legal fees.

BECAUSE OF THE NATURE OF OUR BUSINESS, THE LOSS OF OUR KEY MEMBERS OF OUR MANAGEMENT TEAM COULD DELAY ACHIEVEMENT OF OUR GOALS.

IF ANY OF THE KEY MEMBERS OF OUR MANAGEMENT WERE TO END HIS RELATIONSHIP WITH US, WE COULD EXPERIENCE SIGNIFICANT DELAYS IN OUR BUSINESS AND RESEARCH OBJECTIVES.

We are a small company with only approximately 55 employees. We are highly dependent on several key officer/employees with specialized scientific and technical skills. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain these qualified personnel in our specialty drug and light device areas. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very

few people with their expertise could be hired. Our business, financial condition and results of operations could suffer.

RISKS RELATED TO OUR INDUSTRY

PRODUCT LIABILITY AND OTHER CLAIMS AGAINST US MAY REDUCE DEMAND FOR OUR PRODUCTS OR RESULT IN DAMAGES.

IF WE BECOME SUBJECT TO A PRODUCT LIABILITY CLAIM WE MAY NOT HAVE ADEQUATE INSURANCE COVERAGE AND THE CLAIM COULD ADVERSELY AFFECT OUR BUSINESS.

The development, manufacture and sale of medical products exposes us to the risk of significant damages from product liability claims. Although we currently maintain product liability insurance for coverage of our products in amounts we believe to be commercially reasonable we cannot be certain that the coverage amounts are adequate or that continued coverage will be available at acceptable costs. If the cost is too high, we will have to self-insure. A successful claim in excess of our insurance coverage could have a materially adverse effect on our business, financial condition and results of operations.

OUR BUSINESS INVOLVES ENVIRONMENTAL RISKS AND WE MAY INCUR SIGNIFICANT COSTS COMPLYING WITH ENVIRONMENTAL LAWS AND REGULATIONS.

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. Even though we do not currently manufacture any products, we are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials and specific waste products. When we establish our own production line for the manufacture of the Kerastick(R), we expect that additional environmental laws and regulations will apply to our facility. We believe that we are in compliance in all material respects with currently applicable environmental laws and regulations and we have not made any material capital expenditures for environmental control facilities to date. However, we cannot guarantee that we will not incur significant costs to comply with environmental laws and

regulations in the future. We also cannot guarantee that current or future environmental laws or regulations will not materially adversely effect our operations, business or assets. In addition, although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and this liability could exceed our resources.

WE MAY NOT BE ABLE TO KEEP UP WITH RAPID CHANGES IN THE BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES THAT COULD MAKE SOME OR ALL OF OUR PRODUCTS NON-COMPETITIVE OR OBSOLETE.

COMPETING PRODUCTS AND TECHNOLOGIES MAY MAKE SOME OR ALL OF OUR PROGRAMS OR POTENTIAL PRODUCTS NONCOMPETITIVE OR OBSOLETE.

Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Well-known pharmaceutical, biotechnology and chemical companies are marketing well-established therapies for the treatment of various dermatological conditions including AKs. Doctors may prefer familiar methods that they are comfortable using rather than try our products. Many companies are also seeking to develop new products and

technologies for medical conditions for which we are developing treatments. Our competitors may succeed in developing products that are safer or more effective than ours and in obtaining regulatory marketing approval of future products before we do. We anticipate that we will face increased competition as new companies enter our markets and as the scientific development of PDT/PD advances.

We expect that our principal methods of competition with other PDT companies will be based upon such factors as:

- the ease of administration of our photodynamic therapy,
- the degree of generalized skin sensitivity to light,
- the number of required doses,
- the selectivity of our drug for the target lesion or tissue of interest, and
- the type and cost of our light systems.

We cannot give you any assurance that new drugs or future developments in PDT or in other drug technologies will not have a material adverse effect on our business. Increased competition could result in:

- price reductions,
- lower levels of third-party reimbursements,
- failure to achieve market acceptance, and
- loss of market share,

any of which could have an adverse effect on our business. Further, we cannot give you any assurance that developments by our competitors or future competitors will not render our technology obsolete.

OUR COMPETITORS IN THE BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES MAY HAVE BETTER PRODUCTS, MANUFACTURING CAPABILITIES OR MARKETING EXPERTISE.

Several companies are developing PDT agents other than Levulan(R). These include: QLT PhotoTherapeutics Inc. (Canada); Axcan, Inc. (U.S.); Miravant, Inc. (U.S.); Pharmacyclics, Inc. (U.S.); QuantaNova Canada Ltd. (formerly Scotia Pharmaceuticals) (United Kingdom); and Photogen Technologies, Inc. (U.S.). We are also aware of several overseas companies doing research with ALA, including: Medac GmbH (Germany) which is 25% owned by Schering AG; and Photocure ASA (Norway).

Many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care.

Photocure has received marketing approval of its ALA precursor (ALA methylester) compound with PDT for the treatment of AKs in the European Union, New Zealand and countries in Scandinavia and has applications pending for approval in Australia and the United States. If Photocure receives approval from

the FDA to market its ALA AK product in the U.S., its entry into the marketplace will represent direct competition for our products. We are also aware that Medac is developing ALA PD for fluorescence-guided resection of brain cancer and bladder cancer in Germany.

RISKS RELATED TO OUR STOCK

IF OUTSTANDING OPTIONS AND WARRANTS ARE CONVERTED, THE VALUE OF THOSE SHARES OF COMMON STOCK OUTSTANDING JUST PRIOR TO THE CONVERSION WILL BE DILUTED.

As of February 15, 2002 there were outstanding options and warrants to purchase 2,497,899 shares of common stock, with exercise prices ranging from U.S. $3.25 to $31.00 per share, respectively, and ranging from CDN $4.69 to CDN $10.875 per share, respectively. If the holders exercise a significant number of these securities at any one time, the market price of the common stock could fall. The value of the common stock held by other shareholders will be diluted. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. If the market price of the common stock does not rise above the exercise price of these securities, then they will expire without exercise. The holders are likely to exercise their securities when we would probably be able to raise capital from the public on terms more favorable than those provided in these securities.

RESULTS OF OUR OPERATIONS AND GENERAL MARKET CONDITIONS FOR BIOTECHNOLOGY STOCK COULD RESULT IN THE SUDDEN CHANGE IN THE MARKET VALUE OF OUR STOCK.

From time to time and in particular during the last few years, the price of our common stock has been highly volatile. These fluctuations create a greater risk of capital losses for our shareholders as compared to less volatile stocks. From January 1, 2001 to February 15, 2002, our stock price has ranged from a high of $18.938 to a low of $4.26. Factors that contributed to the volatility of our stock during the last 12 months included:

- disappointing first year product sales,
- general market conditions,
- timing in achieving third-party payor reimbursement for our first therapy, and
- clinical trial results.

The significant general market volatility in similar stage pharmaceutical and biotechnology companies made the market price of our common stock even more volatile.

EFFECTING A CHANGE OF CONTROL OF DUSA WOULD BE DIFFICULT, WHICH MAY DISCOURAGE OFFERS FOR SHARES OF OUR COMMON STOCK.

Our certificate of incorporation authorizes the board of directors to issue up to 100,000,000 shares of stock, 40,000,000 of which are common stock. The board of directors has the authority to determine the price, rights, preferences and privileges, including voting rights, of the remaining 60,000,000 shares without any further vote or action by the shareholders. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future.

ITEM 2. PROPERTIES

In May 1999 we entered into a five year lease for 16,000 sq. ft. of office/warehouse space to be used for offices and manufacturing in Wilmington, Massachusetts. On February 1, 2001, we entered into a five year lease for an additional 24,000 square feet of space at our Wilmington facility. As part of our planned build-out of the facility, in December 2001 we replaced the two five year leases with a new 15 year lease covering the entire building through November 2016. We have the ability to terminate the Wilmington lease after the 10th year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. Our wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., relocated from Tarrytown, New York, to larger facilities, approximately 4,000 sq. ft., in Valhalla, New York in October 1997 under the terms of a five year lease. In 1999, we also entered into a three year lease for approximately 1,300 sq. ft. of office space in Toronto in the same building DUSA previously occupied. This facility accommodates the offices of our President, shareholder services and other staff. See Note 11b to the Company's Notes to the Consolidated Financial Statements.

ITEM 3. LEGAL PROCEEDINGS

We are not involved in any material legal proceedings.

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

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the Nasdaq National Market under the symbol "DUSA." The following are the high and low closing prices for the common stock reported for the quarterly periods shown.

Price range per common share by quarter, 2000:

	First	Second	Third
Nasdaq			
High	$36.00	$30.00	$31.250
Low	21.50	16.00	25.813

Price range per common share by quarter, 2001:

	First	Second	Third
Nasdaq			
High	$18.938	$17.500	$14.140
Low	10.438	11.125	8.730

On March 11, 2002, the closing price of our common stock was $4.75 per share on the Nasdaq Stock Market. On March 11, 2002, there were approximately 671 holders of record of the common stock.

We have never paid cash dividends on our common stock and have no present plans to do so in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The following information is qualified by reference to and should be read in conjunction with the Company's Consolidated Financial Statements and the Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere herein. The selected financial data for the Company set forth below as of and for the years ended December 31, 2001, 2000, 1999, 1998 and 1997 have been derived from the Company's audited consolidated financial statements.

CONSOLIDATED STATEMENT OF OPERATIONS DATA

	Year ended December 31,			
	2001	2000	1999	1998
Revenues	$ 5,390,736	$ 2,120,557	$ --	$ --
Cost of product sales and royalties	2,148,994	1,104,664	--	--
Research and development costs	10,789,906	8,163,419	4,194,532	4,502,391
General and administrative costs	3,654,792	2,615,502	1,818,193	1,729,741
Loss from operations	(11,202,956)	(9,763,028)	(6,012,725)	(6,232,132)
Other income	3,844,860	3,222,273	574,098	515,184
Income tax expense	--	--	90,000	--
Net loss	(7,358,096)	(6,540,755)	(5,528,627)	(5,716,948)
Basic and diluted net loss per common share	$ (0.53)	$ (0.49)	$ (0.50)	$ (0.61)
Weighted average number of shares outstanding	13,791,735	13,285,472	11,061,016	9,365,950

CONSOLIDATED BALANCE SHEETS DATA

	As of December 31,			
	2001	2000	1999	199
Total Assets	$ 75,864,221	$ 82,442,388	$ 28,156,845	$7,140,
Cash and investment securities	64,709,625	74,496,577	26,897,580	6,722,
Deferred revenue	22,585,856	24,805,041	9,791,667	
Shareholders' equity	49,834,537	55,309,796	17,059,928	6,416,

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

When you read this section of this report, it is important that you also read the financial statements and related notes included elsewhere herein. This section contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those we anticipate in these forward-looking statements for many reasons, including the factors described below and in "Risk Factors."

OVERVIEW

We are a pharmaceutical company focused on research and development of our drug, Levulan(R), combined with exposure to light, to treat and detect various medical conditions. In September 2000, we launched our first commercial products, Levulan(R) Kerastick(R) 20% Topical Solution and the BLU-U(R) brand light device, in the United States in cooperation with Berlex Laboratories, Inc. ("Berlex"), the United States affiliate of Schering AG, a German corporation. As of December 2001, approximately 300 BLU-U(R) brand light units were in place, an increase of approximately 200 units as compared to the end of 2000. We primarily rent or lease the BLU-U(R) to physicians, medical institutions and academic centers throughout the country.

We have primarily devoted our resources to funding research and development in order to advance the Levulan(R) PDT/PD technology platform, and as a result, we have experienced significant operating losses. As of December 31, 2001, we had an accumulated deficit of approximately $49,845,000. Achieving our goal of becoming a profitable operating company is dependent upon the market penetration of our products in the United States by Berlex and Schering AG in the rest of world (except Canada), acceptance of our therapy by the medical and consumer constituencies, our ability to meet the supply needs of our customer base, and our ability to develop new products.

While Schering AG has significant expertise in dermatology markets outside the United States, and Berlex has significant expertise in non-dermatology markets in the United States, our products represent Berlex's first dermatology marketing effort in the United States. At the current time, Berlex has 39 sales representatives and area managers who are assigned to the Levulan(R) PDT system.

We have been encouraged by the positive response from many physicians and patients who have used our therapy. However, we recognize that market acceptance has taken longer than we originally anticipated, and has not yet reached the levels that were originally anticipated. We believe that the entrenched nature of other AK therapies, and uncertainties related to the availability and level of third-party reimbursement, has caused potential users of our therapy to delay or decline the use of our therapy. In addition, we also recognize that Berlex has to demonstrate to physicians the clinical value of our new and unique therapy, and the benefits compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. As of January 1, 2002, the national reimbursement code for the BLU-U(R) application procedure, along with a "J-code" that reimburses physicians for the costs of the Levulan(R) Kerastick(R) became effective. Doctors can also bill for any applicable visit fees. The codes will facilitate electronic

billing for our therapy, eliminating paperwork involved with the previous

billing method. We are hopeful that these changes, along with Berlex's ongoing education and marketing programs, will help make Levulan(R) PDT a therapy of choice for AKs.

We have incurred scale-up and certain fixed costs resulting in under-absorbed overhead, which are included in cost of product sales. Management plans to maintain a program to continuously monitor the cost of product sales with the goal of reducing our cost of product sales over time. It is with this focus that management has decided to construct our own Kerastick(R) manufacturing operation in our leased Wilmington, Massachusetts facility. We expect that the development of our own facility will enable us to better manage and control the costs of production; however, our unit cost per Kerastick(R) will increase, until product sales increase significantly. Pre-construction activities associated with architectural and engineering plans for our manufacturing facility commenced in the fourth quarter of 2001 and construction of the facility started in January 2002. The initial build-out is expected to take approximately six months, followed by the facility and drug stability testing as required for FDA approval, which is expected to occur within approximately six months from the completion of the initial build-out. FDA inspection is expected to occur within six months following the construction and testing stages. This new facility will serve to supplant our Kerastick(R) manufacturer.

In February 2001, we agreed to compensate North Safety Products, Inc. ("North"), the manufacturer of our Kerastick(R) brand applicator, for certain overhead expenses associated with the manufacture of the Kerastick(R) to cover underutilization of North's facilities in accordance with an amendment to the purchase and supply agreement, since our recent orders have been below certain previously anticipated levels. In July 2001, we revised this agreement and paid North $1,000,000 in up-front underutilization fees and agreed to make additional payments totaling $400,000 covering the period from the execution of this amendment to the agreement through December 31, 2002. Through December 31, 2001, we had paid North $1,200,000 of the underutilization fees. DUSA has reported the total commitment of $1,400,000 in deferred charges, which is recognized in cost of product sales on a straight-line basis over the term of the amendment. In consideration for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness through December 31, 2002, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures. The term of the agreement ends on December 31, 2002 unless DUSA exercises an option to extend the term through June 30, 2003. If DUSA should decide to extend the term, North will be entitled to payment of additional underutilization fees of up to $500,000, prorated based on the level of Kerastick(R) units produced from July 1, 2001 through June 30, 2003. In addition, North is obligated to provide us with manufacturing records, personnel support, and a list of consultants and suppliers that have supported the development and manufacturing of the Kerastick(R).

On September 26, 2001, we amended our Marketing, Development and Supply Agreement with Schering AG, dated November 1999. With the execution of this amendment, Schering AG and Berlex reimbursed DUSA in the amount of $1,000,000 for costs incurred by DUSA to modify our manufacturing agreement with North. This amount has been reported in deferred liabilities and is being recognized as an offset to cost of product sales on a straight-line basis over the term of the agreement with North. In consideration for this amendment, DUSA agreed to be liable to Schering AG for all consequential damages, including, but not limited to, lost profits, attributed to DUSA's

failure to supply Schering AG's requirements of finished product as defined in

the original agreement. In addition, DUSA agreed to qualify itself as the primary manufacturer and supplier of the Kerastick(R) within six months following the date that North ceases production. DUSA and Schering AG also agreed to terminate the guaranty by Schering AG to DUSA of BLU-U(R) lease payments by physicians, and the secured line of credit promissory note from Schering AG to DUSA for up to $1,000,000 to finance inventory of BLU-U(R) units.

We expect to continue to incur operating losses as we continue to invest in our research and development programs until product sales increase significantly. DUSA's research and development efforts are continuing to expand in both in dermatology (in partnership with Schering AG), and in our internal indication development program for Barrett's esophagus dysplasia. During 2001, we increased our staff to 55 full-time employees by year end as compared to 41 at the end of the previous year, in order to properly support all activities including production, maintenance, customer support, and financial operations for our products, as well as the research and development programs for dermatology and internal indications. We expect to slightly increase our staff in 2002 to support the development of our drug manufacturing facility. While our financial position is strong, DUSA cannot predict when royalties and supply fees that we are entitled to under our Schering AG agreement, along with interest and/or other income may offset the cost of these efforts.

For non-dermatology indications, we may enter into joint development or licensing arrangements, both domestically and internationally, with pharmaceutical companies. To the extent that we do not enter into such arrangements, we may require separate funding to complete the regulatory approval process for non-dermatology products and would likely need additional funds to market these potential products. See "Risk Factors - Our lack of sales and marketing experience could affect our ability to market our non-dermatology products, which could adversely affect our revenues from future product sales."

Our financial position and results of operations are affected by subjective and complex judgments, particularly in the areas of revenue recognition, deferred revenue and the carrying value of deferred charges and prepaid royalties. Changes to the useful lives being used to amortize deferred revenue and charges could materially affect our financial position and results of operations.

As more fully described below and in the Company's Notes to the Consolidated Financial Statements, we derive revenue from several sources including Kerastick(R) sales, rental income from BLU-U(R) brand light sources, research co-development programs and previously received milestone payments. Kerastick(R) sales are recognized upon shipment. Revenues from BLU-U(R) leasing programs are generally deferred for six months until demonstration periods are complete or rights of return expire. Co-development revenue is earned as we perform the research. Deferred revenue relating to previously received milestone payments amounted to $22,300,000 at December 31, 2001 and is being amortized into income over the 12-1/2 year life of our Marketing, Development and Supply Agreement with Schering AG.

At December 31, 2001, we had recorded an intangible asset amounting to approximately $1,600,000, representing payments to suppliers for manufacturing underutilization charges and facilities reimbursement costs, both of which provide us with future benefits over the lives of the underlying agreements. Of this amount, $1,159,000 will be charged to operations in 2002 and the

remainder in 2003 and 2004. We are also amortizing a prepaid royalty over an estimated life of 12-1/2 years, which matches the full-term of the agreement with Schering AG mentioned above.

RESULTS OF OPERATIONS

Comparison of Years ended December 31, 2001, 2000 and 1999

Revenues - Revenues recognized by DUSA in 2001 were $5,391,000, as compared to $2,121,000 in 2000. Of these amounts, we earned research and development revenue of $2,893,000 during 2001 as compared to $723,000 in 2000 from Schering AG to support our dermatology co-development program. Also included in revenues is amortization of up-front milestone and unrestricted grant payments from Schering AG of $1,983,000 in 2001 compared to $496,000 in 2000, reflecting a full year of amortization in 2001. These increases were offset by lower product sales of $515,000 in 2001 as compared to $902,000 in 2000, as Berlex met its distributor's initial Kerastick(R) supply needs in the fourth quarter of 2000 subsequent to DUSA's September 2000 product launch. No revenue was recognized in 1999, as DUSA had not yet launched its first products.

Product sales during 2001 and 2000 primarily reflected sales of the Kerastick(R). Royalty revenues are earned and recognized by DUSA when the Kerastick(R) is sold by Berlex to its distributor, and are payable to DUSA during the quarter following the quarter in which the sales are made. DUSA recognizes supply fee revenue related to these sales when DUSA's supplier ships the Kerastick(R) to Berlex.

Product sales during 2001 also included rental income on BLU-U(R) units of approximately $78,000. There was no rental income recognized in 2000. Initially, DUSA generally leased its BLU-U(R) brand light units for use with the Levulan(R) Kerastick(R). In July 2001, DUSA and Berlex test-marketed a new program, which was then launched nationally in mid-September 2001. Under this program, DUSA rents the BLU-U(R) to physicians for 36 months with no rental payments incurred by physicians and no rental revenue recognized by DUSA for the first six months, while Berlex provides physicians with a supply of Kerastick(R) samples. Physicians have the right to terminate the rental at any time during the 36 month period. We are negotiating with a medical device leasing company to manage the rental program including coordinating payment plans with the physicians. Berlex is actively working to convert physicians to this new marketing program. As of December 31, 2001, 207 BLU-U(R) units are in physicians' offices under the new program. Under this new marketing program, revenues will be recognized over the last 30 months of the rental period. Under our previous marketing program, we sold the BLU-U(R) to a medical device leasing company. We then engaged the leasing company to complete the leasing and/or rental transactions, including coordinating payment plans with the physicians. The leasing company had been paying us for the units within 30 days after installation in the physicians' offices. DUSA, Berlex and the leasing company will continue to support customers that remain on this initial program; however, the majority of such customers have converted to the new program. Under the initial program, physicians have the right to cancel their leases after periods of up to one year. Therefore, payments received by DUSA upon sale of the BLU-U(R) to the leasing company are reported as deferred revenues until the physician's right to cancel the lease has expired. Under the initial program, 45 contracts with physicians have been canceled. 32 of the BLU-U(R) brand light units

under these contracts have been returned as of December 31, 2001. In the event that a customer does cancel a lease, we have agreed to repurchase the units from the leasing company at an agreed upon price. As of December 31, 2001, 102 customers from the initial program have converted to the new program. These units have been repurchased from the leasing company and the corresponding deferred revenue has been reversed from the financial statements. 75 units

leased or rented by physicians remain under the initial program, and 13 units are in the field based on direct sales and demonstration units.

Under our agreement with Schering AG, two-thirds of the agreed upon dermatology research and development expenses, up to $3,000,000 per year for 2000 and 2001, were reimbursable to DUSA by Schering AG. Total research and development reimbursement earned by DUSA in 2001 was $2,893,000. For 2002, Schering AG has agreed to fund the co-development program up to $3,000,000, subject to the results of dermatology feasibility studies currently ongoing and further decisions by the development committee, which meets quarterly. Based on the agreed upon development plan and the timing of the start of the clinical trials, we were only entitled to reimbursement of $723,000 for the year ended December 31, 2000. Future spending levels are subject to mutual agreement of Schering AG and DUSA.

The total amount of up front milestone and unrestricted grant payments received in 2000 and 1999 have been recorded as deferred revenue upon receipt and are recognized as income on a straight-line basis over the term of DUSA's alliance agreement with Schering AG. For the years ended December 31, 2001 and 2000, approximately $1,983,000 and $496,000, respectively, of up front milestone and unrestricted grant payments were reflected in revenues in the Consolidated Statement of Operations.

Cost of Product Sales and Royalties - Cost of product sales and royalties for 2001 were $2,149,000 including $358,000 in direct Kerastick(R) related product costs, $266,000 in shipping and installing the BLU-U(R) in physicians offices, and $226,000 in amortization of deferred charges reflecting consideration paid by us in 2000 to amend our Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan(R). Also included in 2001 cost of product sales is $534,000 in net underutilization costs paid to our drug manufacturer, North Safety Products, Inc, due to orders to North falling below certain previously anticipated levels. In 2001, cost of product sales and royalties also included royalties and supply fees of approximately $63,000 reflecting minimum royalty payments due to DUSA's licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario. In 2001, we began to allocate personnel costs to product sale operations and/or general and administrative functions, as a significant percentage of manufacturing development activities have been completed for our current products. Such personnel-related costs allocated to cost of product sales were approximately $691,000 in 2001. Cost of product sales and royalties for 2000 were $1,105,000, including Kerastick(R) sales to Berlex in the amount of $796,000, royalties and supply fees of $68,000, amortization of deferred charges of $113,000, and approximately $127,000 in costs associated with shipping and installing the BLU-U(R) in physician's offices. There were no product sales and therefore no cost of product sales during 1999.

Inventory costs related to the BLU-U(R) commercial light sources under rental or lease are deferred and recorded in other current assets until the BLU-U(R) is no longer returnable to DUSA by

the physician, which is one year under the initial marketing program. Under the new marketing program, costs of BLU-U(R) inventory will be recognized over the 36 month term of the rental. As of December 31, 2001 and 2000, deferred inventory costs were approximately $764,000 and $262,000.

The higher cost of product sales as compared to revenues from product sales is primarily a result of the lower than anticipated level of Kerastick(R) sales, coupled with overhead attributed to the payment of underutilization costs to our Kerastick(R) supplier, as noted above, and the allocation of personnel to

product sales operations. Management expects that such costs will initially increase in our own facility but would be covered by product revenue assuming the level of Kerastick(R) sales significantly increases, which is dependent upon the market penetration of our products.

In early 2001, in order to meet the production scheduling needs of our third-party manufacturer of the BLU-U(R), National Biological Corporation ("NBC"), we prepaid raw material costs in the amount of $400,000 associated with our orders. This amount is being credited against the final purchase price of finished units, which is due on delivery at the rate of $1,000 per completed unit. At the end of December 2001, approximately $42,000 of this prepayment remained outstanding and was recorded in other current assets. In addition, since we did not order a certain number of BLU-U(R) brand units on January 2, 2002 for delivery in 2002, we paid $100,000 to NBC for certain of its overhead costs. In consideration for this payment, NBC has agreed to maintain its BLU-U(R) manufacturing capabilities in a state of readiness during 2002 with the capability of producing BLU-U(R) units in accordance with established procedures. We will recognize this payment in cost of product sales on a straight-line basis during 2002.

Research and Development Costs - DUSA's research and development costs for the years ended 2001, 2000, and 1999 were approximately $10,790,000, $8,163,000, and $4,195,000, respectively. The increase in 2001 as compared to 2000 is attributable to higher third-party expenditures for dermatology and internal indications coupled with increased personnel costs related to on-going development activities. During 2001, this increase was partially offset by the reassignment of personnel costs to product sale operations and/or general and administrative functions, rather than to research and development costs, as a significant percentage of the development activities were completed for our currently marketed dermatology products in 2000. The increase in 2000 as compared to 1999 is mainly attributed to manufacturing development expenses, reflecting increased personnel costs and pre-production activities for our products prior to market launch. As stated above under "Management's Discussion and Analysis - Revenues," under our agreement with Schering AG, two-thirds, or $2,893,000, of the agreed upon dermatology research and development expenses were reimbursable to DUSA by Schering AG for 2001 as compared to $723,000 for 2000.

In July 2001, the United States Food and Drug Administration ("FDA") completed its review of three Investigational New Drug applications allowing initiation of clinical trials using Levulan(R) PDT for the treatment of onychomycosis (nail fungus), warts, and Barrett's esophagus dysplasia. On October 10, 2001, we initiated a second Phase I/II clinical trial for the treatment of Barrett's esophagus dysplasia. Subject to success in these Phase I/II feasibility studies, DUSA plans to move forward with more expensive pre-pivotal Phase II studies for some or all of these indications,

RELATED PARTY TRANSACTIONS

starting in late 2002. DUSA expects that 2002 research and development costs will increase to approximately $13,500,000 due to increased expenditures for dermatology and internal indications and Phase IV studies mandated by the FDA in connection with our first product approval. Costs and development fees associated with agreements for research projects and clinical studies commit us to make payments of $3,284,000, and $629,000 for 2002, and 2003, respectively. If Schering AG decides to eliminate all, or a portion of the reimbursement budget for the dermatology co-development program our research and development costs could increase significantly unless we delayed or curtailed some or all of

these programs. See "Management's Discussion and Analysis - Contractual Obligations and Other Commercial Commitments."

General and Administrative Cost - General and administrative expenses for the years ended December 31, 2001, 2000, and 1999 were $3,655,000, $2,616,000, and $1,818,000, respectively. The increases in 2001 and 2000 were mainly attributable to the hiring of additional staff commencing in second half of 2000 through the first half of 2001, including key management personnel in administrative, financial, information technology, and operations functions. General and administrative costs are expected to remain stable for 2002 compared to 2001 as staffing levels for these functions have been established.

Interest Income - Interest income was approximately $3,845,000, $3,222,000, and $574,000 for the years ended December 31, 2001, 2000, and 1999, respectively, and is primarily earned on United States government securities. The increase for 2001 reflects earnings on higher investable cash balances as a result of the $15,000,000 received from Schering AG during the fourth quarter of 2000, and the full year impact of approximately $40,700,000 in net proceeds received from a private placement in March 2000. Similarly, the increase for 2000 was also due to $15,000,000 received from Schering AG during the fourth quarter of 1999. Interest income will decline as our investable cash balances are reduced to support DUSA's operating activities.

Income Taxes - As of December 31, 2001, we had net operating loss carryforwards of approximately $29,479,000 and tax credit carryforwards of approximately $1,264,000 for Federal reporting purposes. These amounts expire at various times through 2021. See Note 7 to the Company's Notes to the Consolidated Financial Statements. A provision for alternative minimum tax was recorded in 1999 for $90,000.

Net Losses - DUSA incurred net losses of approximately $7,358,000, or $0.53 per share, $6,541,000, or $0.49 per share, and $5,529,000, or $0.50 per share, for the years ended December 31, 2001, 2000 and 1999, respectively. These losses were within management's expectations, and are expected to continue unless market penetration of our first products increases significantly. DUSA expects an estimated loss in 2002 between $12,300,000 and $13,300,000. This does not include any additional new spending that may be required during the year, such as costs related to the potential acquisition or development of new products or companies; any decision, in cooperation with Schering AG, to increase Levulan(R) PDT dermatology spending levels; any additional Levulan(R) PDT internal clinical trial costs that become justified later in the year; and any extraordinary miscellaneous costs and expenses.

RELATED PARTY TRANSACTIONS

DUSA's Vice President of Business Development and Vice President of Technology are principal shareholders of Lumenetics, Inc., our former light device consultants. During 2000 and 1999, DUSA paid $2,000 and $46,000, respectively, for certain equipment leased under operating leases from Lumenetics. In 2001, DUSA purchased this equipment for $52,000. In addition, we reimbursed Lumenetics for office space and related expenses totaling approximately $146,000 in 1999. All transactions were executed at prices estimated to be fair market values.

QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the quarterly results of operations for the years ended December 31, 2001 and 2000, respectively:

	Quarterly Results For Year Ended December		
	March 31	June 30	September 3
Total revenues	$1,189,960	$1,516,754	$1,436,566
Loss from operations	(2,354,838)	(2,495,046)	(2,795,961)
Net loss	(1,252,060)	(1,563,335)	(1,817,029)
Basic and diluted loss per share	(0.09)	(0.11)	(0.13)

	Quarterly Results For Year Ended December		
	March 31	June 30	September 3
Total revenues	$ 435,157	$ 167,347	$ 139,583
Loss from operations	(1,623,969)	(2,382,555)	(2,558,562)
Net loss	(1,241,225)	(1,439,928)	(1,614,087)
Basic and diluted loss per share	(0.10)	(0.11)	(0.12)

LIQUIDITY AND CAPITAL RESOURCES

We are in a strong cash position to continue and expand our research and development activities for our Levulan(R) PDT/PD platform. Our total assets were $75,864,000 as of December 31, 2001 compared to $82,442,000 as of December 31, 2000. This decrease is mainly attributable to the funding of net operating activities during 2001 with limited product sales.

As of December 31, 2001, we had inventory of $2,333,000, representing finished goods and raw materials, as compared to $1,332,000 as of December 31, 2000. Also, as of December 31, 2001, we had net property and equipment of $3,384,000, as compared to $1,700,000 as of December 31, 2000, due primarily to the installation of new financial and operations systems, and pre-construction costs associated with architectural and engineering plans for our manufacturing facility. DUSA expects to incur costs of approximately $2,700,000 during 2002 for the construction of this facility.

As of December 31, 2001, we had accounts receivable of $121,000 as compared to $915,000 as of December 31, 2000, representing net sales associated with product sales. In addition, a receivable of $865,000 has been recorded as a current asset as of December 31, 2001 as compared

to $723,000 at the end of the same period in the previous year for amounts which are reimbursable by Schering AG for research and development costs under our agreement.

As of December 31, 2001, we had current liabilities of $3,051,000, as compared to $2,837,000 as of December 31, 2000. Since our inception, we have had no long-term debt; however, DUSA is in the process of evaluating financing options for the construction of its manufacturing facility in its Wilmington headquarters. We have been approved for a loan of $2,700,000 to finance such development.

We invest our cash in United States government securities, all of which are classified as available for sale. These securities have an aggregate cost of $54,917,000, and a current aggregate market value of $57,141,000 as of December 31, 2001, resulting in a net unrealized gain on securities available for sale of $2,224,000, which has been included in shareholders' equity. As of December 31, 2000, government securities had an aggregate cost of $56,876,000 and an aggregate market value of $58,055,000, resulting in a net unrealized gain of $1,179,000. Due to fluctuations in interest rates and depending upon the timing of our need to convert government securities into cash to meet our working capital requirements, some gains or losses could be realized. As of December 31, 2001, these securities had interest rates and yields ranging from 4.26% to 7.00% and maturity dates ranging from January 14, 2002 to November 15, 2006. We expect to use approximately $13,000,000 in cash to fund net operating activities during 2002.

We believe that we have sufficient capital resources to proceed with our current development program for Levulan(R) PDT/PD, and to fund operations and capital expenditures for the foreseeable future. We have invested our funds in liquid investments, so that we will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis. DUSA is actively seeking to expand or enhance its business by using its resources to acquire by license, purchase or other arrangements, businesses, technologies, or products. We also plan to continue to actively seek relationships with pharmaceutical or other suitable organizations to help develop and/or market some of our potential non-dermatology products and technologies.

As of December 31, 2001, DUSA had deferred revenues of $22,586,000 as compared to $24,805,000 at December 31, 2000, reflecting net milestone and unrestricted grant payments of $22,312,000 and the deferral of $273,000 in product sales related to our customer's one-year right of return on leases of our commercial light sources. Commencing with our product launch in September 2000, we began to amortize the Schering AG milestone and unrestricted grant payments into revenue. The amortization period is expected to be 12-1/2 years, the term of the Schering AG agreement, based upon current revenue recognition principles. See Note 10 to the Company's Notes to the Consolidated Financial Statements.

We are currently focusing our efforts on providing support to Berlex in its effort to penetrate the marketplace with our unique Levulan(R) PDT therapy for AKs, on conducting the expanded dermatology co-development program with Schering AG, and on furthering development of our internal research and development program. Full development and testing of all potential indications that are currently under development or being considered for development may require additional funding. The timing of expenditures will be dependent on various factors, including:

- progress of our research and development programs,
- continuing support from Schering AG,
- the results of preclinical and clinical trials,
- the timing of regulatory marketing approvals,
- competitive developments,
- the level of sales of our first products,

- any new additional collaborative arrangements, if any, we may enter, and
- the availability of other financing.

We cannot accurately predict the magnitude of revenues from sales of our products. While the net proceeds of the January 1999 and March 2000 offerings coupled with payments received from Schering AG will enable us to maintain our current research program as planned and support the commercialization of Levulan(R) PDT for AKs for the foreseeable future, in order to maintain and expand continuing research and development programs, DUSA may need to raise additional funds through future corporate alliances, financings, or other sources, depending upon the amount of revenues we receive from our first product.

Additionally, Schering AG has the right to terminate our agreement on 12-months written notice. If Schering AG were to decide to terminate our agreement early, we could incur significant additional research and development expenses, and we may have to establish a marketing capability, also at significant expense. In addition, the balance of the deferred revenue mentioned above, and deferred royalty would be recognized in the year of termination.

As of December 31, 2001, we had 55 full-time employees. We have employment agreements with our key executive officers. We have purchased and are the named beneficiary of a key man life insurance contract having a face value of CDN $2,000,000 on the life of our President. We expect only moderate increases in our staff in 2002 to support the development of our drug manufacturing facility as staffing levels related to key management personnel in administrative, financial, technical and operations functions have been established for the commercialization of Levulan(R) PDT.

We have not made any material capital expenditures for environmental control facilities. However, as we are in the process of developing a production line for Kerastick(R) manufacturing, we expect that environmental laws will govern our facility. We have estimated that the capital costs to develop this facility, including equipment, will be approximately $2,700,000. There can be no assurance, however, that we will not be required to incur significant additional costs to comply with environmental laws and regulations in the future, or any assurance that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations. See "Business -- Government Regulation."

CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

DUSA's contractual obligations and other commercial commitments to make future payments under contracts, such as lease agreements, research and development contracts, manufacturing contracts, or other related agreements are as follows at December 31, 2001:

Contractual Commitments	Obligations Due by Period			
	Total	1 Year or Less	2-3 Years	4-5 Years
Operating lease obligations (1)	$4,486,000	$450,000	$668,000	$765,

Research and development projects (2)	$3,913,000	$3,284,000	$629,000
Manufacturing facility development (3)	$2,700,000	$2,700,000	--
Other short-term obligations (4,5)	$300,000	$300,000	--

1) In 2001, DUSA extended its lease commitment for its office and manufacturing space in its Wilmington, Massachusetts headquarters through November 2016. We have the ability to terminate the Wilmington lease after the 10th year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. The operating lease obligations disclosed above include payments for the non-cancelable term of the lease. In addition, as our Valhalla and Toronto lease commitments expire during 2002, the Company is evaluating its alternatives for new office facilities.

2) In addition to the obligations disclosed above, we have contracted with Therapeutics, Inc., a clinical research organization, to manage the clinical development of our products in the field of dermatology. This organization has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from $250,000 to $1,250,000 depending on the regulatory phase of development of products during its management.

3) DUSA has commenced the development of a Kerastick(R) manufacturing facility at our Wilmington, Massachusetts location. Construction started in January 2002. The initial build-out is expected to be completed by June 2002, followed by facility and drug stability testing, which is expected to take approximately six months. FDA inspection, which is expected to occur within approximately six months following the construction and testing stages. The Company has estimated that the costs to construct this facility, including equipment, are approximately $2,700,000 and is evaluating financing options. This cost includes estimates to build the facility and all costs of calibration, validation testing and equipment, and any related FDA approval costs.

4) In January 2002, DUSA paid $100,000 to its third-party manufacturer of the BLU-U(R), National Biological Corporation, since we did not order a certain number of BLU-U(R) brand units for delivery in 2002. In consideration for this payment, NBC has agreed to

maintain its BLU-U(R) manufacturing capabilities in a state of readiness during 2002 with the capability of producing BLU-U(R) units in accordance with established procedures.

5) DUSA has agreed to make additional payments totaling $200,000 during 2002 to its third-party manufacturer of the Kerastick(R), North Safety Products, Inc., covering underutilization fees associated with recent orders falling below certain previously anticipated levels. In consideration

for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures through December 31, 2002 unless DUSA exercises an option to extend the term through June 30, 2003. If DUSA should decide to extend the term, North will be entitled to payment of additional underutilization fees of up to $500,000, prorated based on the level of Kerastick(R) units produced from July 1, 2001 through June 30, 2003.

RECENTLY ISSUED ACCOUNTING GUIDANCE

In September 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities." On January 1, 2001, DUSA adopted SFAS No. 133, which did not have any effect on our financial position or results of operations.

In August 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment of Disposal of Long-lived Assets." This statement supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." SFAS 144 establishes a single accounting model, based on the framework established in SFAS 121, for long-lived assets to be disposed of by sale, and resolves implementation issues related to SFAS 121. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. On January 1, 2002, DUSA adopted this statement, which will have no effect on our financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations" and SFAS No. 142 "Goodwill and Other Intangible Assets." SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after September 30, 2001 and that the use of the pooling-of-interest method is no longer allowed. SFAS No. 142 requires that upon adoption, amortization of goodwill will cease and instead, the carrying value of goodwill will be evaluated for impairment on an annual basis. Identifiable intangible assets will continue to be amortized over their useful lives and reviewed for impairment in accordance with SFAS No. 121. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. On January 1, 2002, DUSA adopted these statements, which will have no effect on our financial position or results of operations.

INFLATION

Although inflation rates have been comparatively low in recent years, inflation is expected to apply upward pressure on our operating costs. We have included an inflation factor in our cost estimates. However, the overall net effect of inflation on our operations is expected to be minimal.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We hold fixed income United States government securities that are subject to interest rate market risks. However, we do not believe that the risk is material as we make our investments in relatively short-term instruments and we strive to match the maturity dates of these instruments to our cash flow needs. A 10% decline in the average yield of these instruments would not have a material effect on our results of operations or cash flows.

FORWARD-LOOKING STATEMENTS SAFE HARBOR

This report, including the Management's Discussion and Analysis, contains various "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 which represent our expectations or beliefs concerning future events, including, but not limited to statements regarding management's beliefs regarding the unique nature of Levulan(R), expectations regarding the timing of results of clinical trials and future development of warts, onychomycosis and Barrett's esophagus dysplasia, intention to evaluate and pursue licensing and acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy, commercialization of additional Levulan(R) dermatology products with Schering AG, hope that our products will be an AK therapy of choice, beliefs regarding revenues from approved and potential products and Levulan's(R) competitive properties, intention to commence clinical trials in 2002, expectations of exclusivity under the Hatch/Waxman Act and other patent laws, intentions to seek additional United States and foreign regulatory approvals, trademarks, and to market outside the United States, beliefs regarding environmental compliance, beliefs concerning patent disputes, the impact of a third-parties regulatory compliance and fulfillment of contractual obligations, the expectations regarding the future funding by Schering AG, plans to monitor cost of product sales, expectations of increases in cost of product sales, expected use of cash resources in 2002, requirements of cash resources for our future liquidity, anticipation of hiring additional personnel, dependence on Schering AG's and Berlex's marketing and third-party suppliers, as well as reimbursement policies for significant revenues, expectations to support independent investigators, expectations for future strategic opportunities and research and development programs, expectations for continuing operating losses, stable administrative costs, increasing research and development costs, levels of interest income and our capital resource needs, expectations for completion of our new manufacturing facilities, expected costs, and anticipated dates for inspection and testing, belief regarding interest rate risks to our investments and effects of inflation and new accounting standards, dependence on key personnel, beliefs concerning product liability insurance, intention to continue to develop integrated drug and light device systems, belief that our new facility will help control costs and intention to hire employees and consultants. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the commitment of Schering AG to the marketing of and research and development activities for our products, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, reliance on third-parties for the production, manufacture, sales and marketing of our products, the securities regulatory process, the maintenance of our patent portfolio and competitive levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by Item 10 is hereby incorporated by reference to the sections entitled "Nominees," "Executive Officers who are not Directors," and "Compliance with Section 16(a) of the Exchange Act" of the Registrant's 2002 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections entitled "Director Compensation," "Executive Compensation," "Board Compensation Committee Report on Executive Compensation," "Performance Graph," "Option Grants in 2001," "Aggregate Option Exercises in 2001 and Option Values at December 31, 2001," and "Other Compensation" of Registrant's 2002 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by Item 12 is hereby incorporated by reference to the section entitled "Security Ownership of Certain Beneficial Owners and Management" of the Registrant's 2002 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 13 is hereby incorporated by reference to the section entitled "Certain Transactions" of the Registrant's 2002 Proxy Statement.

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

A. List of Financial Statements and Schedules

INCLUDED IN ANNUAL REPORT TO SHAREHOLDERS
INCORPORATED HEREIN BY REFERENCE:

Schedules are omitted because they are not required or the information is included in Notes to the Consolidated Financial Statements.

B. Reports on Form 8-K

1. Form 8-K filed on October 10, 2001, which announced an update to investors at the UBS Warburg Global Life Sciences Conference and initiation of DUSA's second clinical trial for the treatment of Barrett's esophagus using Levulan(R) PDT.

C. Exhibits filed as part of this Report

3(a) Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference;

3(b) By-laws of the Registrant, filed as Exhibit 3(ii) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1997, filed November 12, 1997 and are incorporated herein by reference;

4(a) Common Stock specimen, filed as Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1997 filed November 12, 1997, and is incorporated herein by reference;

4(b) Class B Warrant, filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;

10(a) License Agreement between the Company, PARTEQ and Draxis Health Inc. dated August 27, 1991, filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;

10(b) ALA Assignment Agreement between the Company, PARTEQ, and Draxis Health Inc. dated October 7, 1991, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;

10(b.1) Amended and Restated Assignment Agreement between the Company and Draxis Health, Inc. dated April 16, 1999, filed as Exhibit 10(b.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;

10(c) Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated October 1, 1991, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;

10(d) Amendment to Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated April 14, 1994, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-2, No. 33-98030, and is incorporated hereby by reference;

10(e) Amended and Restated License Agreement between the Company and PARTEQ dated March 11, 1998, filed as Exhibit 10(e) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of

Exhibit A have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(f) Incentive Stock Option Plan, filed as Exhibit 10.11 of Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;

10(g) 1994 Restricted Stock Option Plan, filed as Exhibit 1 to Registrant's Schedule 14A definitive Proxy Statement dated April 26, 1995, and is incorporated herein by reference;

10(h) 1996 Omnibus Plan, as amended, filed as Appendix A to Registrant's Schedule 14A Definitive Proxy Statement dated April 26, 2001, and is incorporated herein by reference;

10(i) Purchase and Supply Agreement between the Company and National Biological Corporation dated November 5, 1998, filed as Exhibit 10(i) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

53

10(j) Marketing Development and Supply Agreement between the Company and Schering AG dated November 22, 1999, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(j.1) Letter Amendment to the Marketing Development and Supply Agreement between the Company and Schering AG dated September 26, 2001, filed as Exhibit 10(a) to the Registrant's quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(k) Common Stock Purchase Agreement between the Company and Schering Berlin Venture Corporation dated as of November 22, 1999, filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(l) Light Source Agreement between the Company and Schering AG dated as of November 22, 1999, filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(m) Guaranty dated as of November 22, 1999 by Schering AG in favor

of the Company, filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(n) Secured Line of Credit Promissory Note dated November 22, 1999 with the Company as payee and Schering AG as Holder filed as Exhibit 10.5 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(o) Security Agreement dated as of November 22, 1999 between the Company and Schering AG filed as Exhibit 10.6 to the Registrant's Current Report on Form 8-K

dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(p) Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of September 13, 1999, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated October 14, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(p.1) Amendment to Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of February 15, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended;

10(p.2) Second Amendment to Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of July 26, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended;

10(q) Supply Agreement between the Company and Sochinaz SA dated December 24, 1993, filed as Exhibit 10(q) to Registrant's Form 10K/A filed on March 21, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(q.1) First Amendment to Supply Agreement between the Company and Sochinaz SA dated July 7, 1994, filed as Exhibit 10(q.1) to Registrant's Form 10K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;

10(q.2) Second Amendment to Supply Agreement between the Company and Sochinaz SA dated as of June 20, 2000, filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K dated June 28,

2000, and is incorporated herein by reference;

10(r) Master Vendor Operating Agreement between the Company and International Leasing Corporation dated September 21, 2000, filed as Exhibit 10 to the Registrant's quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2000, filed November 14, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(s) Master Service Agreement between the Company and Therapeutics, Inc. dated as of October 4, 2001, filed as Exhibit 10(b) to the Registrant's quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8,

2001, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference; and

23.1 Consent of Deloitte & Touche LLP.

INDEPENDENT AUDITORS' REPORT

Board of Directors
DUSA Pharmaceuticals, Inc.
Wilmington, Massachusetts

We have audited the accompanying consolidated balance sheets of DUSA Pharmaceuticals, Inc. and its subsidiary (the "Company") as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
February 20, 2002

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

ASSETS

CURRENT ASSETS
- Cash and cash equivalents
- United States government securities
- Accrued interest receivable
- Accounts receivable
- Receivable under co-development program
- Inventory
- Other current assets

  TOTAL CURRENT ASSETS
- Property and equipment, net
- Deferred charges
- Deferred royalty
- Other assets

TOTAL ASSETS

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES
- Accounts payable
- Accrued payroll
- Other accrued expenses
- Deferred revenue
- Due to licensor

  TOTAL CURRENT LIABILITIES
- Deferred revenue
- Other deferred reimbursement

TOTAL LIABILITIES

COMMITMENTS AND CONTINGENCIES (NOTE 11)

SHAREHOLDERS' EQUITY
- Capital Stock
  Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes. Issued and outstanding: 13,865,390 (2000: 13,730,890) shares of common stock, no par.
- Additional paid-in capital
- Accumulated deficit
- Accumulated other comprehensive income

TOTAL SHAREHOLDERS' EQUITY

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	YEAR ENDE	
	2001	
REVENUES		
Product sales and rental income	$ 514,584	$
Research grant and milestone revenue	1,983,336	
Research revenue earned under collaborative agreement	2,892,816	
TOTAL REVENUES	5,390,736	2,
OPERATING COSTS		
Cost of product sales and royalties	2,148,994	1,
Research and development	10,789,906	8,
General and administrative	3,654,792	2,
TOTAL OPERATING COSTS	16,593,692	11,
LOSS FROM OPERATIONS	(11,202,956)	(9,7
OTHER INCOME		
Interest income	3,844,860	3,
LOSS BEFORE INCOME TAX EXPENSE	(7,358,096)	(6,5
Income tax expense	--	
NET LOSS	$ (7,358,096)	$(6,5
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$(.53)	
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	13,791,735	13,

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	COMMON STOCK		ADDITIONAL	
	NUMBER OF SHARES	AMOUNT	PAID-IN CAPITAL	ACCUMULATED DEFICIT
BALANCE, JANUARY 1, 1999	9,365,950	$36,746,993	$ 81,586	$(30,417,96
Comprehensive loss:				
Net loss for period				(5,528,62
Net unrealized loss on United States government securities available for sale				
Total comprehensive loss				
Issuance of common stock for cash through a private placement (net of offering costs of $2,102,861)	1,500,000	5,397,139		
Issuance of common stock to placement agent in connection with the private placement	130,435	900,784		
Issuance of 163,043 warrants to placement agent in connection with the private placement			905,094	
Issuance of additional common stock to placement agent in connection with the private placement	15,000	143,445		
Issuance of additional 1,630 warrants to placement agent in connection with the private placement			9,050	
Issuance of common stock in connection with collaborative agreement	340,458	5,208,333		
Exercises of options	398,922	2,565,333		
Exercises of warrants	157,592	787,960		
Stock based compensation			343,124	
BALANCE, DECEMBER 31, 1999	11,908,357	$51,749,987	$1,338,854	$(35,946,59

See the accompanying Notes to the Consolidated Financial Statements.

F-4

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (CONTINUED)

	COMMON STOCK		ADDITIONAL	
	NUMBER OF SHARES	AMOUNT	PAID-IN CAPITAL	ACCUMULATE DEFICIT
BALANCE, DECEMBER 31, 1999	11,908,357	$51,749,987	$1,338,854	$(35,946,5
Comprehensive loss:				
Net loss for period				(6,540,7
Net unrealized gain on United States government securities available for sale				
Total comprehensive loss				
Issuance of common stock for cash (net of offering costs of $2,051,714)	1,500,000	40,698,286		
Issuance of common stock in connection with supply agreement	26,667	750,000		
Issuance of common stock to consultant	2,500	64,533		
Exercises of options	248,350	1,264,646		
Exercises of warrants	45,016	230,080		
Stock based compensation			521,665	
BALANCE, DECEMBER 31, 2000	13,730,890	$94,757,532	$1,860,519	$(42,487,3
Comprehensive loss:				
Net loss for period				(7,358,0
Net unrealized gain on United States government securities available for sale				
Total comprehensive loss				
Issuance of common stock to consultant	5,000	54,750		
Exercises of options	104,500	478,279		
Exercises of warrants	25,000	150,000		
Stock based compensation			155,067	
BALANCE, DECEMBER 31, 2001	13,865,390	$95,440,561	$2,015,586	$(49,845,4

See the accompanying Notes to the Consolidated Financial Statements.

F-5

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS

	YEAR
	2001
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES	
Net loss	$ (7,358,096)
Adjustments to reconcile net loss to net cash used in operating activities	
Amortization of premiums and accretion of discounts on United States government securities available for sale and investment securities, net	738,699
Depreciation and amortization expense	1,066,915
Amortization of deferred revenue	(1,983,336)
Stock based compensation	155,067
Issue of shares of common stock and warrants to non-employees	54,750
Changes in other assets and liabilities impacting cash flows from operations:	
Accrued interest receivable	66,624
Accounts receivable	793,679
Receivable under co-development program	(141,964)
Inventory	(1,001,114)
Other current assets	(692,710)
Deferred charges	(400,000)
Accounts payable	214,389
Accrued payroll and other accrued expenses	589,436
Income taxes payable	--
Due to licensor	(4,212)
Deferred revenue	(235,849)
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	(8,137,722)
CASH FLOWS USED IN INVESTING ACTIVITIES	
Purchases of United States government securities	(23,282,378)
Proceeds from maturing United States government securities	24,502,758
Purchases of property and equipment	(2,331,551)
Deposits on equipment	98,000
Payment to restructure supplier contract	--
Payments to licensor	(350,000)
NET CASH USED IN INVESTING ACTIVITIES	(1,363,171)

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

	YEAR ENDED	
	2001	2

CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Issuance of common stock and underwriters' options, net of offering costs of $2,051,714 and $2,102,861 for 2000 and 1999, respectively	--	40,6
Proceeds from exercise of options and warrants	628,279	1,4
NET CASH PROVIDED BY FINANCING ACTIVITIES	628,279	42,1
NET INCREASE (DECREASE) IN CASH	(8,872,614)	9,4
CASH AT BEGINNING OF PERIOD	16,441,114	7,0
CASH AT END OF PERIOD	$ 7,568,500	$ 16,4
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION		
Issuance of common stock and warrants to placement agent		
Income tax payments		$9

During 2000, in connection with the amendment of a supply agreement, the Company issued 26,667 unregistered shares of DUSA's Common Stock, at a fair market value of $750,000, to Sochinaz SA (See Note 11).

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2001, 2000, AND 1999

1) NATURE OF BUSINESS

DUSA Pharmaceuticals, Inc. (the "Company" or "DUSA") was established to develop prescription pharmaceutical products for all markets, primarily in the field of photodynamic therapy ("PDT") and photodetection ("PD"), which combines the use of a pharmaceutical product with exposure to light to induce a therapeutic or detection effect. The Company has concentrated its initial efforts on topical and/or local uses of aminolevulinic acid HCl ("Levulan(R)") PDT/PD. On September 28, 2000, the Company launched its first commercial products, Levulan(R) Kerastick(R) 20% Topical Solution and the BLU-U(R) brand light source for the treatment of actinic keratoses (AKs) of the face or scalp in cooperation with Berlex Laboratories ("Berlex"), the United States affiliate of Schering AG, a German corporation.

2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a) Principles of Consolidation - The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., which was formed on March 3, 1994 to be the research and development center for the Company. All intercompany balances and transactions have been eliminated.

b) Basis of Presentation and Use of Estimates - These financial

statements have been prepared in conformity with accounting principles generally accepted in the United States of America. Such principles require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

c) Reclassifications - Certain prior year amounts have been reclassified to conform to the current year presentation. Such reclassifications had no impact on the net loss or shareholders' equity for any period presented.

d) Cash Equivalents - Cash equivalents include short-term highly liquid investments purchased with remaining maturities of 90 days or less. In December 2001, the Company executed a short-term, renewable, irrevocable and unconditional letter of credit for $136,018 in lieu of a security deposit for the construction of the Company's Kerastick(R) manufacturing facility at its Wilmington, Massachusetts location. The cash is held in a separate bank account and is recorded in cash and cash equivalents in the Consolidated Balance Sheets.

e) United States Government Securities Available for Sale - The Company follows the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." This Statement requires the Company to record securities which management has classified as available for sale at fair

market value and to record unrealized gains and losses on securities available for sale as a separate component of shareholders' equity until realized.

As the Company's United States government securities are available for sale, and as management expects to sell a portion of its United States government securities in the next fiscal year in order to meet its working capital requirements, it has classified all securities as current assets. The premiums paid and discounts allowed on the purchase of the securities are amortized into interest income over the life of the securities using the level-yield method.

f) Inventory - Inventory is stated at the lower of cost (first-in, first-out method) or market. Inventory consisting of BLU-U(R) commercial light sources is reclassified to other assets when the BLU-U(R) is shipped to physicians under rental, leasing, or demonstration programs. Inventory identified for research and development activities is expensed in the period in which that inventory is designated for such use.

g) Property and Equipment - Property and equipment are carried at cost less accumulated depreciation. Depreciation is computed on a straight-line basis over the estimated lives of the related assets. Leasehold improvements are amortized over the lesser of their useful

lives or the lease terms.

h) Deferred Charges and Royalties - Deferred charges and royalties which include costs paid in advance to third parties under various agreements are being amortized on a straight-line basis over their expected terms (1-1/2 - 12 years).

Deferred charges, which are being amortized over 18 months and 4-1/2 years, respectively, at December 31, 2001 and 2000 are as follows:

	2001	2000
Facilities underutilization costs	$933,333	$-
Facilities reimbursement costs	660,375	886,792
	$1,593,708	$886,792

Prepaid royalties to PARTEQ are being amortized over 12-1/2 years.

i) Impairment of Long-lived Assets - The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount of fair value less estimated cost to sell.

j) Revenue Recognition - Revenues on product sales of the drug applicator are recognized upon shipment. Revenue earned under the Company's and third parties' rental and lease agreements are recognized in income when free demonstration periods are completed and payments are due and determined to be collected. Research revenue earned under collaborative agreements consists of non-refundable research and development funding from a corporate partner. Research revenue generally compensates the Company for a portion of agreed-upon research and development expenses and is recognized as revenue at the time the research and development activities are performed under the terms of the related agreements and when no future performance obligations exist. Milestone or other up-front payments have been recorded as deferred revenue upon receipt and are recognized as income on a straight-line basis over the term of the Company's agreement with Schering AG (Note 10).

Deferred revenue associated with the Company's milestone payments, unrestricted research grants, and the sale of commercial light sources at December 31, 2001 and 2000 is as follows:

	2001	200
Milestone and unrestricted grant payments	$22,312,498	$24,295,83
Sale of commercial light sources	273,358	509,20
	$22,585,856	$24,805,04

k) Research and Development Costs - Costs related to the conceptual formulation and design of products and processes are expensed as research and development costs as they are incurred.

l) Income Taxes - The Company follows the provisions of SFAS No. 109, "Accounting for Income Taxes," which requires the Company to compute deferred income taxes based on the difference between the financial statement and tax basis of assets and liabilities using tax rates expected to be in effect in the years in which these differences are expected to reverse (Note 7).

m) Basic and Diluted Net Loss Per Share - The Company follows the provisions of SFAS No. 128, "Earnings Per Share." Basic net loss per common share is based on the weighted average number of shares outstanding during each period. Stock options and warrants are not included in the computation of the weighted average number of shares outstanding for dilutive net loss per common share during each of the periods presented in the Statement of Operations, as the effect would be antidilutive. For the years ended December 31, 2001, 2000, and 1999, stock options and warrants totaling approximately 2,548,000, 2,340,000,

and 2,120,000 shares, respectively, have been excluded from the computation of diluted net loss per share.

n) Stock-based compensation - SFAS No. 123, "Accounting for Stock-Based Compensation," addresses the financial accounting and reporting standards for stock or other equity-based compensation arrangements. The Company has elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25, and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by SFAS No. 123. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and other related interpretations. Under this method, the equity-based instrument is

valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which is generally the vesting period.

o) Comprehensive Income - The Company has reported comprehensive income (loss) and its components as part of its statement of shareholders' equity. The only element of comprehensive income, apart from net loss, relates to unrealized gains or losses on United States government securities available for sale.

p) Segment Reporting - The Company presently operates in one segment, which is the development and commercialization of emerging technologies that use drugs in combination with light to treat and detect disease.

q) Fair Value of Financial Instruments - The carrying value of the Company's financial assets and liabilities approximate their fair values due to their short-term nature. Marketable securities are carried at fair market value.

r) Concentration of Credit Risk - The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company is subject to credit risk through short-term investments and mitigates this risk by investing in United States government securities. To date, substantially all of the Company's revenues have been earned from the Company's single collaborator (Note 10).

s) Recently Issued Accounting Guidance - On January 1, 2001, the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which was issued by the Financial Accounting Standards Board. The adoption of this statement did not have any effect on the Company's financial position or results of operations.

In August 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment of Disposal of Long-lived Assets." This statement supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." SFAS 144 establishes a single accounting model, based on the framework established in SFAS 121, for long-lived assets to be disposed of by sale and resolves implementation issues related to SFAS 121. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. On January 1, 2002, the Company adopted this statement, which will have no effect on the Company's financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations" and SFAS No. 142 "Goodwill and Other Intangible Assets." SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 and that the use of the pooling-of-interest method is no longer allowed. SFAS No. 142 requires that upon adoption, amortization of goodwill will cease and instead, the carrying value of goodwill will

be evaluated for impairment on an annual basis. Identifiable intangible assets will continue to be amortized over their useful lives and reviewed for impairment in accordance with SFAS No. 121. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. On January 1, 2002, the Company adopted these statements, which will have no effect on the Company's financial position or results of operations.

3) UNITED STATES GOVERNMENT SECURITIES

Securities available for sale consist of United States Treasury Bills, Notes, and other United States government securities with yields ranging from 4.26% to 7.00% and maturity dates ranging from January 14, 2002 to November 15, 2006. As of December 31, 2001 and 2000, the fair market value and cost basis on such securities were as follows:

	2001	2000
Fair market value	$57,141,125	$58,055,463
Cost basis	54,917,290	56,876,369

Net unrealized gains on such securities for the years ended December 31, 2001 and 2000 were $1,044,741 and $1,261,413, respectively, and have been recorded in accumulated other comprehensive income, which is reported as part of shareholders' equity in the Consolidated Balance Sheets.

4) INVENTORY

Inventory consisted of the following at December 31, 2001 and 2000:

	2001	2000
Finished goods	$2,013,799	$1,151,537
Raw materials	319,281	175,344
Purchased parts and subassemblies	--	5,085
	$2,333,080	$1,331,966

5) OTHER CURRENT ASSETS

Other current assets consisted of the following at December 31, 2001 and 2000:

	2001	2000
Prepaid expenses and deposits	$ 447,520	$ 293,069
Commercial light sources under lease or rental	764,025	261,923
Other current assets	43,405	7,248
	$1,254,950	$ 562,240

6) PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2001 and 2000:

	USEFUL LIVES (YEARS)	2001	
Computer equipment and software	3	$1,703,482	$
Furniture, fixtures and equipment	5	517,465	
Manufacturing equipment	5	1,334,769	
Leasehold improvements	Term of lease	627,109	
Construction work-in-progress	--	397,783	
		4,580,608	2,
Accumulated depreciation and amortization		(1,196,322)	(
		$3,384,286	$1,

7) INCOME TAXES

The tax effect of significant temporary differences representing deferred tax assets and liabilities at December 31, 2001 and 2000 is as follows:

	2001	2000
DEFERRED TAX ASSETS		
Deferred revenue	$ 9,484,363	$ 10,178,889
Intangible assets	652,366	653,318
Accrued charges	17,339	--
Research and development tax credits carryforwards	1,393,428	928,131
Operating loss carryforwards	10,853,611	5,911,149
Capital loss carryforwards	666	165,240
Charitable contribution carryforward	4,198	--
Fixed assets	--	59,668
Total deferred tax assets	22,405,971	17,896,395
DEFERRED TAX LIABILITIES		
Deferred charges	(79,011)	--
Fixed assets	(58,142)	--
Total deferred tax liabilities	$ (137,153)	$ --
Net deferred tax assets before allowance	22,268,818	17,896,395
Valuation allowance	(22,268,818)	(17,896,395)
Total deferred tax asset	$ --	$ --

During the years ended December 31, 2001, 2000, and 1999, the valuation allowance was increased by approximately $4,372,000, $2,631,000, and $2,462,000, respectively, due to the uncertainty of future realization of the net deferred tax assets.

Included in deferred tax assets at December 31, 2001 is approximately $1,600,000 of future benefits which, if realized, will be credited to additional paid in capital rather than results of operations.

As of December 31, 2001, the Company has Federal net operating loss carryforwards for tax purposes of approximately $29,479,000 and research and development tax credits of approximately $1,264,000, both of which, if not utilized, will expire for Federal tax purposes as follows:

RESEARCH AND

	OPERATING LOSS CARRYFORWARDS	DEVELOPMENT TAX CREDITS
2006	$ -	$6,731
2007	-	57,111
2008	-	65,795
2009	-	83,961
2010	-	43,825
2011	8,962,772	102,481
2012	6,840,914	235,314
2018	5,738,119	144,701
2019	1,000	80,724
2020	27,991	158,745
2021	7,907,926	284,315
	$29,478,722	$1,263,703

A reconciliation between the effective tax rate and the statutory Federal rate follows:

	2001		2000	
	$	%	$	%
Income tax expense (benefit) at statutory rates	(2,502,000)	(34.0)	(2,205,000)	(34.0)
State taxes	(500,000)	(6.8)	(425,000)	(6.5)
(Increase) decrease in tax credit carryforwards	(335,000)	(4.6)	38,000	0.5
Increase in valuation allowance	3,265,000	44.4	2,631,000	40.6
Other	72,000	1.0	(39,000)	(0.6)
	--	--	--	--

Income tax expense incurred for the year ended December 31, 1999 was classified as current.

8) SHAREHOLDERS' EQUITY

On January 15, 1999, the Company issued 1,500,000 shares of its common stock at $5.00 per share in a private placement pursuant to Regulation D of the Securities Act of 1933. In connection with the placement, 130,435 shares of common stock were issued as commission to the placement agent. Additional commission was paid to the placement agent in the form of 163,043 five-year warrants, each of which are exercisable into one share of common stock

at $5.00 per share. These shares and warrants have been valued at $1,805,878 and have been recorded as stock offering costs.

Since the Form S-3 Registration Statement which was filed to register the shares in the private placement was not effective as of June 1, 1999, the Company was obligated to issue and did issue 15,000 shares of common stock to the investors and 1,630 additional warrants to the placement agent, i.e. 1% of the shares issued to the investors and 1% of the warrants issued to placement agent. These warrants have the same terms and conditions as the original placement agent warrants. These shares and warrants have been valued at $152,495 and both have been recorded as part of general and administrative costs in the Consolidated Statements of Operations for the year ended December 31, 1999.

On March 22, 2000, the Company issued 1,500,000 shares of its common stock in a private placement pursuant to Regulation D of the Securities Act of 1933. The Company received gross proceeds of $42,750,000. The offering costs associated with the placement were $2,051,714. The shares were registered on a Form S-3 Registration Statement which became effective on March 22, 2000.

In June 2000, the Company amended its Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan(R). As partial consideration for the amendment, DUSA issued 26,667 unregistered shares of DUSA's Common Stock, at a fair market value of $750,000 (Note 11).

On September 18, 2000, the Company granted 2,500 shares of unregistered common stock, without par value, to an outside consultant for compensation of services. These shares were valued at approximately $65,000 and recorded as part of general and administrative costs in the Consolidated Statements of Operations.

On October 4, 2001, the Company granted 5,000 shares of unregistered common stock, without par value, to Therapeutics, Inc., a clinical research organization, engaged to manage the clinical development of the Company's products in the field of dermatology. These shares were valued at approximately $55,000, and are being recognized in research and development expense in the Consolidated Statement of Operations.

9) STOCK OPTIONS AND WARRANTS

a) 1996 Omnibus Plan - On April 11, 1996, the 1996 Omnibus Plan ("Omnibus Plan") was adopted by the Board of Directors, subsequently approved by the shareholders on June 6, 1996, and superceded the Company's previously adopted 1994 Restricted Stock Option Plan and the Incentive Stock Option Plan adopted in 1991. No further grants will be made under the superceded plans. The Omnibus Plan was amended and approved by shareholders on

June 14, 2001 and provides for the granting of awards to purchase up to

a maximum of 20% of the Company's common stock outstanding or a maximum of 2,753,328. The Omnibus Plan is administered by a committee ("Committee") established by the Board of Directors. The Omnibus Plan enables the Committee to grant non-qualified stock options ("NQSO"), incentive stock options ("ISO"), stock appreciation rights ("SAR"), restricted stock ("RS") or other securities determined by the Company, to directors, employees and consultants. To date, the Company has made awards of NQSOs, ISOs, and RSs under the Omnibus Plan.

Non-qualified stock options - All the non-qualified stock options granted under the Omnibus Plan have an expiration period not exceeding ten years and are issued at a price not less than the market value of the common stock on the grant date. The Company grants each individual who agrees to become a director 15,000 NQSO to purchase common stock of the Company. These initial grants vest annually over a four-year period. Thereafter, each director reelected at an Annual Meeting of Shareholders will automatically receive an additional 10,000 NQSO on June 30 of each year except for 2001, for which each director received 5,000 NQSO based on an agreement at the June 14, 2001 shareholder meeting. These grants immediately vest on the date of the grant.

Incentive stock options - Incentive stock options granted under the Omnibus Plan and the superceded 1991 plan have an expiration period not exceeding ten years (five years for ISOs granted to employees who are also ten percent shareholders) and are issued at a price not less than the market value of the common stock on the grant date. These options become exercisable at a rate of one quarter of the total granted on each of the first, second, third and fourth anniversaries of the grant date subject to satisfaction of certain conditions involving continuous periods of service.

The following table summarizes information about all stock options outstanding at December 31, 2001:

	OPTIONS OUTSTANDING		
RANGE OF EXERCISE PRICE	NUMBER OUTSTANDING AT DECEMBER 31, 2001	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE
$3.25 to 7.75	992,450	5.20 years	$7.00
8.05 to 17.63	624,000	7.13 years	12.60
22.00 to 31.00	581,000	8.38 years	29.27
	2,197,450	6.58 years	14.48

Activity under stock option plans during the years ended December 31, 2001, 2000 and 1999 was as follows:

	2001	WEIGHTED AVERAGE EXERCISE PRICE	2000	WEIGHTED AVERAGE EXERCISE PRICE	
Options outstanding, beginning of year	2,140,450	$ 13.54	1,757,800	$ 7.58	1,3
Options granted	215,500	14.53	641,500	28.44	4
Options exercised	(104,500)	5.95	(188,350)	5.57	(
Options cancelled	(54,000)	7.66	(70,500)	16.38	(
Options outstanding, end of year	2,197,450	$ 14.30	2,140,450	$ 13.54	1,7
Options exercisable, end of year	1,364,700	$ 10.97	1,195,013	$ 8.36	1,0

Options that were granted during 2001 have exercise prices ranging from $8.05 to $17.63 per share. Those granted during 2000 have exercise prices ranging from $16.88 to $31.00 per share. During 1999, options were granted with exercise prices ranging from $6.375 to $20.50 per share.

Options which were exercised during these years were exercised at per share prices ranging from $3.25 to $7.25 during 2001, $3.25 to $11.50 during 2000, and $3.25 to $11.25 during 1999.

On August 16, 2000, the Company issued 2,500 fully-vested options to an outside consultant for compensation of services. These options were valued at approximately $26,000, and recorded as part of general and administrative costs in the Consolidated Statements of Operations. These options expired in 2001.

As discussed in Note 11a, on October 21, 1997, the Company issued 85,000 options to PARTEQ. These options were valued at approximately $155,000, $496,000, and $259,000 in 2001, 2000, and 1999, respectively and recorded as part of research and development costs in the Consolidated Statements of Operations in accordance with EITF 96-18. As of December 31, 2001, all of these options remained outstanding.

Also as discussed in Note 11a, on June 23, 1999, the Company issued 10,000 options to PARTEQ. In 1999, these options were valued at approximately $84,000 and recorded as part of research and development costs in the Consolidated Statements of Operations. As of December 31, 2001, all of these options remained outstanding.

Additionally, during the years ended December 31, 2000 and 1999, underwriters' purchase options of 60,000 and 326,422, respectively,

were exercised. At December 31, 2001, there are no remaining underwriters' purchase options outstanding.

As described in Note 2, the Company uses the intrinsic value method to measure compensation expense associated with grants of stock options to employees. Had the Company used the fair value method to measure compensation, the net loss and loss per share would have been reported as follows:

	2001	
NET LOSS		
As reported	($7,358,096)	($6,54
Proforma	($12,993,304)	($12,14
BASIC AND DILUTED NET LOSS PER COMMON SHARE		
As reported	($0.53)	(
Proforma	($0.94)	(

The fair value of the options at the date of grant was estimated using the Black-Scholes model with the following weighted average assumptions:

	2001	2000	1999
Expected life (years)	7	10	10
Risk free interest rate	4.88%	5.76%	6.22%
Expected volatility	70.87%	74.55%	80.70%
Dividend yield	--	--	--

Using these assumptions, the weighted-average fair value per option for the years ended December 31, 2001, 2000, and 1999, was $10.29, 23.07 and $7.50, respectively.

b) Warrants - In consideration of efforts related to the negotiation and execution of various agreements, the Company issued warrants to purchase 350,000 shares of common stock of the Company at CDN $6.79 ($4.21 at December 31, 2001) per share to the Chief Executive Officer of the Company on January 17, 1992. As of December 31, 2001, all 350,000 of the warrants, which were due to expire in January 2002, were outstanding. In January 2002, 50,000 warrants expired and the term on the remaining 300,000 warrants was extended to January 29, 2007.

In connection with an agreement dated October 6, 1993, the Company issued its investor relations firm a warrant to purchase up to 50,000 shares of the authorized stock of the Company at $6 per share. During 2001 and 2000, the investor relations firm exercised 25,000 shares in each year.

In connection with an agreement with its international investor relations advisor, in 1995 the Company issued warrants for 20,000 shares of the Company's common stock, exercisable at a price of $4.00 per share. During 2000, all 20,000 warrants were exercised.

As discussed in Note 8, in 1999 the Company issued 163,043 warrants with an exercise price of $5.00 per share. As of December 31, 2001, 449 of the warrants were outstanding and expire in 2004.

10) COLLABORATION AGREEMENT

In November 1999, DUSA signed a dermatology Marketing, Development and Supply Agreement with Schering AG. DUSA granted to Schering AG the right to promote, market, sell and distribute the Levulan(R) Kerastick(R) 20% Topical Solution with PDT for non-hyperkeratotic AKs of the face or scalp on a worldwide basis (with the exception of Canada). Schering AG and DUSA intend to co-develop and commercialize additional ALA products for other dermatology disorders. Under the agreement, Schering AG has the exclusive right to market, promote and sell the products that are developed in the co-development program. The co-development program reflects agreed upon dermatology research and development projects with total spending, subject to the agreement of the Development Committee, of $4,500,000 annually. Due to timing of the start of clinical trials, the reimbursement for 2000 and 2001 was approximately $723,000, and $2,892,000, respectively. For 2002, Schering AG has agreed to fund the co-development program up to $3,000,000, subject to the results of dermatology feasibility studies currently ongoing and further decisions by the development committee, which meets quarterly.

In December 1999, under the terms of this agreement, DUSA received $15,000,000, reflecting an $8,750,000 cash milestone payment and $6,250,000 for which a Schering AG affiliate purchased 340,458 shares of DUSA's common stock. In December 2000, the Company received an additional $15,000,000 from Schering AG that reflected an unrestricted research grant of $8,000,000 for future research and development support to be used at DUSA's discretion, and a milestone payment of $7,000,000 based on receiving FDA approval of the commercial model of the BLU-U(R) and the first commercial sale of a Levulan(R) Kerastick(R). This is the final payment due from Schering AG related to DUSA's initial products for the treatment of non-hyperkeratotic actinic keratoses (AK's) of the face or scalp. The Company will continue to receive royalties and supply fees from Schering AG based upon the sales levels of the Kerastick(R).

The milestone payments of $15,750,000, the $8,000,000 for future research and development support, and the premium on the issuance of shares, $1,041,667, have been recorded as deferred revenue and are being recognized over the term of the agreement, approximately 12 years.

The Marketing, Development and Supply Agreement terminates on a

product-by-product basis in each country in the territory on the later of (i) 12-1/2 years after the first commercial sale of a respective product in such country, or (ii) the expiration of patents pertaining to the manufacture, sale or use of such product in such country. It terminates in its entirety upon the expiration of the agreement with respect to all products in all countries covered by the agreement. Subject to various terms and conditions, the parties may terminate the agreement earlier.

DUSA is responsible for the manufacture and supply of the Levulan(R) Kerastick(R) to Schering AG for resale to the medical community. Schering AG pays DUSA a supply price for products, as well as a royalty on product sales. Schering AG has also agreed to promote the BLU-U(R), which DUSA rents or leases to dermatologists and other physicians, medical facilities and academic centers throughout the country. DUSA is responsible for maintenance and repair of the BLU-U(R) units.

On September 26, 2001, DUSA and Schering AG agreed to amend their Marketing, Development and Supply Agreement, dated November 22, 1999. With the execution of this amendment, Schering AG and its United States affiliate, Berlex Laboratories, Inc., agreed to reimburse DUSA $1,000,000 for costs DUSA incurred to modify its manufacturing agreement with North Safety Products, Inc. ("North"), the manufacturer of the Company's Kerastick(R) brand applicator, as discussed in Note 11. This amount has been reported in deferred liabilities and is being recognized as an offset to cost of product sales on a straight-line basis over the term of the amendment. In consideration for this amendment, DUSA agreed to be responsible for certain additional liabilities in the event of DUSA's failure to supply Schering AG's requirements of finished product as defined in the original agreement. In addition, DUSA agreed to use its best efforts to qualify itself as the primary manufacturer and supplier of the Kerastick(R) within six months following the date that North ceases production. DUSA and Schering AG also agreed to terminate a guaranty by Schering AG to DUSA of BLU-U(R) lease payments by physicians, and the secured line of credit promissory note from Schering AG to DUSA for up to $1,000,000 to finance inventory of BLU-U(R) units.

11) COMMITMENTS AND CONTINGENCIES

a) PARTEQ Agreements - The Company licenses certain patents underlying its Levulan(R) PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, the Company has been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell certain products, including ALA. The agreement covers certain use patent rights.

When the Company is selling its products directly, it has agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where the Company has a sublicensee, such as Schering AG, it will pay 6% and 4% when patent rights do and do not exist, respectively, on

its net selling price less the cost of goods for products sold to the sublicensee, and 6% of payments the Company receives on sales of products by the sublicensee.

For the years ended December 31, 2001 and 2000, actual royalties based on product sales were approximately $3,300 and $5,800, however, based on the minimum royalty requirements, the Company incurred a total liability of $62,000, $68,000, and $70,000 in 2001, 2000, and 1999, respectively. This expense has been recorded in cost of product sales and royalties in 2001 and 2000, and research and development costs in 1999. Commencing with the initial product launch, annual minimum royalties to PARTEQ on sales of products must total at least CDN $100,000 ($62,000 as of December 31, 2001).

The Company is also obligated to pay 5% of any lump sum sublicense fees paid to the Company, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts.

In October 1997, the Company and PARTEQ revised the License Agreement and the parties signed an Amended and Restated License Agreement on March 11, 1998. PARTEQ received options on October 27, 1997 to purchase 85,000 shares of common stock of the Company at an exercise price of $10.875 per share which vested over four years on the anniversary date of the granting of the option. The value of the options included in the Consolidated Statements of Operations as part of research and development costs was $155,000, $496,000, and $259,000 for 2001, 2000 and 1999, respectively.

The Company entered into an extension of the Research Agreement effective April 1, 1999 with PARTEQ. As partial consideration, the Company granted fully vested options to PARTEQ to purchase 10,000 shares of common stock of the Company at an exercise price of $9.25 per share. The options have a term of 10 years and have been valued at $84,000 and recorded as part of research and development costs in the Consolidated Statements of Operations in 1999.

The Company has also provided PARTEQ with additional funding support of $29,000 and $50,000 in 2000 and 1999, respectively. The cash funding has been included in the Consolidated Statements of Operations as part of research and development costs.

b) Lease Agreements - The Company has entered into lease commitments for office space rental in Wilmington, Massachusetts, Valhalla, New York, and in Toronto, Ontario including an extended lease commitment for its office and manufacturing space in its Wilmington

headquarters through November 2016. The Company has the ability to terminate the Wilmington lease after the 10th year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. The minimum lease payments disclosed below include the non-cancelable term of the lease. As the Valhalla and Toronto lease commitments expire during 2002, the Company is evaluating its options on these

commitments. Future minimum lease payments related to these agreements for years subsequent to December 31, 2001 are as follows:

	MINIMUM LEASE PAYMENTS
2002	$450,000
2003	327,000
2004	341,000
2005	375,000
2006	390,000
Beyond 2006	2,603,000
	$4,486,000

Rent expense incurred under these operating leases was approximately $461,000, $297,000, and $240,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

c) Light Source Supply - Effective November 5, 1998, the Company entered into a purchase and supply agreement with National Biological Corporation ("NBC"), under which the Company has agreed to order all of its supply of certain light sources from NBC. The agreement has a 10 year term, subject to earlier termination for breach or insolvency or for convenience. In order to meet the production scheduling needs of NBC, DUSA has prepaid for raw material costs in the amount of $400,000 associated with the Company's then existing order. This amount has and will be credited against the final purchase price, which will be due on the delivery of finished units at the rate of $1,000 per unit. At the end of December 2001, approximately $43,000 of this prepayment remained outstanding and was recorded in other current assets.

In January 2002, the Company paid NBC $100,000 to cover certain overhead costs as the Company will not order the minimum required number of BLU-U(R) brand units for delivery in 2002. In consideration for this payment, NBC has agreed to maintain its BLU-U(R) manufacturing capabilities in a state of readiness during 2002 with the capability of producing BLU-U(R) units in accordance with established procedures. The Company will recognize this payment in cost of product sales on a straight-line basis during 2002.

d) Research Agreements - The Company has entered into a series of agreements for research projects and clinical studies. As of December 31, 2001, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $3,284,000, and $629,000 for 2002 and 2003, respectively. On October 4, 2001, the

Company executed a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years to engage Therapeutics to manage the clinical development of the Company's products in the field of dermatology. Minimum payments under this agreement have been included in the total future payments as noted above. In addition, with the execution of this agreement, Therapeutics received 5,000 shares of the Company's common stock valued at $55,000, and also has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from $250,000 to $1,250,000 depending on the regulatory phase of development of products during its management.

e) North Safety Products Inc. - In September 1999, DUSA entered into a purchase and supply agreement with North for the manufacture and supply of the Kerastick(R) brand applicator. The Company agreed to purchase from North a certain portion of its total commercial requirements for supply of the Kerastick(R) for sale in the United States and Canada. Prices for the product are based on the quantities of Kerastick(R) ordered, which are subject to change depending on various product costs and competitive market conditions. The Company also reimbursed North for the construction of certain facilities at North's manufacturing facilities in the amount of $311,000. The initial agreement had a five-year term, which could be extended for additional one-year periods.

In February 2001, the Company agreed to compensate North for certain overhead expenses associated with the manufacture of the Kerastick(R) to cover underutilization of North's facilities since recent orders have been below certain previously anticipated levels. Approximately $401,000 of underutilization charges were recorded in cost of product sales based on the production levels through June 2001 in accordance with an amendment to the purchase and supply agreement. In July 2001, DUSA revised this agreement with North pertaining to the payment of underutilization fees as recent orders have been below certain previously anticipated levels. With the execution of this amendment, the Company paid North $1,000,000 in up-front underutilization fees, and agreed to pay an additional $400,000 covering the period from the execution of this amendment to the agreement through December 31, 2002 of which $200,000 has been paid as of December 31, 2001. The Company has reported the total commitment of $1,400,000 in deferred charges, which is being recognized in cost of product sales on a straight-line basis over the term of the amendment. Of this amount, $1,000,000 of the underutilized fees were reimbursed through an amendment to the Company's Marketing, Development and Supply Agreement with Schering AG as discussed in Note 10. In consideration for the underutilization fees, North has agreed to maintain its Kerastick(R) manufacturing capabilities in a state of readiness, with the capability of producing at least 25,000 Kerastick(R) units per month in accordance with established procedures. In addition, North is obligated to provide the Company with manufacturing records, personnel support, and a list of consultants and suppliers that have supported the development and manufacturing of the Kerastick(R). The term of the agreement ends on December 31, 2002 unless DUSA exercises an option to extend the term through

June 30, 2003. If DUSA should decide to extend the term, North will be entitled to payment of additional underutilization fees of up to $500,000, prorated based on the level of Kerastick(R) units produced from July 1, 2001 through June 30, 2003.

f) Supply Agreement Modification - In June 2000, the Company amended its Supply Agreement with Sochinaz SA, the manufacturer of the bulk active drug ingredient used in Levulan(R). The amendment grants an option to DUSA to extend the term of the Supply Agreement for an additional three years to December 3, 2007. As consideration for the amendment, DUSA agreed to reimburse Sochinaz SA for a portion of its costs to bring its manufacturing facilities in Switzerland into compliance with the FDA's cGMPs. DUSA paid $250,000 in cash and issued 26,667 unregistered shares of DUSA's common stock, at a fair market value of $750,000. The $1,000,000 has been reported as a deferred charge and is being recognized in cost of product sales on a straight-line basis over the original term of the contract, through November 2004.

g) Kerastick(R) Manufacturing Line - Following the amendments to the Company's agreement with North that will lead to the expiration of the Company's current Kerastick(R) manufacturing arrangement by June 30, 2003, and the Company's commitment to Schering AG through its Marketing, Development and Supply Agreement, as amended, the Company commenced the development of a Kerastick(R) manufacturing facility at its Wilmington facility to ensure certainty of supply in the future. Construction started in January 2002, and is expected to be completed during 2002. As of December 31, 2001, the Company has expended $398,000 for certain pre-construction activities, which have been classified as construction work-in-progress in property and equipment in the Consolidated Balance Sheets.

12) OTHER AGREEMENT

Third-party Leasing Company - In September 2000, the Company engaged a medical device leasing company to complete the leasing transactions, including coordinating payment plans with the physicians, for its BLU-U(R) brand light device. The Company will sell the BLU-U's(R) to the leasing company, and will be paid for the units by the leasing company shortly after installation in the physician's offices. However, since physicians have the right to cancel their leases after one year, such revenues will be deferred until their right to cancel has expired. In the event a physician does cancel a lease, the Company has agreed to repurchase the units at an agreed upon price.

13) RELATED PARTY TRANSACTIONS

The Company's Vice President of Business Development and Vice President of Technology are principal shareholders of Lumenetics, Inc., the Company's former light device consultants. During 2000 and 1999, the Company paid $2,000 and $46,000, respectively, for certain equipment leased under operating leases from Lumenetics. In 2001, the

Company purchased this equipment for $52,000. In addition, the Company also reimbursed Lumenetics for office space and related expenses totaling approximately $146,000 in 1999.

EXHIBIT INDEX

3(a)	Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference.....
3(b)	By-laws of the Registrant, filed as Exhibit 3(ii) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1997, and are incorporated herein by reference.....
4(a)	Common Stock specimen, filed as Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1997, and are incorporated herein by reference.....
4(b)	Class B Warrant, filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference.....
10(a)	License Agreement between the Company, PARTEQ and Draxis Health Inc. dated August 27, 1991, filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference.....
10(b)	ALA Assignment Agreement between the Company, PARTEQ, and Draxis Health Inc. dated October 7, 1991, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference.....
10(b.1)	Amended and Restated Assignment between the Company and Draxis Health Inc., dated April 16, 1999, filed as Exhibit 10(b.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference.....
10(c)	Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated October 1, 1991, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference.....
10(d)	Amendment to Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated April 14, 1994, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-2, No. 33-98030, and is incorporated hereby by reference.....

10(e) Amended and Restated License Agreement between the Company and PARTEQ dated March 11, 1998, filed as Exhibit 10(e) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of Exhibit A have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and Rule 406 of the Securities Act of 1933, and is incorporated herein by reference.....

10(f) Incentive Stock Option Plan, filed as Exhibit 10.11 of Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference...

10(g) 1994 Restricted Stock Option Plan, filed as Exhibit 1 to Registrant's Schedule 14A definitive Proxy Statement dated April 26, 1995, and is incorporated herein by reference.....

10(h) 1996 Omnibus Plan, as amended, filed as Appendix A to Registrant's Schedule 14A definitive Proxy Statement dated April 26, 2001, and is incorporated herein by reference.....

10(i) Purchase and Supply Agreement between the Company and National Biological Corporation dated November 5, 1998, filed as Exhibit 10(i) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and Rule 406 of the Securities Act of 1933, and is incorporated herein by reference.....

10(j) Marketing Development and Supply Agreement between the Company and Schering AG dated November 22, 1999, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and is incorporated herein by reference....

10(j.1) Letter Amendment to Marketing Development and Supply Agreement between the Company and Schering AG dated September 26, 2001, filed as Exhibit 10(a) to the Registrant's quarterly report on Form 10Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, and is incorporated herein by reference.....

10(k) Common Stock Purchase Agreement between the Company and Schering Berlin Venture Corporation dated as of November 22, 1999, filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, and is incorporated herein by reference.....

10(l) Light Source Agreement between the Company and Schering AG dated as of November 22, 1999, filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the

	Securities Exchange Act of 1934, and is incorporated herein by reference.....
10(m)	Guaranty dated as of November 22, 1999 by Schering AG in favor of the Company, filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, and is incorporated herein by reference.....
10(n)	Secured Line of Credit Promissory Note dated November 22, 1999 with the Company as payee and Schering AG as Holder filed as Exhibit 10.5 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, and is incorporated herein by reference.....
10(o)	Security Agreement dated as of November 22, 1999 between the Company and Schering AG filed as Exhibit 10.6 to the Registrant's Current Report on Form 8-K dated November 22, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, and is incorporated herein by reference.....
10(p)	Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of September 13, 1999, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated October 13, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, and is incorporated herein by reference.....
10(p.1)	Amendment to Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of February 15, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended.....
10(p.2)	Second Amendment to Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of July 26, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b of the Securities Exchange Act of 1934, as amended.....
10(q)	Supply Agreement between the Company and Sochinaz SA dated December dated December 24, 1993, filed as Exhibit 10(q) to Registrants Form 10K/A filed on March 21, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, and is incorporated herein by reference.....
10(q.1)	First Amendment to Supply Agreement between the Company and Sochinaz SA dated July 7, 1994 filed as Exhibit 10(q.1) to Registrant's Form 10K for the fiscal year ended December 31, 1999, and is incorporated herein by reference.....

10(q.2) Second amendment to Supply Agreement between the Company and Sochinaz SA dated as of June 20, 2000, filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K dated June 28, 2000, and is incorporated herein by reference.....

10(r) Master Vendor Operating Agreement between the Company and International Leasing Corporation dated September 21, 2000, filed as Exhibit 10 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2000, filed November 14, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, and is incorporated herein by reference.....

10(s) Master Service Agreement between the Company and Therapeutics, Inc. dated as of October 4, 2001, filed as Exhibit 10(b) to the Registrant's quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference.....

23.1 Consent of Deloitte & Touche LLP .....

SIGNATURES

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

(Registrant) DUSA Pharmaceuticals, Inc.

By (Signature and Title) /s/D. Geoffrey Shulman President

Date: March 15, 2002

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

/s/D. Geoffrey Shulman --- D. Geoffrey Shulman, MD, FRCPC	Director, Chairman of the Board, President, Chief Executive Officer, (Principal Executive Officer)	March 15, 200 --- Date
/s/Mark C. Carota --- Mark C. Carota	Vice President, Operations	March 15, 20 ---

/s/Ronald L. Carroll Ronald L. Carroll	Vice President, Business Development	March 15, 20
/s/Scott L. Lundahl Scott L. Lundahl	Vice President, Technology	March 15, 20
/s/Stuart L. Marcus Stuart L. Marcus, MD, PhD	Vice President, Scientific Affairs	March 15, 20
/s/John E. Mattern John E. Mattern	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 20
/s/William R. McIntyre William R. McIntyre	Vice President, Regulatory Affairs	March 15, 20
/s/Paul A. Sowyrda Paul A. Sowyrda	Vice President, Product Development and Marketing	March 15, 20
/s/John H. Abeles John H. Abeles	Director	March 15, 20
/s/David Bartash David Bartash	Director	March 15, 20
/s/Jay M. Haft Jay M. Haft, Esq.	Director	March 15, 20
/s/Richard C. Lufkin Richard C. Lufkin	Director	March 15, 20
/s/Nanette W. Mantell Nanette W. Mantell	Secretary	March 15, 20