DUSA PHARMACEUTICALS INC
Form 10-K
March 16, 2001

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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, 2000

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 (Address of principal executive offices)	01887 (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 13, 2001 was $158,074,527.

The number of shares of common stock outstanding of the Registrant as of March 13, 2001 was 13,755,890.

DOCUMENTS INCORPORATED BY REFERENCE

Document incorporated by reference to this Report is:

(1) Proxy Statement for the 2001 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 22-31, 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, 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.

We launched our first product, the Levulan(R) Kerastick(R) 20% Topical Solution with PDT using our first light device product, called the BLU-U(TM), for the treatment of actinic keratoses, or AKs, of the face or scalp, in September 2000. AKs are precancerous skin lesions caused by chronic sun exposure. AKs can develop over time into a form of skin cancer called squamous cell carcinoma.

In November 1999, we signed a marketing, development and supply agreement with Schering AG, a German corporation, for 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). Schering AG also promotes the BLU-U(TM); however, we are responsible for distributing, primarily by leasing the units, as well as for repairs and maintenance. In the United States, Schering AG's United States affiliate, Berlex Laboratories, Inc., is marketing these products. 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 2001. The parties may agree to continue to fund the co-development program beyond this date. Under the terms of the agreement, we have received $30,000,000, including $23,750,000 in cash milestone 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."

During 2001, we decided with Schering AG to fund development of acne, warts and onychomycosis, more commonly known as nail fungus. We started a new acne trial in November 2000 and expect to begin trials in warts and onychomycosis during 2001. We are also currently supporting independent investigator trials to advance clinical programs such as the use of Levulan(R) PDT to prevent restenosis, a narrowing of blood vessels following balloon angioplasty; to treat Barrett's esophagus, a potentially precancerous condition of the throat; and other internal disorders.

During the first quarter of 2000, we strengthened our financial condition by selling 1,500,000 shares of our common stock in a private placement at a purchase price of $28.50 per share. See "Management's Discussion and Analysis Financial Condition and Results of Operations -- Liquidity and Capital Resources."

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) and Kerastick(R) are registered trademarks, and the trademark application for the BLU-U(TM) is pending. These trademarks are also registered in Europe and applications are pending in other parts of the world.

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 Launch of our First Product. We are working with our dermatology marketing partner, Schering AG in the United States, to optimize the marketing efforts of the Berlex team for our first PDT system, the Levulan(R) Kerastick(R) 20% Topical Solution with our BLU-U(TM) for the treatment of AKs of the face or scalp.

- 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 develop new drug formulations and light devices to target large markets with unmet medical needs, such as prevention of restenosis, treatment of Barrett's Esophagus, treatment of brain cancer, and 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.

- 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.

- Consider the Addition of Complimentary Products. We intend to evaluate and pursue licensing and acquisition opportunities for complementary products 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

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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 a multiple course of therapy. 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 the 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 enzyme 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 inflammatory cells, such as acne and psoriasis, and

- in certain normally fast-growing tissues, such as hair follicles 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% 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(TM) 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 easily portable. It can be used in a physician's office, requires minimal floor space, and plugs into a standard electrical outlet. The BLU-U(TM) 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.

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.

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For treatment of AKs, our BLU-U(TM) 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 acne or 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."

We also have an agreement with Richard Wolf Medical Instruments Corp. for the supply of proprietary non-laser light sources and cystoscopes to be used in our clinical trials for bladder cancer detection. The Wolf light device was utilized by the investigators in our Phase I/II clinical trial for bladder cancer detection. See "Business -- Our Products, Internal Indications; -- Supply Partners."

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 $8,163,419 in 2000, $4,194,532 in 1999 and $4,502,391 in 1998.

PRODUCT/INDICATION	REGULATORY STATUS
DERMATOLOGY	
Levulan(R) Kerastick(R) and BLU-U(TM) for PDT of AKs	Approved; Phase IV
Levulan(R) PDT for Acne	Phase I/II
Levulan(R) PDT for Onychomycosis (Nail Fungus)	Phase I/II2
Levulan(R) PDT for Persistent Hand and Foot Wart Removal	Phase I/II2
Levulan(R) PDT for Psoriasis	Investigator Study
Levulan(R) PDT for Cutaneous T-Cell Lymphoma	Investigator Study
OTHER INDICATIONS	
Levulan(R) PDT for Prevention of Restenosis	Investigator Study

Levulan(R) PDT for Barrett's Esophagus	Investigator Study
Levulan(R) for Bladder Cancer Detection	Phase I/II3
Levulan(R) PDT for Dysfunctional Uterine Bleeding	Investigator Study
Levulan(R) PDT/PD for Cervical Intraepitheleal Neoplasia	Investigator Study
Levulan(R) PD-guided resection and PDT for Brain Cancer	Protocol under development

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

(2) To commence in 2001.

(3) No current trial.

DERMATOLOGY INDICATIONS

Actinic Keratoses (AKs). AKs are superficial precancerous skin lesions usually appearing as rough, scaly patches of skin with some underlying redness. The current preferred methods of treating AKs are cryotherapy, or the freezing of skin, using liquid nitrogen, and 5-flourouracil 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 14-18 hours later with exposure to our BLU-U(TM) for approximately 17 minutes. We plan to complete two Phase IV trials as required by the FDA. One study will evaluate the long-term effects of our therapy. The second trial, which will be completed shortly, tests for allergic skin reactions to our therapy. We believe that Levulan(R) PDT for AKs will become a therapy of choice as more people become aware of its benefits.

Acne. Acne is a common skin condition caused by the blockage and/or inflammation of sebaceous (oil) glands. In our ongoing dose-ranging clinical trial, we are targeting 50 patients with mild to moderate facial inflammatory acne. Traditional treatments for this form of 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.

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 have begun co-development of a therapy for this indication, and expect to commence clinical trials later this year. The first study will be a Phase I/II fluorokinetic study to examine the PpIX uptake and accumulation in infected nails using Levulan(R) topical solution and PDT.

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

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

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. Often, the warts still persist despite all attempts at treatment and we refer to them as 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. Based on these results, we have included development of Levulan(R) PDT for warts in the dermatology co-development program with Schering AG. We expect that a feasibility study will start later this year.

INTERNAL INDICATIONS

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 investigators studied seven patients with a total of eight blockages of the femoral (leg) artery. Each of the patients had undergone conventional balloon angioplasty for blockages in the femoral artery within the previous two to six months, and all of the patients had developed restenosis and associated symptoms, including leg pains, calf pains, and muscle cramps while walking. In the study, patients received oral doses of Levulan(R) and then underwent a second balloon angioplasty procedure. After the angioplasty procedure, red laser light was delivered to the site through the transparent angioplasty balloon. There were no reported complications from the procedure. All of the patients had symptomatic relief and, during the six-month follow-up period, none of the patients had any recurrence of symptoms. At the end of the six-month period, the investigators examined all the treated arteries, each of which remained open to some degree.

Testing showed no evidence of restenosis at three sites; 25% restenosis at three sites; and 40% restenosis at two sites. We are currently supporting a new randomized controlled investigator study to further evaluate the use of Levulan(R) PDT in the prevention of restenosis following balloon angioplasty. Should this second study show positive results, we plan to begin our own development program for this indication.

Barrett's Esophagus. Barrett's esophagus is a potentially precancerous condition of the esophagus which occurs when the lining of the esophagus converts to stomach-type tissue in response to chronic exposure to stomach acid. Over time, the area of the esophagus affected can develop precancerous and eventually cancerous cells. The condition is often undetected until the disease reaches later stages.

There are no effective treatments for early-stage Barrett's esophagus. Doctors treat milder forms of the condition with medication, to reduce stomach acid. A current treatment for more advanced, precancerous, Barrett's esophagus involves surgery to remove affected areas of the esophagus.

Since European studies have shown that Barrett's esophagus cells can be destroyed by Levulan(R) PDT and replaced by normal esophageal cells, we are supporting a new investigator study

involving the use of Levulan(R) PDT with red laser light for the treatment of Barrett's esophagus. In addition, we expect to start our own Phase I study later this year.

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. In addition, we learned from a survey of urologists that an oral dose of Levulan(R) and a flexible device would be preferable to the test products used in the study. We delayed any further clinical trials for this indication while a newly designed cystoscope was developed by Richard Wolf which may be suitable for an office-based procedure. We have not yet decided on further development plans for this indication.

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 to treat this common skin condition, Renova(R)2. 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% solution over the entire area including the photodamaged skin. After 14-18 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 upon these results, we have proposed two studies on the treatment of photodamaged skin to Schering AG for development after other dermatology indications are further advanced.

Hair Removal. Unwanted hair is a common problem that is experienced by both men and women of all races and skin colors. Currently, permanent hair removal involves procedures using

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

electrolysis or lasers. Electrolysis requires insertion of an electrified needle into each hair follicle. It requires numerous treatments over extended periods of time that can have varying degrees of success. Laser treatments do not require a needle but, instead, heat the hairs by absorption of laser light energy. Laser treatments work best for individuals with light skin and dark hair, but usually they do not work as well for individuals with darker skin tones. We believe that due to the selective properties of Levulan(R) PDT for targeting rapidly growing cells, such as hair follicle cells, as well as our previously reported Phase I/II clinical trial results, we may be able to achieve biologically targeted permanent hair removal without the need for heating or burning the individual hairs. We have agreed with Schering AG to consider co-development of this indication in the future.

OTHER POTENTIAL INTERNAL INDICATIONS

Dysfunctional Uterine Bleeding. Dysfunctional uterine bleeding occurs when the lining of the uterus (the endometrium) responds abnormally to the hormonal changes associated with menstruation. Treatments for dysfunctional uterine bleeding include hysterectomy, or removal of the uterus by surgery, or endometrial ablation, the destruction of the lining of the uterus by surgical or thermal methods. In endometrial ablation treatments where the uterus is not removed, incomplete ablation and/or damage to the muscle wall of the uterus can result. Preclinical studies have shown that removal of the lining of the uterus can be accomplished by a single Levulan(R) PDT treatment, without causing harm to the underlying muscle layer. Therefore, we propose to use Levulan(R) PDT as a less invasive and less costly treatment for dysfunctional uterine bleeding. We have supported research by independent investigators using Levulan(R) to treat this condition in clinical studies at centers in the United Kingdom and the United States. These studies have shown that endometrial tissue selectively absorbs Levulan(R) with no evidence of toxicity. We believe our product system is a good candidate for clinical trials because Levulan(R) is selectively absorbed by the lining of the uterus and activated by light sources which can be inserted into the uterus without the need to anesthetize the patient. We began supporting a pilot human trial for treatment of dysfunctional uterine bleeding in January 2000. We now are considering modifications to the light probe used in this study to facilitate development of this procedure.

Cervical Intraepitheleal Neoplasia. Cervical intraepitheleal neoplasia, or CIN, is a common precancerous condition of the cervix. Doctors use the pap smear (cervical cytology specimens) to screen for cancerous and precancerous 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.

In March 1997, an investigator-sponsored study showed the selectivity of Levulan(R) PDT/PD for CIN tissue. During 2001, we expect to consider supporting a new investigator-sponsored study to examine the use of Levulan(R) as an adjunct to pap smears.

Brain Cancer. Despite standard therapies which include surgical tumor removal, radiation therapy, and chemotherapy, adult patients with newly diagnosed high-grade malignant brain cancers generally survive only one to two years. Independent European investigators have reported that systemic ALA may cause photosensitization of tumors but not the normal white matter of the brain. These investigators have used ALA-induced fluorescence as a guide for the more complete removal of brain cancer than would be possible using white light alone. During 2001 we intend to initiate a clinical study to examine the selectivity of brain tumor fluorescence using different doses of

Levulan(R) and to follow that study with one combining fluorescence-guided resection and Levulan(R) PDT.

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 may 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 2001, with Schering AG contributing two-thirds of the joint committee-approved budget, while we contribute the remaining one-third. For 2001, the parties have committed to a budget of $3,954,000 thus far. Schering AG also has limited rights to negotiate with us for rights to non-dermatology products which we intend to develop with other corporate partners.

We have received $30,000,000 from Schering AG, including $23,750,000 in cash milestones and unrestricted research payments and $6.25 million for which a Schering AG affiliate received 340,458 shares of our common stock. No further

milestone payments are due for this first indication.

The launch of Levulan(R) PDT by Schering AG's United States affiliate, Berlex Laboratories, Inc., represents our partner's entree into the U.S. dermatology marketplace. 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(TM). We primarily lease the BLU-U(TM) to dermatologists and other physicians and we have engaged a leasing company to complete the leasing transactions. We have agreed to maintain and repair the BLU-U(TM) units under lease/maintenance agreements. Under the terms of a guaranty, Schering AG has agreed to guarantee the lease payments by each lessee up to our cost of the BLU-U(TM) from our third-party manufacturer. The guaranty will expire on the second anniversary of the first delivery to an end-user of a BLU-U(TM). In addition, Schering AG has agreed to provide us with an interest-free line of credit for up to $1,000,000 to finance inventory of BLU-U(TM) units. The BLU-U(TM) units would secure our repayment of any amounts which we may borrow under the line of credit. Any amounts we draw on the line of credit must be repaid within 12 months.

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 NBC for the manufacture of some of our light sources, including the BLU-U(TM). 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 order to meet the production scheduling needs of our third-party manufacturer of the BLU-U(TM), we have agreed to prepay for raw material costs in the amount of $400,000 associated with our 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 do not order a certain number of BLU-U(TM) brand units for delivery in 2002, we will pay $100,000 to our manufacturer to cover certain overhead costs. We do not know at this time whether we will be required to make this payment as we depend upon Berlex to market our products.

The agreement has a ten-year term, subject to earlier termination for breach or insolvency or for convenience. However, a termination for convenience requires 12 months' prior written notice, which may not be given before the third anniversary of the date of the agreement.

Richard Wolf Medical Instruments Corp. We entered an agreement with Wolf in May 1997 for the supply to us, at no cost, of proprietary non-laser light sources and cystoscopes, along with technical and regulatory support, for use in our first Phase I/II clinical trial for bladder cancer detection. The Wolf light device was utilized by the investigators in the clinical trial and Wolf has designed a new device for us to evaluate. We have the right under the agreement to qualify other manufacturers' light sources and/or cystoscopes with the FDA for use in Levulan(R) PD of bladder cancer.

North Safety Products. In September 1999, we entered into a purchase and supply agreement with 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.

The agreement has a five-year term, which may be extended. North has the right to terminate the agreement earlier if certain minimum levels of product orders are not reached. Similarly, we can terminate for stated breaches of the agreement. In early 2001, we tentatively agreed to compensate North on an interim basis for certain overhead expenses associated with the manufacture of the Kerastick(R) if our orders fall below certain levels on an annual basis.

Sochinaz SA. Under an agreement dated December 24, 1993, 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 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, the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell products which are precursors of PpIX, including ALA. The agreement covers certain use patent rights. It also includes 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 9a 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.

We paid a minimum royalty of CDN $100,000 to PARTEQ during 1998. Following the receipt of FDA approval in December 1999, we paid PARTEQ a milestone payment of CDN $100,000 and, a prorated annual minimum royalty payment on sales of products which totaled CDN $3,836. For 2000 and going forward, annual minimum royalties to PARTEQ on sales of products must total at least CDN $100,000. Since we entered into the agreement with Schering AG, we were also obligated to pay to PARTEQ additional minimum payments in amounts up to CDN $1.1 million which has now been paid, including a credit for the CDN $100,000 paid in 1998, based upon the milestone payments we received from Schering AG.

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 two percent 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.

We entered into a license agreement effective August 27, 1991 with PARTEQ Research & Development Innovations, the licensing arm of Queen's University at Kingston, Ontario, and Draxis Health, Inc. Under this agreement, we hold an exclusive worldwide license to certain patent rights from PARTEQ in the United States and a limited number of foreign countries.

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 guaranty 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 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 of America 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. Japanese Patent No. 273032, which relates to the basic method of using ALA, has recently been opposed and, as a result, the Japanese Patent Office Board of Appeals revoked the patent. With PARTEQ's assistance, we are 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 such a contest or any assurance that we will decide to spend the funds required to complete the contest. 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 seven 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(TM) 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. We have purchased key pieces of equipment to prepare for the establishment of a limited production line so that a second source could manufacture the Kerastick(R).

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. 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."

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); Miravant, Inc. (U.S.); Pharmacyclics, Inc. (U.S.); 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; ESC Medical Systems Ltd. (Israel); and Photocure (Norway).

Photocure has completed clinical trials and has filed an application for European marketing approval of its ALA precursor (ALA methylester) compound with PDT for the treatment of AK's. Photocure is also conducting trials in the United States. We are aware that medac is developing ALA PDT for bladder cancer detection and for fluorescent-guided resection of brain 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 provide 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.

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 via 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, there may be other types of drug applications that 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 and the commercial version of our BLU-U(TM) was approved on September 26, 2000.

We are currently conducting Phase I/II studies on the use of ALA for the treatment of acne. 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 devices, 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(TM) 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 "file it". 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

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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(TM) 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 marketed 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. 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 involve 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 do not have any plans to make any material capital expenditures for environmental control facilities. However, 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 2000, we had 41 full-time employees. We have employment agreements with several of 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. 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.

IF WE FAIL TO OBTAIN ADEQUATE LEVELS OF REIMBURSEMENT FOR OUR PRODUCTS FROM THIRD-PARTY PAYORS, OUR REVENUES AND PROFITS COULD BE SIGNIFICANTLY LIMITED.

Our profitability will depend, in part, on the availability of reimbursement to patients or physicians for the cost of our products from third-party payors such as governmental programs, private insurance and private health plans. To date, physicians in several states have received reimbursement for treatments using our Levulan(R) with PDT therapy. However, official reimbursement policy has been established in only a few jurisdictions. We cannot predict whether levels of reimbursement for our drug and light combination therapy will be high enough to allow us to realize a reasonable profit margin. Third-party payors may deny reimbursement if the payor determines that our particular new therapy is unnecessary, inappropriate or not cost effective. If patients or physicians are not entitled to receive reimbursements similar to reimbursements for competing therapies, patients will have to pay for the unreimbursed amounts. Some medicare providers may require physicians to prescribe 5-FU to treat AKs because 5-FU is an inexpensive treatment, or limit the number of AK treatments in a particular year. These reimbursement factors could limit our revenues, and our profits, if physicians or patients choose therapies with higher reimbursements than may be assigned to our therapy, or if government agencies or other third-party payors mandate a treatment regimen. The reimbursement status of newly-approved health care products is highly uncertain. We are relying on Schering AG to obtain reimbursement codes from third-party payors. If levels of reimbursement are decreased in the future, the demand for our products could diminish or our ability to sell our products on a profitable basis could be hurt.

BECAUSE NEITHER WE NOR SCHERING AG, OUR MARKETING PARTNER FOR DERMATOLOGY PRODUCTS, HAS ANY EXPERIENCE MARKETING OR SELLING DERMATOLOGY PRODUCTS IN THE UNITED STATES, OUR REVENUES FROM ROYALTIES AND PRODUCT SALES MAY BE LIMITED.

The commercial success of Levulan(R) Kerastick(R) with PDT for AKs of the face or scalp will partly depend on the effective marketing in the United States of Levulan(R) Kerastick(R) with PDT for

AKs by Schering AG through its affiliate, Berlex Laboratories, Inc. While Schering AG has experience marketing dermatology products in Europe, neither Schering AG, Berlex nor DUSA has any experience marketing dermatology products in the United States. Schering AG has hired and trained 43 sales representatives and area managers who are dedicated to the marketing of the Levulan(R) PDT system. However, many of our competitors in the AK market already have experienced, well-funded, marketing and sales operations in the United States. If Schering AG fails to adequately 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.

SINCE WE RELY HEAVILY ON OUTSIDE CONTRACTORS AS SOLE SUPPLIERS AND MANUFACTURERS OF OUR LEVULAN(R) KERASTICK(R) AND BLU-U(TM), 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. We 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(TM). While we have purchased equipment in order to establish a second source with a limited production line for the manufacture of our Kerastick(R), if it becomes necessary, any new manufacturer would have to pass inspection by the FDA. None of our manufacturers have produced 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(TM) 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'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.

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ANY FAILURE TO COMPLY WITH ONGOING GOVERNMENTAL REGULATIONS IN THE UNITED STATES OR TO OBTAIN FOREIGN REGULATORY APPROVALS WILL LIMIT OUR ABILITY TO MARKET OUR FIRST PRODUCT.

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, Levulan(R) Kerastick(R) and the BLU-U(TM) 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 are required to conduct two Phase IV follow-up studies; one to evaluate the long-term recurrence rate of AKs after treatment with our new therapy, and the second to test for allergic skin reactions to the Levulan(R) Kerastick(R). 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.

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. 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 product in foreign countries. The introduction

of our product in foreign markets will subject us to foreign regulatory

clearances, which may be unpredictable and uncertain, and which may impose substantial additional costs and burdens which Schering AG and 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(TM), must be manufactured in compliance with the current requirements of ISO 9000. Our third-party manufacturer is not currently qualified under ISO 9000. 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 obtain foreign regulatory approval 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 over the next several quarters as we expand research and development of new products and establish ourselves in the marketplace. As of December 31, 2000, our accumulated deficit was approximately $42,487,000. 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 that currently available treatments;
- we receive sufficient reimbursement for our products; and
- we can, either together with a partner 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(TM) 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(TM) 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 two 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 our 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 and if we do not enter an agreement with a corporate partner who has the experience and resources to perform these roles for other products, 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, we compete with many companies that 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 counterparts 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 Research and Development Innovation, 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 guaranty 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 on 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 40 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. While we have not experienced any product liability claims, 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 use 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. We believe that we are in compliance in all material respects with applicable environmental laws and regulations and we do not expect to make material capital expenditures for environmental control facilities in the near-term. However, we cannot guaranty that we will not incur significant costs to comply with environmental laws and regulations in the future. We also cannot guaranty 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.

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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); Miravant, Inc. (U.S.); Pharmacyclics, Inc. (U.S.); 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; ESC Medical Systems Ltd. (Israel); and Photocure (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 completed clinical trials and has filed an application for European marketing approval of its ALA precursor (ALA methylester) compound with PDT for the treatment of AKs. We are also aware that medac is developing ALA PDT for bladder cancer detection and for flourescent-guided resection of brain 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 28, 2001 there were outstanding options and warrants to purchase 2,599,649 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. In addition, there are approximately 449 outstanding placement agent warrants from a private placement completed in 1999. 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 year, 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, 2000 to January 31, 2001, our stock price has ranged from a high of $36.00 to a low of $12.375. Factors that contributed to the volatility of our stock during the last 12 months included:

- timing of BLU-U(TM) receipt of marketing approval from the FDA;
- timing and potential success of the launch of our first products;
- timing and potential success in achieving satisfactory third-party payor reimbursement for our first therapy; and
- general market conditions.

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 million shares of stock, 40 million 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 million 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 (5) 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 (5) year lease for an additional 24,000 square feet of space at our Wilmington facility. Annual rent on a triple net basis will total $314,000.00 per year beginning as of February 1, 2001 and will increase each year during the term up to approximately $351,000. 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 (5) year lease at an annual rental in 2000 of approximately $123,000. In 1999, we also entered into a three (3) 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. Annual rent payments will total CDN $31,272 per year beginning August 1, 1999, plus approximately CDN $29,122 for lease operating costs this year.

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, 1999:

	First	Second	Third
Nasdaq			
High	$8.563	$11.563	$16.000
Low	5.531	7.250	10.375

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

On March 13, 2001, the closing price of our common stock was $13.00 per share on the Nasdaq Stock Market. On March 13, 2001, there were approximately 721 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 presented below for the years ended December 31, 2000, 1999, 1998, 1997 and 1996 have been derived from the Company's audited financial statements.

CONSOLIDATED STATEMENT OF OPERATING DATA

	Year ended December 31,			
	2000	1999	1998	1997

Revenues	$ 2,120,557	$ --	$ --	$ --
Cost of product sales	1,104,664	--	--	--
Research and development costs	8,163,419	4,194,532	4,502,391	6,252,830
Other operating expenses	2,559,502	1,818,193	1,729,741	1,760,409
Loss from operations	(9,707,028)	(6,012,725)	(6,232,132)	(8,013,239)
Other income	3,222,273	574,098	515,184	893,147
Income tax expense	56,000	90,000	--	--
Net loss	(6,540,755)	(5,528,627)	(5,716,948)	(7,120,092)
Basic and diluted net loss per common share	$ (0.49)	$ (0.50)	$ (0.61)	$ (0.76)
Weighted average number of shares outstanding	13,285,472	11,061,016	9,365,950	9,358,038

CONSOLIDATED BALANCE SHEET DATA

			As of December 31,		
	2000	1999	1998	1997	
Total Assets	$82,442,388	$28,156,845	$ 7,140,675	$13,081,248	$20
Cash and investment securities	74,496,577	26,897,580	6,722,132	12,767,142	19
Deferred revenue	24,805,041	9,791,667	--	--	
Shareholders' equity	55,309,796	17,059,928	6,416,146	12,019,351	19

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

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. From our inception in 1991 until September 2000 we were classified as a development stage enterprise. However, in late September 2000, we launched our first commercial products, Levulan(R) Kerastick(R) 20% Topical Solution and the BLU-U(TM) brand light device, in cooperation with Berlex Laboratories, Inc. (Berlex), the United States affiliate of Schering AG. From the product launch through the end of the year, DUSA entered into over 100 contracts for BLU-U(TM) brand light units. We primarily lease the BLU-U(TM) to physicians, medical institutions and academic centers throughout the country. Now that our products have been launched, we are no longer classified as a development stage enterprise and, accordingly, the development stage disclosures have been eliminated from the accompanying financial statements.

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, 2000, we had an accumulated deficit of $42,487,349. Our transition from a development-stage company to a profitable operating company is dependent upon,

among other things, the market penetration by Berlex of our products and our ability to meet the supply needs of the growing customer base.

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 hired and trained 43 sales representatives and area managers who are dedicated to the Levulan(R) PDT system. We are excited about the early positive response from physicians and patients who have used our therapy, but we do not expect full market penetration until after third-party reimbursement costs for our products are established during the coming months by insurance companies and state and federal healthcare agencies.

Currently, we are meeting Berlex's supply requirements; however, any significant delays in delivery of sufficient product supplies from our sole source third-party suppliers of Levulan(R), the Kerastick(R) and/or the BLU-U(TM), once reimbursement policies are determined, would have a significant adverse impact on our financial results. We are increasing our inventory of raw materials and products to help us manage the marketplace as it develops, and in February 2001 we leased additional space in our Wilmington, Massachusetts facilities to provide immediate warehouse, office space, and production areas should we need to develop our own manufacturing capabilities. We are also

investigating other suppliers for components of our products so that we could react more quickly if our supply was interrupted for any reason.

DUSA's research and development efforts are continuing to expand, both in dermatology (in partnership with Schering AG), and in our internal indication development programs. During 2000, we doubled our staff to a total of 41 full-time employees by year end, in order to support all activities relating to production, maintenance, customer support for our initial and future products, as well as the research and development programs for dermatology and internal indications. We expect that we will continue to significantly increase our staff during 2001. While our financial position is strong following a private placement early in 2000 and receipt of $15,000,000 of payments from Schering AG in December 2000, DUSA cannot precisely 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.

In June 2000, we amended our Supply Agreement with Sochinaz SA, the supplier of our bulk drug product, to include an option to allow us to extend the term of the agreement 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 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. The total $1,000,000 has been reported as deferred charges and is being amortized over the original term of the Supply Agreement which would have expired on December 3, 2004.

Also during the year, we terminated our shareholders rights plan and redeemed all of the rights that were outstanding at a cost of approximately $14,000.

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 -- We must receive separate approval for each of our potential products before we can sell them commercially in the United States or abroad; and -- 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."

RESULTS OF OPERATIONS

Comparison of Years ended December 31, 2000, 1999 and 1998

Revenues - Revenue recognized by DUSA in 2000 was $2,120,557, reflecting its first sales of the Kerastick(R) based on its product launch in September 2000. This amount includes research and development revenue of $722,570 reflecting revenue earned payments from Schering AG to support our dermatology co-development program and $495,833 representing the amortization of milestone and unrestricted grant payments also from Schering AG. The total amount of up front payments has been recorded as deferred revenue upon receipt and is recognized as income on a straight-line basis over the term of the Company's alliance agreement with Schering AG. No revenue was recognized in 1999 and 1998 as DUSA was a development stage corporation.

Product sales during 2000 were $902,154, primarily reflecting the sales of the Kerastick(R). The royalties are earned and recognized by DUSA when the Kerastick(R) is sold by Berlex to its distributor, and are due and 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. We primarily lease the BLU-U(TM) to our customers and have engaged a medical device leasing company to complete the leasing transactions, including coordinating payment plans with the physicians. We sell the BLU-U(TM)'s to the leasing company, which pays us for the units within thirty (30) days after installation in the physician's offices. However, because physicians have the right to cancel their leases after one year, these revenues are reported as deferred revenues until the right to cancel the lease has expired. In the event a customer does cancel a lease, we have agreed to repurchase the units at an agreed upon price. Under this arrangement, we will recognize revenue from the distribution of BLU-U(TM)s beginning in late 2001.

Under our agreement with Schering AG, two-thirds of the agreed upon dermatology research and development expenses, up to $3,000,000 per year, are reimbursable to DUSA by Schering AG, for 2000 and 2001. Based on the agreed upon development plan and the timing of the start of the clinical trials, we are entitled to reimbursement of $722,570 for the year ended December 31, 2000. In early 2001, both parties agreed upon the development program that will be subject to reimbursement for 2001. The total research and development budget for approved co-development projects so far totals $3,954,000 for 2001, which will entitle us to a reimbursement from Schering of $2,636,000. We expect that Schering AG will continue to share the dermatology research and development costs beyond this year. However, the level of reimbursement is not guaranteed under our agreement.

Cost of Product Sales - Cost of product sales for the year ended December 31, 2000 were $1,104,664, primarily reflecting Kerastick(R) sales to Berlex in the amount of $796,219 and royalties and supply fees of approximately $68,000 reflecting minimum royalty payments due to DUSA's licensor. Also included in cost of product sales is the amortization of deferred charges of approximately $113,000 reflecting consideration paid by us to amend our Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan(R), as well as costs incurred for shipping and installing the BLU-U(TM) in physician's offices. Inventory costs related to the BLU-U(TM) units that are

leased are deferred and recorded as other current assets until the customer's right to cancel its lease after one year expires. As of December 31, 2000, deferred inventory costs were $261,923. There were no product sales and therefore no cost of product sales during 1998 or 1999.

In order to meet the production scheduling needs of our third-party manufacturer of the BLU-U(TM), we have agreed to prepay for raw material costs in the amount of $400,000 associated with our current orders. This amount will be credited against the final purchase price, which will be due on delivery of finished units at the rate of $1,000 per unit. In addition, if we do not order a certain number of BLU-U(TM) brand units for delivery in 2002, we have agreed to pay $100,000 to our manufacturer for certain overhead costs. We do not know at this time whether we will be required to make this payment as we depend upon Berlex to market our products. Similarly, in early 2001, we tentatively agreed to compensate our third-party manufacturer of the Kerastick(R) on an interim basis for certain overhead expenses if our orders fall below certain levels on an annual basis.

Research and Development Costs - DUSA's research and development costs for the years ended 2000, 1999 and, 1998 were $8,163,419, $4,194,532 and $4,502,391, respectively. The

$4,000,000 increase in 2000 over 1999 levels is mainly attributed to manufacturing development expenses, reflecting increased personnel costs and pre-production activities. As stated above under "Revenue", under our agreement with Schering AG, approximately two-thirds of the agreed upon dermatology research and development expenses, up to $3,000,000 for 2001, are reimbursable to DUSA by Schering AG. The decrease in research and development costs from 1998 to 1999 reflected our efforts to delay some of our research programs while we were awaiting FDA approval of our first product and completion of a dermatology corporate alliance.

DUSA expects that 2001 research and development costs will increase as compared to 2000 due to increased expenditures for dermatology and internal indications coupled with a full year of higher personnel costs related to manufacturing development activities. Costs and development fees associated with agreements for research projects and clinical studies commit us to make payments of $483,000, $399,000 and $112,000 for 2001, 2002 and 2003, respectively. See Note 11d to the Notes to the Consolidated Financial Statements.

As we implement our dermatology program with Schering AG, and expand our internal indication programs, we expect clinical research and development expenses to increase significantly. In late 2000, we initiated a Phase I/II clinical trial of Levulan(R) PDT for moderate to severe acne vulgaris of the face, and we expect to begin clinical studies on onychomycosis, initially testing drug uptake and conversion in infected nails, shortly. In addition, DUSA plans to initiate clinical trials using Levulan(R) PDT for treatment of warts during 2001.

With respect to internal indications for Levulan(R) PDT, we intend to initiate new DUSA-sponsored clinical protocols for the treatment of Barrett's esophagus and brain cancer during 2001. DUSA is also supporting and collaborating in new investigator studies on Barrett's esophagus and restenosis inhibition. Additional indications being considered for further development include detection and treatment of cervical dysplasia and dysfunctional uterine bleeding. Based upon a survey of urologists that followed our initial bladder cancer photodetection study, we believe that this indication would require significant development efforts with respect to a more flexible light device, as well as a different drug formulation and we may seek an alliance partner to pursue this indication. We have not yet decided on further development plans for

this indication.

General and Administrative Costs. General and administration expenses for the years ended December 31, 2000, 1999, and 1998 were $2,559,502, $1,818,193, and $1,729,741, respectively. During 2000, the Company hired additional staff, including key management personnel in technical and operations functions. These costs are expected to continue to increase significantly for 2001, then more slowly as we continue to add personnel at all levels of the organization.

Interest Income. Interest income was $3,222,273, $574,098, and $508,256 for the periods ended December 31, 2000, 1999 and 1998, respectively, and is primarily earned on United States government securities. The $2,648,175 increase in interest income for 2000 as compared to 1999 is mainly attributed to the $15,000,000 received from Schering AG during the fourth quarter of 1999, and the net proceeds of approximately $40,700,000 received from a private placement in March 2000. Interest income is expected to increase in 2001 due to additional payments of $15,000,000 received from Schering in December 2000. However, if our product sales, which are dependent upon the market penetration by Berlex and our ability to meet the supply needs of the growing customer base do not offset our expenditures, interest income will decline as funds are spent for our research and development programs. See Note 5 to the Notes to Consolidated Financial Statements.

Income Taxes. As of December 31, 2000, we had net operating loss carryforwards of approximately $15,753,000 and tax credit carryforwards of approximately $928,000 for federal reporting purposes. These amounts expire at various times through 2020. See Note 7 to the Notes to the Consolidated Financial Statements. In 2000, a provision for taxes of $56,000 was recorded primarily reflecting various states net worth tax. A provision for alternative minimum tax was recorded in 1999 for $90,000.

Net Losses - The Company incurred a net loss of $6,540,755, or $0.49 per share, $5,528,627 or $.50 per share, and $5,716,948 or $.61 per share for the years ended December 31, 2000, 1999 and 1998, respectively. These losses were within management's expectations and losses are expected to be incurred until the successful market penetration of our first products.

QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the quarterly results of operations for the years ended December 31, 2000 and 1999, respectively:

	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

	Quarterly Results For Year Ended December		
	March 31	June 30	September 3
Total revenues	$-	$-	$-
Loss from operations	(1,189,582)	(1,552,221)	(1,321,701)
Net loss	(1,029,322)	(1,429,282)	(1,192,135)
Basic and diluted loss per share	(0.10)	(0.13)	(0.11)

RECENTLY ISSUED ACCOUNTING GUIDANCE

In December 1999, the staff of the Securities Exchange Commission (SEC) issued Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements". SAB 101 provides guidance related to revenue recognition based on interpretations and practices followed by the SEC and summarizes certain of the SEC's view in applying generally accepted accounting principles (GAAP) to revenue recognition in financial statements. We adopted SAB 101 as of January 1, 2000 and we apply these revenue recognition policies in accordance with GAAP.

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. The new standard, which must be adopted on January 1, 2001, requires that all companies record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies

for hedge accounting. The adoption of SFAS No. 133 will not have a significant impact on the financial position or results of operations of the Company.

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 $82,442,388 as of December 31, 2000 compared to $28,156,845 as of December 31, 1999. The increase is the direct result of the completion of the private placement of the Company's shares in the first quarter of this year and the receipt of $15,000,000 in milestone and research support payments from Schering AG. These payments from Schering AG were based upon the parties' Marketing, Development and Supply Agreement entered on November 22, 1999 and consisted of an $8,000,000 unrestricted research grant for future research and development support to be used at its discretion, and an additional milestone payment of $7,000,000 based upon the first commercial sale of our products. These are the final payments related to DUSA's initial products, the Levulan(R) Kerastick(R) 20% topical solution, and the BLU-U(TM) brand light device, for the treatment of non-hyperkeratotic actinic keratoses of the face or scalp.

As of December 31, 2000, we had inventory of $1,331,966, representing finished goods, raw material and purchased parts and subassemblies. Also, as of the same date, we had net fixed assets of $1,699,530, as compared to $428,350 as of December 31, 1999, due primarily to the acquisition of equipment. We expect to make significant additional capital expenditures during 2001 in order to acquire equipment for a back-up second source of supply for the manufacture of the Kerastick(R), as required under our contract with Schering AG.

As of December 31, 2000, we had accounts receivable of $914,959 representing net sales associated with product sales. In addition, based on our co-development program with Schering AG, a receivable of $722,570 has been recorded as a current asset.

As of December 31, 2000, we had current liabilities of $2,836,758, as compared to $1,305,250 as of December 31, 1999. Since our inception, we have had no long-term debt. DUSA has a secured line of credit from Schering AG for up to $1 million to help us finance inventory purchases of our BLU-U(TM) from our supplier. This line of credit is interest-free but must be re-paid within one year of our first draw down of funds. As of the end of the year, we had not drawn down any part of this credit facility.

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 $56,876,369, and a current aggregate market value of $58,055,463 as of December 31, 2000, resulting in a net unrealized gain on securities available for sale of $1,179,094, which has been included in shareholders' equity. As of December 31, 1999, government securities had an aggregate cost of $19,951,281 and an aggregate market value of $19,868,962, resulting in a net unrealized loss of $82,319. 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. These securities currently have interest rates and yields ranging from 4.67% to 7.20% and maturity dates ranging from January 12, 2001 to August 15, 2005.

We believe that we have sufficient capital resources to proceed with our current development program for Levulan(R) PDT/PD 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 may also use its resources to acquire by license, purchase or other arrangements, businesses, technologies, or products that enhance or expand DUSA's business.

As of December 31, 2000, DUSA had deferred revenues of $24,805,041 compared to $9,791,667 at December 31, 1999 reflecting milestone and unrestricted grant payments of $24,295,834 (including a premium of 20% on the issuance of shares of DUSA's common stock to a Schering AG affiliate) and the deferral of $509,207 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, we began to amortize the Schering AG milestone and unrestricted grant payments during the fourth quarter of 2000, when the first products were placed in physicians' offices. The amortization period is expected to be approximately 12 years, the term of the Schering AG agreement, based upon current revenue recognition principles. See Note 10 to the Notes to the Consolidated Financial Statements.

Our management team is currently focusing its attention 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 developing plans for several internal research and development indications. 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;

- 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.

If sufficient funds are available, we may also use our resources to acquire by license, purchase or other arrangements, businesses, technologies, or products that complement, enhance, or expand our business. We continue to actively seek relationships with pharmaceutical or other suitable organizations to market some of our potential non-dermatology products and technologies, or to provide funding for research projects.

As of the end of 2000, we had 41 full-time employees. We have employment agreements with several of our key executive officers. We have purchased and are the named beneficiary of a key man life insurance, having a face value of CDN $2.0 million on the life of our President. We expect that we will continue to hire or retain significantly more employees and consultants as commercialization of Levulan(R) PDT continues, particularly in the operations, financial and regulatory areas.

We have not made any material capital expenditures for environmental control facilities in the near-term. If we decide, in the future, to establish a limited production line for the manufacture of the Kerastick(R), we expect that environmental laws will govern our facility, but we do not expect these laws to require material capital expenditures. There can be no assurance, however, that we will not be required to incur significant 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."

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.

MARKET RISK

We hold fixed income U.S. 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 ten percent 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 start of clinical trials in 2001 for warts, onychomycosis and brain cancer, intention to develop new drug formulations and light devices and to evaluate and pursue licensing and acquisition opportunities, commercialization of additional Levulan(R) dermatology products with Schering AG, belief that our new products will be the AK therapy of choice, beliefs regarding the efficacy of potential hair removal, CIN and other indications and Levulan(R)'s competitive properties, expectations of exclusivity under the Hatch/Waxman Act and other patent laws, intentions to seek additional U.S. 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, requirements of cash resources for our future liquidity, anticipation of hiring additional personnel, dependence on 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, increasing research and development costs, levels of interest income and our capital resource needs. 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 timely development, FDA 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 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 2001 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information requested be 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 2000", "Aggregate Option Exercises in 2000 and Option Values at December 31, 2000", and "Other Compensation" of Registrant's 2001 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 2001 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 2001 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 other than those referred to above 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 December 21, 2000, which announced the

receipt of milestone payments from Schering AG based upon the parties Marketing Development and Supply Agreement.

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

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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 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 Exhibit 1 to Registrant's Schedule 14A Definitive Proxy Statement dated April 27, 1998, 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(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(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, 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;

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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.

23.1 Consent of Deloitte & Touche LLP

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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, 2000 and 1999 and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2000. 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, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Deloitte & Touche LLP
Boston, Massachusetts
February 23, 2001

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

ASSETS

CURRENT ASSETS

Cash and cash equivalents	$ 16,
U.S. government securities	58,
Accrued interest receivable	
Accounts receivable	
Receivable under co-development program	
Inventory	1,
Other current assets	
TOTAL CURRENT ASSETS	79,
Property and equipment, net	1,
Deferred charges	
Deferred royalty	
Other assets	
	$ 82,

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES	
Accounts payable	$
Accrued payroll	
Other accrued expenses	1,
Deferred revenue	
Due to licensor	
Income taxes payable	
TOTAL CURRENT LIABILITIES	2,
Deferred revenue	24,
	27,
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: 13,730,890 (1999: 11,908,357) shares of common stock, no par.	94,
Additional paid-in capital	1,
Accumulated deficit	(42,
Accumulated other comprehensive income	1,
	55,
	$ 82,

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	YEAR ENDED DECE	
	2000	1999
REVENUES		
Product sales	$ 902,154	$ -
Research grant and milestone revenue	495,833	-
Research revenue earned under collaborative agreements	722,570	-
TOTAL REVENUES	2,120,557	-
OPERATING COSTS		
Cost of product sales	1,104,664	-
Research and development	8,163,419	4,194,53
General and administrative	2,559,502	1,818,19

TOTAL OPERATING COSTS	11,827,585	6,012,72
LOSS FROM OPERATIONS	(9,707,028)	(6,012,72
OTHER INCOME		
Interest income	3,222,273	574,09
Gain on foreign currency exchange	--	-
	3,222,273	574,09
LOSS BEFORE INCOME TAX EXPENSE	(6,484,755)	(5,438,62
Income tax expense	56,000	90,00
NET LOSS	$ (6,540,755)	$ (5,528,62
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (.49)	$ (.5
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	13,285,472	11,061,01

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(a)

	COMMON STOCK		ADDITIONAL	
	NUMBER OF SHARES	AMOUNT	PAID-IN CAPITAL	ACCUMULA DEFI
BALANCE, DECEMBER 31, 1997	9,365,950	$36,746,993	$ --	$(24,701,0
Comprehensive loss:				
Net loss for period				(5,716,9
Net unrealized gain on U.S. government securities available for sale				
Total comprehensive loss				
Stock based compensation			81,586	
BALANCE, DECEMBER 31, 1998	9,365,950	$36,746,993	$ 81,586	$(30,417,9
Comprehensive loss:				
Net loss for period				(5,528,6
Net unrealized loss on U.S. 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 1,630.43 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	$(35,946,5

DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (CONTINUED)

	COMMON STOCK		ADDITIONAL	
	NUMBER OF SHARES	AMOUNT	PAID-IN CAPITAL	ACCUMULATE DEFICI
BALANCE, DECEMBER 31, 1999	11,908,357	$51,749,987	$1,338,854	$(35,946,594
Comprehensive loss:				
Net loss for period				(6,540,755
Net unrealized gain on U.S. 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	$(42,487,349

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEA
	2000
CASH FLOWS USED IN OPERATING ACTIVITIES	
Net loss	$ (6,540,755)
Adjustments to reconcile net loss to net cash used in operating activities	
Amortization of premiums and accretion of discounts on U.S. government securities available for sale and investment securities, net	(318,647)
Depreciation and amortization expense	410,473
Amortization of deferred revenue	(495,833)
Gain on foreign currency exchange	--
Stock based compensation to non-employees	521,665
Issue of shares of common stock and warrants to non-employees	64,533
Changes in other assets and liabilities impacting cash flows from operations:	
Accounts receivable	(914,959)
Receivable under co-development program	(722,570)
Inventory	(1,331,966)
Accrued interest receivable	(723,463)
Other current assets	(429,407)
Accounts payable	(16,609)
Income taxes payable	(34,000)
Due to licensor	47,004
Accrued payroll and other accrued expenses	1,025,906
Deferred revenue	15,509,207
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	6,050,579
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES	
Purchases of United States government securities	(50,506,441)
Proceeds from maturing United States government securities	13,900,000
Purchases of property and equipment	(1,553,350)
Deposits on equipment	(70,369)
Payment to restructure supplier contract	(250,000)
Payments to licensor	(350,936)
NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES	(38,831,096)

See the accompanying Notes to the Consolidated Financial Statements.

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

	2000
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	40,698,286
Proceeds from exercise of options and warrants	1,494,727
NET CASH PROVIDED BY FINANCING ACTIVITIES	42,193,013
EFFECT OF EXCHANGE RATES ON CASH	--
NET INCREASE (DECREASE) IN CASH	9,412,496
CASH AT BEGINNING OF PERIOD	7,028,618
CASH AT END OF PERIOD	$16,441,114

SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION

Issuance of common stock and warrants as compensation to placement agent	
Income tax payments	$ 140,724

During 2000, in connection with the amendment of a supply agreement, the Company issued 26,666.66 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.

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DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2000, 1999, AND 1998

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 was classified as a development stage enterprise from its inception and has concentrated its initial efforts upon seeking regulatory approval in the United States for topical and/or local uses of aminolevulinic acid HCl ("Levulan(R)") PDT/PD. During 1998, the Company filed a New Drug Application (NDA) with the Food and Drug Administration (FDA) for use of the Levulan(R) Kerastick(R) 20% Topical Solution with photodynamic therapy for non-hyperkeratotic actinic keratoses (AKs) of the face or scalp. On September 26, 2000, the Company received marketing approval from the United States Food and Drug Administration (FDA) for its commercial BLU-U(TM) brand light device. Effective September 28, 2000, the Company launched its first commercial products, Levulan(R) Kerastick(R) 20% Topical Solution and the BLU-U(TM) brand light source for this indication in cooperation with Berlex Laboratories, (Berlex), the United States affiliate of Schering AG. As such, the Company is no longer classified as a development stage enterprise and, accordingly, such disclosures have been eliminated from these financial statements.

2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

e) U.S. 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 management expects to sell a portion of its U.S.

government securities in the next fiscal year in order to meet its working capital requirements, it has classified them 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 identified for research and development activities is expensed in the period in which that inventory is designed for such use.

Inventory related to commercial light sources, if the unit is leased through a third-party, is reflected in other current assets until such time as satisfaction of all conditions and terms of the sale of the light source have been met, and when the customer's right of return expires, normally after one year. Such inventory reflected in other current assets at December 31, 2000 was $261,923.

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 Royalty - Deferred charges and royalty include costs paid in advance to third parties under various agreements and are being amortized on a straight-line basis over their expected terms (4 - 12 years).

i) Impairment of Long-lived Assets - The Company reviews its long-lived assets for impairment when 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 cost to sell.

j) Revenue Recognition - Revenues on product sales of the drug applicator are recognized upon shipment. Revenue on the sale of commercial light sources is deferred, if the unit is leased through a third-party, and recognized in income upon satisfaction of all conditions and terms of the sale to the Company's third-party purchaser/lessor and when the lessee/customer's right of return expires, normally after one year. 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.

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

	2000
Milestone and unrestricted grant payments	$24,295,834
Sale of commercial light sources	509,207
	$24,805,041

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 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 the period, as the effect would be antidilutive. For the years ended December 31, 2000, 1999, and 1998, stock options and warrants totaling

approximately 2,340,000, 2,120,000, and 1,750,000, respectively, have been excluded from the computation of 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 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 that is recorded by the Company relates to unrealized gains or losses on 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 principle. 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 a single collaborator.

s) Recently Issued Accounting Pronouncements - In December 1999, the staff of the Securities Exchange Commission (SEC) issued Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements". SAB 101 provides guidance related

to revenue recognition based on interpretations and practices followed by the SEC and summarizes certain of the SEC's view in applying generally accepted accounting principles (GAAP) to revenue recognition in financial statements. The Company's adoption of SAB 101 as of January 1, 2000 did not have any effect on the its financial statements.

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The new standard, which must be adopted on January 1, 2001, requires that all companies record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. The adoption of SFAS No. 133 will not have a significant impact on the financial position or results of operations of the Company.

3) OTHER CURRENT ASSETS

Other current assets consist of the following at December 31, 2000 and 1999:

	2000
Prepaid expenses and deposits	$293,069
Commercial light sources under lease	261,923
Other current assets	7,248
	$562,240

4) INVENTORY

Inventory commenced with the product launch in September 2000 and consists of the following at December 31, 2000:

Finished goods	$1,151,537
Raw materials	175,344
Purchased parts and subassemblies	5,085
	$1,331,966

There was no inventory at December 31, 1999.

5) U.S. GOVERNMENT SECURITIES

Securities available for sale consist of United States Treasury Bills, Notes, and other United States government agencies with yields ranging from 4.67% to 7.20% and maturity dates ranging from January 12, 2001 to August 15, 2005. As of December 31, 2000 and 1999, the fair market value and cost basis on such securities were as follows:

	2000
Fair market value	$58,055,463
Cost basis	56,876,369

Net unrealized gain (loss) on such securities for the year ended December 31, 2000 and 1999 was $1,261,413 and ($87,853), respectively, and has been recorded as part of shareholders' equity as a component of accumulated other comprehensive income (loss).

6) PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2000 and 1999:

	USEFUL LIVES (YEARS)	2000	
Computer equipment	3	$ 564,288	$2
Furniture, fixtures and equipment	5	382,685	1
Manufacturing equipment	5	822,872	2
Leasehold improvements	Term of lease	485,809	
		2,255,654	7
Accumulated depreciation and amortization		(556,124)	(2
		$1,699,530	$4

7) INCOME TAXES

The tax effect of significant temporary differences representing deferred tax assets is as follows:

	2000
DEFERRED TAX ASSET	
Deferred revenue	$ 10,178,889
Intangible assets	653,318
Research and development tax credits carryforwards	928,131
Minimum tax credit carryforward	--

Operating loss carryforwards	5,911,149
Capital loss carryforwards	165,240
Fixed assets	59,668
Net deferred tax assets	17,896,395
Valuation allowance	(17,896,395)
	$ --

Management cannot assess the likelihood that the future tax benefits will be realized because the Company was a development stage corporation from its inception through its product launch in September 2000 and has cumulative net losses. Accordingly, the net tax benefit does not satisfy the recognition criteria set forth in SFAS No. 109 and, therefore, a valuation allowance has been provided.

As of December 31, 2000, the Company has net operating loss carryforwards for tax purposes of approximately $15,753,000 and research and development tax credits of approximately $928,000 both of which, if not utilized, will expire for Federal tax purposes as follows:

	OPERATING LOSS CARRYFORWARDS	RESEARCH AND DEVELOPMENT TAX CREDITS
2006	$ --	$ 6,731
2007	--	57,111
2008	--	65,795
2009	--	83,961
2010	--	43,825
2011	3,133,940	102,481
2012	6,840,914	235,314
2018	5,738,119	144,702

2019	40,082	80,724
2020	--	107,487
	$15,753,055	$928,131

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

	2000	
	$	%
Income tax expense (benefit) at statutory rate	(2,205,322)	(34.0)
State taxes	(424,614)	(6.5)
(Increase) decrease in tax credit carryforwards	37,682	0.5
Increase in valuation allowance	2,630,946	40.6
Other	17,308	.3
	56,000	.9
Income tax expense consists of:		
Current	56,000	--
Deferred	--	--
	56,000	--

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 and non-accountable expense allowance to the placement agent. Additional compensation 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 1,630.43 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 administration costs in the Consolidated Statements of Operations.

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 26,666.66 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 administration costs in the Consolidated Statements 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 and approved by the shareholders on June 6, 1996. The Omnibus Plan supercedes 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 provides for the granting of awards to purchase up to a maximum of 15% of the Company's common stock outstanding. 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 options ("RSO") or other securities determined by the Company, to directors, employees and consultants. To date, the Company has made awards of NQSOs, ISOs, and restricted stock grants 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 has granted each individual who agrees to become a director 15,000 NQSO to purchase common stock of the Company. These shares 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. The exercise price of such options is the closing stock market price on the date of the grant. All of the stock options granted

automatically to directors of the Company subsequent to 1999 immediately vests 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 or engagement.

The following table summarizes information about all stock options outstanding at December 31, 2000:

	OPTIONS OUTSTANDING		
RANGE OF EXERCISE PRICE	NUMBER OUTSTANDING AT DECEMBER 31, 2000	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE
$3.25 to 7.75	1,156,950	5.50 years	$6.67
8.38 to 16.94	444,500	7.18 years	12.11
26.19 to 31.00	539,000	9.33 years	29.45
	2,140,450	6.81 years	13.54

Stock option plans activity during the years ended December 31, 2000, 1999 and 1998 were as follows:

	2000	WEIGHTED AVERAGE EXERCISE PRICE	1999	WEI AV EXE
Options outstanding, beginning of year	1,757,800	$ 7.58	1,375,300	$
Options granted	641,500	28.44	465,000	
Options exercised	(188,350)	5.57	(72,500)	
Options cancelled	(70,500)	16.38	(10,000)	
Options outstanding, end of year	2,140,450	$13.54	1,757,800	$
Options exercisable, end of year	1,195,013	$ 8.36	1,007,800	$

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

Options which were exercised during these years were exercised at per share prices ranging from $3.25 to $11.50 during 2000, and at per share prices ranging from $3.25 to $11.25 during 1999. No options were exercised in fiscal 1998.

Options that were granted during 2000 have exercise prices ranging from $16.88 to $31.00 per share. Those granted during 1999 have exercise prices ranging from $6.375 to $20.50 per share. During 1998, options were granted with exercise prices ranging from $3.25 to $11.50 per share.

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 administration costs in the Consolidated Statements of Operations.

As discussed in Note 11a, on October 21, 1997, the Company issued 85,000 options to PARTEQ, 26,511 of which have been assigned to certain PARTEQ researchers. These options were valued at approximately $496,000, $259,000, and $82,000 in 2000, 1999, and 1998, respectively and recorded as part of research and development costs in the Consolidated Statements of Operations.

Also as discussed in Note 11a, on June 23, 1999, the Company issued 10,000 options to PARTEQ, 3,166 of which have been assigned to certain PARTEQ researchers. These options were valued at approximately $84,000 and recorded as part of research and development costs in the Consolidated Statements of Operations.

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:

	2000	
NET LOSS		
As reported	($6,540,755)	($5,52
Proforma	($12,147,732)	($8,30
BASIC AND DILUTED NET LOSS PER COMMON SHARE		
As reported	($0.49)	(
Proforma	($0.91)	(

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

	2000	1999	1998
Expected life (years)	10	10	10
Risk free interest rate	5.76%	6.22%	5.57%
Expected volatility	74.55%	80.70%	68.94%
Dividend yield	--	--	--

Using these assumptions, the weighted-average fair value per option for the years ended December 31, 2000, 1999, and 1998, was $23.07, $7.50 and $6.83, respectively. As SFAS No. 123 has not been applied to options granted prior to January 1, 1995, the resulting proforma compensation cost may not be representative of that to be expected in future years.

b) Warrants - In consideration of efforts related to the negotiation and execution of various agreements including the License Agreement, the Company issued warrants to purchase 350,000 shares of common stock of the Company at CDN $6.79 ($4.53 at December 31, 2000) per share to the Chief Executive Officer of the Company on January 17, 1992. These warrants expire on January 28, 2002 and were all outstanding as of December 31, 2000.

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. The warrant expires on October 14, 2001. During 2000, the investor relations firm exercised 25,000 shares underlying the warrant.

In connection with an agreement with its international investor relations advisor, in 1995 the Company agreed to issue warrants for 20,000 shares of the Company's common stock, exercisable at a price of $4.00 per share, a premium from the closing stock market price of the Company's common stock on the day immediately preceding the date of the grant. During 2000, all 20,000 warrants were exercised.

As discussed in Note 8, in 1999 the Company issued 164,673 warrants with an exercise price of $5.00 per share. As of December 31, 2000, 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, a German corporation. 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 for 2000 and 2001. In accordance with this agreement, Schering AG has agreed to fund two-thirds, up to $3,000,000, of the program. Due to timing of the start of clinical trials, the reimbursement for 2000 was approximately $723,000.

In December 1999, under the terms of this agreement, DUSA received $15,000,000 million reflecting an $8,750,000 cash milestone payment and $6,250,000 for which a Schering AG affiliate received 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(TM) 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 issuance of shares to the Schering AG affiliate was made at a premium of 20%, or $1,041,667, while the milestone payments of $15,750,000 and the $8,000,000 for future research and development support have been recorded as deferred revenue and will be recognized over the term of the agreement.

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 will be responsible for the manufacture and supply of the Levulan(R) Kerastick(R) to Schering AG for resale to the medical community. Schering AG will pay DUSA a supply

price for products, as well as a royalty on product sales. Schering AG has also agreed to promote the BLU-U(TM), which DUSA leases, through an independent leasing company, to dermatologists, medical facilities and other physicians. DUSA will maintain and repair the BLU-U(TM) units

under lease/maintenance agreements with the end-users. Under the terms of a Guaranty, Schering AG has agreed to guarantee the lease payments by each lessee up to the cost to DUSA of the BLU-U(TM) from DUSA's third-party manufacturer. The Guaranty will expire on the second anniversary of the first delivery to an end-user of a BLU-U(TM). In addition, Schering AG has agreed to provide DUSA with an interest-free line of credit for up to $1,000,000 to finance inventory of BLU-U(TM) units. Under the terms of a Secured Line of Credit Promissory Note and Security Agreement, repayment is secured by the BLU-U(TM) units. The maturity date of the Note is twelve months following the date of the first advance under the Note. No amounts have been advanced as of December 31, 2000.

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, 2000, 1999 and 1998, the Company incurred a liability of $68,000, $70,000, and $69,000, respectively, based on minimum royalty requirements. Going forward, annual minimum royalties to PARTEQ on sales of products must total at least CDN $100,000 ($66,667 as of December 31, 2000).

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 will vest over four (4) years on the anniversary date of the granting of the option. PARTEQ has assigned 26,511 of these options to certain of its researchers. The value of the options included in the Consolidated Statements of Operations as part of research and development costs was $496,000, $259,000 and $82,000 for 2000, 1999 & 1998, respectively.

The Company entered into an extension of the Research Agreement effective April 1, 1999 with PARTEQ. As partial consideration, the Company granted options to PARTEQ to purchase 10,000 shares of common stock of the Company at an exercise price of $9.25 per share. PARTEQ has assigned 3,166 of these options to certain of its researchers. 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 Valhalla, New York, in Wilmington, Massachusetts and in Toronto, Ontario including a new lease commitment for additional office space in its Wilmington headquarters. Future minimum lease payments related to these agreements for years subsequent to December 31, 2000 are as follows:

	MINIMUM LEASE PAYMENTS
2001	$ 463,000
2002	454,000
2003	331,000
2004	258,000
2005	211,000
Beyond 2005	18,000
	$1,735,000

Rent paid under these operating leases was approximately $297,000, $240,000, and $151,000 for the years ended December 31, 2000, 1999, and 1998, 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 ten-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 agreed to prepay for raw material costs in the amount of $400,000 associated with our current order.

This amount will be credited against the final purchase price which will be due on delivery of finished units at the rate of $1,000 per unit. In addition, we agreed that if we do not order a certain number of BLU-U(TM) brand units for delivery in 2002, we will pay $100,000 to

our manufacturer to cover certain overhead costs.

d) Research Agreements - The Company has entered into a series of agreements for research projects and clinical studies. As of December 31, 2000, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $483,000, $399,000 and $112,000 for 2001, 2002 and 2003, respectively.

e) North Safety Products Inc. - In September 1999, DUSA entered in a purchase and supply agreement with North Safety Products, Inc. (North) for the manufacture and supply of the Kerastick(R) brand applicator. The Company has 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 agreement has a five-year term, which may be extended for additional one-year periods. North has the right to terminate the agreement earlier if certain minimum levels of product orders are not reached. Similarly, DUSA can terminate the agreement early for stated breaches of the agreement. The Company has committed to reimburse North for the construction of certain facilities at North's manufacturing facilities in the amount of $311,000. In early 2001, we tentatively agreed to compensate North on an interim basis for certain overhead expenses associated with the manufacture of the Kerastick(R) if our orders fall below certain levels on an annual basis.

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 26,666.66 unregistered shares of DUSA's Common Stock, at a fair market value of $750,000. The $1,000,000 has been reported as deferred charges and is recognized in cost of goods sold on a straight-line basis over the original term of the contract.

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(TM) brand light device. The Company will sell the BLU-U(TM)'s to the leasing company, and will be paid for the units by the leasing company shortly after installation in the physician's offices. However, as 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 and also reimbursed Lumenetics for office space and related expenses totaling approximately $146,000. On February 26, 2001, the Company purchased such leased equipment for $52,000.

The Company also paid legal fees and expenses of $382,000 in 2000, $395,000 in 1999, and $183,550 in 1998 to Lane and Mantell, a professional corporation in which the Company's secretary was a principal.

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 Exhibit 1 to Registrant's Schedule 14A definitive Proxy Statement dated April 27, 1998, 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,

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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

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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(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

23.1 Consent of Deloitte & Touche LLP

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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 16, 2001

/s/ D. Geoffrey Shulman D. Geoffrey Shulman, MD,	Director, Chairman of the Board, President, Chief Executive Officer, (Principal Executive Officer)	March 16, 20 Date

FRCPC

/s/ Mark C. Carota	Vice President, Operations	March 16, 20
Mark C. Carota		Date
/s/ Ronald L. Carroll	Vice President, Business Development	March 16, 20
Ronald L. Carroll		Date
/s/ Scott L. Lundahl	Vice President, Technology	March 16, 20
Scott L. Lundahl		Date
/s/ Stuart L. Marcus	Vice President, Scientific Affairs	March 16, 20
Stuart L. Marcus, MD, PhD		Date
/s/ John E. Mattern	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 20
John E. Mattern		Date
/s/ William R. McIntyre	Vice President, Regulatory Affairs	March 16, 20
William R. McIntyre		Date
/s/ Paul A. Sowyrda	Vice President, Product Development and Marketing	March 16, 20
Paul A. Sowyrda		Date
/s/ John H. Abeles	Director	March 16, 20
John H. Abeles		Date
/s/ James P. Doherty	Director	March 16, 20
James P. Doherty, BSc		Date

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/s/ Jay M. Haft	Director	March 16, 20
Jay M. Haft, Esq.		Date
/s/ Richard C. Lufkin	Director	March 16, 20
Richard C. Lufkin		Date
/s/ Nanette W. Mantell	Secretary	March 16, 20
Nanette W. Mantell		Date