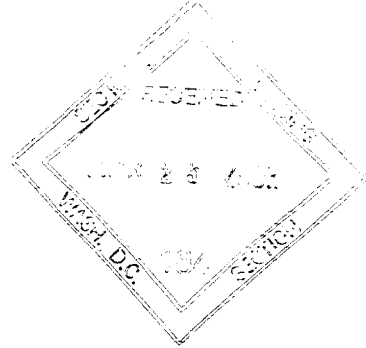


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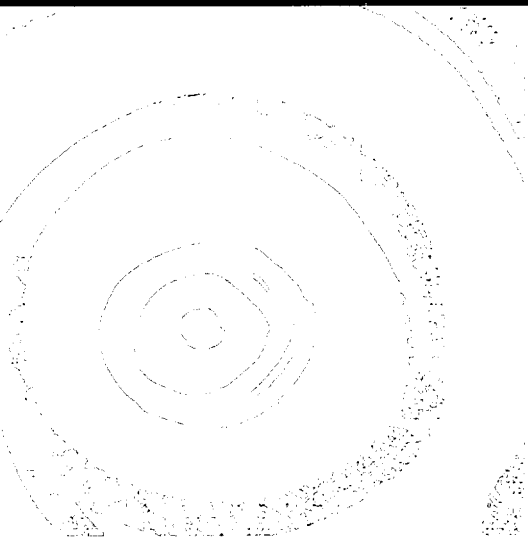


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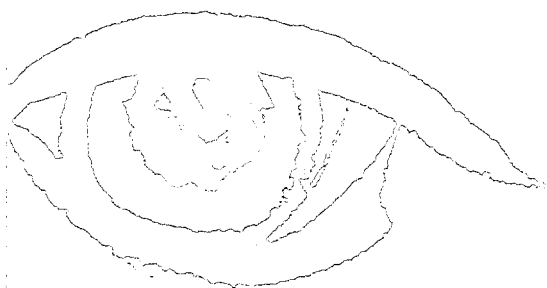
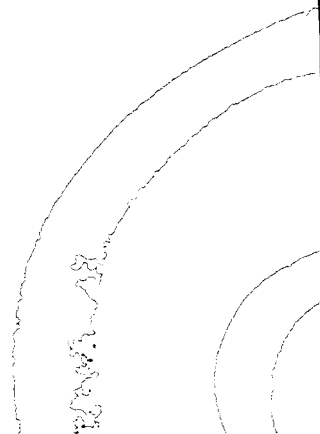
annual report 2002



D U S A

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Fellow Shareholders,

The last 2 years have been the most difficult in the Company's history. Following the FDA approval of our first products in September 2000, and after forming a dermatology collaboration with a major multi-national pharmaceutical company, sales expectations for DUSA's Levulan® PDT in dermatology were very high. Unfortunately, actual sales to date have been far below those expectations, to the point that in June 2002, our former dermatology partner sent us a notice of termination, which led to early termination of the agreement as of September 1, 2002.

Nonetheless, this turn of events has resulted in what I believe is a unique opportunity for DUSA going forward. Besides having FDA-approved products and a strong cash position, DUSA has been transformed into a vertically integrated pharmaceutical company. This means that not only are we fully responsible for the development, manufacture and marketing of our products, but we also retain 100% of our sales revenues, rather than having to share them with a partner. Therefore, if we are able to increase sales levels substantially, which is now our key area of focus for 2003, DUSA could be in a very good position.

Since reacquiring the rights to our products, DUSA has begun to institute its own marketing approach, based on education of physicians, supporting efforts to improve reimbursement to physicians for our therapy, and development of clinical studies which, if successful, could expand our AK market. For the first time, DUSA will have its own booth at educational meetings, such as the upcoming annual meeting of the American Academy of Dermatology. We also expect to commence regional test marketing strategies during 2003.

BLU-U® placements at year-end totaled 328 units, up from 282 at year-end 2001. Kerastick® end user sales during 2002 totaled 7,116 units, up slightly from the 2001 level of 7,071 units, but still representing only a tiny fraction of the potential dermatology market opportunity. DUSA management is hopeful that Kerastick® usage will increase during 2003, especially later in the year as our new marketing and educational programs begin to take effect.

The Company also continues to support development efforts for Levulan® PDT in the treatment of Barrett's esophagus dysplasia, having reported recently on some positive follow-up data in a small group of patients. DUSA is currently seeking a development and marketing partner for this indication.

The termination of our dermatology collaboration resulted in a net income of \$5.8 million for the year, although the Company expects to report ongoing operating losses until such time as sales of our products increase significantly. Net cash burn for 2002 was approximately \$11.8 million, and DUSA finished the year with approximately \$52.9 million of cash, cash equivalents and short-term investments, leaving the Company in a very solid financial position to proceed with its current development and marketing programs. Following the termination of our dermatology collaboration, the Company also decided to stop funding certain clinical development programs and reduced headcount by 20%, in order to control costs and focus the Company on meeting our core sales and development objectives.

In summary, although everyone at DUSA has been very disappointed by the initial sales levels, I am pleased to report that in the few short months since DUSA regained our dermatology rights, many positive steps have been taken that we believe lay the groundwork for increasing product sales in 2003 and beyond.

Thank you for your patience and support,  
Yours truly,

A handwritten signature in cursive script, appearing to read "D. Geoffrey Shulman". The signature is written in black ink and is positioned above the typed name.

D. Geoffrey Shulman, MD, FRCPC

President

March 17, 2003

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, 2002

DUSA Pharmaceuticals, Inc.  
(Exact Name of Registrant as Specified in Its Charter)

NEW JERSEY  
(State or Other Jurisdiction of  
Incorporation or Organization)

22-3103129  
(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, no par value  
(Title of Class)

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

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.

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

The aggregate market value of the voting and non-voting common equity stock held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the Registrant's most recently completed second fiscal quarter was \$25,814,033.

The number of shares of common stock outstanding of the Registrant as of March 5, 2003 was 13,887,612.

DOCUMENTS INCORPORATED BY REFERENCE

Document incorporated by reference to this Report is:

- (1) Proxy Statement for the 2003 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 19 through 28, 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, development and marketing of our first drug, the Levulan<sup>®</sup> brand of aminolevulinic acid HCl, or ALA, with light, for use, or potential use, in a broad range of medical conditions. When we use Levulan<sup>®</sup> and follow it with exposure to light to treat a medical condition, it is known as Levulan<sup>®</sup> photodynamic therapy, or Levulan<sup>®</sup> PDT. When we use Levulan<sup>®</sup> and follow it with exposure to light to detect medical conditions it is known as Levulan<sup>®</sup> photodetection, or Levulan<sup>®</sup> PD.

Our first products, the Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT and the BLU-U<sup>®</sup> brand light source were launched in the United States in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma.

On November 22, 1999, we signed a marketing, development and supply agreement with Schering AG, a German corporation, for our dermatology products. We granted to Schering AG the right to promote, market, sell, and distribute our Levulan<sup>®</sup> Kerastick<sup>®</sup> with PDT for AKs of the face or scalp on a worldwide basis (with the exception of Canada). In the United States, Schering AG's United States affiliate, Berlex Laboratories, Inc., marketed these products. Schering AG also promoted the BLU-U<sup>®</sup>; however, we were responsible for distributing the BLU-U<sup>®</sup> units, as well as for their repair and maintenance. We leased or rented the BLU-U<sup>®</sup> to physicians, medical institutions and academic centers throughout the country. We were also co-developing for commercialization with Schering AG additional Levulan<sup>®</sup> products for other dermatology disorders. Under the agreement, Schering AG had the exclusive right to market, promote, sell and distribute the products which were developed in the co-development program. On September 1, 2002, DUSA and Schering AG terminated the agreement and DUSA reacquired all rights it had granted to Schering AG. Consequently, DUSA has commenced marketing its products directly, and is now responsible for all regulatory, customer service, and other related activities which will result in significant new expenses, especially if we decide to develop a sales force in the future.

Also, as a result of the termination of our collaboration, we have reevaluated our operations and have reduced research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. These objectives include increasing the sales of our AK products in the United States, conducting clinical trials which, if successful, could support a broader AK indication, and seeking a partner to help develop and market Levulan<sup>®</sup> PDT for the treatment of dysplasia in patients with

Barrett's esophagus. In addition, we continue to support independent investigator trials to advance research in the use and applicability of Levulan<sup>®</sup> PDT for indications in dermatology, as well as for ablation of low-grade and high-grade dysplasia in Barrett's esophagus, among others. See section entitled "Business – Internal Indications."

We are developing Levulan<sup>®</sup> 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<sup>®</sup>, Kerastick<sup>®</sup> and BLU-U<sup>®</sup> are registered trademarks. These trademarks are also registered in Europe, Canada, and in other parts of the world. See sections entitled "Business – Licenses; and – Patents and Trademarks."

We were incorporated on February 21, 1991, under the laws of the State of New Jersey. Our principal executive offices are 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 have financed our operations to date, primarily from sales of securities in public offerings, private and offshore transactions that are exempt from registration under the Securities Act of 1933, as amended, (the "Act"), and from payments received as part of the agreement with Schering AG. See sections entitled "Management's Discussion and Analysis of Financial Condition – Overview; – Results of Operations; and – Liquidity and Capital Resources."

### **Business Strategy**

The following are the key elements of our strategy:

- *Support the Marketing of our First Products.* DUSA is in the process of implementing a new marketing, education, and development strategy. The Company is focusing on meeting the needs of dermatologists, and educating them about the benefits of our therapy, in an effort to increase product sales over time. Our activities include the support of medical education, participation in dermatology conferences, support of Company-sponsored research and development efforts and independent investigator studies, and support of efforts to improve third party reimbursement. DUSA has decided not to create a nationwide sales force, or to seek a new dermatology marketing partner at this time; however, we do intend to carry out limited regional test marketing during 2003.
- *Leveraging our Levulan<sup>®</sup> PDT/PD Platform to Develop Additional Products.* In the field of dermatology, we are planning clinical studies related to AKs that, if successful, could lead to enlarged market opportunities for our approved products. We are also supporting independent investigator studies that may lead to additional Levulan<sup>®</sup> products for other skin conditions such as psoriasis, photorejuvenation, inflammatory acne, warts, molluscum contagiosum, oily skin, and acne rosacea. Outside of dermatology, we are developing products that target large markets with unmet medical needs, such as the treatment of high-grade dysplasia within Barrett's esophagus dysplasia.
- *Enter into Additional Strategic Alliances.* If we determine that the development program for a non-dermatology indication may be beyond our own resources or may be advanced to market more rapidly by collaborating with a corporate partner, we may seek opportunities to license, market or co-promote our products. We are currently seeking a strategic partner to join in the development, marketing, and distribution of our treatment for Barrett's esophagus dysplasia. In addition, we recently completed a license of ALA technology for the fluorescence-guided resection of brain cancer which provides for potential additional joint development activities.
- *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 the resulting 'anecdotal' human data for use in evaluating potential indications for corporate development.

We will also continue to monitor independent research in order to identify other potential new indications.

## 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," or a pre-cursor of this type of drug, which tends to collect 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 also generally a potent activator of photosensitizers. Red light penetrates more deeply into tissues, and is better suited for treating cancers and deeper tissues. However, it is generally not as strong an activator of photosensitizers. Different photosensitizers do not absorb all colors of visible light in the same manner. For any given photosensitizer, some colors are more strongly absorbed than others.

Another consideration in selecting a light source is the location of the target tissue. Lesions on the skin which are easily accessible can generally be treated with a non-laser light source. Internal indications, which are often more difficult to access, may require a laser in order to focus the light into a small fiber optic delivery system that can 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 also can allow for multiple courses of therapy. 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. Generally, photosensitizers or light used separately have no PDT/PD effects.

## Our Levulan® PDT/PD Platform

### Our Levulan® Brand of ALA

We have a unique approach to PDT and PD, using the human cell's own natural processes. Levulan® 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®) is added from outside the cell, bypassing this normal feedback inhibition. The ALA is then converted through a number of steps into a potent natural photosensitizer named protoporphyrin IX, or PpIX. This is the compound that is activated by light during Levulan® PDT/PD, especially in fast growing cells. Any PpIX that remains after treatment is eliminated naturally by the same biosynthetic pathway.



We believe that Levulan<sup>®</sup> is unique among PDT/PD agents. It has the following features:

- *Naturally Occurring.* ALA is a naturally occurring substance found in virtually all living human cells.
- *Small Molecule.* Levulan<sup>®</sup> is a small molecule that is easily absorbed whether delivered topically, orally, or intravenously.
- *Highly Selective.* Levulan<sup>®</sup> 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, conversion into PpIX and targeted light delivery make this a highly selective process. Therefore, under appropriate conditions, we can achieve selective clinical effects in targeted tissues with minimal effects to normal surrounding and underlying tissues.
- *Controlled Activation.* Levulan<sup>®</sup> 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<sup>®</sup> is more pronounced in:

- rapidly growing diseased tissues, such as precancerous and cancerous lesions,
- conditions characterized by rapidly proliferating cells such as those found in psoriasis, and certain microbes and
- in certain normally fast-growing tissues, such as hair follicles, sebaceous glands, esophageal mucosa and the lining of the uterus.

#### **Our Kerastick<sup>®</sup> Brand Applicator**

We designed our proprietary Kerastick<sup>®</sup> specifically for use with Levulan<sup>®</sup>. It is a single-use, disposable applicator, which allows for the rapid preparation and uniform application of Levulan<sup>®</sup> topical solution in standardized doses. The Kerastick<sup>®</sup> has two separate glass ampoules, one containing Levulan<sup>®</sup> powder and one containing a liquid vehicle, both enclosed within a single 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 the ampoules and shakes the Kerastick<sup>®</sup> according to directions to mix the contents into a solution. The Kerastick<sup>®</sup> tip is then dabbed on to the individual AK lesions, releasing a predetermined amount of Levulan<sup>®</sup> 20% topical solution.

#### **Our Light Sources**

Customized light sources are critical to successful Levulan<sup>®</sup> PDT/PD because the effectiveness of Levulan<sup>®</sup> therapy depends on delivering light at an appropriate wavelength and intensity. 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<sup>®</sup> 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<sup>®</sup>. The light source is reasonably compact and portable. It can be used in a physician's office, requires only a moderate amount of floor space, and plugs into a standard electrical outlet. The BLU-U<sup>®</sup> also incorporates a proprietary regulator that controls the optical power of the light source to within specified limits. It has a simple control panel consisting of an on-off key switch and digital timer which turns off the light automatically at the end of the treatment. The BLU-U<sup>®</sup> is also compliant with CE marking and ISO 9001 requirements.

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

- safer,
- simpler to use,
- more reliable, and
- far less expensive.

For treatment of AKs, our BLU-U<sup>®</sup> 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 that may extend several millimeters into the skin or other tissue, for example, 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<sup>®</sup> PDT and PD. See section entitled "Business – Patents and Trademarks."

Our Levulan<sup>®</sup> 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 \$12,121,606 in 2002, \$10,789,906 in 2001, and \$8,163,419 in 2000.

<u>INDICATION/PRODUCT</u>	<u>STATUS OF REGULATORY STUDIES</u>
<b>Dermatology</b>	
Levulan <sup>®</sup> Kerastick <sup>®</sup> and BLU-U <sup>®</sup> for PDT of AKs	Approved; Phase IV
Levulan <sup>®</sup> PDT for Onychomycosis (Nail Fungus)	Phase I/II <sup>1</sup>
Levulan <sup>®</sup> PDT for Persistent Foot Wart Removal	Phase I/II <sup>1</sup>
Levulan <sup>®</sup> PDT for Acne	Phase I/II <sup>1</sup>
Levulan <sup>®</sup> PDT for Broad Area AKs	Phase III <sup>2</sup>
<b>Other Indications</b>	
Levulan <sup>®</sup> PDT for Barrett's Esophagus Dysplasia	Phase I/II
Levulan <sup>®</sup> induced fluorescence guided resection for brain cancer	European Phase III <sup>3 4</sup>

1. Further Phase II development for the onychomycosis, warts, and acne indications is not planned at this time
2. Phase III study to be proposed to FDA in early 2003
3. Licensed from Photonamic GmbH & Co. KG
4. European Phase III trial results may not be acceptable to the FDA in the United States

### Dermatology Indications

As of January 1, 2003, DUSA assumed all responsibility for its dermatology research and development program. In the prior 2 years, our former dermatology marketing partner had contributed nearly \$3 million per year to the program. With our decision to focus on clinical trials which, if successful, could support a broader AK indication, together with the obligation to complete our Phase IV long-term AK study, we determined that Phase II corporate studies on other dermatology indications should be put on hold until such time as increasing revenues and/or other clinical data make such trials justifiable. However, DUSA is continuing to support a wide range of independent investigator studies using the Levulan<sup>®</sup> Kerastick<sup>®</sup> that could lead to new indications for future development.

**Actinic Keratoses (AKs).** AKs are superficial precancerous skin lesions usually appearing as rough, scaly patches of skin with some underlying redness. The traditional methods of treating AKs are cryotherapy, or the freezing of skin, using liquid nitrogen; and 5-fluorouracil cream, or 5-FU. Although both methods can be effective, each has limitations and can result in significant side effects. Cryotherapy is non-selective, is usually painful at the site of freezing and can cause blistering and loss of skin pigmentation, leaving white spots. In addition, because there is no standardized treatment protocol, results are not uniform. 5-FU can be highly irritating and requires twice-a-day application by the patient for approximately 2 to 4 weeks, resulting in inflammation, redness and erosion or rawness of the skin. Following the treatment, an additional 1 to 2 weeks of healing is required. Our approved treatment method involves applying Levulan® 20% topical solution using the Kerastick® to the AK lesions, followed 14 to 18 hours later with exposure to our BLU-U® for approximately 17 minutes. In 2001, we successfully completed the first of two Phase IV trials required by the Food and Drug Administration, or FDA, testing for allergic skin reactions to our therapy. The second trial, which began in 2002, to evaluate the long-term effects of our therapy, is currently underway. We have also started development activities in order to commence clinical trials which, if successful, could support a broader AK indication to enhance the Levulan® product line.

As of March 1, 2003, a new national reimbursement code for Medicare and other third party payors for the BLU-U® application procedure, and the cost of the Levulan® Kerastick®, became effective. Doctors can also bill for any applicable visit fees. However, some physicians have suggested that even the new reimbursement levels still do not fully reflect the required efforts to routinely execute our therapy in their practices. In addition, others have reported problems prior to March 1, 2003 of receiving reimbursement at previously approved levels, or at all. These issues have affected the economic competitiveness with other AK therapies and have hindered the adoption of our therapy in many cases. Accordingly, we are continuing to support efforts to improve reimbursement levels to physicians, working with the major private insurance carriers to reimburse our therapy, and are attempting to resolve related billing and payment issues. We are hopeful that the recent changes to reimbursement, plus future improvements, along with our education and marketing programs, will help make Levulan® PDT a common therapy for AKs over time.

**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 can pose risks of systemic side effects such as liver disease and/or adverse interactions with other medications. DUSA and its former marketing partner commenced a vehicle-controlled, randomized, multicenter clinical feasibility trial for this indication in 2001. Levulan® 20% topical solution or vehicle was applied to infected toenails, followed in 3 to 6 hours by exposure to broadband red light. Results from the Phase I/II study on onychomycosis indicated that Levulan® PDT, as used in that study, was not successful in treating the disease in the majority of patients. The Company believes that with some adjustments to the protocol, Levulan® PDT might still be an effective treatment for this disease. However, further Phase II development of this indication is not planned at this time.

**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 commonly consult a physician. The physician's next line of therapy is usually cryotherapy with liquid nitrogen, which is applied by the doctor every 1-4 weeks for anywhere from weeks to months, or even years in rare cases. This treatment is painful and can occasionally leave scars. Some dermatologists use lasers to treat warts, although this process can also take many treatments with no guarantee of success. Sometimes warts still persist despite all attempts at treatment. Warts that have been present for a year or more, despite therapy, are termed recalcitrant warts.

In a 1999 independent Danish randomized clinical trial using ALA PDT on 30 patients with 250 recalcitrant warts, the investigator reported that one of the treatment groups showed a 70% elimination of recalcitrant warts through a 12-month period. In 2001, together with our former marketing partner, we began a vehicle-controlled, randomized, multicenter clinical feasibility trial, to enroll 64 patients with plantar warts persisting after a single standard treatment. The trial involved applying Levulan® to the warts followed either 3 to 6 or 16 to 24 hours later by light treatment using a broadband red light. Patients received up to 3 retreatments of partially responding and non-responding warts at two-week intervals.

Although this study was not designed to be statistically significant, DUSA believes that this data, combined with published independent results, are sufficient to justify continued development of this indication at some time in the future. However, further Phase II development for this indication is not planned at this time.

*Acne.* Acne is a common skin condition caused by the blockage and/or inflammation of sebaceous (oil) glands. Traditional treatments for mild to moderate facial inflammatory acne include over-the-counter topical medications for mild cases, and prescription topical medications or oral antibiotics for mild to moderate cases. An oral retinoid drug called Accutane<sup>®1</sup> is the most commonly prescribed treatment for cystic acne and can also be used for moderate to severe inflammatory acne. Over-the-counter treatments are not effective for many patients and can result in side effects including drying, flaking and redness of the skin. Prescription antibiotics lead to improvement in many cases, but patients must often take them on a long-term basis. Accutane<sup>®</sup> 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<sup>®</sup> PDT therapy for acne we would be seeking to improve or clear patients' acne without the need for long-term oral therapy and with fewer side effects than current therapies.

As part of the co-development program with our former partner, a dose-ranging clinical trial was completed in 2001. However, the specific low dose protocol tested was not able to replicate the positive clinical results seen in previous independent research using higher drug doses but which also was associated with significant side effects. Further Phase II development for this indication is not planned at this time.

#### Other Potential Dermatology Indications

*Facial Photodamaged Skin.* Photodamaged skin, which is skin damaged by the sun, occurs primarily in fair-skinned individuals after many years of sun exposure. Signs of photodamaged skin include roughness, wrinkles and brown spots. AKs also tend to occur in areas of photodamaged skin. There are numerous consumer cosmetic and herbal products which claim to lessen or relieve the symptoms of photodamaged skin. In most cases, there is little scientific data to support these claims. The FDA has approved only one prescription drug, Renova<sup>®2</sup>, to treat this common skin condition. Patients generally use the product for between 6 and 24 weeks before improvement may be observed. There are also a number of FDA approved laser and light-based treatments being used in the treatment of photodamaged skin.

As part of our AK clinical trials, we conducted a Phase II safety and efficacy study, testing 64 patients with 3 to 7 AK lesions of the face or scalp within an area of photodamaged skin. The physician investigators applied Levulan<sup>®</sup> 20% topical solution over the entire area including the photodamaged skin. After 14 to 18 hours, the patients were treated with blue light at differing light doses. Investigators noted marked improvement in skin roughness in the treated areas in two-thirds of the patients after treatment with Levulan<sup>®</sup> PDT as well as some degree of improvement of wrinkles and brown spots. However, 10 of the 64 patients found that the burning and stinging of the PDT therapy was too uncomfortable and as a result the treatment was either terminated early or the light power was reduced. No patients reported a serious treatment-related adverse event. Based on this data, we believe that this is a future potential indication for Levulan<sup>®</sup> PDT.

There are numerous other potential uses for Levulan<sup>®</sup> PDT/PD in dermatology. We are currently supporting, or may in the future support, research in several of these areas, as appropriate, with corporate Phase I-III trials, 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 conditions such as psoriasis, photorejuvenation, inflammatory acne, warts, molluscum contagiosum, oily skin, acne rosacea, and cancers, such as squamous cell carcinomas and cutaneous T-cell lymphomas.

<sup>1</sup> Accutane<sup>®</sup> is a registered trademark of Hoffmann-La Roche.

<sup>2</sup> Renova<sup>®</sup> is a registered trademark of Johnson & Johnson.

## Internal Indications

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

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

Independent European studies have reported that in late-stage Barrett's esophagus the high-grade dysplasia can be destroyed by ALA PDT. In a randomized, controlled European investigator study supported by DUSA, Levulan<sup>®</sup> PDT has been shown to allow the conversion of early-stage Barrett's esophagus with low-grade dysplasia and portions of Barrett's esophageal lining back to normal esophageal lining.

During the second half of 2001, we started two Phase I/II studies for the treatment of early and late-stage Barrett's esophagus, respectively, using systemic Levulan<sup>®</sup> followed by red laser light in varying light doses. Patients were randomized to receive various light doses, with retreatment if required, and follow-up for 24 months after the initial treatment. In our clinical trial in which the primary efficacy goal is the ablation of High Grade Dysplasia, or HGD, in Barrett's esophagus (late stage Barrett's esophagus), 6 patients with HGD have been treated with Levulan PDT. Of the 6 patients treated, 5 had complete clearing of their areas of high-grade dysplasia, and 4 of those patients have now been followed for a period greater than 1 year, indicating a durable response. No esophageal scarring or ruptures were noted in the course of this study. In our low-grade dysplasia (early stage) clinical trial in which the primary efficacy goal is the conversion of Barrett's esophagus to normal esophagus, 11 patients have been treated with Levulan PDT and are still being followed. There was 1 patient in this study that had mild esophageal scarring without symptoms. The most common adverse events in both studies were mild to moderate nausea and vomiting. In order to control ongoing research and development costs, we have chosen not to enroll any additional patients to these studies, but will continue to follow the patients that have already been treated.

**Brain Cancer.** Despite standard therapies that include surgical tumor removal, radiation therapy, and chemotherapy, adult patients with the most aggressive high-grade malignant brain tumor type, glioblastoma multiforme, generally survive only 1 year. Independent European investigators have reported that systemic ALA dosing before surgical resection of tumors resulted in selective fluorescence of only the tumors. The normal white matter of the brain showed no fluorescence. These investigators used ALA-induced fluorescence in a study involving 52 patients with glioblastoma multiforme as a guide for the more complete removal of tumors than would be possible using white light alone. This technique is called fluorescence-guided resection.

In December 2002, we entered into a License and Development Agreement with Photonamic GmbH & Co. KG, a recently formed subsidiary of medac GmbH, a German pharmaceutical company. This agreement provides for the licensing to us of Photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. The technology provides DUSA with access to a systemic formulation of ALA, and a significant amount of pre-clinical data, both of which could also be useful and are also licensed to DUSA for certain other indications, including Barrett's esophagus dysplasia. Photonamic is currently conducting a European Phase III clinical trial in which ALA-induced fluorescence is used to guide surgical tumor resection in patients suffering from glioblastoma multiforme. European Phase III trial results may not be acceptable by the FDA in the United States and we do not intend, at this time, to repeat

this study in the United States. These clinical trials are expected to continue through late 2004 at a minimum, so safety and efficacy for the brain cancer indication is still to be determined. See section entitled "Business – Licenses".

#### Other Potential Internal Indications

There may be numerous other potential therapeutic and cancer detection uses for Levulan® PDT/PD, and we are currently supporting, or may in the future support, research in several of these areas, as appropriate, with corporate-sponsored clinical 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 the potential non-dermatology indications include detection and/or treatment of gastrointestinal tumors, bladder cancer, pre-cancer and cancer of the oral cavity, and pre-cancer and cancer of the larynx.

#### Supply Partners

*National Biological Corporation.* In November 1998, we entered into a purchase and supply agreement with National Biological Corporation ("NBC") for the manufacture of some of our light sources, including the BLU-U®. 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 it fails to meet our supply needs. Under these circumstances, we would also have a worldwide license to import, use, sell or dispose of the light sources under NBC's technology within the field of PDT. Also, NBC has agreed that it will not supply light sources that may be used to compete with our business. In early 2001, we prepaid NBC for raw material costs in the amount of \$400,000 associated with our then current order. During 2002, the balance of this credit was applied to other invoices and no amount remained outstanding at December 31, 2002. The agreement has a 10-year term, subject to earlier termination for breach or insolvency or for convenience. However, a termination for convenience requires 12 months' prior written notice.

*North Safety Products.* In September 1999, we entered into a purchase and supply agreement with North Safety Products, Inc., or North, a unit of Norcross Safety Products, LLC, for the manufacture and supply of our Kerastick® brand applicator. In light of our decision to build our own manufacturing facilities and since orders for Kerastick® units did not meet the parties' expectations, the agreement was terminated on December 31, 2002. See section entitled "Business – Manufacturing."

In anticipation of the termination of this agreement, DUSA ordered approximately 45,000 Kerastick® units, which were delivered to DUSA during the fourth quarter of 2002. This inventory is intended to meet product demand until DUSA's manufacturing facility is approved by the FDA and functional, which is expected in late 2003.

*Sochinaz SA.* Under an agreement dated December 24, 1993, Sochinaz SA ("Sochinaz") manufactures and supplies substantially all of our requirements of Levulan® 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 3 years until December 3, 2007. While we can obtain alternative supply sources in certain circumstances, any new supplier would have to be inspected and qualified by the FDA.

*medac GmbH.* In December 2002, we entered into a supply agreement with medac GmbH in connection with the Photonamic license agreement mentioned above. We have a license to market and sell the formulation exclusively in the United States and in several other countries and non-exclusively in the rest of the world subject to certain field limitations. The supply agreement covers medac's current systemic dosage formulation for use in brain cancer, Barrett's esophagus, if we require it, as well as for other mutually agreed upon indications. The agreement provides for minimum purchase requirements following our first

commercial sale. In addition, the agreement has a term of 10 years from the date of our first commercial sale, subject to earlier termination rights, as well as successive one-year renewal terms.

## Licenses

*PARTEQ Research and Development Innovations.* We license the patents underlying our Levulan<sup>®</sup> PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations ("PARTEQ"), the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, which became effective August 27, 1991, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ's method patent rights, to make, have made, use and sell products which are precursors of PpIX, including ALA. The agreement also covers any improvements discovered, developed or acquired by or for PARTEQ, or Queen's University, to which PARTEQ has the right to grant a license. A non-exclusive right is reserved to Queen's University to use the subject matter of the agreement for non-commercial educational and research purposes. A right is reserved to the Department of National Defense Canada to use the licensed rights for defense purposes including defense procurement but excluding sales to third-parties.

When we are selling our products directly, we have agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where we have a sublicensee, 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. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 in order to retain the license. We have the right to terminate the PARTEQ agreement with or without cause upon 90 days notice. See "Note 14(a) to the Company's Notes to the Consolidated Financial Statements".

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

*Photonamic GmbH & Co. KG.* In December, we entered into a license and development agreement with Photonamic GmbH & Co. KG, a recently formed subsidiary of medac GmbH, a German pharmaceutical company. This agreement provides for the licensing to us of Photonamic's proprietary technology related to aminolevulinic acid (ALA), the compound we use in our Levulan<sup>®</sup> Photodynamic Therapy (PDT) and Photodetection (PD).

Under the terms of the License and Development Agreement, we received a license for the United States and several other countries, to use Photonamic's technology, including pre-clinical and clinical data, related to ALA for systemic dosing in the field of brain cancer, and for indications which the parties may jointly develop during the term of their collaboration. Additionally, we are entitled to use the pre-clinical data for indications which we may develop on our own. Photonamic is currently conducting a European Phase III clinical trial in which ALA-induced fluorescence is used to guide surgical tumor resection in patients suffering from the most aggressive form of adult brain tumor, glioblastoma multiforme. This clinical trial is expected to continue through late 2004, at a minimum. We paid a \$500,000 up-front license fee, and will be obligated to pay certain regulatory milestones and royalties on net sales of any brain cancer product which utilizes the Photonamic technology. Should Photonamic's clinical study be successful, we will be obligated to proceed with development of the product in the United States in order to retain the license for the use of the technology in the treatment of brain cancer. The agreement has a term of 10 years from the date of first

approval of a product using Photonamic's technology, subject to earlier termination rights, as well as one-year renewal terms.

## Patents and Trademarks

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

Our ability to compete successfully depends, in part, on our ability to defend our patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We have no product patent protection for the compound ALA itself, as our basic patents are for methods of detecting and treating various diseased tissues using ALA or related compounds called precursors, in combination with light. Even where we have patent protection, there is no guarantee that we will be able to enforce our patents. Patent litigation is expensive, and we may not be able to afford the costs. We own or exclusively license patents and patent applications related to the following:

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

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

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

We have limited patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counterparts in only four foreign countries, two of which are the subject of legal action. See sections entitled "Risk Factors – Risks Related to DUSA"; and "Legal Proceedings".

Japanese Patent No. 273032, which we have licensed from PARTEQ, relates to our basic methods of use. While this patent was opposed and the Japanese Patent Office Board of Appeals revoked this patent, the patent was subsequently restored, in amended form, by the Japanese Patent Office. This restoration of Japanese Patent 2731032 resulted from successful pursuit of an appeal of the revocation before the Tokyo High Court.

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.

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 section entitled "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 seek registration of trademarks in the United States, and other countries where we may market our products. To date, we have been issued 22 trademark registrations, and other applications are pending.

### **Manufacturing**

Historically, our drug, Levulan<sup>®</sup>, the Kerastick<sup>®</sup> brand applicator and the BLU-U<sup>®</sup> brand light source were each manufactured by a single third-party supplier. See section entitled "Business – Supply Partners."

Contemporaneously with an amendment of our agreement with North, which provided for early termination of the current Kerastick<sup>®</sup> manufacturing arrangement, and in order to meet our obligations to our former dermatology marketing partner, we decided to build a Kerastick<sup>®</sup> manufacturing line at our Wilmington facility. We believe that the development of our own manufacturing capabilities will enable us to better manage and control the costs of production; however, until product sales increase significantly our unit cost per Kerastick<sup>®</sup> at our new facility will be higher. The construction process is now complete and FDA inspection is expected during 2003. We anticipate that our current inventory levels will meet product demand until our new manufacturing facility is approved by the FDA and functional.

### **Distribution**

As of September 1, 2002, DUSA engaged Moore Medical Corporation, a national distributor and marketer of medical and surgical supplies, to be its exclusive distributor of the Kerastick<sup>®</sup> in the United States. The agreement has a one-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, either party may terminate the agreement earlier, on certain terms, or in the event that the other party shall have materially breached any of its obligations in the agreement.

### **Marketing and Sales**

Under our agreement with our former dermatology marketing partner, marketing and sales of Levulan<sup>®</sup> PDT products were the responsibility of the partner. As a result of the termination of that relationship, we are in the process of implementing our own marketing, education, and development strategy. For now, we have decided not to create a nationwide sales force, or to seek a new dermatology marketing partner. Instead, we are focusing on establishing a clear position for our therapy in the marketplace, meeting

the needs of dermatologists, and educating them about the benefits of our therapy, in an effort to increase product sales over time. This is being accomplished through the support of medical education activities, participation in dermatology conferences, support of Company-sponsored research and development efforts and independent investigator studies, and support of efforts to improve third party reimbursement.

Draxis holds the rights to market Levulan<sup>®</sup> PDT in Canada. See section entitled "Business – Licenses." The Health Protection Branch - Canada has granted marketing approval for the Levulan<sup>®</sup> Kerastick<sup>®</sup> with PDT using the BLU-U<sup>®</sup> for AKs of the face or scalp and we have had discussions with Draxis to establish a supply arrangement for the Canadian market. However, Draxis has not yet indicated if or when they might begin marketing our products in Canada.

### Competition

Commercial development of PDT agents other than Levulan<sup>®</sup> is currently being pursued by a number of companies. These include: QLT PhotoTherapeutics Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and Pharmacyclics, Inc. (U.S.). We are also aware of several companies conducting research with ALA or ALA-related compounds, including: medac GmbH and Photonamic GmbH & Co. KG (Germany); and PhotoCure ASA (Norway) who entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound with PDT for the treatment of AK in the European Union, New Zealand, and countries in Scandinavia. PhotoCure has also filed for regulatory approvals in Australia and the United States. In the United States, PhotoCure has received a notice of approvability from the FDA. Upon PhotoCure receiving approval from the FDA to market its product in the United States, its entry into the marketplace will likely represent direct competition for our products. In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the patents covered by our agreement with PARTEQ, relating to 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to us so that we may participate directly in this litigation. We filed an answer setting forth our defenses and a related countersuit alleging that PhotoCure's activities infringe the patent. The case is in its earliest stages so we are unable to predict the outcome at this time, but our intention is to vigorously defend our intellectual property. See section entitled "Business – Legal Proceedings".

In December 2002, Axcan Pharma Inc. announced that it had received a notice of approvability from the FDA for the use of its product, PHOTOFRIN<sup>®3</sup>, for photodynamic therapy in the treatment of high grade dysplasia associated with Barrett's esophagus. Axcan reported that it expects a final approval of its new drug application within the next few months. The approval would allow Axcan to be the first to market a PDT therapy for this indication, which we are also pursuing.

The pharmaceutical industry is highly competitive. 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. 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.

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<sup>3</sup> PHOTOFRIN<sup>®</sup> is a registered trademark of Axcan Pharma Inc.

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

Our current primary competitors for our first products are the existing therapies for treatment of AKs. See section entitled "Business – Dermatology Indications, Actinic Keratoses." Our principal method of competition with these therapies is patient benefits, including rapid healing and excellent cosmetic results.

### **Government Regulation**

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

- approval of manufacturing facilities, including adherence to current good manufacturing, laboratory and clinical practices during production and storage known as cGMPs, GLPs and GCPs respectively,
- controlled research and testing of products,
- applications for marketing approval containing manufacturing, preclinical and clinical data to establish the safety and efficacy of the product, and
- control of marketing activities, including advertising and labeling.

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

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

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

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

In Phase I, studies are usually conducted on a small number of healthy human volunteers to determine the maximum tolerated dose and any product-related side effects of a product. Phase I studies generally require several months to complete, but can take longer, depending on the drug and the nature of

the study. Phase II studies are conducted on a small number of patients having a specific disease to determine the most effective doses and schedules of administration. Phase II studies generally require from several months to 2 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 6 months to 4 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 1 to 4 years to complete, although reviews of treatments for AIDS, cancer and other life-threatening diseases may be accelerated, expedited or subject to fast track treatment. The process may take substantially longer if, among other things, the FDA has questions or concerns about the safety and/or efficacy of a product. In general, the FDA requires properly conducted, adequate and well-controlled clinical studies demonstrating safety and efficacy with sufficient levels of statistical assurance. However, additional information may be required. For example, the FDA also may request long-term toxicity studies or other studies relating to product safety or efficacy. Even with the submission of such data, the FDA may decide that the application does not satisfy its regulatory criteria for approval and may disapprove the NDA. Finally, the FDA may require additional clinical tests following NDA approval to confirm safety and efficacy, often referred to as Phase IV clinical trials.

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

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

We are currently conducting Phase I/II studies to examine the use of ALA for the treatment of Barrett's esophagus with areas of high-grade dysplasia. Other than the FDA-approved use of the Levulan<sup>®</sup> Kerastick<sup>®</sup> with PDT for treatment of AKs, our other potential products still require significant development, including additional preclinical and/or 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<sup>®</sup> in any future products will be successfully developed, prove to be safe and effective in clinical trials, or receive applicable regulatory marketing approvals.

Medical devices, such as our light source device, are also subject to the FDA's rules and regulations. These products are required to be tested, developed, manufactured and distributed in accordance with FDA regulations, including good manufacturing, laboratory and clinical practices. Under the Food, Drug & Cosmetic Act, all medical devices are classified as Class I, II or III devices. The classification of a device affects the degree and extent of the FDA's regulatory requirements, with Class III devices subject to the most stringent requirements and FDA review. Generally, Class I devices are subject to general controls (for example, labeling and adherence to the cGMP requirement for medical devices), and Class II devices are subject to general controls and special controls (for example, 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<sup>®</sup> has been classified as a Class III device. We are developing a device for the Barrett's esophagus indication which we believe will also be classified as Class III and be subject to the highest level of FDA regulation. Approval of Class III devices require the filing of a PMA application supported by extensive data, including preclinical and clinical trial data, to demonstrate the safety and effectiveness of the device. If human clinical trials of a device are required and the device presents a "significant risk," the manufacturer of the device must file an investigational device exemption or "IDE" application and receive FDA approval prior to commencing human clinical trials. At present, our devices are being studied in preclinical and clinical trials under our INDs.

Following receipt of the PMA application, if the FDA determines that the application is sufficiently complete to permit a substantive review, the agency will accept it for filing and further review. Once the submission is filed, the FDA begins a review of the PMA application. Under the Food, Drug and Cosmetics Act, the FDA has 180 days to review a PMA application. The review of PMA applications more often occur over a significantly protracted time period, and the FDA may take up to 2 years or more from the date of filing to complete its review.

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

Medical products containing a combination of drugs, including biologic drugs, or devices may be regulated as "combination products" in the United States. A combination product generally is defined as a product comprised of components from 2 or more regulatory categories (drug/device, device/biologic, drug/biologic, etc.). In December 2002, the FDA established the Office of Combination Products, or OCP, whose responsibilities, according to the FDA, will cover the entire regulatory life cycle of combination products, including jurisdiction decisions as well as the timeliness and effectiveness of pre-market review, and the consistency and appropriateness of post-market regulation.

In connection with our NDA for the Levulan<sup>®</sup> Kerastick<sup>®</sup> with PDT for AKs, a combination filing (including a PMA for the BLU-U<sup>®</sup> light source device and the NDA for the Levulan<sup>®</sup> Kerastick<sup>®</sup>) 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<sup>®</sup> 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 5 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 may take many 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<sup>®</sup> Kerastick<sup>®</sup> 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 5 year period of marketing exclusivity from the date of NDA approval for new chemical entities approved after September 24, 1984. Levulan<sup>®</sup> is a new chemical

entity and market exclusivity under this law 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.

Over time, we also intend to market our products outside of the United States. 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. Prior to marketing a product in other countries, approval by that nation's regulatory authorities must be obtained. Our former marketing partner was responsible for applying for marketing approvals outside the United States for Levulan<sup>®</sup> PDT for dermatology uses and did file applications for approval in Austria, Australia, South Africa and Brazil. However, as we have determined that we should concentrate solely on the United States market at this time, we authorized our former partner to withdraw the application for regulatory approval of Levulan<sup>®</sup> PDT in Australia, and have now followed the same course for the applications in Austria and South Africa. The approvals for the Levulan<sup>®</sup> Kerastick<sup>®</sup> and BLU-U<sup>®</sup> in Brazil are being transferred to us and we intend to maintain these registrations. The regulatory approvals for Canada held by Draxis Health, Inc. will not be affected.

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 no assurance that we will be able to get approval for any of our potential products from any importing nations' regulatory authorities or be able to participate in the foreign pharmaceutical market.

Our research and development activities have involved the controlled use of certain hazardous materials, such as mercury in fluorescent tubes. While we do not currently manufacture any products, we are subject to various laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products. During the design, construction and validation phases of our new Kerastick<sup>®</sup> facility, we have taken steps to ensure that appropriate environmental controls associated with the facility comply with environmental laws and standards. We can give no assurance that we will not have to make significant additional expenditures in order to comply with environmental laws and regulations in the future. Also, we cannot assure 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 2002, we had 43 full-time employees. Our staffing levels for key management personnel in administrative, financial, technical and operations functions had been established to support the sales levels of Levulan<sup>®</sup> PDT that did not materialize. However, following the reacquisition of our product

rights, we downsized our staffing levels by approximately 20%. Also, during the fourth quarter of 2002, both our Vice President of Regulatory Affairs and Vice President of Business Development ended their employment with us. However, they are both consulting on a part-time, as needed, basis. We have employment agreements with our key executive officers. We have purchased, and are the named beneficiary of, a key man life insurance policy having a face value of CDN \$2,000,000 on the life of our President. We also retain numerous independent consultants and the services of key researchers at leading university centers whose activities are coordinated by our employees. For example, in June 2002, the Company renewed its master service agreement, effective June 15, 2001, with Therapeutics, Inc. to manage the clinical development of DUSA's products in the field of dermatology. We intend to hire other employees and consultants as needed.

### **Internet Information**

Our internet site is located at [www.dusapharma.com](http://www.dusapharma.com). Copies of our reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K may be accessed from our website, free of charge, as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission.

### **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<sup>®</sup> Kerastick<sup>®</sup> with PDT for the treatment of AKs of the face or scalp.**

*We have only limited experience marketing or selling dermatology products and, as a result, our revenues from product sales may suffer.*

The commercial success of Levulan<sup>®</sup> Kerastick<sup>®</sup> with PDT for AKs of the face or scalp will partly depend on the effective marketing of our products in the United States, and we have only limited marketing experience selling dermatology products in the United States or elsewhere. Effective September 1, 2002, DUSA and our former marketing partner terminated the parties' marketing, development and supply agreement. As a result of this termination, DUSA reacquired all rights it granted under the agreement. For now, DUSA has decided not to create a nationwide sales force, or to seek a new dermatology marketing partner. Instead, DUSA intends to focus on establishing a clear position for our therapy in the marketplace, meeting the needs of dermatologists, and educating them about the benefits of our therapy, in an effort to increase product sales over time. This will be accomplished through the support of medical education activities, participation in dermatology conferences, support of Company-sponsored research and development efforts and independent investigator studies, and support of efforts to improve third party reimbursement. If these efforts fail, then sales of the Kerastick<sup>®</sup> will be adversely affected. During 2003, we intend to conduct some limited regional test marketing strategies. Depending on the responses, we may

consider developing a sales force of our own. If we do establish a marketing and sales force capability, it will involve significant expense, and we will be doing so without the experience of having marketed pharmaceutical products in the past.

*If product sales do not increase significantly or if we do not obtain additional funding, we will not be able to advance our other potential development programs as quickly as we would like to, which would delay the approval process and marketing of new potential products.*

The development and commercialization process is costly and delays and/or unanticipated costs could adversely affect our financial condition. If we do not generate sufficient revenues from our approved products, there can be no guarantee that we will obtain the funding resources necessary to continue the development of our potential dermatology and/or other products, as such requirements would require DUSA to commit substantially greater capital than we have to research and development of such products and we may not have sufficient funds to complete all of our programs.

*If we cannot improve physician reimbursement and/or convince more private insurance carriers to reimburse physicians for our therapy, adoption of our therapy may suffer.*

As of March 1, 2003, the national reimbursement code for Medicare and other third-party payors for the BLU-U<sup>®</sup> application procedure, and for the costs of the Levulan<sup>®</sup> Kerastick<sup>®</sup>, became effective. Doctors can also bill for any applicable visit fees. However, some physicians have suggested that even the new reimbursement levels still do not fully reflect the required efforts to routinely execute our therapy in their practices. In addition, others have reported problems prior to March 1, 2003 of receiving reimbursement at previously approved levels, or at all. These issues have affected the economic competitiveness of our products with other AK therapies and hence have hindered the adoption of our therapy in many cases. Accordingly, we are continuing to support efforts to improve reimbursement levels to physicians, working with the major private insurance carriers to reimburse our therapy, and are attempting to resolve related billing and payment issues. We are hopeful that the recent changes to reimbursement, plus future improvements, along with our education and marketing programs, will help make Levulan<sup>®</sup> PDT a common therapy for AKs over time. However, if improvements are not made to reimbursement, adoption of our therapy will suffer.

*Since we rely heavily on outside contractors as sole suppliers and manufacturers of Levulan<sup>®</sup> and BLU-U<sup>®</sup>, and have recently terminated our agreement with our outside Kerastick<sup>®</sup> manufacturer, and do not yet have our own Kerastick<sup>®</sup> manufacturing facility approved by the FDA, our marketing efforts and sales may suffer if our existing supply of product fails in any way to adequately provide us the quality and quantity of the products we need.*

We are not currently approved to manufacture any of our products on our own. We have terminated our agreement with our outside Kerastick<sup>®</sup> manufacturer, and are in the process of validating our own Kerastick<sup>®</sup> manufacturing facility. However, we have not yet had our facility approved by the FDA, and have not yet produced commercial quantities of Kerastick<sup>®</sup> units in the facility. We also have only one source for both Levulan<sup>®</sup> and the BLU-U<sup>®</sup>. We have not ordered any new BLU-U<sup>®</sup> units since 2001. Manufacturers, and/or their subcontractors, often encounter difficulties when products are manufactured for the first time, re-starting production after a long lay-off, or large quantities of new products are manufactured, 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 we seek to commence, re-start or increase production. Any manufacturing problems could delay or limit our supplies or prevent commercialization of our products. If we or our 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 may not be able to quickly or inexpensively replace it. If there are any quality or supply problems with any components or materials supplied to our manufacturers for our products, we may not be able to quickly remedy them.

If we are unable to meet the supply needs of our customers, our business, financial condition and results of operations would be adversely affected.

*If we are unable to obtain FDA approval of our manufacturing site in a timely manner, any resulting interruption in the supply of Kerastick® units could have an adverse effect on our revenue.*

Our supply agreement with North Safety Products, Inc. terminated on December 31, 2002. We have completed construction of our Kerastick® manufacturing facility and are in the process of validating our methods and preparing a submission to the FDA shortly for review. FDA approval is expected in late 2003. If we encounter difficulties or delays in completing our manufacturing facility, applying for approval, obtaining FDA approval of the facility, or in manufacturing commercial quantities of the Kerastick®, such difficulties or delays would adversely affect our business, financial condition or results of operations.

*Any failure to comply with ongoing governmental regulations in the United States will limit our ability to market our first products.*

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

- approval of manufacturing facilities, including adherence to "good manufacturing and laboratory practices" during production and storage,
- controlled research and testing of products even after approval, and
- control of marketing activities, including advertising and labeling.

Both the manufacture and marketing of our first products, the Levulan® Kerastick® and the BLU-U® are subject to continuing FDA review. We and 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, we and 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 we and our third-party manufacturers fail to comply with these requirements, DUSA would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products.

As part of our approval from the FDA, we were required to conduct two Phase IV follow-up studies. We have successfully completed the first study; the second study, to evaluate the long-term recurrence rate of AKs after treatment with our new therapy, began in 2002, and is scheduled for completion in 2003. 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 any assurance that our third-party supply sources, or our own new Kerastick® facility, if initially approved, will continue to meet all applicable FDA regulations in the future. If we, or any of our manufacturers, fail to maintain compliance with FDA regulatory requirements, it would be time consuming and costly to remedy the problem(s) or 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 of 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.

*We have significant losses and anticipate continued losses for the foreseeable future.*

We have a history of operating losses. We expect to have continued losses through at least 2003 as we continue research and development of new products and attempt to increase sales in the marketplace. As of December 31, 2002, our accumulated deficit was \$44,082,927. We cannot predict whether any of our products will achieve significant market acceptance or generate sufficient revenues to become profitable. Our commercial success will depend on whether:

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

If we are unable to protect our proprietary technology, trade secrets or know-how, we may not be able to operate our business profitably.

*We have limited patent protection and if we are unable to protect our proprietary rights, competitors might be able to develop similar products to compete with our products and technology.*

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

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

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

We have limited patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counter-parts in only four foreign countries. Even with the issuance of additional patents, other parties are free to develop other uses of ALA, including medical uses, and to market ALA for such uses, assuming that they have obtained appropriate regulatory marketing approvals. Certain forms of ALA are commercially available chemical products. ALA in the chemical form has been commercially supplied for decades, and is not itself subject to patent protection and there are reports of several third-parties conducting clinical studies with ALA for the

treatment of certain conditions in countries outside the United States where PARTEQ does not have patent protection. Additionally, enforcement of a given patent may not be practicable or an economically viable alternative.

Our patent protection in the Netherlands may be diminished or lost entirely. In early 2003, we received notice that Netherlands Patent No. 9021172, which relates to the basic method of using ALA, is being opposed. Under Dutch patent law, we are permitted to file a response to this opposition. We can at this time give no assurance of the likelihood of success of this opposition or any assurance that we will decide to spend the funds required to oppose the opposition. The Netherlands is not a major pharmaceutical market so the loss of this patent, if it were to occur, is unlikely to have significant impact on our potential revenues.

Our patent protection in Australia may be diminished or lost entirely. In 2002, we received notice of a lawsuit filed in Australia by PhotoCure ASA alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ Research & Development Innovations (the technology transfer arm of Queen's University at Kingston, Ontario) to us, relating to our 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to us so that we may participate directly in this litigation. We have filed a response to the allegations of invalidity in court and have also filed a counter suit alleging that PhotoCure's activities in Australia infringe the patent. We can at this time give no assurance of the likelihood of success of the action alleging invalidity or any assurance that we will decide to spend the funds required to complete the litigation. Australia is a significant pharmaceutical market for AK therapies, and loss of this patent could adversely affect us in at least two ways. First, if we seek to enter the Australia market, the lack of a patent would probably retard or diminish our market share. Second, even if we did not seek to market in Australia, third-parties might not be interested in licensing the product in Australia without patent protection, and this might limit our potential revenues from this market.

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

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

***Patent litigation is expensive, and we may not be able to afford the costs.***

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

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.

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® Kerastick® with the BLU-U® 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® Kerastick® with the BLU-U® for PDT to treat AKs, and our efforts to achieve the broader AK indication, 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 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 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 these 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 1 to 3 years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan® PDT products are based on new technology. To the best of our knowledge, the FDA has approved only 3 drugs for use in photodynamic therapy, including Levulan®. 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® PDT or PD is safe and effective for any new use we are studying. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy. We must also obtain foreign regulatory clearances before we can market any potential products in foreign markets. The foreign regulatory approval process includes all of the risks associated with obtaining FDA marketing approval and may impose substantial additional costs.

*Our lack of sales and marketing experience could affect our ability to market our non-dermatology products, which could adversely affect our revenues from future product sales.*

Currently, we have no experience in developing, training or managing a sales force. We will incur substantial additional expenses if we have to undertake these business activities, and the costs of establishing a sales force may exceed our product revenues. In addition, companies that may compete with us currently have extensive and well-funded marketing and sales operations. Any marketing and sales efforts, such as regional test marketing strategies, that we undertake 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.*

Since our sales goals for our first product have not been met, and may not be met in the future, we may need substantial additional funds to fully develop, manufacture, market and sell 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.

If funding is insufficient, we will have to continue to delay, reduce in scope or eliminate some or all of our research and development programs as we are doing in 2003. 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.

**Because of the nature of our business, the loss of key members of our management team could delay achievement of our goals.**

*If any of the key members of our management were to end their relationship with us, we could experience significant delays in our business and research objectives.*

We are a small company with only 43 employees. We are highly dependent on several key officer/employees with specialized scientific and technical skills. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain these qualified personnel in our specialty drug and light device areas. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our business, financial condition and results of operations could suffer.

#### **Risks Related to our Industry**

**Product liability and other claims against us may reduce demand for our products or result in damages.**

*If we become subject to a product liability claim we may not have adequate insurance coverage and the claim could adversely affect our business.*

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

*Our business involves environmental risks and we may incur significant costs complying with environmental laws and regulations.*

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. Even though we do not currently manufacture any products, we are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials and specific waste products. Now that we are establishing our own production line for the manufacture of the Kerastick<sup>®</sup>, we are subject to additional environmental laws and regulations. During the design, construction and validation phases of our new Kerastick<sup>®</sup> facility, we have taken steps to ensure that appropriate environmental controls associated with the facility comply with environmental laws and standards. We believe that we are in compliance in all material respects with currently applicable environmental laws and regulations. However, we cannot guarantee that we will not incur significant costs to comply with environmental laws and regulations in the future. We also cannot guarantee that current or future environmental laws or regulations will not materially adversely affect our operations, business or assets. In addition, although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and this liability could exceed our resources.

We may not be able to keep up with rapid changes in the biotechnology and pharmaceutical industries that could make some or all of our products non-competitive or obsolete.

*Competing products and technologies may make some or all of our programs or potential products noncompetitive or obsolete.*

Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Well-known pharmaceutical, biotechnology and chemical companies are marketing well-established therapies for the treatment of various dermatological conditions including AKs. Doctors may prefer familiar methods that they are comfortable using rather than try our products. Many companies are also seeking to develop new products and technologies for medical conditions for which we are developing treatments. Our competitors may succeed in developing products that are safer or more effective than ours and in obtaining regulatory marketing approval of future products before we do. We anticipate that we will face increased competition as new companies enter our markets and as the scientific development of PDT/PD advances.

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

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

We cannot give 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 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<sup>®</sup>. These include: QLT PhotoTherapeutics Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and Pharmacyclics, Inc. (U.S.). We are also aware of several companies conducting research with ALA or ALA-related compounds, including: medac GmbH and Photonamic GmbH & Co. KG (Germany); and PhotoCure ASA (Norway) which entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications.

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

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound with PDT for the treatment of AKs in the European Union, New Zealand, and countries in Scandinavia. PhotoCure has also filed for regulatory approvals in Australia and the United States. In the United States, PhotoCure has received a notice of approvability from the FDA. Upon PhotoCure receiving approval from

the FDA to market its product in the United States, its entry into the marketplace will likely represent direct competition for our products. See section entitled "Business – Legal Proceedings".

Axcan Pharma Inc. has announced that it has received preliminary approval from the FDA for the use of its product, PHOTOFRIN<sup>®</sup>, for photodynamic therapy in the treatment of high grade dysplasia associated with Barrett's esophagus. Axcan reported that it expects a final approval of its new drug application within the next few months. The approval would allow Axcan to be the first to market a PDT therapy for this indication, which we are also pursuing.

#### Risks Related to Our Stock

If the stock price rises, and if outstanding options and warrants are converted, the value of those shares of common stock outstanding just prior to the conversion will be diluted.

As of February 15, 2003 there were outstanding options and warrants to purchase 2,540,774 shares of common stock, with exercise prices ranging from U.S. \$2.90 to \$31.00 per share, respectively, and ranging from CDN \$4.69 to CDN \$10.875 per share, respectively. Currently, the market price of the common stock is lower than all options and warrants, so their exercise is unlikely at this time. However, if the stock price rises and 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.

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, 2002 to February 15, 2003, our stock price has ranged from a high of \$7.83 to a low of \$1.32. Factors that contributed to the volatility of our stock during the last 12 months included:

- disappointing product sales,
- termination of our Schering AG agreement,
- general market conditions,
- timing and amounts of third-party payor reimbursement for our therapy, and
- clinical trial results.

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

If our market capitalization remains at a level significantly below our cash value, we could be subject to a tender offer that does not reflect the potential value of our business and could minimize the return to our shareholders of their investments.

The price of our common stock has been negatively impacted by disappointing product sales, the termination of our Schering AG agreement, general market conditions, and the limited acceptance of the value of our therapy. Based on this, our share price traded at a level below our cash value during much of 2002. Until such time that we demonstrate the potential value of our therapy in the marketplace and our share price is more reflective of such potential value, there is an increased risk of companies offering to acquire us at reduced values which do not reflect the business potential of our assets.

Effecting a change of control of DUSA would be difficult, which may discourage offers for shares of our common stock.

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

On September 27, 2002, the Company adopted a shareholder rights plan (the "Rights Plan") at a special meeting of the Board of Directors. The Rights Plan provides for the distribution of one right as a dividend for each outstanding share of common stock of the Company to holders of record as of October 10, 2002. Each right entitles the registered holder to purchase one one-thousandths of a share of preferred stock at an exercise price of \$37.00 per right. The rights will be exercisable subsequent to the date that a person or group either has acquired, obtained the right to acquire, or commences or discloses an intention to commence a tender offer to acquire, 15% or more of the Company's outstanding common stock (or 20% of the outstanding common stock in the case of a shareholder or group who beneficially held in excess of 15% at the record date), or if a person or group is declared an Adverse Person, as such term is defined in the Rights Plan. The rights may be redeemed by the Company at a redemption price of one one-hundredth of a cent per right until ten days following the date the person or group acquires, or discloses an intention to acquire, 15% or 20% or more, as the case may be, of the Company, or until such later date as may be determined by the Board.

Under the Rights Plan, if a person or group acquires the threshold amount of common stock, all holders of rights (other than the acquiring shareholder) may, upon payment of the purchase price then in effect, purchase shares of common stock having a value of twice the purchase price. In the event that the Company is involved in a merger or other similar transaction where it is not the surviving corporation, all holders of rights (other than the acquiring shareholder) shall be entitled, upon payment of the purchase price then in effect, to purchase common stock of the surviving corporation having a value of twice the purchase price. The rights will expire on October 10, 2012, unless previously redeemed. The Board has adopted certain amendments to the Company's Certificate of Incorporation consistent with the terms of the Rights Plan. The Rights Plan could discourage, delay or prevent a person or group from acquiring 15% or more (or 20% or more in the case of certain parties) or our common stock, thereby limiting, perhaps, the ability of our shareholders to benefit from such a transaction.

## ITEM 2. PROPERTIES

In May 1999 we entered into a five year lease for 16,000 sq. ft. of office/warehouse space to be used for offices and manufacturing in Wilmington, Massachusetts. On February 1, 2001, we entered into a five year lease for an additional 24,000 square feet of space at our Wilmington facility. As part of our planned build-out of the facility, in December 2001 we replaced the two 5 year leases with a new 15 year lease covering the entire building through November 2016. We have the ability to terminate the Wilmington lease after the 10<sup>th</sup> year (2011) of the lease by providing the landlord with notice at least 7 and one-half months prior to the date on which the termination would be effective. In October 2002, we entered into a five year lease commitment for approximately 2,000 square feet, for our wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., replacing the space DUSA previously occupied. Commencing in August 2002, we entered into a five year lease for different office space for our Toronto location, at approximately half the cost of our previous office space. This facility accommodates the Toronto office of our President and shareholder services representative. See "Note 14(b) to the Company's Notes to the Consolidated Financial Statements".



**ITEM 3. LEGAL PROCEEDINGS**

In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985 is invalid. Australian Patent No. 624985 is one of the patents covered by our agreement with PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University, relating to 5-aminolevulinic acid technology. PhotoCure instituted this proceeding on April 12, 2002 in the Federal Court of Australia, Victoria District Registry. As a consequence of this action, Queen's University has assigned the Australian patent to us so that we may participate directly in this litigation. We filed an answer setting forth our defenses and a related countersuit alleging that PhotoCure's activities infringe the patent. The case is in its earliest stages so we are unable to predict the outcome at this time, but our intention is to vigorously defend our intellectual property. See section entitled "Business – Patents and Trademarks; and – Competition". For other patent matters, see section entitled "Risk Factors – If we are unable to protect our proprietary technology, trade secrets or Know-how, we may not be able to operate our business profitably."

**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, 2001:*

	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
NASDAQ				
High	\$18.938	\$17.500	\$14.140	\$11.150
Low	10.438	11.125	8.730	7.290

*Price range per common share by quarter, 2002:*

	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
NASDAQ				
High	\$7.830	\$4.550	\$2.690	\$1.890
Low	3.790	1.840	1.400	1.320

On March 5, 2003, the closing price of our common stock was \$1.569 per share on the NASDAQ National Market. On March 5, 2003, there were approximately 664 holders of record of our 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 in this report. The selected financial data for the Company set forth below as of and for the years ended December 31, 2002, 2001, 2000, 1999 and 1998 have been derived from the Company's audited consolidated financial statements.

### *Consolidated Statements of Operations Data*

	Year ended December 31,				
	2002 (1)	2001	2000	1999	1998
Revenues (1)	\$25,483,238	\$5,390,736	\$2,120,557	\$ -	\$ -
Cost of product sales and royalties (1)	5,253,424	2,148,994	1,104,664	-	-
Research and development costs (1)	12,121,606	10,789,906	8,163,419	4,194,532	4,502,391
General and administrative costs	5,591,039	3,654,792	2,615,502	1,818,193	1,729,741
Income (loss) from operations	2,517,169	(11,202,956)	(9,763,028)	(6,012,725)	(6,232,132)
Other income, net	3,245,349	3,844,860	3,222,273	574,098	515,184
Income tax expense	-	-	-	90,000	-
Net income (loss)	5,762,518	(7,358,096)	(6,540,755)	(5,528,627)	(5,716,948)
Basic and diluted net income (loss) per common share	\$ 0.42	\$ (0.53)	\$ (0.49)	\$ (0.50)	\$ (0.61)
Weighted average number of shares outstanding	13,877,566	13,791,735	13,285,472	11,061,016	9,365,950

### *Consolidated Balance Sheets Data*

	As of December 31,				
	2002	2001	2000	1999	1998
Total assets	\$60,949,973	\$75,864,221	\$82,442,388	\$28,156,845	\$7,140,675
Cash and investment securities	52,879,543	64,709,625	74,496,577	26,897,580	6,722,132
Deferred revenue (1)	5,100	22,585,856	24,805,041	9,791,667	-
Long-term debt (2)	1,517,500	-	-	-	-
Shareholders' equity	56,057,730	49,834,537	55,309,796	17,059,928	6,416,146

(1) Includes the recognition in 2002 of approximately \$20,990,000 in revenues, \$2,638,000 in cost of product sales and \$639,000 in research and development costs as a result of the termination of our former dermatology collaboration arrangement. See section entitled "Management's Discussion and Analysis - Overview, Termination of Dermatology Collaboration Agreement". These amounts were previously deferred and were being amortized into operations over 1 to 12.5 years.

(2) Excludes current portion of long-term debt.

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

*When you read this section of this report, it is important that you also read the financial statements and related notes included elsewhere in this report. 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

DUSA is a pharmaceutical company engaged primarily in the research, development, and marketing of a drug named 5-aminolevulinic acid, or ALA, used in combination with appropriate light devices in order to detect or treat a variety of medical conditions. The trademark for our brand of ALA is Levulan<sup>®</sup>. When Levulan<sup>®</sup> is used and followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan<sup>®</sup> is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our first products, which were launched in September 2000 in the United States, are Levulan<sup>®</sup> 20% topical solution using our Kerastick<sup>®</sup> brand applicator, and our BLU-U<sup>®</sup> brand light unit. Our products are used together to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp.

We have primarily devoted our resources to funding research and development in order to advance the Levulan<sup>®</sup> PDT/PD technology platform, and as a result, we have experienced significant operating losses. As of December 31, 2002, we had an accumulated deficit of approximately \$44,083,000. Achieving our goal of becoming a profitable operating company is dependent upon the market penetration of our products, acceptance of our therapy by the medical and consumer constituencies, and our ability to develop new products.

We have been encouraged by the positive response from many physicians and patients who have used our therapy, but recognize that we have to demonstrate the clinical value of our new and unique therapy, and the benefits compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. We also recognize that market acceptance has taken longer than we originally anticipated, and has not reached the levels that were originally expected.

As of March 1, 2003, the national reimbursement code for Medicare and other third-party payors for the BLU-U<sup>®</sup> application procedure, and for the costs of the Levulan<sup>®</sup> Kerastick<sup>®</sup>, became effective. Doctors can also bill for any applicable visit fees. However, some physicians have suggested that even the new reimbursement levels still do not fully reflect the required efforts to routinely execute our therapy in their practices. In addition, others have reported problems prior to March 1, 2003 of getting reimbursed at the level indicated, or at all. These issues have affected the economic competitiveness of our products with other AK therapies and hence have hindered the adoption of our therapy in many cases. Accordingly, we are continuing to support efforts to improve reimbursement levels to physicians, work with the major private insurance carriers to reimburse our therapy, and to resolve related billing and payment issues, which we believe could significantly improve physician adoption. We are hopeful that the recent changes to reimbursement, plus future improvements, along with our education and marketing programs, will help make Levulan<sup>®</sup> PDT a common therapy for AKs over time.

We expect to continue to incur operating losses, despite this year's net gain due to the financial reporting of the termination of our dermatology collaboration agreement, until the successful market penetration of our first products occurs. We are focusing our near-term dermatology research and development efforts on the commencement of clinical trials which, if successful, could lead to approval of a broader AK indication. As a result of the termination of our former dermatology collaboration arrangement, we have reevaluated our expenses and intend to minimize research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. During 2002, we decreased our staff to 43 full-time employees by year-end as compared to 55 at the end of the previous year. We expect to slightly increase our staff in 2003 as we focus on marketing activities and customer support

associated with reacquiring the rights to our AK products, and research and development programs for dermatology and internal indications. While our financial position is strong, we cannot predict when product sales along with interest and/or other income may offset the cost of these efforts.

We have incurred scale-up and certain fixed costs resulting in under-absorbed overhead, which are included in cost of product sales and royalties. Once our manufacturing facility is operational, management plans to continuously monitor the cost of product sales with the goal of reducing our costs over time. We expect that the development of our own facility will enable us to better manage and control the costs of production; however, our unit cost per Kerastick<sup>®</sup> is expected to be higher initially, until product sales increase significantly. Construction started in January 2002, and was completed during 2002. Facility qualification, process validation, drug product stability testing, and FDA review and approval are expected to be completed during 2003. This new facility replaces our former third-party Kerastick<sup>®</sup> manufacturer.

For non-dermatology indications, such as treatment of dysplasia in patients with Barrett's esophagus, we may enter into joint development or licensing arrangements, both domestically and internationally, with pharmaceutical or medical device companies, as we did with Photonamic for fluorescent-guided resection of brain cancer. However, at this point in time, we have decided not to seek a new dermatology collaboration. To the extent that we do not enter into such arrangements, we may require separate funding to complete the regulatory approval process for our non-dermatology products and would likely need additional funds to market such products.

*Termination of Dermatology Collaboration Agreement* – On September 1, 2002, DUSA and Schering AG, our former marketing and development partner for Levulan<sup>®</sup> PDT in the field of dermatology, terminated our marketing, development and supply agreement, dated November 22, 1999, as amended. As a result, we reacquired all of the rights we granted to Schering AG under the agreement. Co-development revenue from Schering AG was earned as we performed research, and deferred revenue relating to previously received milestone payments was being amortized into income over the 12- year life of our terminated agreement. Due to the termination of the agreement, unamortized deferred revenue and related deferred charges were recognized in the Consolidated Statement of Operations for the year ended December 31, 2002, resulting in a net profit for 2002 rather than a net loss had the agreement remained effective.

Schering AG agreed to continue its financial support for the dermatology research and development program for the remainder of 2002, including payments totaling \$2,050,000 by December 31, 2002, and to complete several ongoing clinical studies for our benefit. No further payments are due to us from Schering AG. Schering AG will transfer all of its interest in the regulatory filings it made in Brazil. However, as we have determined that we should concentrate solely on the US market at this time, we authorized Schering AG to withdraw the applications for regulatory approval of Levulan<sup>®</sup> PDT in Austria, Australia, and South Africa. The regulatory approvals for Canada (held by Draxis Health, Inc.) and Brazil will be maintained.

Due to the termination of our former dermatology collaboration arrangement, we evaluated certain items on our Consolidated Balance Sheet for the timing of revenue recognition and potential impairment. These items included unamortized deferred revenue related to non-refundable milestone payments previously received under the Schering AG agreement, and approximately \$6,950,000 in assets, including our nearly completed manufacturing facility, raw material and finished goods inventories, commercial light units in the field, and deferred charges and royalties. As a result of this analysis, in addition to normal amortization recorded prior to the termination of the agreement, we recorded the following items in our financial statements for the year ended December 31, 2002:

<u>Statement of Operations Item</u>	<u>Balance Sheet Item</u>	<u>Revenue Recognition/ Asset Impairment</u>	<u>Financial Statement Footnote Reference</u>
<u>Revenues:</u>			
Research grant and milestone revenue	Deferred revenue	\$20,990,274	Note 10
<u>Operating Costs:</u>			
Cost of product sales	Deferred charges	542,766	Note 7
	Inventory	1,705,364	Note 5
	BLU-U <sup>®</sup> units under lease or rental	389,647	Note 6
Research and development costs	Deferred royalty	639,051	Note 7
Total Charges to Operating Costs		\$3,276,828	

We concluded that the carrying value of our nearly completed manufacturing facility is more likely than not to be fully recoverable after considering the effects of the change in business circumstances caused by the termination of our former dermatology collaboration arrangement. Therefore, no impairment charges associated with the facility were recorded in 2002; however, we will continue to periodically review the carrying value of the facility.

Following the reacquisition of rights from our former partner, we commenced our own marketing, education, and development strategy. We will continue to develop and implement such strategies directly and will incur significant expenses relating to these activities. On September 1, 2002, we entered into an exclusive distribution agreement with Moore Medical Corporation to distribute the Kerastick<sup>®</sup> throughout the United States. See section entitled "Management's Discussion and Analysis – Overview, Third-party Distribution Agreement." For now, we have decided not to create a nationwide sales force, or to seek a new dermatology marketing partner. Should we decide to hire a sales force, we will incur significant expenses relating to these activities. Initially, we intend to focus on establishing a clear position for our therapy in the marketplace, meeting the needs of dermatologists, and educating them about the benefits of our therapy, in an effort to increase product sales over time. This will be accomplished through the support of medical education activities, participation in dermatology conferences, support of Company-sponsored research and development efforts and independent investigator studies, and support of efforts to improve third party reimbursement. We intend to carry out some limited regional test marketing strategies during 2003, and depending on the response, we may consider building a sales force in the future. We are also planning clinical studies, which if successful, could support a broader AK indication. We are also offering a new BLU-U<sup>®</sup> placement program for physicians, rather than the former rental and long-term lease arrangements, and have introduced a Kerastick<sup>®</sup> sampling program to allow new doctors to become familiar with the therapy.

**Third Party Distribution Agreement** – Effective September 1, 2002, we engaged Moore Medical Corporation, a national distributor and marketer of medical and surgical supplies, to be our exclusive distributor of the Kerastick<sup>®</sup> in the United States. The agreement has a 1 year term, which can be automatically renewed for additional 1 year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, either party may terminate the agreement earlier, on certain terms, or in the event that the other party shall have materially breached any of its obligations in the agreement. Moore has a right to return its inventory of Kerastick<sup>®</sup> units for full credit for a period of time prior to and after the expiration date of the agreement. Accordingly, we recognize product sales when Moore sells the Kerastick<sup>®</sup> to the end-user as the price is fixed and final to Moore at that point.

**Third-party Kerastick<sup>®</sup> Manufacturer Agreement Modification** – In early 2001, we agreed to compensate North Safety Products, Inc. ("North"), the manufacturer of our Kerastick<sup>®</sup> brand applicator, for certain overhead expenses associated with the manufacture of the Kerastick<sup>®</sup> to cover underutilization of North's facilities, in accordance with an amendment to the purchase and supply agreement, since our order levels were below certain previously anticipated levels. We reported the total commitment of \$1,400,000 in deferred charges, and recognized this amount in cost of product sales and royalties from July 2001 through December 2002. In consideration for the underutilization fees, North agreed to maintain its Kerastick<sup>®</sup>

manufacturing capabilities in a state of readiness through December 31, 2002. North manufactured and delivered approximately 45,000 Kerastick<sup>®</sup> units to us during the fourth quarter of 2002. In September 2001, in accordance with an amendment to our former agreement with Schering AG, Schering AG reimbursed \$1,000,000 of the costs we incurred to modify our manufacturing agreement with North. This amount was reported in deferred liabilities and was recognized as an offset to cost of product sales and royalties on a straight-line basis over the term of the agreement with North through December 2002.

In early 2001, in order to meet the production scheduling needs of our third-party manufacturer of the BLU-U<sup>®</sup>, National Biological Corporation ("NBC"), we prepaid raw material costs in the amount of \$400,000 associated with our orders. This amount was credited against the final purchase price of finished units, which was due on delivery at the rate of \$1,000 per completed unit. At the end of December 2001, approximately \$42,000 of this prepayment remained outstanding and was recorded in other current assets. During 2002, the balance of this credit was applied to other invoices and no amount remained outstanding at December 31, 2002. The agreement has a term of 10 years which expires in 2008, subject to earlier termination for breach or insolvency or for convenience on 12 months prior written notice.

*Shareholder Rights Plan* – In order to protect the long term interest of our shareholders, we adopted a Shareholder Rights Plan, on September 27, 2002. See "Note 10 to the Notes to the Consolidated Financial Statements – Shareholder Rights Plan." The Shareholder Rights Plan is designed to prevent an acquirer from gaining control of the company without offering a fair price to all of our shareholders. The Shareholder Rights Plan was not adopted by the Board in response to any specific offer or threat, but rather is intended to protect the interests of shareholders in the event we are confronted in the future with an unfriendly takeover attempt. Issuance of shares of common stock under the Shareholder Rights Plan could be used to make a change in control of our company more difficult or costly by diluting stock ownership of persons seeking to obtain control of us. In addition, the Board of Directors adopted certain amendments to our Certificate of Incorporation which are consistent with the terms of the Plan.

*License and Supply Agreements* – On December 30, 2002, we entered into a license and development agreement with Photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company, and a supply agreement for the licensed formulation with medac. These agreements provide for the licensing to us of Photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. The technology provides us with access to a systemic formulation of ALA, and a significant amount of pre-clinical data, both of which could also be useful and are licensed to us for certain other indications. Photonamic is currently conducting a European Phase III clinical trial in which ALA-induced fluorescence is used to guide surgical tumor resection in patients suffering from the most aggressive form of adult brain tumor, glioblastoma multiforme. This clinical trial is expected to continue through late 2004, at a minimum. Our license covers both this primary clinical indication as well as other brain cancers. Based on the license agreement, DUSA paid Photonamic a non-refundable \$500,000 milestone payment in early 2003. This amount was charged to research and development costs in the Consolidated Statement of Operations in the year ended December 31, 2002.

We will also be obligated to pay certain regulatory milestones and royalties on net sales of a brain cancer product under the terms of the license and development agreement and will purchase product under the supply agreement for mutually agreed upon indications. Should Photonamic's clinical study be successful, we will be obligated to proceed with development of the product in the United States in order to retain the license for the use of the technology to treat brain cancer. We are unable to determine at this time whether these obligations will mature.

*Australian Patent Litigation* – In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ to us, relating to 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to us so that we may participate directly in this litigation. We have filed an answer setting forth our defenses and a related countersuit alleging that PhotoCure's activities infringe the patent. The case is in its earliest stages so we are unable to predict the outcome at this time.

## Critical Accounting Policies

In May 2002, the United States Securities and Exchange Commission ("SEC") issued disclosure guidance and proposed rules for "critical accounting policies" entitled "Disclosure in Management's Discussion and Analysis about the Application of Critical Accounting Policies." The SEC defines "critical accounting policies" as those that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods and that can significantly affect our financial position and results of operations. Our accounting policies are disclosed in Note 2 to the Notes to the Consolidated Financial Statements. Since all of these accounting policies do not require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We have discussed these policies and the underlying estimates used in applying these accounting policies with our audit committee. We consider the following policies and estimates to be critical to our financial statements.

*Revenue Recognition* – Revenues on product sales of the Kerastick<sup>®</sup> are recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred, and there is reasonableness of collection. Research revenue earned under collaborative agreements consisted of non-refundable research and development funding from our former dermatology collaboration partner. Research revenue generally compensates us 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 our agreement with our former collaborator. Although we make every effort to assure the reasonableness of our estimates, significant unanticipated changes in our estimates due to business, economic, or industry events could have a material impact on our results of operations. As a consequence of the termination of DUSA's former dermatology collaboration arrangement, we recorded \$20,990,000 of previously received research grant and milestone revenue, in addition to normal amortization recorded prior to the termination, in our Consolidated Statements of Operations for the year ended December 31, 2002, resulting in a net profit for the year despite minimal product sales. See section entitled "Management's Discussion and Analysis – Overview, Termination of Dermatology Collaboration Agreement."

*Inventory* – Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method. Inventories are continually reviewed for slow moving, obsolete and excess items. Inventory items identified as slow-moving are evaluated to determine if an adjustment is required. Additionally, our industry is characterized by regular technological developments that could result in obsolete inventory. Although we make every effort to assure the reasonableness of our estimates, any significant unanticipated changes in demand, technological development, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. In September 2002, based on the termination of our former dermatology collaboration arrangement, we recorded lower of cost or market adjustments of \$2,095,000 for excess inventory and commercial light units under lease, rental, or trial arrangements to cost of product sales in our Consolidated Statements of Operations for the year ended December 31, 2002. We used sales projections to estimate the appropriate level of inventory that should remain on the Consolidated Balance Sheet. Management believes that the level of remaining inventory is reasonable in light of our current sales forecasts and uncertainties relating to the timing of FDA approval of our manufacturing facility. Should we be unable to achieve the forecasted sales, additional adjustments may be recorded to cost of goods sold. See section entitled "Management's Discussion and Analysis – Overview, Termination of Dermatology Collaboration Agreement."

*Valuation Of Long-lived and Intangible Assets* – We review long-lived and intangible assets, comprised of property, plant and equipment, deferred charges, and deferred royalties for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected

future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. When it is determined that the carrying value of long-lived or intangible assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, the asset is written down to its estimated fair value on a discounted cash flow basis. In 2002, we concluded that the termination of our former dermatology collaboration arrangement did not cause any impairment of our manufacturing facility under construction, but did result in impairment charges to operations of \$1,182,000 related to adjustments of certain intangible assets as more fully discussed in Note 3 to the Notes to the Consolidated Financial Statements. See section entitled "Management's Discussion and Analysis – Overview, Termination of Dermatology Collaboration Agreement." At December 31, 2002, our total property, plant and equipment had a carrying value of \$5,230,000, including \$2,596,000 associated with our manufacturing facility, and we had no intangible assets recorded as of that date.

*Stock-based Compensation* – We have elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of Accounting Principles Board Opinion No. 25, and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by Statement of Financial Accounting Standards ("SFAS") No. 123. Stock or other equity-based compensation for non-employees is 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, in the case of stock options, is generally the vesting period. As we utilize stock and stock options as one means of compensating employees, consultants, and others, the accounting for stock-based compensation could, under certain circumstances, result in a material effect on our results of operations, but would not affect cash flow based on our current stock option plan.

#### **Results of Operations - Year Ending December 31, 2002 As Compared to 2001**

*Revenues* – Total revenues for the year ended December 31, 2002 were \$25,483,000, as compared to \$5,391,000 in 2001. Research grant and milestone revenues were \$22,312,000 in 2002, as compared to \$1,983,000, and included the one-time recognition in September 2002 of unamortized up-front milestone and unrestricted grant payments previously received from Schering AG totaling \$20,990,000 due to the finalization of this relationship in September 2002, and normal amortization of \$1,322,000 received prior to the termination. In 2001, research grant and milestone revenue included normal amortization of \$1,983,000. See section entitled "Management's Discussion and Analysis – Overview, Termination of Dermatology Collaboration Agreement." Revenues for 2002 also included \$2,851,000 of research and development reimbursement which we earned from our former marketing partner, as compared to \$2,893,000 in 2001. Due to the termination of this agreement, we will not receive any co-development revenue from Schering AG subsequent to 2002.

Revenues for 2002 also included product sales and rental income of \$319,000, as compared to \$515,000 in 2001, reflecting \$209,000 of direct Kerastick<sup>®</sup> sales from our distributor, Moore Medical Corporation, to physicians. We believe that the decline in direct Kerastick<sup>®</sup> sales in 2002 as compared to 2001 is due mainly to the limited acceptance of our therapy, reimbursement issues, and need for additional medical education for the optimum use of our therapy. Also included in 2002 product sales and rental income were royalty revenues of \$77,000 which we earned for Kerastick<sup>®</sup> sales by Berlex, the subsidiary of our former marketing partner, to its distributor. In 2002, we had no direct Kerastick<sup>®</sup> sales to Berlex. In 2001, product sales and rental income included direct Kerastick<sup>®</sup> sales of \$358,000 to Berlex as Berlex purchased Kerastick<sup>®</sup> units to fill the anticipated forecasts at the time the units were ordered, royalty revenues of \$55,000, rental income of \$78,000, and miscellaneous product sales of \$24,000.

In September 2002, we initiated a new BLU-U<sup>®</sup> placement strategy as part of our new marketing initiatives. Under this plan, physicians receive the BLU-U<sup>®</sup> unit in exchange for an agreement to purchase



a minimum of 24 Kerastick<sup>®</sup> units each year. Previous BLU-U<sup>®</sup> marketing programs, which included leasing or renting the BLU-U<sup>®</sup> to physicians, medical institutions and academic centers, have been terminated. As of December 31, 2002, excluding BLU-U<sup>®</sup> units installed at clinical trial sites or sold to our former partner, 328 BLU-U<sup>®</sup> units were in place, up from the 282 units at December 31, 2001. Kerastick<sup>®</sup> sales to end-users were 7,116 in 2002 as compared to 7,071 in 2001. We believe that as doctors become more familiar with the benefits of Levulan<sup>®</sup> PDT, if an FDA approval for a broader AK indication claim is achieved, and improved reimbursement for physicians is attained, more widespread adoption of our technology should occur over time.

**Cost of Product Sales and Royalties** – Cost of product sales and royalties for the year ended December 31, 2002 were \$5,253,000, as compared to \$2,149,000 in 2001. The increase was mainly attributed to the recognition of \$2,638,000 for lower of cost or market inventory adjustments, increased depreciation taken on BLU-U<sup>®</sup> units, and deferred charges associated with our amended Supply Agreement with Sochinaz SA, which were based on (i) the termination of our former dermatology collaboration arrangement, (ii) limited product sales since the September 2000 product launch, and (iii) our expectation of no significant near-term increases in Kerastick<sup>®</sup> sales levels and/or BLU-U<sup>®</sup> placements. See section entitled “Management’s Discussion and Analysis – Overview, Termination of Dermatology Collaboration Agreement.” A summary of the components of cost of product sales and royalties for the years ended December 31, 2002 and 2001 including direct and indirect costs for supporting our product is provided below:

	<u>Year Ended December 31,</u>		
	<u>2002</u>	<u>2001</u>	<u>Increase (Decrease)</u>
<b>Cost of Product Sales and Royalties</b>			
Recognition for lower of cost or market inventory adjustments, increased depreciation taken on BLU-U <sup>®</sup> units, and deferred charges as a result of the termination of our collaboration agreement with Schering AG	\$ 2,638,000	\$ -	\$2,638,000
Internal manufacturing costs (e.g. customer service, quality assurance, purchasing, and other product support operations) assigned to products	1,189,000	691,000	498,000
Costs incurred to ship, install and service the BLU-U <sup>®</sup> in physicians offices including depreciation	834,000	266,000	568,000
Royalty and supply fees (1)	64,000	63,000	1,000
Net underutilization costs (2)	333,000	534,000	(201,000)
Amortization of deferred charges (3)	151,000	226,000	(75,000)
Direct Kerastick <sup>®</sup> product costs including related testing (4)	<u>44,000</u>	<u>369,000</u>	<u>(325,000)</u>
Total cost of product sales and royalties	<u>\$5,253,000</u>	<u>\$2,149,000</u>	<u>\$3,104,000</u>

- 1) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario.
- 2) Underutilization costs commenced in 2001 based on an agreement with our thirty-party Kerastick<sup>®</sup> manufacturer, North Safety Products, Inc., due to orders falling below certain previously anticipated levels.
- 3) Amortization of deferred charges reflects consideration paid by us in 2000 to amend our Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan<sup>®</sup>. Amortization for 2002 reflects amount recorded prior to the termination of our former dermatology collaboration arrangement.
- 4) For 2002, direct Kerastick<sup>®</sup> product costs reflect costs recognized based on direct Kerastick<sup>®</sup> sales since September 1, 2002 to our distributor, Moore Medical Corporation. See section entitled “Management’s Discussion and Analysis - Overview, Third-party Distribution Agreement.”

Historically, inventory costs related to the BLU-U<sup>®</sup> units under rental or lease were deferred until the BLU-U<sup>®</sup> was no longer returnable to us by the physician, which was one year under the initial marketing program. As of December 31, 2002 and 2001, BLU-U units included in property, plant and equipment amounted to approximately \$473,000 and \$764,000, net of depreciation of \$473,000 and \$69,000. This decrease includes an additional \$390,000 of depreciation expense recorded in 2002 reflecting a shortened useful life of our BLU-U<sup>®</sup> units under lease, rental, or trial arrangements to reflect a three-year asset life. This accelerated depreciation policy is attributed to the low level of BLU-U<sup>®</sup> placements to date, the termination of our former dermatology collaboration arrangement, including the decision not to launch the BLU-U<sup>®</sup> in non-US markets (except possibly Canada and/or Brazil) at this time, and management's expectations that near-term placements will be limited. See Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.

*Research and Development Costs* – Research and development costs for the year ended December 31, 2002 were \$12,122,000 as compared to \$10,790,000 for 2001. This increase in research and development costs for 2002 is attributable to the write-off of \$639,000 of previously deferred royalties associated with payments to PARTEQ, our licensor, and a \$500,000 milestone payment under our license agreement signed on December 30, 2002 between DUSA and Photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company. This agreement provides for the licensing to us of Photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. Research and development costs for 2002 also included higher third-party expenditures in support of our FDA mandated Phase IV clinical study of the long-term efficacy of our marketed product, clinical feasibility studies in other dermatological indications, and our Phase I/II clinical studies on the safety and efficacy of Levulan PDT treatment of Barrett's esophagus with and without dysplasia. As stated above, under our former agreement with Schering AG, \$2,851,000 of the agreed upon dermatology research and development expenses were reimbursed to us by Schering AG for 2002 as compared to \$2,893,000 for 2001.

The currently approved Levulan<sup>®</sup> Kerastick<sup>®</sup> only allows application of Levulan<sup>®</sup> to individual lesions using the Kerastick<sup>®</sup>, so we are seeking to apply Levulan<sup>®</sup> to the entire face or scalp in a broad area actinic keratoses (BAAK) treatment. We are developing a revised protocol for our BLU-U<sup>®</sup> treatment allowing the use of the Levulan<sup>®</sup> Kerastick<sup>®</sup> for the BAAK indication after a much shorter drug incubation time. We believe that should clinical development of this indication be successful and approved as a broader AK indication, the market penetration of the therapy could be significantly enhanced. We also intend to complete our FDA-required Phase IV long-term AK tracking study before the end of 2003.

Data from our Phase I/II study on resistant plantar warts was encouraging, but was not designed to be statistically significant. However, our Phase II study on onychomycosis (nail fungus) did not appear to show success in treating the disease in the majority of patients. Further Phase II development for the warts and onychomycosis indications are not planned at this time in order to control our total research and development spending for 2003 and beyond. This strategy should keep us in a strong financial position as we develop the BAAK indication, complete the long-term tracking study, and implement activities to increase revenues from the current product.

We have also been conducting Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. While limited investigator studies in the high-grade dysplasia indication will still be funded, we do not expect to fund full Phase II or III clinical trials for this indication on our own. As of January 2003, with 12 months of follow up in 4 patients, and 6 months in 1 patient, results of the high-grade dysplasia (HGD) study of five patients showed a continued absence of dysplasia (i.e. complete ablation), no strictures, and no signs of mucosal overgrowth. In our low-grade dysplasia (early stage) clinical trial in which the primary efficacy goal is the conversion of Barrett's esophagus to normal esophagus, 11 patients have been treated with Levulan PDT and are still being followed. There was 1 patient in this study that had mild esophageal scarring without symptoms. We have begun soliciting potential partners for this indication. Management's goal is to complete a partnership for this indication during 2003; however, there can be no assurance that we will be able to consummate any collaboration, or whether we will be able to obtain terms acceptable to us.

We also anticipate continued funding for various investigator studies involving the Kerastick®.

**General and Administrative Costs** – General and administrative expenses for the year ended December 31, 2002 increased to \$5,591,000 as compared to \$3,655,000 for 2001. This increase is mainly attributed to higher legal expenses incurred in 2002 of \$1,970,000 as compared to \$490,000 in 2001, due primarily to patent defense costs, the termination of our former dermatology collaboration arrangement, and strategic initiatives. It is expected that legal expenses will remain at elevated levels as long as the patent dispute continues. We also incurred employee separation costs of approximately \$395,000 during 2002. There were no employee separation costs in 2001.

**Other Income** – Other income for the year ended December 31, 2002 decreased to \$3,245,000, as compared to \$3,845,000 in 2001. This decrease was attributed to lower interest income of \$2,745,000 in 2002 as compared to \$3,753,000 in 2001 reflecting a decrease in investable cash balances as we used cash to support our operating activities, and lower yields. Interest income will continue to decline as our investable cash balances are reduced to support our operating activities. Gains on the sale of securities of \$500,000 in 2002 partly offset this decline on interest income as compared to \$92,000 in 2001 in order to meet current and planned operating requirements. During 2002, we incurred interest expense of \$47,000 on borrowings associated with the construction of our new Kerastick® manufacturing facility, which has been capitalized in property and equipment in the Consolidated Balance Sheet as of December 31, 2002.

**Income Taxes** – Although we had net income for 2002, there was no income tax expense. The majority of the revenue we recognized in connection with the termination of the Schering AG agreement had been taxable in prior years for income tax purposes. As of December 31, 2002, we had net operating loss carryforwards of approximately \$45,125,000 and tax credit carryforwards of approximately \$1,605,000 for Federal reporting purposes. These amounts expire at various times through 2022. See Note 11 to the Notes to the Consolidated Financial Statements.

**Net Income (Loss)** – For the year ended December 31, 2002, we earned net income of \$5,763,000, or \$.42 cents per share, as compared to a net loss of (\$7,358,000), or (\$.53) cents per share, for 2001. As a result of the termination of our former dermatology collaboration arrangement, net income for 2002 included a one-time increase of approximately \$17,713,000, excluding normal amortization recorded prior to termination, based on the acceleration of previously deferred revenue and costs, and other related adjustments for impairment. See section entitled “Management’s Discussion and Analysis – Overview, Termination of Dermatology Collaboration Agreement.” Subsequent to 2002, we expect to incur net losses until the successful market penetration of our first products occurs.

#### **Results of Operations - Year Ending December 31, 2001 As Compared To 2000**

**Revenues** – We recognized revenues for the year ended December 31, 2001 of \$5,391,000, as compared to \$2,121,000 in 2000. Of these amounts, we earned research and development revenue of \$2,893,000 during 2001 as compared to \$723,000 in 2000 from Schering AG to support our dermatology co-development program. Also included in revenues were amortization of up-front milestone and unrestricted grant payments from Schering AG of \$1,983,000 in 2001 compared to \$496,000 in 2000, reflecting a full year of amortization in 2001. These increases were offset by a decline in product sales to \$515,000 in 2001 as compared to \$902,000 in 2000, as Berlex filled the distributor's anticipated Kerastick® supply needs, in the fourth quarter of 2000, subsequent to our September 2000 product launch. We recognized royalty revenues which were earned when the Kerastick® was sold by Berlex to its distributor, and were payable to us during the quarter following the quarter in which the sales were made. We recognized supply fee revenue related to these sales when our supplier shipped the Kerastick® to Berlex.

Product sales during 2001 also included rental income on BLU-U® units of approximately \$78,000. There was no rental income recognized in 2000. Initially, we generally leased our BLU-U® brand light units for use with the Levulan® Kerastick®. In July 2001, we test-marketed a new program, which was then launched nationally in mid-September 2001. Under this program, we rented the BLU-U® to physicians for 36 months with no rental payments incurred by physicians and no rental revenue recognized by us for the first 6 months, while Berlex provided physicians with a supply of Kerastick® samples.

Under our former agreement with Schering AG, two-thirds of the agreed upon dermatology research and development expenses, up to \$3,000,000 per year for 2000 and 2001, were reimbursed to us by Schering AG. We earned total research and development reimbursement in 2001 of \$2,893,000. Based on the agreed upon development plan and the timing of the start of the clinical trials, we were only entitled to reimbursement of \$723,000 for the year ended December 31, 2000.

The total amount of up-front milestone and unrestricted grant payments received in 2000 and 1999 were recorded as deferred revenue upon receipt and were recognized as income on a straight-line basis over the stated term of our terminated agreement with Schering AG. For the years ended December 31, 2001 and 2000, approximately \$1,983,000 and \$496,000, respectively, of up-front milestone and unrestricted grant payments were reflected in revenues.

*Cost of Product Sales and Royalties* – Cost of product sales and royalties for the year ended December 31, 2001 were \$2,149,000, as compared to \$1,105,000 in 2000. A summary of the components of cost of product sales and royalties for the years ended December 31, 2001 and 2000 including direct and indirect costs for supporting our product is listed below:

	<u>Year Ended December 31,</u>		<u>Increase (Decrease)</u>
	<u>2001</u>	<u>2000</u>	
<b>Cost of Product Sales and Royalties</b>			
Internal manufacturing costs (e.g. customer service, quality assurance, purchasing, and other product support operations) assigned to support products (1)	\$ 691,000	\$ -	\$ 691,000
Costs incurred to ship, install, and service the BLU-U <sup>®</sup> in physicians offices including depreciation	266,000	128,000	138,000
Royalty and supply fees to DUSA's licensor (2)	63,000	68,000	(5,000)
Net underutilization costs (3)	534,000	-	534,000
Amortization of deferred charges (4)	226,000	113,000	113,000
Direct Kerastick <sup>®</sup> product costs including related testing	<u>369,000</u>	<u>796,000</u>	<u>(427,000)</u>
Total cost of product sales and royalties	<u>\$2,149,000</u>	<u>\$1,105,000</u>	<u>\$1,044,000</u>

- 1) Allocation of internal support costs assigned to support product commenced in 2001 as a significant percentage of manufacturing development activities have been completed for our current products.
- 2) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario.
- 3) Underutilization costs commenced in 2001 based on an agreement with our third-party Kerastick<sup>®</sup> manufacturer, North Safety Products, Inc., due to orders falling below certain previously anticipated levels.
- 4) Amortization of deferred charges reflects consideration paid by us in 2000 to amend our Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan<sup>®</sup>.

Inventory costs related to the BLU-U<sup>®</sup> commercial light sources under rental or lease were deferred and recorded in other current assets until the BLU-U<sup>®</sup> was no longer returnable to us by the physician, which was 1 year under the initial marketing program. As of December 31, 2001 and 2000, deferred inventory costs were approximately \$764,000 and \$262,000.

**Research and Development Costs** – Our research and development costs for the year ended December 31, 2001 were approximately \$10,790,000, as compared to \$8,163,000 in 2000. The increase for 2001 was attributable to higher third-party expenditures for dermatology and internal indications coupled with increased personnel costs related to ongoing development activities. During 2001, this increase was partially offset by the reassignment of personnel costs to product sale operations and/or general and administrative functions, rather than to research and development costs, as a significant percentage of the development activities were completed for our currently marketed dermatology products in 2000. As stated above under "Management's Discussion and Analysis – Revenues," under our agreement with our former marketing partner, two-thirds, or \$2,893,000, of the agreed upon dermatology research and development expenses were reimbursable to us by Schering AG for 2001 as compared to \$723,000 for 2000.

**General and Administrative Costs** – General and administrative costs for the year ended December 31, 2001 were \$3,655,000, as compared to \$2,616,000 for 2000. The increase for 2001 was mainly attributable to the hiring of additional staff commencing in the second half of 2000 through the first half of 2001, including key management personnel in administrative, financial, information technology, and operations functions.

**Other Income** – Other income for the year ended December 31, 2001 was approximately \$3,845,000, as compared to \$3,222,000 for 2000. The increase for 2001 mainly reflected earnings on higher investable cash balances as a result of the \$15,000,000 received from our former marketing partner during the fourth quarter of 2000, and the full year impact of approximately \$40,700,000 in net proceeds received from a private placement of our common stock in March 2000.

**Net Losses** – For the year ended December 31, 2001, we incurred a net loss of approximately (\$7,358,000), or (\$0.53) per share, as compared to (\$6,541,000), or (\$0.49) per share, in 2000. These losses were within management's expectations.

#### Related Party Transactions

Our Vice President of Technology and former Vice President of Business Development are principal shareholders of Lumenetics, Inc., our former light device consultants. During 2000, we paid \$2,000 for certain equipment leased under operating leases from Lumenetics. In 2001, we purchased this equipment for \$52,000. All transactions were executed at prices estimated to be fair market values.

#### Quarterly Results of Operations

The following is a summary of the quarterly results of operations for the years ended December 31, 2002 and 2001, respectively:

	Quarterly Results For Year Ended December 31, 2002			
	March 31	June 30	September 30	December 31
Total revenues	\$1,325,498	\$1,429,978	\$22,565,754	\$162,008
Income (loss) from operations	(3,641,970)	(4,222,468)	15,065,172	(4,683,565)
Net income (loss)	(2,867,551)	(3,437,566)	15,760,873	(3,693,238)
Basic and diluted income (loss) per share	(0.21)	(0.25)	1.13	(0.27)

	Quarterly Results For Year Ended December 31, 2001			
	March 31	June 30	September 30	December 31
Total revenues	\$1,189,960	\$1,516,754	\$1,436,566	\$1,247,456
Loss from operations	(2,354,838)	(2,495,046)	(2,795,961)	(3,557,111)
Net loss	(1,252,060)	(1,563,335)	(1,817,029)	(2,725,672)
Basic and diluted loss per share	(0.09)	(0.11)	(0.13)	(0.20)

## Liquidity and Capital Resources

We are in a strong cash position to continue to fund our research and development activities for our Levulan<sup>®</sup> PDT/PD dermatology platform. Our total assets were \$60,950,000 as of December 31, 2002 compared to \$75,864,000 as of December 31, 2001. This decrease is attributable to the funding of net operating activities during 2002.

As of December 31, 2002, we had inventory of \$1,189,000, representing finished goods and raw materials, as compared to \$2,333,000 as of December 31, 2001. Also, as of December 31, 2002, we had net property and equipment of \$5,230,000, as compared to \$4,148,000 as of December 31, 2001, due primarily to construction costs associated with our new manufacturing facility.

As of December 31, 2002, we had accounts receivable of \$37,000 as compared to \$121,000 as of December 31, 2001, representing net sales associated with Kerastick<sup>®</sup> product sales. In addition, a receivable of \$865,000 had been recorded as a current asset as of December 31, 2001 reflecting an amount reimbursable by our former marketing partner for research and development costs under our agreement. For 2002, based on the termination of this agreement, we received payments for reimbursement of research and development costs to which we were entitled prior to December 31, 2002.

As of December 31, 2002, we had current liabilities of \$3,375,000, as compared to \$3,051,000 as of December 31, 2001. Prior to 2002, we had no long-term debt; however, in May 2002 we entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of our manufacturing facility and borrowed \$1,900,000 of a \$2,700,000 commitment, of which the remaining amount lapsed on June 30, 2002. On August 1, 2002, we commenced monthly loan payments with fixed monthly principal payments of \$22,500 plus interest, which are scheduled to continue through June 30, 2009. Interest in the first year of the loan is based on a 360-day LIBOR-based rate, which resulted in a 4% interest rate for the initial year of the Note. Prior to expiration of the 360-day LIBOR-based rate for each year of the loan, we can either continue to choose a LIBOR-based rate at that time, execute a one-time conversion to a fixed rate loan, or repay the loan balance. As of December 31, 2002, the total outstanding loan balance is \$1,787,500, of which \$270,000 is current. Approximately \$3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan.

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 \$43,180,000, and a current aggregate market value of \$45,815,000 as of December 31, 2002, resulting in a net unrealized gain on securities available for sale of \$2,635,000, which has been included in shareholders' equity. As of December 31, 2001, government securities had an aggregate cost of \$54,917,000 and an aggregate market value of \$57,141,000, resulting in a net unrealized gain of \$2,224,000. Due to fluctuations in interest rates and depending upon the timing of our need to convert government securities into cash to meet our working capital requirements, some gains or losses could be realized. As of December 31, 2002, these securities had interest rates and yields ranging from 3.95% to 7.21% and maturity dates ranging from January 21, 2003 to February 15, 2007. As of December 31, 2001, these securities had interest rates and yields ranging from 4.26% to 7.00% and maturity dates ranging from January 14, 2002 to November 15, 2006.

We believe that we have sufficient capital resources to proceed with our current dermatology research, development, manufacturing, and marketing programs for Levulan<sup>®</sup> PDT, and to fund operations and capital expenditures for the foreseeable future, particularly with the current reduction in research and development spending. 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.

We are currently focusing our near-term research and development efforts on our dermatology development program to treat BAAK. As a result of the termination of our former dermatology collaboration arrangement, we have reevaluated our operations and intend to minimize research and development and related general and administrative expenditures that are not directly related to our core objectives for 2003. We also intend to invest in research, development, manufacturing, and marketing programs for Levulan<sup>®</sup> PDT

in support of our efforts to penetrate the marketplace with our unique Levulan<sup>®</sup> PDT therapy for AKs. We may seek to expand or enhance our business by using resources to acquire by license, purchase or other arrangements, businesses, new technologies, or products, especially in PDT-related areas. However, at this time, we intend to focus primarily on increasing the sales of dermatology products, and on seeking a partner to help develop and market Levulan<sup>®</sup> PDT for the treatment of dysplasia in patients with Barrett's esophagus. Full development and testing of all potential indications would require additional funding. The timing of expenditures will be dependent on various factors, including:

- the level of sales of our first products including the success of our marketing programs based on reacquiring the rights to Levulan<sup>®</sup> PDT,
- progress of our research and development programs,
- the results of preclinical and clinical trials,
- the timing of regulatory marketing approvals,
- competitive developments,
- the results of patent disputes,
- 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 common stock offerings coupled with payments received from our former marketing partner will enable us to maintain our current research program as planned and support the commercialization of Levulan<sup>®</sup> PDT for AKs for the foreseeable future, in order to maintain and expand continuing research and development programs, we may need to raise additional funds through future corporate alliances, financings, or other sources, depending upon the amount of revenues we receive from our first product.

Additionally, we may have to establish a marketing capability, also at significant expense.

As of December 31, 2002, we had 43 full-time employees. Our staffing levels for key management personnel in administrative, financial, technical and operations functions had been established to support the sales levels of Levulan<sup>®</sup> PDT that did not materialize. However, following the reacquisition of our product rights, we downsized our staffing levels by approximately 20%. Also, during the fourth quarter of 2002, both our Vice President of Regulatory Affairs and Vice President of Business Development ended their employment with us; however, they are consulting on a part-time, as-needed, basis. We have employment agreements with our key executive officers. We have purchased and are the named beneficiary of a key man life insurance contract having a face value of CDN \$2,000,000 on the life of our President.

We have incurred certain environmental control costs as part of our development of a production line for Kerastick<sup>®</sup> manufacturing to ensure that our facility complies with environmental standards. We have estimated that the capital costs to develop this facility, including equipment, will be approximately \$2,700,000, most of which has been expended. There can be no assurance, however, that we will not be required to incur significant additional costs to comply with environmental laws and regulations in the future, or any assurance that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations. See section entitled "Business - Government Regulation."

#### **Contractual Obligations and Other Commercial Commitments**

Our contractual obligations and other commercial commitments to make future payments under contracts, such as lease agreements, research and development contracts, manufacturing contracts, or other related agreements are as follows at December 31, 2002 are listed below:

Obligations Due by Period

	<u>Total</u>	<u>1 Year or Less</u>	<u>2-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
Operating lease obligations (1)	\$4,113,000	\$ 401,000	\$882,000	\$810,000	\$2,020,000
Research and development projects (2)	4,200,000	3,433,000	767,000	-	-
Manufacturing facility development (3)	100,000	100,000	-	-	-
Secured term loan promissory note (4)	1,787,500	270,000	540,000	540,000	437,500

- 1) In 2001, we extended our lease for office and manufacturing space in our Wilmington, Massachusetts headquarters through November 2016. We have the ability to terminate the Wilmington lease after the 10<sup>th</sup> year (2011) of the lease by providing the landlord with notice at least 7 1/2 months prior to the date on which the termination would be effective. In August 2002, we entered into a 5 year lease for our new Toronto location. In October 2002, we also entered into a new 5 year lease at our Valhalla location, and have the ability to terminate the Valhalla lease after the 3<sup>rd</sup> year. The operating lease obligations disclosed above include payments for the non-cancelable term of all operating leases.
- 2) We have estimated that the proposed development, including clinical studies relating to a broader Levulan<sup>®</sup> PDT AK treatment, rather than individual AK lesions, to the face and scalp could cost approximately \$2,300,000, with \$1,533,000 and \$767,000 expected to be incurred in 2003 and 2004, respectively. We will be in a better position to estimate this commitment as we work with the FDA to determine the necessary protocols. In addition to the obligations disclosed above, we have contracted with Therapeutics, Inc., a clinical research organization, to manage the clinical development of our products in the field of dermatology. This organization has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000, depending on the regulatory phase of development of products under Therapeutics' management.
- 3) We commenced the construction of a Kerastick<sup>®</sup> manufacturing facility at our Wilmington, Massachusetts location in January 2002. The initial build-out was completed in June 2002, and we commenced facility qualification, process validation, and drug product stability testing, which is expected to take approximately 6 months and be completed in early 2003. FDA review and approval is also expected to take 6 months, with an estimated completion date in late 2003. This review process should commence after the completion of all validation and certain stability activities, as well as the preparation and submission of an NDA supplement. We have estimated that the cost to build and complete testing of this facility, including equipment, will be approximately \$2,700,000. This cost includes estimates to build the facility and all costs of construction, calibration, validation testing and equipment. As of December 31, 2002, the Company has capitalized \$2,596,000 for this facility.
- 4) In May 2002, we entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed \$1,900,000 with fixed monthly principal payments of \$22,500 plus interest, which are scheduled to continue through June 30, 2009.

Recently Issued Accounting Guidance

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment of Disposal of Long-lived Assets." This statement supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." SFAS 144 establishes a single accounting model, based on the framework established in SFAS 121, for long-lived assets to be disposed of by sale, and resolves implementation issues related to SFAS 121. SFAS No. 144 is effective for fiscal years beginning after



December 15, 2001 and interim periods within those fiscal years. On January 1, 2002, DUSA adopted this statement, which had no effect on our financial position or results of operations upon adoption.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect on the method used on reported results. We have determined that we will continue to account for stock-based compensation to employees under the provisions of APB Opinion No. 25 and will make all required disclosures in our financial reports to comply with SFAS 148.

In December 2002, the EITF reached conclusion on EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." This consensus provides guidance in determining when a revenue arrangement with multiple deliverables should be divided into separate units of accounting, and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The provisions of EITF No. 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We will evaluate multiple element arrangements in accordance with this EITF upon its effective date for new arrangements into which it enters.

#### **Inflation**

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

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We hold fixed income United States government securities that are subject to interest rate market risks. However, we do not believe that the risk is material as we make our investments in relatively short-term instruments and we strive to match the maturity dates of these instruments to our cash flow needs. A 10% decline in the average yield of these instruments would reduce interest income by approximately \$258,000 based on our December 31, 2002 balance in U.S. government securities.

We currently have exposure to interest rate risk under a secured term loan promissory note which we issued to fund the construction of our manufacturing facility. Interest on this loan is at a LIBOR-based rate, and calls for an annual renewal on June 30<sup>th</sup> of each year through June 30, 2009 to either the applicable LIBOR-based rate or a one-time conversion to a fixed rate loan. The current loan rate is based on a LIBOR rate of 1.75% (LIBOR is 1.45% at December 31, 2002). Our exposure to interest rate risk due to changes in LIBOR is not expected to be material.

#### **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<sup>®</sup> and its use and potential use, expectations regarding the timing of results of clinical trials and future development of warts, onychomycosis, facial photodamaged skin, acne, Barrett's esophagus dysplasia and other potential indications, intention to pursue licensing, or acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy and marketing, our intention to develop a sales force, hope that our products will be an AK therapy of choice and barriers to achieving that status, beliefs regarding revenues from approved and potential products and Levulan's<sup>®</sup> competitive properties, intention to postpone or commence clinical trials and investigator studies in 2003, expectations of exclusivity under the Hatch/Waxman Act and other patent laws, intentions to seek additional United States and foreign regulatory approvals, trademarks, and to market outside the United

States, beliefs regarding environmental compliance, beliefs concerning patent disputes, the impact of a third-party's regulatory compliance and fulfillment of contractual obligations, plans to monitor cost of product sales, expectations of increases in cost of product sales, expected use of cash resources in 2003, requirements of cash resources for our future liquidity, anticipation of hiring additional personnel, effect of reimbursement policies on revenues, expectations for future strategic opportunities and research and development programs, expectations for continuing operating losses, expectations regarding the adequacy and availability of insurance, stable administrative costs, status of research and development costs, levels of interest income and our capital resource needs, intention to sell securities to meet capital requirements, expectations for completion of our new manufacturing facilities and its expected costs, and anticipated dates for inspection and testing, beliefs regarding the adequacy of our inventory of Kerastick® units, belief regarding interest rate risks to our investments and effects of inflation and new accounting standards, dependence on key personnel, beliefs concerning product liability insurance, intention to continue to develop integrated drug and light device systems, belief that our new facility will help control costs and our principal methods of competition. 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 and foreign regulatory approval, and market acceptance of our products, reliance on third-parties for the production, manufacture, sales and marketing of our products, the securities regulatory process, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Independent Auditors' Report.....	F-1
Consolidated Balance Sheets.....	F-2
Consolidated Statements of Operations.....	F-3
Consolidated Statements of Shareholders' Equity.....	F-4
Consolidated Statements of Cash Flows .....	F-5
Notes to the Consolidated Financial Statements .....	F-7

**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 2003 Proxy Statement.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by Item 11 is hereby incorporated by reference to the sections entitled "Director Compensation," "Executive Compensation," "Board Compensation Committee Report on Executive Compensation," "Performance Graph," "Option Grants in 2002," "Aggregate Option Exercises in 2002 and Option Values at December 31, 2002," and "Other Compensation" of Registrant's 2003 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 and Related Stockholder Matters" of the Registrant's 2003 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 2003 Proxy Statement.

**ITEM 14. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

D. Geoffrey Shulman, our principal executive officer and principal financial officer, has reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 240.13a-14(c) and 15d-14(c)) as of a date within 90 days before the filing date of this annual report. Based on that evaluation, Dr. Shulman has concluded that our current disclosure controls and procedures are effective in timely providing him with material information relating to us which is required to be disclosed in the reports we file or submit under the Exchange Act.

**Changes in Internal Controls**

There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the date we carried out this evaluation.

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K**

A. *List of Financial Statements and Schedules*

	<u>Page Number</u>
INCLUDED IN ANNUAL REPORT TO SHAREHOLDERS INCORPORATED HEREIN BY REFERENCE:	
Independent Auditors' Report.....	F-1
Consolidated Balance Sheets.....	F-2
Consolidated Statements of Operations .....	F-3
Consolidated Statements of Shareholders' Equity .....	F-4
Consolidated Statements of Cash Flows .....	F-5
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Schedules are omitted because they are not required or the information is included in Notes to the Consolidated Financial Statements.

B. *Reports on Form 8-K*

- a) Form 8-K, filed on October 11, 2002, announcing the adoption on September 27, 2002 of a Shareholder Rights Plan and the declaration of a dividend distribution of one preferred share purchase right to each shareholder of record on October 10, 2002.

C. *Exhibits filed as part of this Report*

- 3(a)(i) 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(a)(ii) Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002 and incorporated herein by reference; and
- 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;
- 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;
- 4(c) Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K dated September 27, 2002, filed October 11, 2002, and is incorporated herein by reference; and
- 4(d) Rights Certificate relating to the rights granted to holders of common stock under the Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K, dated September 27, 2002, filed October 11, 2002, and is incorporated herein by reference.
- 10(a) License Agreement between the Company, PARTEQ and Draxis Health Inc. dated August 27, 1991, filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
- 10(b) ALA Assignment Agreement between the Company, PARTEQ, and Draxis Health Inc. dated October 7, 1991, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
- 10(b.1) Amended and Restated Assignment Agreement between the Company and Draxis Health, Inc. dated April 16, 1999, filed as Exhibit 10(b.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
- 10(c) Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated October 1, 1991, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
- 10(d) Amendment to Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated April 14, 1994, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-2, No. 33-98030, and is incorporated hereby by reference;
- 10(e) Amended and Restated License Agreement between the Company and PARTEQ dated March 11, 1998, filed as Exhibit 10(e) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of Exhibit A have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(f) Incentive Stock Option Plan, filed as Exhibit 10.11 of Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;

- 10(g) 1994 Restricted Stock Option Plan, filed as Exhibit 1 to Registrant's Schedule 14A definitive Proxy Statement dated April 26, 1995, and is incorporated herein by reference;
- 10(h) 1996 Omnibus Plan, as amended, filed as Appendix A to Registrant's Schedule 14A Definitive Proxy Statement dated April 26, 2001, and is incorporated herein by reference;
- 10(i) Purchase and Supply Agreement between the Company and National Biological Corporation dated November 5, 1998, filed as Exhibit 10(i) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(j) 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-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(k) Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of September 13, 1999, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated October 14, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(k.1) Amendment to Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of February 15, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(p.1) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, filed on March 15, 2002, and is incorporated herein by reference;
- 10(k.2) Second Amendment to Purchase and Supply Agreement between the Company and North Safety Products, Inc. dated as of July 26, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(p.2) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, filed on March 15, 2002, and is incorporated herein by reference;
- 10(l) Supply Agreement between the Company and Sochinaz SA dated December 24, 1993, filed as Exhibit 10(q) to Registrant's Form 10-K/A filed on March 21, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(l.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 Annual Report on Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
- 10(l.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(m) Master Service Agreement between the Company and Therapeutics, Inc. dated as of October 4, 2001, filed as Exhibit 10(b) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference;

- 10(n) Commercial Loan Agreement, Secured Term Loan Promissory Note and Pledge and Security Agreement between the Company and Citizens Bank of Massachusetts dated May 13, 2002 filed as Exhibit 99.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, filed May 14, 2002, and is incorporated herein;
- 10(o) Collaboration Termination Agreement, effective September 1, 2002, between DUSA and Schering AG, the Company's former marketing partner, filed as Exhibit 10 to Registrant's Current Report on Form 8-K dated August 27, 2002, and is incorporated herein by reference;
- 10(p) Wholesale Distribution Agreement, effective September 1, 2002, between DUSA and Moore Medical Corporation, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, 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) Program Agreement between the Company and Auric Capital Corp. dated April 18, 2002, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, filed on May 14, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(r) License and Development Agreement between DUSA Pharmaceuticals, Inc. and Photonamic GmbH & Co. KG dated as of December 30, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended; and
- 10(s) Supply Agreement between DUSA Pharmaceuticals, Inc. and medac GmbH dated as of December 30, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended.
- 23 Independent Auditors' Consent of Deloitte & Touche LLP.
- 99(a) Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
- 99(b) Press Release dated March 11, 2003.

## 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, 2002 and 2001, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2002. 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, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts  
February 14, 2003

**DUSA PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2002	2001
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 7,064,596	\$ 7,568,500
United States government securities	45,814,947	57,141,125
Accrued interest receivable	699,664	923,459
Accounts receivable	36,720	121,280
Receivable under co-development program	-	864,534
Inventory, net	1,188,659	2,333,080
Prepays and other current assets	915,704	490,925
<b>Total current assets</b>	<u>55,720,290</u>	<u>69,442,903</u>
Property, plant and equipment, net	5,229,683	4,148,311
Deferred charges and royalty	-	2,273,007
<b>TOTAL ASSETS</b>	<u><u>\$60,949,973</u></u>	<u><u>\$75,864,221</u></u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 552,891	\$ 314,889
Accrued payroll	476,602	681,190
Other accrued expenses	2,070,150	1,781,085
Current maturities of long-term debt	270,000	-
Deferred revenue	5,100	273,358
<b>Total current liabilities</b>	<u>3,374,743</u>	<u>3,050,522</u>
Long-term debt, net of current	1,517,500	-
Deferred revenue	-	22,312,498
Other deferred reimbursement	-	666,664
<b>TOTAL LIABILITIES</b>	<u>4,892,243</u>	<u>26,029,684</u>
Commitments and Contingencies (Note 14)		
<b>Shareholders' Equity</b>		
Capital Stock		
Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares.	95,490,561	95,440,561
Issued and outstanding: 13,887,612 (2001: 13,865,390) shares of common stock, no par.		
Additional paid-in capital	2,015,586	2,015,586
Accumulated deficit	(44,082,927)	(49,845,445)
Accumulated other comprehensive income	2,634,510	2,223,835
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<u>56,057,730</u>	<u>49,834,537</u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<u><u>\$ 60,949,973</u></u>	<u><u>\$75,864,221</u></u>

See the accompanying Notes to the Consolidated Financial Statements.



**DUSA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2002	2001	2000
<b>REVENUES</b>			
Product sales and rental income	\$ 319,378	\$ 514,584	\$ 902,154
Research grant and milestone revenue	22,312,498	1,983,336	495,833
Research revenue earned under collaborative agreement	<u>2,851,362</u>	<u>2,892,816</u>	<u>722,570</u>
<b>TOTAL REVENUES</b>	<u>25,483,238</u>	<u>5,390,736</u>	<u>2,120,557</u>
<b>OPERATING COSTS</b>			
Cost of product sales and royalties	5,253,424	2,148,994	1,104,664
Research and development	12,121,606	10,789,906	8,163,419
General and administrative	<u>5,591,039</u>	<u>3,654,792</u>	<u>2,615,502</u>
<b>TOTAL OPERATING COSTS</b>	<u>22,966,069</u>	<u>16,593,692</u>	<u>11,883,585</u>
<b>INCOME (LOSS) FROM OPERATIONS</b>	<u>2,517,169</u>	<u>(11,202,956)</u>	<u>(9,763,028)</u>
<b>OTHER INCOME, NET</b>			
Interest income	2,745,143	3,753,019	3,222,273
Realized gain on sale of United States government securities	<u>500,206</u>	<u>91,841</u>	<u>-</u>
<b>TOTAL OTHER INCOME</b>	<u>3,245,349</u>	<u>3,844,860</u>	<u>3,222,273</u>
<b>NET INCOME (LOSS)</b>	<u>\$ 5,762,518</u>	<u>\$ (7,358,096)</u>	<u>\$ (6,540,755)</u>
<b>BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE</b>	<u>\$ 0.42</u>	<u>\$ (0.53)</u>	<u>\$ (0.49)</u>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING</b>	<u>13,877,566</u>	<u>13,791,735</u>	<u>13,285,472</u>

See the accompanying Notes to the Consolidated Financial Statements.

**DUSA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**

	Common Stock Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
BALANCE, JANUARY 1, 2000	<u>11,908,357</u>	<u>\$51,749,987</u>	<u>\$1,338,854</u>	<u>\$(35,946,594)</u>	<u>\$(82,319)</u>	<u>\$17,059,928</u>
Comprehensive loss:						
Net loss for period				(6,540,755)		(6,540,755)
Net unrealized gain on United States government securities available for sale					1,261,413	1,261,413
Total comprehensive loss						<u>\$(5,279,342)</u>
Issuance of common stock for cash (net of offering costs of \$2,051,714)	1,500,000	40,698,286				40,698,286
Issuance of common stock in connection with supply agreement	26,667	750,000				750,000
Issuance of common stock to consultant	2,500	64,533				64,533
Exercises of options	248,350	1,264,646				1,264,646
Exercises of warrants	45,016	230,080				230,080
Stock based compensation			521,665			521,665
BALANCE, DECEMBER 31, 2000	<u>13,730,890</u>	<u>\$94,757,532</u>	<u>\$1,860,519</u>	<u>\$(42,487,349)</u>	<u>\$1,179,094</u>	<u>\$55,309,796</u>
Comprehensive loss:						
Net loss for period				(7,358,096)		(7,358,096)
Net unrealized gain on United States government securities available for sale (net of realized gains of \$91,841)					1,044,741	1,044,741
Total comprehensive loss						<u>\$(6,313,355)</u>
Issuance of common stock to consultant	5,000	54,750				54,750
Exercises of options	104,500	478,279				478,279
Exercises of warrants	25,000	150,000				150,000
Stock based compensation			155,067			155,067
BALANCE, DECEMBER 31, 2001	<u>13,865,390</u>	<u>\$95,440,561</u>	<u>\$2,015,586</u>	<u>\$(49,845,445)</u>	<u>\$2,223,835</u>	<u>\$49,834,537</u>
Comprehensive income:						
Net income for period				5,762,518		5,762,518
Net unrealized gain on United States government securities available for sale (net of realized gains of \$500,206)					410,675	410,675
Total comprehensive income						<u>6,173,193</u>
Issuance of common stock to consultant	22,222	50,000				50,000
BALANCE, DECEMBER 31, 2002	<u>13,887,612</u>	<u>\$95,490,561</u>	<u>\$2,015,586</u>	<u>\$(44,082,927)</u>	<u>\$2,634,510</u>	<u>\$56,057,730</u>

See the accompanying Notes to the Consolidated Financial Statements.

**DUSA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**

	Year Ended December 31,		
	2002	2001	2000
<b>CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>			
Net income (loss)	\$5,762,518	\$(7,358,096)	\$(6,540,755)
Adjustments to reconcile net income (loss) to net cash used in operating activities			
Amortization of premiums and accretion of discounts on United States government securities available for sale and investment securities, net	(378,089)	738,699	(318,647)
Depreciation and amortization expense	3,247,129	1,066,915	410,473
Amortization of deferred revenue	(22,312,498)	(1,983,336)	(495,833)
Stock based compensation	-	155,067	521,665
Issue of shares of common stock to consultant	50,000	54,750	64,533
Changes in other assets and liabilities impacting cash flows from operations:			
Accrued interest receivable	223,795	66,624	(723,463)
Accounts receivable	84,560	793,679	(914,959)
Receivable under co-development program	864,534	(141,964)	(722,570)
Inventory	1,144,421	(1,001,114)	(1,331,966)
Prepays and other current assets	(424,779)	(190,608)	(429,407)
Deferred charges	(100,000)	(400,000)	-
Accounts payable	238,002	214,389	(16,609)
Accrued payroll and other accrued expenses	84,477	585,224	1,128,910
Income taxes payable	-	-	(90,000)
Deferred revenue	(268,258)	(235,849)	15,509,207
<b>Net cash provided by (used in) operating activities</b>	<u>(11,784,188)</u>	<u>(7,635,620)</u>	<u>6,050,579</u>
<b>CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>			
Purchases of United States government securities	(6,131,356)	(23,282,378)	(50,506,441)
Proceeds from maturing and sales of United States government securities	18,246,298	24,502,758	13,900,000
Purchases of property, plant and equipment	(2,622,158)	(2,833,653)	(1,553,350)
Deposits on equipment	-	98,000	(70,369)
Payment to restructure supplier contract	-	-	(250,000)
Payments to licensor	-	(350,000)	(350,936)
<b>Net cash provided by (used in) investing activities</b>	<u>9,492,784</u>	<u>(1,865,273)</u>	<u>(38,831,096)</u>

See the accompanying Notes to the Consolidated Financial Statements.

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

	Year ended December 31,		
	2002	2001	2000
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>			
Issuance of common stock and underwriters' options, net of offering costs of \$2,051,714 for 2000	-	-	40,698,286
Proceeds from long-term debt	1,900,000	-	-
Payments of long-term debt	(112,500)	-	-
Proceeds from exercise of options and warrants	-	628,279	1,494,727
<b>Net cash provided by financing activities</b>	<b>1,787,500</b>	<b>628,279</b>	<b>42,193,013</b>
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>(503,904)</b>	<b>(8,872,614)</b>	<b>9,412,496</b>
<b>CASH AT BEGINNING OF PERIOD</b>	<b>7,568,500</b>	<b>16,441,114</b>	<b>7,028,618</b>
<b>CASH AT END OF PERIOD</b>	<b>\$7,064,596</b>	<b>\$7,568,500</b>	<b>\$16,441,114</b>
Cash paid for interest	\$ 41,066	-	-
Income tax payments	-	-	\$ 90,000

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

See the accompanying Notes to the Consolidated Financial Statements.

1) NATURE OF BUSINESS

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

2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

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

*d) Cash and Cash Equivalents* – Cash equivalents include short-term highly liquid investments purchased with original maturities of 90 days or less. In December 2001, the Company executed a short-term, renewable, irrevocable and unconditional letter of credit for \$136,018 in lieu of a security deposit for the construction of the Company's Kerastick<sup>®</sup> manufacturing facility at its Wilmington, Massachusetts location. The cash is held in a separate bank account and is recorded in cash and cash equivalents in the Consolidated Balance Sheets. This line of credit was renewed in December 2002 and has a balance of \$137,883 at December 31, 2002.

*e) United States Government Securities* – The Company follows the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." This Statement requires the Company to record securities which management has classified as available for sale at fair market value and to record unrealized gains and losses on securities available for sale as a separate component of shareholders' equity until realized.

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

*f) Inventory* – Inventory is stated at the lower of cost (first-in, first-out method) or market. Inventory consisting of BLU-U<sup>®</sup> commercial light sources is reclassified to property, plant and equipment when the BLU-U<sup>®</sup> is shipped to physicians under rental, leasing, or demonstration programs. Inventory identified for research and development activities is expensed in the period in which that inventory is designated for such use. In September 2002, based on the termination of the

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED  
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Company's former dermatology collaboration arrangement, the Company recorded lower of cost or market adjustments of \$2,095,000 for excess inventory and commercial light units under lease, rental, or trial arrangements to cost of product sales in its Consolidated Statements of Operations for the year ended December 31, 2002. (See "Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.")

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

*h) Deferred Charges and Royalties* – Deferred charges and royalties which include costs paid in advance to third parties under various agreements are amortized over their expected terms. (See "Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.")

*i) Impairment of Long-lived Assets* – The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. When it is determined that the carrying value of long-lived or intangibles assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, the asset is written down to its estimated fair value on a discounted cash flow basis. In September 2002, the Company concluded that the termination of the Company's former dermatology collaboration arrangement did not have any impairment on its manufacturing facility under construction, but did result in impairment adjustments to certain intangible assets. (See "Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.")

*j) Revenue Recognition* – Revenues on product sales of the Kerastick<sup>®</sup> are recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred, and there is reasonable assurance of collection. 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 our collaborator. Based on the termination of the Company's former dermatology collaboration arrangement, the Company recorded \$20,990,000 of research grant and milestone revenue, in addition to normal amortization recorded prior to the termination, in its Consolidated Statements of Operations during the year ended December 31, 2002. (See "Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.")

*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. Purchased technology, including the costs of licensed technology for a particular research project and that do not have alternative future uses, are expensed at the time the costs are incurred.

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

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*m) Basic and Diluted Net Income (Loss) Per Share* – The Company follows the provisions of SFAS No. 128, "Earnings Per Share." Basic net income (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 income (loss) per common share during each of the periods presented in the Statement of Operations, as the effect would be antidilutive. For the years ended December 31, 2002, 2001, and 2000, stock options and warrants totaling approximately 2,553,000, 2,548,000, and 2,340,000 shares, respectively, have been excluded from the computation of diluted net income (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, "Accounting for Stock Issued to Employees," and to provide disclosures based on the fair value method in the Notes to the Consolidated Financial Statements as permitted by SFAS No. 123. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which is generally the vesting period.

As described above, 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 income (loss) and net income (loss) per share would have been reported as follows:

	2002	2001	2000
<b>Net Income (loss)</b>			
As reported	\$5,762,518	(\$7,358,096)	(\$6,540,755)
Effect on net income (loss) if fair value method had been used	(3,880,231)	(5,635,208)	(5,606,977)
Proforma	\$1,882,287	(\$12,993,304)	(\$12,147,732)
<b>Basic and diluted net income (loss) per common share</b>			
As reported	\$0.42	(\$0.53)	(\$0.49)
Effect on net income (loss) per common share if fair value method had been used	(0.28)	(0.41)	(0.42)
Proforma	\$0.14	(\$0.94)	(\$0.91)

DUSA PHARMACEUTICALS, INC.

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

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Expected life (years)	7	7	10
Risk free interest rate	4.89%	4.88%	5.76%
Expected volatility	72.84%	70.87%	74.55%
Dividend yield	-	-	-

Using these assumptions, the weighted-average fair value per option for the years ended December 31, 2002, 2001, and 2000, was \$2.53, 10.29 and \$23.07, respectively.

*o) Comprehensive Income* – The Company has reported comprehensive income (loss) and its components as part of its Consolidated Statement of Shareholders' Equity. The only element of comprehensive income, apart from net income (loss), relates to unrealized gains or losses on United States government securities.

*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. The fair market value of the Company's long-term debt is estimated based on quoted market prices of similar issues having a similar remaining maturity. The carrying value of the Company's long-term debt approximates its market value.

*r) Concentration of Credit Risk* – The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company is subject to credit risk through short-term investments and mitigates this risk by investing in United States government securities.

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

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect on the method used on reported results. The Company has determined



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that it will continue to account for stock-based compensation to employees under the provisions of APB Opinion No. 25 and will make all required disclosures in its financial reports to comply with SFAS 148.

In December 2002, the EITF reached conclusion on EITF Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." This consensus provides guidance in determining when a revenue arrangement with multiple deliverables should be divided into separate units of accounting, and, if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. The provisions of EITF No. 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company will evaluate multiple element arrangements in accordance with this EITF upon its effective date for new arrangements into which it enters.

**3) TERMINATION OF DERMATOLOGY COLLABORATION AGREEMENT**

On September 1, 2002, DUSA and Schering AG, the Company's former marketing and development partner for Levulan<sup>®</sup> PDT in the field of dermatology, terminated the parties' marketing, development and supply agreement, dated November 22, 1999. As a result of this termination, DUSA reacquired all rights it granted to Schering AG under the agreement. In addition, Schering AG agreed to continue its financial support for the dermatology research and development program for the remainder of 2002, including cash payments totaling \$2,050,000, which were received prior to December 31, 2002.

Because of this termination, DUSA evaluated certain items in its Consolidated Balance Sheet for the timing of revenue recognition and potential impairment as a result of the termination of the Company's former dermatology collaboration arrangement. These items included (i) the unamortized deferred revenue related to non-refundable milestone payments previously received under the Schering AG agreement and (ii) approximately \$6,950,000 in assets including the Company's nearly completed manufacturing facility, raw material and finished goods inventories, commercial light units in the field, and deferred charges and royalties. As a result of this analysis, in addition to normal amortization recorded prior to the termination, the Company recorded the following items in its financial statements for the year ended December 31, 2002:

<u>Statement of Operations Item</u>	<u>Balance Sheet Item</u>	<u>Revenue Recognition / Asset Impairment</u>	<u>Footnote Reference</u>
<u>Revenues:</u>			
Research grant and milestone revenue	Deferred revenue	\$20,990,274	Note 10
<u>Operating Costs:</u>			
Cost of product sales	Deferred charges	\$ 542,766	Note 7
	Inventory	1,705,364	Note 5
	BLU-U <sup>®</sup> units under lease or rental	389,647	Note 6
Research and development costs	Deferred royalty	639,051	Note 7
Total Charges to Operating Costs		\$ 3,276,828	

After considering the effects of the change in business circumstances caused by the termination of the Company's former dermatology collaboration arrangement, the Company also concluded that the carrying value of its nearly completed manufacturing facility is more likely than not fully recoverable. Therefore, no impairment charges were recorded in 2002; however, the Company will continue to periodically review the carrying value of the facility.

DUSA PHARMACEUTICALS, INC.

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All amounts under the co-development reimbursement have been received as of December 31, 2002, and based on the termination of the Company's former dermatology collaboration arrangement there will be no co-development reimbursement subsequent to 2002.

In December 1999, under the terms of the marketing, development and supply agreement, DUSA received \$15,000,000, reflecting an \$8,750,000 cash milestone payment and \$6,250,000 for which a Schering AG affiliate purchased 340,458 shares of DUSA's common stock. In December 2000, the Company received an additional \$15,000,000 from Schering AG that reflected an unrestricted research grant of \$8,000,000 for future research and development support to be used at DUSA's discretion, and a milestone payment of \$7,000,000 based on receiving FDA approval of the commercial model of the BLU-U<sup>®</sup> and the first commercial sale of a Levulan<sup>®</sup> Kerastick<sup>®</sup>. The Company also received royalties and supply fees from Schering AG based upon the sales levels of the Kerastick<sup>®</sup>. Effective September 1, 2002, such royalty and supply fees have ceased based on the termination of the Company's former dermatology collaboration arrangement.

The milestone payments of \$15,750,000, the \$8,000,000 for future research and development support, and the premium on the issuance of shares, \$1,041,667, were initially recorded as deferred revenue and were being recognized over the term of the agreement, approximately 12 years. However, the unamortized deferred revenue of \$20,990,000 as of September 1, 2002 was recognized in revenue based on the termination of the Company's former dermatology collaboration arrangement as noted in the above table.

The marketing, development and supply agreement would have terminated on a product-by-product basis in each country in the territory on the later of (i) 12½ 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.

On September 26, 2001, DUSA and Schering AG amended the now terminated marketing, development and supply agreement. With the execution of this amendment, Schering AG and its United States affiliate, Berlex Laboratories, Inc., agreed to reimburse DUSA \$1,000,000 for costs DUSA incurred to modify its manufacturing agreement with North Safety Products, Inc. ("North"), the manufacturer of the Company's Kerastick<sup>®</sup> brand applicator. This amount was reported in deferred liabilities and recognized in 2002 as an offset to cost of product sales on a straight-line basis over the term of the amendment.

4) UNITED STATES GOVERNMENT SECURITIES

Securities available for sale consist of United States Treasury Bills, Notes, and other United States government securities with yields ranging from 3.95% to 7.21% and maturity dates ranging from January 21, 2003 to February 15, 2007. The fair market value and cost basis on such securities were as follows as of December 31, 2002 and 2001:

	2002	2001
Fair market value	\$45,814,947	\$57,141,125
Cost basis	43,180,437	54,917,290

Net unrealized gains on such securities for the years ended December 31, 2002 and 2001 were \$410,675 and \$1,044,741, respectively, and have been recorded in accumulated other comprehensive income, which is reported as part of shareholders' equity in the Consolidated Balance Sheets.

**DUSA PHARMACEUTICALS, INC.**  
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**5) INVENTORY**

Inventory consisted of the following at December 31, 2002 and 2001:

	<u>2002</u>	<u>2001</u>
Finished goods	\$1,047,941	\$2,013,799
Raw materials	140,718	319,281
	<u>\$1,188,659</u>	<u>\$2,333,080</u>

DUSA had built up significant inventory levels to support sales effort by Schering AG. However, in September 2002, the Company recorded lower of cost or market adjustments for excess BLU-U<sup>®</sup> inventory of \$1,594,000, and \$111,000 for bulk Levulan<sup>®</sup> based on (i) the termination of the Company's former dermatology collaboration arrangement, (ii) limited product sales since the September 2000 product launch, and (iii) the Company's expectation of no significant near-term increases in Kerastick<sup>®</sup> sales levels and/or BLU-U<sup>®</sup> placements. The inventory charges were recorded in cost of product sales and royalties in the Company's Consolidated Statements of Operations for the year ended December 31, 2002. (See "Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.")

**6) PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consisted of the following at December 31, 2002 and 2001:

	<u>Useful Lives (Years)</u>	<u>2002</u>	<u>2001</u>
Computer equipment and software	3	\$1,856,540	\$1,703,482
BLU-U <sup>®</sup> units in physicians' offices	3	945,436	832,964
Furniture, fixtures and equipment	5	523,831	517,465
Manufacturing equipment	5	1,447,087	1,334,769
Leasehold improvements	Term of lease	666,344	627,109
Construction work-in-progress	-	2,596,492	397,783
		<u>8,035,730</u>	<u>5,413,572</u>
Accumulated depreciation and amortization		<u>(2,806,047)</u>	<u>(1,265,261)</u>
		<u>\$5,229,683</u>	<u>\$ 4,148,311</u>

Depreciation expense totaled \$1,540,786, \$715,734, and \$281,516 for 2002, 2001, and 2000, respectively.

In September 2002, the Company shortened the useful life of its BLU-U<sup>®</sup> units under lease, rental, or trial arrangements to reflect a three-year asset life, and recorded an additional \$390,000 of depreciation expense. This accelerated depreciation policy is attributed to the low level of BLU-U<sup>®</sup> placements to date, the termination of the Company's former dermatology collaboration arrangement, including the decision not to launch the BLU-U<sup>®</sup> in non-US markets (except possibly Canada and/or Brazil) at this time, and management's expectations that near-term placements will be limited. The

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additional depreciation expense was recorded in cost of product sales and royalties in the Company's Consolidated Statements of Operations for the year ended December 31, 2002. (See "Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.")

Construction work-in-process includes our Kerastick<sup>®</sup> Manufacturing Line that is currently planned to be put in service in late 2003 or early 2004 with a useful live of approximately 15 years.

7) DEFERRED CHARGES AND ROYALTIES

In September 2002, based on the termination of the Company's former dermatology collaboration arrangement, the Company charged (i) \$509,000 to cost of product sales and royalties for deferred charges associated with its amended Supply Agreement with Sochinaz SA, the manufacturer of the bulk drug ingredient used in Levulan<sup>®</sup>, (ii) \$33,000 to cost of product sales and royalties for deferred charges associated with underutilization costs paid to National Biological Corporation ("NBC"), the manufacturer of our BLU-U<sup>®</sup>, and (iii) \$639,000 to research and development costs for deferred royalties associated with payments to PARTEQ, the Company's licensor. These amounts represented the unamortized balances of previously deferred costs which were being amortized over periods ranging from 1 to 12- years.

Deferred charges and deferred royalties, which include costs paid in advance to third parties under various agreements were being amortized on a straight-line basis over the initial expected terms, were as follows as of December 31, 2001 (there were no outstanding deferred charges as of December 31, 2002):

	<u>2001</u>
Deferred Charges	
Facilities underutilization costs	\$ 933,333
Facilities reimbursement costs	660,375
Deferred Royalty	<u>679,299</u>
Total Deferred Charges and Royalty	<u>\$2,273,007</u>

8) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following at December 31, 2002 and 2001:

	<u>2002</u>	<u>2001</u>
Accrued research and development costs	\$473,543	\$795,347
Accrued product related costs	463,340	689,857
Accrued license milestone	500,000	-
Accrued legal and other professional fees	297,966	146,199
Accrued employee benefits	207,833	55,576
Other accrued expenses	127,468	94,106
	<u>\$2,070,150</u>	<u>\$1,781,085</u>

**DUSA PHARMACEUTICALS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED**  
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**9) LONG-TERM DEBT**

Long-term debt consisted of the following as of December 31, 2002 (there was no long-term debt as of December 31, 2001):

	<u>2002</u>
Secured term loan promissory note	\$1,787,500
Less: Current maturities	(270,000)
	<u>\$1,517,500</u>

In May 2002, DUSA entered into a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed \$1,900,000 of a \$2,700,000 commitment. The remaining unused amount of the commitment lapsed on June 30, 2002. DUSA made only interest payments at the prime rate through July 1, 2002, and on August 1, 2002 commenced monthly loan repayments with fixed monthly principal amounts of \$22,500 plus interest, which are scheduled to continue through June 30, 2009. Based on the terms of the Note, the Company had an option to select a fixed rate or a rate at the LIBOR interest rate plus 1.75%, for varying LIBOR periods. The Company selected a 360-day LIBOR-based rate that resulted in a 4% interest rate for the initial year of the Note. Prior to expiration of the 360-day LIBOR-based rate for each year of the loan, DUSA can either continue to choose a LIBOR-based rate at that time, execute a one-time conversion to a fixed rate loan, or repay the loan balance. The Company capitalized approximately \$47,000 of interest in 2002 related to the Note. Approximately \$3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan. Principal payments due in each of the next five years amount to \$270,000 per year.

**10) DEFERRED REVENUE**

In September 2002, based on the termination of the Company's former dermatology collaboration arrangement, the Company accelerated the recognition of \$20,990,000 of previously unamortized research grant and milestone revenue, in addition to normal amortization recorded prior to the termination, in the Company Consolidated Statements of Operations for the year ended December 31, 2002. (See "Note 3 to the Notes to the Consolidated Financial Statements - Termination of Dermatology Collaboration Agreement.")

Deferred revenue, both short and long-term, consisted of the following at December 31, 2002 and 2001:

	<u>December 31,</u> <u>2002</u>	<u>December 31,</u> <u>2001</u>
Milestone and unrestricted grant payments	\$ -	\$22,312,498
Lease or rental of BLU-U <sup>®</sup> units	-	273,358
Sale of Levulan <sup>®</sup> Kerastick <sup>®</sup> units	5,100	-
	<u>\$5,100</u>	<u>\$22,585,856</u>

Effective September 1, 2002, DUSA engaged a third-party distributor to be its exclusive distributor of the Levulan<sup>®</sup> Kerastick<sup>®</sup> in the United States. The Company has recorded \$5,100 of deferred revenue for Kerastick<sup>®</sup> units sold to the distributor as the price was not fixed and final, since the distributor has a right of return on Kerastick<sup>®</sup> units. (See "Note [15] 16 to the Notes to the Consolidated Financial Statements - Third-Party Distribution Agreement".)

DUSA PHARMACEUTICALS, INC.  
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During the first half of 2002, deferred revenue of \$273,000 related to the sale of BLU-U<sup>®</sup> units was reclassified to other accrued expenses, then repaid to a third party.

11) INCOME TAXES

The tax effect of significant temporary differences representing deferred tax assets and liabilities at December 31, 2002 and 2001 is as follows:

	<u>2002</u>	<u>2001</u>
<b>Deferred Tax Assets</b>		
Deferred revenue	\$ 2,000	\$ 9,484,000
Intangible assets	588,000	652,000
Accrued charges	46,000	17,000
Research and development tax credits carryforwards	2,144,000	1,394,000
Operating loss carryforwards	18,253,000	10,854,000
Capital loss carryforwards	1,000	1,000
Charitable contribution carryforward	4,000	4,000
Deferred Charges	405,000	-
License fee	202,000	-
Reserves	823,000	-
Total deferred tax assets	<u>22,468,000</u>	<u>22,406,000</u>
<b>Deferred Tax Liabilities</b>		
Deferred charges	-	(79,000)
Fixed assets	(8,000)	(58,000)
Total deferred tax liabilities	<u>\$ (8,000)</u>	<u>\$ (137,000)</u>
Net deferred tax assets before allowance	22,460,000	2,269,000
Valuation allowance	(22,460,000)	(22,269,000)
Total deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

During the years ended December 31, 2002, 2001, and 2000, the valuation allowance was increased by approximately \$191,000, \$4,372,000, and \$2,631,000, respectively, due to the uncertainty of future realization of the net deferred tax assets.

Included in deferred tax assets at December 31, 2002 and 2001 is \$1,600,000 in both years of future benefits which, if realized, will be credited to additional paid in capital rather than results of operations.

**DUSA PHARMACEUTICALS, INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED  
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As of December 31, 2002, the Company has Federal net operating loss carryforwards for tax purposes of approximately \$45,125,000 and research and development tax credits of approximately \$1,605,000, both of which, if not utilized, will expire for Federal tax purposes as follows:

	Operating loss carryforwards	Research and development tax credits
2006	\$ -	\$ 7,000
2007	-	57,000
2008	-	66,000
2009	-	84,000
2010	-	44,000
2011	2,325,000	102,000
2012	6,638,000	235,000
2013	6,841,000	-
2018	5,738,000	145,000
2019	1,000	81,000
2020	28,000	159,000
2021	8,934,000	284,000
2022	14,620,000	341,000
	<u>\$45,125,000</u>	<u>\$1,605,000</u>

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

	2002		2001		2000	
	\$	%	\$	%	\$	%
Income tax expense (benefit) at statutory rates	1,959,000	34.0	(2,502,000)	(34.0)	(2,205,000)	(34.0)
State taxes	371,000	6.4	(500,000)	(6.8)	(425,000)	(6.5)
(Increase) decrease in tax credit carryforwards	(603,000)	(10.5)	(335,000)	(4.6)	38,000	0.5
Change in valuation allowance including revisions of prior year estimates	(1,737,000)	(30.1)	3,265,000	44.4	2,631,000	40.6
Other	10,000	0.2	72,000	1.0	(39,000)	(0.6)
	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>

**12) SHAREHOLDERS' EQUITY**

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<sup>®</sup>. As partial consideration for the amendment, DUSA issued 26,667 unregistered shares of DUSA's Common Stock, at a fair market value of \$750,000.

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 were recorded as part of general and administrative costs in the Consolidated Statements of Operations.

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

On June 15, 2002, the Company granted 22,222 shares of unregistered common stock, without par value, pursuant to an agreement for services to Therapeutics, Inc. These shares were valued at \$50,000 in 2002, and were recorded in research and development expense in the Consolidated Statement of Operations.

On September 27, 2002, the Company adopted a shareholder rights plan (the "Rights Plan") at a special meeting of the Board of Directors. The Rights Plan provides for the distribution of one right as a dividend for each outstanding share of common stock of the Company to holders of record as of October 10, 2002. Each right entitles the registered holder to purchase one one-thousandths of a share of preferred stock at an exercise price of \$37.00 per right. The rights will be exercisable subsequent to the date that a person or group either has acquired, obtained the right to acquire, or commences or discloses an intention to commence a tender offer to acquire, 15% or more of the Company's outstanding common stock (or 20% of the outstanding common stock in the case of a shareholder or group who beneficially held in excess of 15% at the record date), or if a person or group is declared an Adverse Person, as such term is defined in the Rights Plan. The rights may be redeemed by the Company at a redemption price of one one-hundredth of a cent per right until ten days following the date the person or group acquires, or discloses an intention to acquire, 15% or 20% or more, as the case may be, of the Company, or until such later date as may be determined by the Board.

Under the Rights Plan, if a person or group acquires the threshold amount of common stock, all holders of rights (other than the acquiring shareholder) may, upon payment of the purchase price then in effect, purchase shares of common stock having a value of twice the purchase price. In the event that the Company is involved in a merger or other similar transaction where it is not the surviving corporation, all holders of rights (other than the acquiring shareholder) shall be entitled, upon payment of the purchase price then in effect, to purchase common stock of the surviving corporation having a value of twice the purchase price. The rights will expire on October 10, 2012, unless previously redeemed. The Board has adopted certain amendments to the Company's Certificate of Incorporation consistent with the terms of the Rights Plan.

### 13) STOCK OPTIONS AND WARRANTS

*a) 1996 Omnibus Plan* – The 1996 Omnibus Plan ("Omnibus Plan"), as amended, provides for the granting of awards to purchase up to a maximum of 20% of the Company's common stock outstanding or a maximum of 2,753,328. The Omnibus Plan is administered by a committee ("Committee") established by the Board of Directors. The Omnibus Plan enables the Committee to grant non-qualified stock options ("NQSO"), incentive stock options ("ISO"), stock appreciation rights ("SAR"), restricted stock ("RS"), or other securities determined by the Company, to directors, employees and consultants. To date, the Company has made awards of NQSOs, ISOs, and RSs under the Omnibus Plan.

*Non-qualified stock options* – All the NQSOs 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 initially grants each individual who agrees to become a director 15,000 NQSO to purchase common stock of the Company. These initial grants vest annually over a four-year period and, thereafter, each director reelected at an Annual Meeting of Shareholders will automatically receive an additional 10,000 NQSO on June 30 of each year except for 2001, for



DUSA PHARMACEUTICALS, INC.

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which each director received 5,000 NQSO based on an agreement at the June 14, 2001 shareholder meeting. These grants immediately vest on the date of the grant.

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

The following table summarizes information about all stock options outstanding at December 31, 2002:

Range of exercise price	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
	Number outstanding at December 31, 2002	Weighted average remaining contractual life	Weighted average exercise price	Number exercisable at December 31, 2002	Weighted average exercise price
\$2.90 to 6.38	731,700	6.19 years	\$ 5.11	501,700	\$ 5.34
6.69 to 8.63	463,750	3.34 years	7.67	463,750	7.67
9.25 to 15.64	462,000	6.19 years	11.80	365,626	11.37
15.75 to 27.31	275,125	7.63 years	23.65	168,000	23.75
31.00 to 31.00	<u>320,500</u>	7.18 years	31.00	<u>167,750</u>	31.00
	<u>2,253,075</u>	5.92 years	12.95	<u>1,666,826</u>	11.75

Activity under stock option plans during the years ended December 31, 2002, 2001 and 2000 was as follows:

	2002	Weighted average exercise price	2001	Weighted average exercise price	2000	Weighted average exercise price
Options outstanding, beginning of year	2,197,450	\$14.30	2,140,450	\$13.54	1,757,800	\$7.58
Options granted	275,000	3.65	215,500	14.53	641,500	28.44
Options exercised	-	-	(104,500)	5.95	(188,350)	5.57
Options cancelled	<u>(219,375)</u>	<u>14.67</u>	<u>(54,000)</u>	<u>7.66</u>	<u>(70,500)</u>	<u>16.38</u>
Options outstanding, end of year	<u>2,253,075</u>	<u>\$12.95</u>	2,197,450	<u>\$14.30</u>	<u>2,140,450</u>	<u>\$13.54</u>
Options exercisable, end of year	<u>1,666,826</u>	<u>\$11.75</u>	<u>1,364,700</u>	<u>\$10.97</u>	<u>1,195,013</u>	<u>\$8.36</u>

Options that were granted during 2002, 2001 and 2000 have exercise prices ranging from \$2.90 to \$4.01 per share, \$8.05 to \$17.63 per share, and \$16.88 to \$31.00 per share, respectively.

There were no option exercises in 2002. Options which were exercised during 2001 and 2000 were exercised at per share prices ranging from \$3.25 to \$7.25, and \$3.25 to \$11.50, respectively.

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 were recorded as part of general and administrative costs in the Consolidated Statements of Operations. These options expired in 2001.

On October 21, 1997, the Company issued 85,000 options to PARTEQ. These options were valued at approximately \$155,000 and \$496,000 in 2001 and 2000, respectively and recorded as part of research and development costs in the Consolidated Statements of Operations in accordance with EITF 96-18. As of December 31, 2002, all of these options remained outstanding.

Also as discussed in Note 14(a), on June 23, 1999, the Company issued 10,000 options to PARTEQ. As of December 31, 2002, all of these options remained outstanding.

*b) Warrants* – On January 17, 2002, the Company extended the term of 300,000 Class B warrants, which were previously issued to the Chief Executive Officer of the Company, from January 29, 2002 to January 29, 2007. 50,000 of the Class B warrants lapsed. No compensation expense resulted from the extension of these warrants as the intrinsic value of these warrants at the date of extension was zero. As of December 31, 2002, 300,000 of the remaining warrants were outstanding. The exercise price of the warrants is CDN \$6.79 (U.S. \$4.30 at December 31, 2002).

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

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

In 1999 the Company issued 163,043 warrants as commission to a placement agent with an exercise price of \$5.00 per share. As of December 31, 2002 and 2001, 449 of the warrants were outstanding and expire in 2004.

#### 14) COMMITMENTS AND CONTINGENCIES

*a) PARTEQ Agreements* – The Company licenses certain patents underlying its Levulan<sup>®</sup> 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, 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, 2002, 2001 and 2000, actual royalties based on product sales were approximately \$12,200, \$3,300, and \$5,800, respectively, however, based on the minimum royalty requirements, the Company incurred a total liability of \$64,000, \$63,000 and \$68,000 in 2002, 2001, and 2000, respectively, which has been recorded in cost of product sales and royalties. Commencing with the initial product launch, annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$64,000 as of December 31, 2002).

DUSA PHARMACEUTICALS, INC.

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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.

*b) Lease Agreements* – The Company has entered into lease commitments for office space in Wilmington, Massachusetts, Valhalla, New York, and Toronto, Ontario including an extended lease commitment in 2001 for its office and manufacturing space in its Wilmington headquarters through November 2016. The Company has the ability to terminate the Wilmington lease after the 10<sup>th</sup> year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. Commencing in August 2002, the Company entered into a new 5 year lease commitment for its Toronto location. In October 2002, the Company also entered into a 5 year extended lease commitment at its Valhalla location. The minimum lease payments disclosed below include the non-cancelable term of the lease. Future minimum lease payments related to these agreements for years subsequent to December 31, 2002 are as follows:

	<u>Minimum Lease Payments</u>
2003	\$ 401,000
2004	417,000
2005	465,000
2006	400,000
2007	410,000
Beyond 2007	<u>2,020,000</u>
	<u>\$4,113,000</u>

Rent expense incurred under these operating leases was approximately \$458,000, \$461,000, and \$297,000 for the years ended December 31, 2002, 2001, and 2000, respectively.

*c) Research Agreements* – The Company has entered into a series of agreements for research projects and clinical studies. As of December 31, 2002, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$3,433,000 and \$767,000 for 2003 and 2004, respectively. On October 4, 2001, the Company executed a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years to engage Therapeutics to manage the clinical development of the Company's products in the field of dermatology. Minimum payments under this agreement have been included in the total future payments as noted above. Upon execution of this agreement, Therapeutics received 5,000 shares of the Company's common stock valued at \$55,000, received an additional grant of 22,222 shares valued at \$50,000. Therapeutics has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000 depending on the regulatory phase of development of products during Therapeutics' management.

*d) Legal Matters* – In April 2002, DUSA received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, which was provided to us by PARTEQ, alleging that Australian Patent No. 624985 is invalid. Australian Patent No. 624985 is one of the patents licensed by PARTEQ to DUSA, relating to the Company's 5-aminolevulinic acid technology. As a consequence of this action, Queen's University has assigned the Australian patent to DUSA so that DUSA may participate directly in this litigation. DUSA has filed an answer setting forth its defenses and a related countersuit alleging that PhotoCure's activities infringe the patent. The case is in its earliest stages so the Company is unable to predict the outcome at this time.

15) LICENSE AND SUPPLY AGREEMENTS

On December 30, 2002, DUSA entered into a License and Development Agreement with Photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company, and a supply agreement with medac. These agreements provide for the licensing to DUSA of Photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. Based on the license agreement, DUSA will make a non-refundable \$500,000 milestone payment to Photonamic in 2003. This liability was charged to research and development costs in the Consolidated Statement of Operations in 2002, and is included in other accrued expenses in the Consolidated Balance Sheet at December 31, 2002. The Company may also be obligated to pay certain regulatory milestones and royalties on net sales of a brain cancer product under the terms of the License and Development Agreement, and will purchase product under the supply agreement for mutually agreed upon indications. Should Photonamic's clinical study be successful, DUSA will be obligated to proceed with development of the product in the United States in order to retain the license for the use of the technology to treat brain cancer. Such additional obligations are undeterminable at this time.

16) THIRD-PARTY DISTRIBUTION AGREEMENT

Effective September 1, 2002, DUSA engaged Moore Medical Corporation, a national distributor and marketer of medical and surgical supplies, to be its exclusive distributor of the Kerastick<sup>®</sup> in the United States. The agreement has a one-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, either party may terminate the agreement earlier, on certain terms, or in the event that the other party shall have materially breached any of its obligations in the agreement. Moore has a right to return its inventory of Kerastick<sup>®</sup> units for full credit for a period of time prior to and after the expiration date of the agreement. Accordingly, DUSA recognizes product sales when Moore sells the Kerastick<sup>®</sup> to the end-user as the price is fixed and final to Moore at that point.

17) RELATED PARTY TRANSACTIONS

The Company's Vice President of Technology and former Vice President of Business Development are principal shareholders of Lumenetics, Inc., the Company's former light device consultants. During 2000, the Company paid \$2,000 for certain equipment leased under operating leases from Lumenetics. In 2001, the Company purchased this equipment for \$52,000.

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 11, 2003

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

<u>/s/D. Geoffrey Shulman</u> D. Geoffrey Shulman, MD, FRCPC	Director, Chairman of the Board, President, Chief Executive Officer, (Principal Executive Officer), Chief Financial Officer (Principal Financial and Accounting Officer)	<u>March 11, 2003</u> Date
<u>/s/Mark C. Carota</u> Mark C. Carota	Vice President, Operations	<u>March 11, 2003</u>
<u>/s/Scott L. Lundahl</u> Scott L. Lundahl	Vice President, Technology	<u>March 11, 2003</u>
<u>/s/Stuart L. Marcus</u> Stuart L. Marcus, MD, PhD	Vice President, Scientific Affairs	<u>March 11, 2003</u>
<u>/s/Paul A. Sowyrda</u> Paul A. Sowyrda	Vice President, Product Development and Marketing	<u>March 11, 2003</u>
<u>/s/John H. Abeles</u> John H. Abeles	Director	<u>March 11, 2003</u>
<u>/s/David Bartash</u> David Bartash	Director	<u>March 11, 2003</u>
<u>/s/Jay M. Haft</u> Jay M. Haft, Esq.	Director	<u>March 11, 2003</u>
<u>/s/Richard C. Lufkin</u> Richard C. Lufkin	Director	<u>March 11, 2003</u>

DUSA PHARMACEUTICALS, INC.

CERTIFICATIONS

I, D. Geoffrey Shulman, certify that:

1. I have reviewed this annual report on Form 10-K of DUSA Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 11, 2003

/s/ D. Geoffrey Shulman

D. Geoffrey Shulman

Director, Chairman of the Board, President, Chief  
Executive Officer (principal executive officer), Chief  
Financial Officer (principal financial and accounting  
officer)

**Directors**

D. Geoffrey Shulman, MD, FRCPC  
John H. Abeles, MD  
David M. Bartash  
Jay M. Haft, Esq.  
Richard C. Lufkin

**Officers**

D. Geoffrey Shulman, MD, FRCPC  
President

Mark Carota  
VP Operations

Scott Lundahl  
VP, Technology and Device Development

Stuart Marcus, MD, PhD  
VP, Scientific Affairs and Chief Medical Officer

Paul Sowyrda, MBA  
VP, Marketing and Sales

Nanette W. Mantell, Esq.  
Secretary

**Annual Meeting**

The annual meeting of shareholders will be held at the offices of DUSA Pharmaceuticals, Inc., 25 Upton Drive, Wilmington, MA on Thursday, June 19, 2003 commencing at 11:00 a.m. Formal notice of the meeting, together with the proxy statement and a form of proxy, will be mailed to each shareholder of record who is a shareholder on the record date, i.e., April 24, 2003.

**Form 10-K**

For regulatory purposes in the United States, the Company files an annual report on Form 10-K. A copy is enclosed herewith, which has been modified and reformatted from the original version filed with the SEC for printing purposes only. Additional copies may be obtained by any shareholder without charge upon request to the Company, 555 Richmond Street West, Suite 300, P.O. Box 704, Toronto, Ontario M5V 3B1.

**Stock Listings**

DUSA Pharmaceuticals, Inc. common stock is listed on the NASDAQ Stock Market.

NASDAQ ticker symbol: DUSA

**Transfer Agent and Registrar**

American Stock Transfer & Trust Company  
59 Maiden Lane  
New York, NY 10038  
212.936.5100 telephone

Please direct inquiries to:

Shari Lovell  
Director, Shareholder Services  
DUSA Pharmaceuticals, Inc.  
555 Richmond Street West, Suite 300, P.O. Box 704,  
Toronto, Ontario M5V 3B1  
416.363.5059 telephone  
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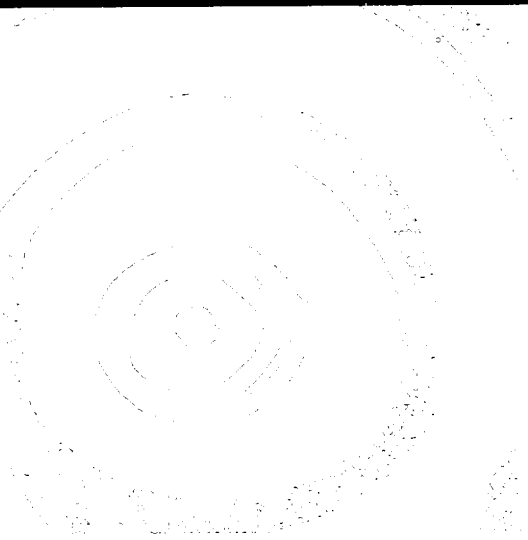
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