DUSA PHARMACEUTICALS INC
Form 10-K
March 16, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2003

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

NEW JERSEY	22-3103129
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer)

25 Upton Drive Wilmington, Massachusetts	01887
(Address of Principal Executive Offices)	(Zip Code)

Commission File Number: 0-19777

Registrant's telephone number, including area code: (978) 657-7500

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

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

Common Stock, 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 |X| 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 |X|

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 $20,809,257.

The number of shares of common stock outstanding of the Registrant as of March 10, 2004 was 16,391,372.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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 28 through 41, 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

DUSA is 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, Levulan(R) brand of aminolevulinic acid HCl, or ALA, with light, for use in a broad range of medical conditions. When we use Levulan(R) and follow it with exposure to light to treat a medical condition, it is known as Levulan(R) photodynamic therapy, or Levulan(R) PDT. When we use Levulan(R) and follow it with exposure to light to detect medical conditions it is known as Levulan(R) photodetection, or

Levulan(R) PD.

Our products, the Levulan(R) Kerastick(R) 20% Topical Solution with PDT and the BLU-U(R) brand light source were launched in the United States in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp under a marketing, development and supply agreement with Schering AG, our former marketing collaborator. 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. In addition, in September 2003 we received clearance from the FDA to market the BLU-U(R) without Levulan(R) PDT for the treatment of moderate inflammatory acne vulgaris.

In September 2002, DUSA reacquired all marketing and product rights from Schering AG when the parties terminated their marketing, development and supply agreement. Consequently, DUSA commenced marketing its products directly in January 2003, and is wholly responsible for all regulatory, sales, marketing, customer service, and other related product activities.

As a result of reacquiring our product rights, we evaluated our expenses and increased the level of marketing and sales activities, while minimizing expenditures that were not directly related to our core objectives for 2003. We have incurred significant marketing and sales expenses in 2003, including the costs associated with the launching of our initial sales force and other related marketing activities. See section entitled "Business-Marketing and Sales". At this time, our objectives include focusing on increasing the sales of our approved products in the United States, conducting clinical trials which, if successful, could lead to additional dermatology indications, and seeking a partner to help develop and market Levulan(R) PDT for the treatment of high-grade 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(R) PDT for indications in dermatology, as well as for ablation of low-grade and high-grade dysplasia in patients with Barrett's esophagus, among others. See section entitled "Business - Internal Indications".

We are developing Levulan(R) PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA(R), DUSA Pharmaceuticals, Inc.(R), Levulan(R), Kerastick(R) and BLU-U(R) are registered trademarks. Several of these trademarks are also registered in Europe, Australia, 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"), including a private placement under Regulation D of the Act which was consummated on February 27, 2004, and from payments received as part of the agreement with our former marketing collaborator. See sections entitled "Management's Discussion and Analysis of Financial Condition - Overview; -

Results of Operations; and - Liquidity and Capital Resources".

BUSINESS STRATEGY

The key elements of our strategy include the following:

- Support the Marketing and Sales of our Products. In October 2003, DUSA launched its own small sales force comprised of direct sales representatives and various independent sales organizations. Due to the initial success of these activities, DUSA plans to expand its sales capacity in 2004.

- Physician Education Support. Commencing with the reacquisition of our product rights, we began to implement a new medical education plan. Efforts to support these activities include financial support of medical education, participation in dermatology conferences, and improvement of third party reimbursement.

- Leveraging our Levulan(R)PDT/PD Platform to Develop Additional Products. Based on market research completed in 2003, we are planning Phase II clinical studies related to the treatment of photodamaged skin and moderate to severe acne vulgaris that, if successful, could lead to significant market opportunities for our products. These studies are expected to commence in mid 2004. In 2003, we received clearance from the FDA to market the BLU-U(R)without Levulan(R), to treat moderate inflammatory acne vulgaris, which supports a multi-use capability of our BLU-U(R), in addition to its use in our approved AK therapy. Outside of dermatology, we are developing a product that targets a large market, for the treatment of high-grade dysplasia in patients with Barrett's esophagus.

- Enter into Additional Strategic Alliances. If we determine that the development program for a given 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. We may also consider acquiring additional dermatology products that complement our Levulan(R)PDT technology.

- Use the Results of Independent Researchers to Identify New Applications. We continue to support research by independent investigators so that we have the benefit of the resulting 'anecdotal' human data for use in evaluating potential indications for corporate development. Such independent investigator studies may lead to additional Levulan(R)products for other skin conditions such as psoriasis, onychomycosis, warts, molluscum contagiosum, oily skin, and acne rosacea. We 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 be treated with either laser or non-laser light sources. Internal indications, which are often more difficult to access, usually require lasers in order to focus light into small fiber optic delivery systems that can be passed through an endoscope or into hollow organs.

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 generally 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. Photosensitizers without activation by light have no PDT/PD effects.

OUR LEVULAN(R) PDT/PD PLATFORM

OUR LEVULAN(R) BRAND OF ALA

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

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

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

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

- Highly Selective. Levulan(R) is not itself a photosensitizer, but is a pro-drug that is converted through a cell-based process into the photosensitizer PpIX. The combination of topical application, tissue specific uptake, 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(R)has no PDT effect without exposure to light at specific wavelengths, so the therapy is easily controlled.

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

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

- conditions characterized by rapidly proliferating cells 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(R) BRAND APPLICATOR

We designed our proprietary Kerastick(R) specifically for use with Levulan(R). It is a single-use, disposable applicator, which allows for the rapid preparation and uniform application of Levulan(R) topical solution in standardized doses. The Kerastick(R) has two separate glass ampoules, one containing Levulan(R) 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(R) according to directions to mix the contents into a solution. The Kerastick(R) tip is then dabbed on the individual AK lesions, releasing a predetermined amount of Levulan(R) 20% topical solution.

OUR LIGHT SOURCES

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

- are compact and tailored to fit specific medical needs,
- are pre-programmed and easy to use, and
- provide cost-effective therapy.

Our proprietary BLU-U(R) is a fluorescent light source that can treat the entire face or scalp at one time. 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(R) also incorporates a proprietary regulator that controls the optical power of the light source to within specified limits. It has a simple control panel consisting of an on-off key switch and digital timer which turns off the light automatically at the end of the treatment. The BLU-U(R) is also compliant with CE marking and ISO 9001 requirements.

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

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

For treatment of AKs, our BLU-U(R) uses blue light which penetrates superficial skin lesions and is a potent activator of PpIX. Longer red wavelengths penetrate more deeply into tissue but are not as potent activators of PpIX. Therefore, for treatment of superficial lesions of the skin, such as AKs, we are using relatively low intensity, non-laser blue light sources, which are designed to treat large areas, such as the entire face or body. For treatment of diseases that may extend several millimeters into the skin or other tissues, including many forms of cancer; high-powered red light is usually preferable. In addition, DUSA received clearance from the FDA in September 2003 to market the BLU-U(R) without Levulan(R) for the treatment of moderate inflammatory acne vulgaris.

In 2004, DUSA will test its new proprietary endoscopic light delivery system in a small Phase II single-center clinical study of the efficacy and safety of Levulan(R) PDT for the treatment of high grade dysplasia in patients with Barrett's esophagus. Our new system is designed to ease the process by which physicians place fiber optics used for endoscopic light delivery within

hollow target organs such as the esophagus. Currently, for the treatment of Barrett's esophagus dysplasia, insertion of a fiber optic is done by placement of a balloon catheter system, which requires approximately three insertions into the patient's esophagus, with blind light treatment by the physician (the endoscope is removed before light treatment and then replaced afterwards). DUSA's proprietary endoscopic light delivery allows fiber optic placement and light treatment to the esophagus to be performed under direct visualization, in a single insertion. Our device thus allows the endoscopic light treatment to be performed more rapidly, under direct visualization, and at greater comfort to the patient.

OUR PRODUCTS

The following table outlines our products and currently planned product candidates. Our research and development expenses for the last three years were $5,403,961 in 2003, $12,121,606 in 2002, and $10,789,906 in 2001.

INDICATION/PRODUCT	STATUS
DERMATOLOGY	
Levulan(R)Kerastick(R)and BLU-U(R)for PDT of Aks	
Levulan(R)PDT for Photodamaged Skin	
Levulan(R)PDT for Moderate to Severe Acne Vulgaris	
BLU-U(R)Treatment of Moderate Inflammatory Acne Vulgaris Without Levulan(R)	
OTHER INDICATIONS	
Levulan(R)PDT for Barrett's Esophagus Dysplasia	
Levulan(R)Induced Fluorescence Guided Resection for Brain Cancer	E
DUSA(R)Endoscopic Light Delivery System	

1. Phase IV final study report was filed with the FDA in January 2004.
2. Phase II IND was filed with the FDA in February 2004.
3. Phase II study planned to be proposed to the FDA by mid 2004.
4. In September 2003, the FDA provided market clearance for the use of the BLU-U(R) for the light alone treatment of moderate inflammatory acne vulgaris.
5. Licensed from Photonamic GmbH & Co. KG.
6. European Phase III trial results may not be acceptable to the FDA in the United States.
7. Phase II pilot clinical trial planned to commence by mid 2004.

DERMATOLOGY INDICATIONS

In September 2002, DUSA assumed all responsibility for its dermatology research and development program as a result of the termination of our former marketing, development and supply agreement with Schering AG. Our former dermatology marketing partner had contributed nearly $3 million per year to the program during 2000, 2001, and 2002. Since reacquiring our product rights, we have focused on formulating our own development program. We have decided to develop Phase II clinical programs for photodamaged skin and moderate to severe acne vulgaris which, if successful, could lead to additional dermatological indications and significant market opportunities. These trials are expected to be initiated in mid 2004. DUSA also continues to support a wide range of independent investigator studies using the Levulan(R) Kerastick(R) that could lead to additional 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(R) 20% topical solution using the Kerastick(R) to the AK lesions, followed 14 to 18 hours later with exposure to our BLU-U(R) for approximately 17 minutes. In 2001, we successfully completed the first of two Phase IV trials required by the Food and Drug 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, was completed in late 2003 and the final report was submitted to the FDA in January 2004.

During 2003, we continued to support efforts to improve reimbursement levels to physicians. Such efforts included working with the Centers for Medicare and Medicaid Services (CMS) to reverse the bundling of the drug cost with the procedure fee, which had occurred effective March 1, 2003. In November 2003, CMS agreed to reinstate the code for physicians to bill the drug cost separate from the procedure fee. As a result, effective January 1, 2004, there is a revised national reimbursement code for Medicare for the BLU-U(R) application procedure and the cost of the Levulan(R) Kerastick(R). 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. We believe that the issues related to reimbursement have affected the economic competitiveness of our therapy with other AK therapies and have hindered its adoption in many cases.

In addition, we continue to work to educate private insurance carriers so that they will approve our therapy for coverage. As of December 31, 2003, several of the major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, plus future improvements, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time.

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 occur frequently in areas of photodamaged skin. There are numerous consumer cosmetic and herbal products which claim to lessen or relieve the symptoms of photodamaged skin. In most cases, there is little scientific data to support these claims. The FDA has approved only one prescription drug, Renova(R)(1), 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(R) 20% topical solution over the entire area including the photodamaged skin. After 14 to 18 hours, the patients were treated with blue light at differing light doses. Investigators noted marked improvement in skin roughness in the treated areas in two-thirds of the patients after treatment with Levulan(R) PDT as well as some degree of improvement of wrinkles and brown spots. However, 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. During 2003, DUSA-supported independent investigator studies for photodamaged skin were completed including a short-incubation study using different light sources: a BLU-U(R), pulsed dye lasers, and intense pulsed light sources. Certain of the independent investigator studies focused on providing evidence which may be used to help optimize the method of treatment for future studies. According to recent peer-reviewed publications, these studies have shown that, when Levulan(R) is applied to the entire face for as little as one hour followed by treatment with the BLU-U(R), or pulsed light sources, efficacy in removing AKs is similar to that of our Phase III trials, which used spot application on each AK and overnight incubation. Additionally, these studies report that patients' skin have shown improvements in various photodamaged skin parameters, including skin quality, sallowness, roughness, fine wrinkling, and Griffiths score, a photonumeric scale for the assessment of skin photodamage. Accordingly, based on the results of our previous Phase II safety and efficacy study, the results of independent investigator studies, and other anecdotal reports, we are planning to initiate a DUSA-sponsored Phase II study in mid 2004.

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. For cystic acne, an oral retinoid drug called Accutane(R)(2) is the most commonly prescribed treatment. It is also commonly 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, with the associated risks of increased antibiotic resistance. Accutane(R) can have a variety of side effects, from dryness of the lips and joint pains, to birth defects, and elevated levels of triglycerides and/or liver enzymes. With Levulan(R) PDT therapy for moderate to severe acne vulgaris 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.

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

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

As part of the co-development program with our former partner, a dose-ranging clinical trial was completed in 2001. The specific low drug 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. However, based on results of independent investigator studies that were completed during 2003, we believe that this is a potential significant indication for Levulan(R) PDT. A protocol for this indication is under development as we plan to initiate a DUSA-sponsored Phase II study during 2004. The study will utilize the BLU-U(R) and short-incubation, broad-area application of the Levulan(R) Kerastick(R). This combination has been reported in published independent investigator studies as being effective, while having minimal treatment-related side effects.

In addition, DUSA received clearance from the FDA in September 2003 to market the BLU-U(R) without Levulan(R) PDT for the treatment of moderate inflammatory acne vulgaris.

OTHER POTENTIAL DERMATOLOGY INDICATIONS

There are numerous other potential uses for Levulan(R) PDT/PD in dermatology, and we are currently supporting, or may in the future support research in several of these areas, with corporate-sponsored 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 the additional potential uses for Levulan(R) in dermatology include treatment of skin conditions such as psoriasis, onychomycosis, warts, molluscum contagiosum, oily skin, acne rosacea, and cancers, such as squamous cell carcinomas and cutaneous T-cell lymphomas.

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.

Medical treatment of the condition has commonly included lifelong anti-reflux therapy with drugs called proton pump inhibitors to reduce stomach acid, while treatment for more advanced, precancerous, Barrett's esophagus dysplasia involves surgery to remove affected areas of the esophagus. The role of anti-reflux surgery, and/or medical devices is also being evaluated by the medical community. In August 2003, a competitor received approval for its PDT therapy for Barrett's esophagus. See section entitled "Business - Competition ".

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

During 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(R) 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 was the ablation of high-grade dysplasia, or HGD, in Barrett's esophagus (late stage Barrett's esophagus), six patients with HGD were treated with Levulan(R) PDT. Of the six patients treated, five had complete clearing of their areas of high-grade dysplasia, and four of those patients have now been followed for a period greater than 1 year, which indicates a durable response for complete HGD ablation. One patient dropped from follow-up at the 2-month visit. No esophageal scarring or ruptures were noted in the course of this study. HGD ablation continues in the patients followed. In our low-grade dysplasia (early stage) clinical trial in which the primary efficacy goal was the conversion of Barrett's esophagus to normal esophagus, 10 of the 11 patients that were treated with Levulan(R) PDT are still being followed. Complete Barrett's esophagus mucosal ablation after a single Levulan(R) PDT treatment remained stable in 3/10 (30%) patients. Two-year follow-up data for most patients is being collected. 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 during 2003, we chose not to enroll any additional patients to these studies, but will continue to follow the patients that have already been treated.

In preparation for a Phase II clinical trial, we are planning to initiate a small single-center pilot Phase II clinical trial in 2004 using DUSA's new proprietary endoscopic light delivery device for the treatment of HGD.

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.

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In December 2002, we entered into a License and Development Agreement with 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. 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(R) 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 gastro-intestinal 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(R). We have agreed to order from NBC all of our supply needs of these light sources for the United States and Canada, and NBC has agreed to supply us with the quantities we order. If an opportunity arises, the parties have agreed to negotiate the terms under which NBC would supply us with light sources for sale in countries other than the current territories.

NBC has granted to us a license to manufacture the light sources if 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. In addition, NBC has agreed that it will not supply light sources that may be used to compete with our business. 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.

Sochinaz SA. Under an agreement dated December 24, 1993, Sochinaz SA ("Sochinaz") manufactures and supplies substantially all of our requirements of Levulan(R) worldwide from its FDA approved facility in Switzerland. In June 2000, we amended the agreement to include an option to allow us to extend the term for an additional 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, 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(R) PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations ("PARTEQ"), the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, which became effective August 27, 1991, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ's 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 (U.S. $77,000 as of December 31, 2003) 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 15(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 PARTEQ license agreement to the extent they relate to Canada. On February 24, 2004, we reacquired these rights and agreed to pay an upfront fee and a royalty on sales of the Levulan(R) Kerastick(R) in Canada over a five-year term following the first commercial sale in Canada. We will now be responsible for any royalties which would be due to PARTEQ for Canadian sales. Draxis also agreed to assign to us the Canadian regulatory approvals for the Levulan(R) Kerastick(R) with PDT for AKs. We also hold Canadian regulatory approval for the BLU-U(R). We expect to launch our Levulan(R) Kerastick(R) and BLU-U(R) in Canada in 2004.

Photonamic GmbH & Co. KG. 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 aminolevulinic acid (ALA), the compound we use in our Levulan(R) Photodynamic Therapy (PDT) and Photodetection (PD).

Under the terms of the 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 of $1,250,000 upon FDA acceptance of a registration application for a brain cancer product in the United States, an additional $1,250,000 upon registration of the product, and royalties of 12.5% on net sales under the terms of the License and Development Agreement 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 aspects 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:

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

These patents expire no earlier than 2009, and certain patents are entitled to terms beyond that date. Effective September 29, 2003, the United States Patent and Trademark Office extended the term of U.S Patent No. 5,079,262, with respect to our approved AK indication for Levulan(R), until September 29, 2013.

Under the license agreement with PARTEQ, 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, one of which is the subject of legal action. See sections entitled "Risk Factors - Risks Related to DUSA"; and "Legal Proceedings".

We can provide 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 provide no assurance 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 provide no assurance 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 employees, licensing partners, consultants, universities, pharmaceutical companies and agents contain provisions designed to protect the confidentiality of our proprietary information. However, we can provide no assurance 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 provide no assurance 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 products (like PARTEQ's patents); (ii) patents relating to special compositions and formulations; (iii) limited marketing exclusivity that may be available under the Hatch-Waxman Act and any counterpart protection available in foreign countries and (iv) patent term extension under the Hatch-Waxman Act. 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(R), the Kerastick(R) brand applicator and the BLU-U(R) brand light source were each manufactured by single third-party suppliers. In December 2002, we terminated our agreement with North Safety Products, Inc., a unit of Norcross Safety Products, LLC, for the manufacture and supply of our Kerastick(R), in light of our decision to build a Kerastick(R) 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(R) at our new facility will be higher. On July 14, 2003, we received FDA approval to manufacture the Levulan(R) Kerastick(R) at our facility, and in February 2004 we commenced manufacturing in support of our plan to maintain a reasonable level of Kerastick(R) inventory based on sales projections. This facility will also be utilized to produce clinical supplies for our own studies in addition to investigator studies which we plan to support.

DISTRIBUTION

Effective December 10, 2003, DUSA signed an amended agreement with Moore Medical Corporation ("Moore"), a national distributor and marketer of medical and surgical supplies, to remove Moore's exclusivity rights and allow DUSA to use other third-party distributors to sell its products. Since then, we have appointed two additional distributors. Third-party distributors have also been authorized to sell the BLU-U(R) on the Company's behalf. All distributors have the right for a period of time following termination of their respective agreement, to return their inventory of product.

MARKETING AND SALES

Under the agreement with our former dermatology marketing partner, marketing and sales of Levulan(R) PDT products were the responsibility of the partner. As a result of the termination of that relationship in September 2002, we commenced implementing our own marketing and sales strategy.

In August 2003, we hired an Associate Vice President of Sales, and in October 2003 we hired, trained, and deployed a sales force, which was initially comprised of six direct representatives, various independent representatives, and an independent sales distributor, designed to focus on most of our key geographic markets in the United States. At the end of December 2003 we hired our seventh direct representative in a key target market, and in January 2004 we continued to expand our sales capacity by adding one more direct representative and an independent representative in another key target market. Due to the success of our initial sales launch, we plan to continue to expand our sales capacity during 2004.

The Health Protection Branch - Canada has granted marketing approval for the Levulan(R) Kerastick(R) with PDT using the BLU-U(R) for AKs of the face or scalp. Pursuant to an agreement dated February 24, 2004 Draxis agreed to assign to us the rights to market the product in Canada. See section entitled "Business - Licenses". We expect to launch our products in Canada in 2004.

COMPETITION

Commercial development of PDT agents other than Levulan(R) is currently being pursued by a number of companies. These include: QLT PhotoTherapeutics Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); Pharmacyclics, Inc. (U.S.); 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. Several of these companies are also commercializing and/or conducting research with ALA or ALA-related compounds.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AK and basal cell carcinoma, called BCC, in the European Union, New Zealand, Australia, and countries in Scandinavia. PhotoCure has also filed for regulatory approval in the United States for these indications. PhotoCure has received a notice of approvability from the FDA for its AK therapy and has stated that it expects the FDA to approve its product in the first half of 2004. If PhotoCure receives FDA approval to market its product in the United States, and if it enters into the marketplace, its product will directly compete with 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 one of the patents covered by our agreement with PARTEQ, Australian Patent No. 624985, relating to ALA, 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 certain activities of PhotoCure and its marketing partner, Galderma S.A., infringe the patent. The case is ongoing and we are unable to predict the outcome at this time. DUSA believes that the final hearing in the Federal Court of Australia will occur in April 2004. See section entitled "Legal Proceedings".

In August 2003, Axcan Pharma Inc. received FDA approval for the use of its product, PHOTOFRIN(R)(3), for photodynamic therapy in the treatment of high grade dysplasia associated with Barrett's esophagus. This approval enabled Axcan to be the first company to market a PDT therapy for this indication, which we are also pursuing.

There are also non-PDT products for the treatment of AKs, including cryotherapy with liquid nitrogen, 5-fluorouracil, and imiquimod, which was approved on or about March 3, 2004. The pharmaceutical industry is highly competitive, and 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.

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.

In September 2003 we received FDA clearance to market the BLU-U(R) without Levulan(R) for the treatment of moderate inflammatory acne vulgaris. Numerous laser or non-laser light sources provide direct competition to our BLU-U(R).

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

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(3) PHOTOFRIN(R)is a registered trademark of Axcan Pharma Inc.

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 cGMP, GLP and GCP, 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(R) Kerastick(R) 20% Topical Solution with PDT for treatment of AKs of the face or scalp. The commercial version of our BLU-U(R), used together with the Kerastick(R) to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp, was approved on September 26, 2000. We also received clearance from the FDA in September 2003 to market the BLU-U(R) without Levulan(R) PDT for the treatment of moderate inflammatory acne vulgaris.

We are following patients who completed our Phase I/II studies to examine the use of Levulan(R) for the treatment of Barrett's esophagus with areas of high-grade dysplasia. Other than the FDA-approved use of the Levulan(R) Kerastick(R) 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(R) in any future products will be successfully developed, prove to be safe and effective in clinical trials, or receive applicable regulatory marketing approvals.

Medical devices, such as our light source device, are also subject to the FDA's rules and regulations. These products are required to be tested, developed, manufactured and distributed in accordance with FDA regulations, including good manufacturing, laboratory and clinical practices. Under the Food, Drug & Cosmetic Act, all medical devices are classified as Class I, II or III devices. The classification of a device affects the degree and extent of the FDA's regulatory requirements, with Class III devices subject to the most stringent requirements and FDA review. Generally, Class I devices are subject to general controls (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(R) is part of a combination product as defined by FDA and therefore has been classified as a Class III device. We are developing an endoscopic 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 premarket approval, or 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. In addition, a PMA for a device which forms part of a combination product will not be approved unless and until the NDA for the corresponding drug is also approved.

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(R) Kerastick(R) with PDT for AKs, a combination filing (including a PMA for the BLU-U(R) light source device and the NDA for the Levulan(R) Kerastick(R)) was submitted to the Center for Drug Evaluation and Research. The PMA was then separated from the NDA submission by the FDA and reviewed by the FDA's Center for Devices and Radiological Health. Based upon this experience, we anticipate that any future NDAs for Levulan(R) PDT/PD will be a combination filing accompanied by PMAs. There is no guarantee that PDT products will continue to be regulated as combination products.

The United States Drug Price Competition and Patent Term Restoration Act of 1984 known as the Hatch-Waxman Act establishes a 5 year period of marketing

exclusivity from the date of NDA approval for new chemical entities approved after September 24, 1984. Levulan(R) is a new chemical entity and market exclusivity 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.

We also intend to market our products outside of the United States beginning with Canada later this year. 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 had been responsible for applying for marketing approvals outside the United States for Levulan(R) 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(R) PDT in Australia, and have now followed the same course for the applications in Austria and South Africa. In 2003, we also advised our former partner to withdraw the applications for the Levulan(R) Kerastick(R) and BLU-U(R) in Brazil as it was determined that such rights cannot be transferred to us. We are in the process of determining the requirements to reapply in Brazil, and have not determined if we will reapply in any of the other countries at this time. We also are investigating whether we can resubmit our application in Australia with additional clinical results we have obtained since withdrawing that application in order to satisfy the Australian regulatory requirements for approval.

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 provide 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. 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(R) facility, we have taken steps to ensure that appropriate environmental controls associated with the facility comply with environmental laws and standards. We can provide 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. See section entitled "Legal Proceedings".

EMPLOYEES

At the end of 2003, we had 50 full-time employees and 1 part-time employee. Our 2002 staffing levels for key management personnel in administrative, financial, technical and operations functions had been established to support the initial expected sales levels of Levulan(R) PDT that did not materialize. Therefore, following the reacquisition of our product rights in September 2002, we downsized our staffing levels by approximately 20%. Since that time, we have been gradually adding employees as needed, including our direct sales force.

We have employment agreements with all of our key executive officers. We have purchased, and are the named beneficiary of, a key man life insurance policy having a face value of CDN $2,000,000 on the life of our President. We also retain numerous independent consultants and the services of key researchers at leading university centers whose activities are coordinated by our employees. We intend to hire other employees and consultants as needed.

INTERNET INFORMATION

Our internet site is located at 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

You should carefully consider and evaluate all of the information in, or incorporated by reference in, this prospectus. The following are among the risks we face related to our business, assets and operations. They are not the only ones we face. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the value of the securities being offered by this prospectus.

This section of the prospectus contains forward-looking 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 risks factors described below and elsewhere in this prospectus. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this prospectus.

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 APPROVED PRODUCTS, THE LEVULAN(R) KERASTICK(R) WITH THE BLU-U(R) BRAND LIGHT SOURCE FOR THE TREATMENT OF AKS OF THE FACE OR SCALP, AND THE BLU-U(R) WITHOUT LEVULAN(R) FOR THE TREATMENT OF MODERATE INFLAMMATORY ACNE.

WE HAVE ONLY LIMITED EXPERIENCE MARKETING AND SELLING PHARMACEUTICAL PRODUCTS AND, AS A RESULT, OUR REVENUES FROM PRODUCT SALES MAY SUFFER.

If we are unable to successfully market and sell our approved products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. As of September 1, 2002, DUSA and our former marketing partner for dermatology products terminated the parties' marketing, development and supply agreement. As a result of this termination, DUSA is solely responsible for marketing its approved dermatology products in the United States and the rest of the world. We will be doing so without the experience of having marketed pharmaceutical products in the past. In October 2003, DUSA began hiring a small direct sales force and has engaged a small number of independent sales representatives to market our products. Acquiring and retaining marketing and sales force capabilities involves significant expense, and current sales levels are not offsetting the expenses related to these efforts. We may need to hire additional sales people to penetrate the market. If our sales and marketing efforts fail, then sales of the Kerastick(R) and the BLU-U(R) will be adversely affected.

IF WE CANNOT IMPROVE PHYSICIAN REIMBURSEMENT AND/OR CONVINCE MORE PRIVATE INSURANCE CARRIERS TO ADEQUATELY REIMBURSE PHYSICIANS FOR OUR THERAPY, SALES OF OUR LEVULAN(R) KERASTICK(R) FOR AKS PRODUCT MAY SUFFER.

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan(R) Kerastick(R) for AKs therapy will be limited. While we continue to support efforts to improve reimbursement levels TO physicians and are working with the major private insurance carriers to improve coverage for our therapy, if our efforts are not successful, adoption of our therapy and sales of our products could be negatively impacted. As of January 1, 2004, a new national reimbursement code for Medicare and other third-party payors for the BLU-U(R) PDT application procedure and for the costs of thE Levulan(R) Kerastick(R) 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 PDT therapy in their practices.

SINCE WE NOW OPERATE THE ONLY FDA APPROVED MANUFACTURING FACILITY FOR THE KERASTICK(R) AND CONTINUE TO RELY HEAVILY ON SOLE SUPPLIERS FOR THE MANUFACTURE OF LEVULAN(R) AND THE BLU-U(R), ANY SUPPLY OR MANUFACTURING PROBLEMS COULD NEGATIVELY IMPACT OUR SALES.

If we experience problems producing Kerastick(R) units in our new facility, or either of our contract suppliers fail tO supply DUSA's requirements

of Levulan(R) or the BLU-U(R), our business, financial condition and results of operations would suffer. WE are not currently approved to manufacture the BLU-U(R) on our own and have not ordered any new BLU-U(R) units since 2001. In additiON, while we have received FDA approval to manufacture the Kerastick(R) in our own manufacturing facility, we have not yet produceD commercial quantities of Kerastick(R) units in the facility on a regular basis.

Manufacturers and their subcontractors often encounter difficulties when commercial quantities of products are manufactured for the first time, or 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 and our suppliers seek to commence, re-start and increase production. Any manufacturing problems could delay or limit our supplies which would hinder our marketing and sales efforts.

If our facility, any facility of our contract manufacturers, or any equipment in those facilities, is damaged or destroyed, we may not be able to quickly or inexpensively replace it. Likewise, if there are any quality or supply problems with any components or materials needed to manufacturer our products, we may not be able to quickly remedy the problem(s).

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

Both the manufacture and marketing of our products, the Levulan(R) Kerastick(R) with the BLU-U(R) for AKs and the BLU-U(R) WITHOUT Levulan(R) to treat moderate inflammatory acne are subject to continuing FDA review as well as comprehensive regulation by the FDA anD by state and local regulatory authorities. 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.

If we, or any of our contract manufacturers, fail to comply with these requirements, DUSA may be limited in the jurisdictions in which we are permitted to sell our products. Additionally, if we or our manufacturers fail to comply with applicable regulatory approval requirements, a regulatory agency may also:

- send us warning letters,

- impose fines and other civil penalties on us,
- seize our products,
- 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, and/or
- criminally prosecute us.

We and our manufacturers must continue to comply with the FDA's current Good Manufacturing Practice, commonly known as cGMP, and equivalent 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.

As part of our FDA approval for the Levulan(R) Kerastick(R) for AK, we were required to conduct two Phase IV follow-UP studies. We have successfully completed the first study; and submitted our final report on the second study to the FDA in January 2004. While we believe this second study was also a success, the FDA may request additional information and/or studies. Additionally, if previously unknown problems with the product, a manufacturer or its facility are discovered in the future, 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 guarantee that our third-party supply sources, or our own new Kerastick(R) facility, 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 PRODUCT SALES DO NOT INCREASE SIGNIFICANTLY WE MAY NOT BE ABLE TO ADVANCE DEVELOPMENT OF OUR OTHER POTENTIAL PRODUCTS AS QUICKLY AS WE WOULD LIKE TO, WHICH WOULD DELAY THE APPROVAL PROCESS AND MARKETING OF NEW POTENTIAL PRODUCTS.

If we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon some or all of DUSA's product development programs. The pharmaceutical development and commercialization process is time consuming and costly, and any delays might result in higher costs which could

adversely affect our financial condition. Without sufficient product sales, DUSA might be required to seek additional funding. There is no guarantee that adequate funding sources could be found to continue the development of all our potential products. DUSA might be required 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 or any of our development programs.

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 2004 as we attempt to increase sales of our approved products in the marketplace and continue research and development of potential new products. As of December 31, 2003, our accumulated deficit was $58,909,781. Although sales of the Kerastick(R) have increased with the addition of our saleS force and our ongoing medical education activities, we cannot predict whether any of our products will achieve significant market acceptance or generate sufficient revenues to enable us to become profitable.

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 our Levulan(R) brand of the compound ALA. Our basic patents are for methods of detecting and treating various diseased tissues using ALA (or related compounds called precursors), in combination with light. We own or exclusively license patents and patent applications related to the following:

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

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 where we have patent protection, there is no guarantee that we will be able to enforce our patents. Additionally, enforcement of a given patent may not be practicable or an economically viable alternative.

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 ALA technology, is invalid. As a consequence of this action, Queen's University assigned the Australian patent to DUSA so that we can participate directly in the 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

our patent. We cannot predict the outcome of PhotoCure's action alleging invalidity. Australia is a significant pharmaceutical market for AK therapies, and loss of this patent could negatively impact us in at least two ways. First, if we are able to enter the Australia market, the lack of a patent would probably retard or diminish our market share. Second, third-parties might not be interested in licensing the product in Australia without patent protection which would limit potential revenues from this market.

Some of the indications for which we are developing therapies may not be covered by the claims in any of our existing patents. Even with the issuance of additional patents to DUSA, 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. ALA in the chemical form has been commercially supplied for decades, and is not itself subject to patent protection. There are reports of third-parties conducting clinical studies with ALA in countries outside the United States where PARTEQ does not have patent protection. In addition, a number of third-parties are seeking patents for uses of ALA not covered by our patents. These other uses, whether patented or not, and the commercial availability of ALA, could limit the scope of our future operations because ALA products could come on the market which would not infringe our patents but would compete with our Levulan(R) products even though they arE marketed for different uses.

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 our patents in the United States, that third-party could challenge the validity of our patent(s). We cannot guarantee that a third-party 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.

Additionally, 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 could also request the declaration of a patent interference between one of our issued U.S. patents and one of its patent applications. Any interference proceedings likely would require participation by us and/or PARTEQ, could involve substantial legal fees and result in a loss or lessening of our patent protection.

WE HAVE ONLY TWO THERAPIES THAT HAVE RECEIVED REGULATORY APPROVAL OR CLEARANCE AND WE CANNOT PREDICT WHETHER WE WILL EVER DEVELOP OR COMMERCIALIZE ANY OTHER PRODUCTS.

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

We do not know if any of our products will ever be commercially successful. Currently, we are developing a single drug compound, ALA, under the trademark Levulan(R), with light for a number of different medical conditions using photodynamic therapy, oR PDT. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products. Except for DUSA's two approved therapies, all of our other potential products are at an early stage of development and subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

- delays in product development, clinical testing or manufacturing,
- unplanned expenditures in product development, clinical testing or manufacturing,
- failure in clinical trials or failure to receive regulatory approvals,
- emergence of superior or equivalent products,
- inability to market products due to third-party proprietary rights, and
- failure to achieve market acceptance.

We cannot predict how long the development for our early stage 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 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 Levulan(R) 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 application to the FDA seeking approval to market a new drug, called an NDA, can be filed, 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(R) 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(R). This factor may lengthen the approval process. We face much trial and error and we may fail at numerous stages along the way.

We cannot predict whether we will obtain approval for any of our potential products. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan(R) PDT or photodetection, known as 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.

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 products 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. In addition to the funds we recently received in connection with a private placement in February 2004, we may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. We cannot predict whether any financing will be available on acceptable terms.

Dependent on the extent of available funding, we may continue to delay, reduce in scope or eliminate some of our research and development programs as we did in 2003. We may also choose to license rights to third parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own which could reduce our potential revenues.

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

We are a small company with only 51 employees. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer. 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 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 other qualified personnel in our specialty drug and light device areas.

RISKS RELATED TO OUR INDUSTRY

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

WE HAVE HAD A LAWSUIT FILED AGAINST US BASED ON A PRODUCT LIABILITY CLAIM WHICH, REGARDLESS OF MERIT, COULD RESULT IN A DAMAGE AWARD FOR WHICH WE MAY NOT HAVE ADEQUATE INSURANCE COVERAGE.

The development, manufacture and sale of medical products exposes us to product liability claims related to the use or misuse of our products. Product liability claims can be expensive to defend and may result in significant judgments against us. On January 29, 2004, we were served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland. The case has been removed to the U.S. District Court, Eastern District of Michigan, Southern Division. The complaint alleges unspecified damages suffered by the plaintiff arising from recurrence of epileptic or similar seizures following exposure to the BLU-U(R). We are unable to predict the outcome of this litigation. 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. A successful claim in excess of our insurance coverage could materially harm our business, financial condition and results of operations. Additionally, we cannot guarantee that continued product liability insurance coverage will be available in the future at acceptable costs. If the cost is too high, we may have to self-insure.

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. 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 have established our own production line for the manufacture of the Kerastick(R), we are subject to additional environmental laws and regulations. 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 COMPETE AGAINST TRADITIONAL TREATMENT METHODS OR 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 BASED ON TRADITIONAL TREATMENT METHODS MAY MAKE SOME OR ALL OF OUR PROGRAMS OR POTENTIAL PRODUCTS NONCOMPETITIVE OR OBSOLETE.

Well-known pharmaceutical, biotechnology and chemical companies are marketing well-established therapies for the treatment of many of the same conditions we are seeking to treat including AKs, acne, photodamaged skin and

Barrett's esophagus. Doctors may prefer to use familiar methods, rather than trying our products. Reimbursement issues may affect the economic competitiveness of our products as compared to other more traditional therapies.

Many companies are also seeking to develop new products and technologies, and receiving approval for medical conditions for which we are developing treatments. Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Our competitors may succeed in developing products that are safer or more effective than ours. 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.

We cannot guarantee that new drugs or future developments in 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 adversely affect our business. Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technology obsolete.

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

We anticipate that we will face increased competition as the scientific development of PDT/PD advances and new companies enter our markets. Several companies are developing PDT agents other than Levulan(R). 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 commercializing and/or 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.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AKs and basal cell carcinoma in the European Union, New Zealand, Australia and countries in Scandinavia. PhotoCure has also filed for regulatory approvals in the United States, and has received a notice of approvability from the FDA for its AK product. If PhotoCure receives FDA product approval in the United States and successfully enters the United States marketplace, its product will represent direct competition for our products.

Axcan Pharma Inc. has announced that it has received FDA approval for the use of its product, PHOTOFRIN(R), for PDT in the treatment of high grade dysplasia associated with Barrett's esophagus. Axcan is the first company to

market a PDT therapy for this indication, which we are also pursuing.

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 method of PDT,
- 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.

RISKS RELATED TO OUR STOCK

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

As of March 1, 2004 there were outstanding options and warrants to purchase 2,709,825 shares of common stock, with exercise prices ranging from U.S. $1.60 to $31.00 per share, and ranging from CDN $4.69 to CDN $10.875 per share, respectively. In addition, DUSA granted investors of a private placement rights to purchase up to an aggregate of an additional 337,500 shares of common stock at $11.00 per share. These additional investment rights expire April 14, 2004, or 30 trading days from the closing of the private placement, which occurred on March 2, 2004. If the holders exercise a significant number of these securities at any one time, the market price of the common stock could fall, and the value of the common stock held by other shareholders would be diluted. The holders of the options, warrants and rights 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. 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, 2003 to March 10, 2004, the price of our stock has ranged from a low of $1.40 to a high of $14.87. Factors that contributed to the volatility of our stock during the last 12 months included:

- levels of product sales,
- general market conditions,
- increased marketing activities,
- changes in third-party payor reimbursement for our therapy, and
- failure to close a strategic partnership for Barrett's esophagus.

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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 FALLS BACK TO 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 ON THEIR INVESTMENTS.

The price of our common stock has been negatively impacted by disappointing product sales, the termination of our dermatology marketing, development and supply agreement in late 2002, 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 2003. If our share price again falls below our cash value, there may be a 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, we adopted a shareholder rights plan at a special meeting of DUSA's board of directors. 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) of our common stock, thereby limiting, perhaps, the ability of our shareholders to benefit from such a transaction.

The rights plan provides for the distribution of one right as a dividend for each outstanding share of our common stock 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 our 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 DUSA 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 DUSA, or until such later date as may be determined by the our board of directors.

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Under the rights plan, if a person or group acquires the threshold amount of common stock, all holders of rights (other than the acquiring person or group) may, upon payment of the purchase price then in effect, purchase shares of common stock of DUSA having a value of twice the purchase price. In the event that we are involved in a merger or other similar transaction where DUSA is not the surviving corporation, all holders of rights (other than the acquiring person or group) 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. Our board of directors has also adopted certain amendments to DUSA's certificate of incorporation consistent with the terms of the rights plan.

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 10th 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. This facility accommodates the Toronto office of our President and shareholder services representative. See "Note 15(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 ongoing and we are unable to predict the outcome at this time. DUSA believes that the final hearing in the Federal Court of Australia will occur in April 2004.

In March 2003, we received notice that our Netherlands patent was being formally challenged by an anonymous agent, and we filed a formal response to the opposition. The Netherlands Patent Office has issued a notice that the patent was upheld and granted in amended form on February 10, 2004. The opponent's right to appeal has expired. 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".

In December 2003, DUSA was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging, among other things, that DUSA's BLU-U(R) caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint names Berlex Laboratories, Inc., a subsidiary of our former marketing partner, as another defendant. The damages are unspecified. The case has been removed to the U.S. District Court, Eastern District of Michigan, Southern Division. While it is not possible to predict or determine the outcome of this action, we believe that the costs associated with all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one period to the extent costs are not covered by our insurance.

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, 2002:

	First	Second	Third	Fourth
NASDAQ				
High	$ 7.83	$ 4.55	$ 2.69	$ 1.89
Low	3.79	1.84	1.40	1.32

Price range per common share by quarter, 2003:

	First	Second	Third	Fourth
NASDAQ				
High	$ 1.77	$ 3.16	$ 6.45	$ 6.44
Low	1.45	1.75	2.50	4.50

On March 10, 2004, the closing price of our common stock was $10.02 per share on the NASDAQ National Market. On March 10, 2004, there were 678 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 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 set forth below has been derived from the Company's audited consolidated financial statements.

CONSOLIDATED STATEMENTS OF OPERATIONS DATA

	Year ended Decembe		
	2003	2002 (1)	2001
Revenues (1)	$ 970,109	$ 25,483,238	$ 5,390,736
Cost of product sales and royalties (1)	3,481,248	5,253,424	2,148,994
Research and development costs (1)	5,403,961	12,121,606	10,789,906
Marketing and sales costs	2,494,405	--	--
General and administrative costs	6,343,680	5,591,039	3,654,792
Income (loss) from operations	(16,753,185)	2,517,169	(11,202,956)
Other income, net	1,926,331	3,245,349	3,844,860
Income tax expense	--	--	--
Net income (loss)	(14,826,854)	5,762,518	(7,358,096)
Basic and diluted net income (loss) per common share	$ (1.06)	$ 0.42	$ (0.53)
Weighted average number of shares outstanding	13,936,482	13,877,566	13,791,735

CONSOLIDATED BALANCE SHEETS DATA

	As of December 31,			
	2003	2002	2001	2000
Total assets	$44,697,488	$60,949,973	$75,864,221	$82,442,38
Cash and investment securities (2)	37,969,476	52,879,543	64,709,625	74,496,57
Deferred revenue (1)	129,900	5,100	22,585,856	24,805,04
Long-term debt (3)	1,247,500	1,517,500	--	-
Shareholders' equity	40,232,049	56,057,730	49,834,537	55,309,79

(1) 2002 includes the recognition 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 "Results of Operations, 2002 Dermatology Collaboration Termination". These amounts were previously deferred and were being amortized into operations over periods ranging from 1 to 12.5 years.

(2) Includes restricted cash and investment securities classified as long-term assets.

(3) 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(R). When Levulan(R) is used and followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan(R) is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our products, which were launched in September 2000 in the United States, are Levulan(R) 20% topical solution using our Kerastick(R) brand applicator, and our BLU-U(R) 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. In addition, we received market clearance from the FDA in September 2003 to market the BLU-U(R) without Levulan(R) for the treatment of moderate inflammatory acne vulgaris.

We have primarily devoted our resources to fund research and development in order to advance the Levulan(R) PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of December 31, 2003, we had an accumulated deficit of approximately $58,910,000. Achieving our goal of becoming a profitable operating company is dependent upon acceptance of our therapy by the medical and consumer constituencies, and our ability to develop new products.

During 2003, we implemented our new sales, marketing, physician education, and development strategies following the reacquisition of our rights from our former marketing partner in September 2002. The October 1, 2003 launch of DUSA's initial sales force and related marketing and sales activities has resulted in significant additional expenses. However, the impact on sales was positive. Kerastick(R) unit sales to end-users were 11,172 for 2003, as compared to 7,116 for 2002, with fourth quarter 2003 sales totaling 5,478 as compared to 1,722 in the fourth quarter 2002. Although the costs related to the addition of our sales force and related marketing activities are currently greater than the gross profit generated from the increased sales, we are encouraged with the initial increase in sales, and will continue our efforts to penetrate the market. We expect to continue to incur operating losses until sales of our products increase substantially. See section entitled "Results of Operations - Marketing and Sales Costs". At this time, our core objectives include focusing on increasing sales in the United States, conducting clinical trials which, if successful, could lead to additional dermatology indications, and seeking a partner to help develop and market Levulan(R) 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(R) PDT for other indications in dermatology.

We have continued to support efforts to improve reimbursement levels to physicians. Such efforts included working with the Centers for Medicare and Medicaid Services (CMS) to reverse the bundling of the drug cost with the procedure fee, which had occurred effective March 1, 2003. In November 2003, CMS agreed to reinstate the code for physicians to bill the drug cost separate from the procedure fee. As a result, effective January 1, 2004, there is a separate code for the costs of the Levulan(R) Kerastick(R), and a revised reimbursement code for the BLU-U(R) application procedure. Doctors can also bill for any applicable visit fees. However, some physicians have suggested that even the new reimbursement levels do not fully reflect the required efforts to routinely employ our therapy in their practices. These issues have affected the economic competitiveness of our products with other AK therapies and hence have hindered the adoption of our therapy. In addition, we continue to work to educate the major private insurance carriers such that they will approve our therapy for coverage. As of December 31, 2003, several major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, along with our education and marketing programs, more widespread adoption by the medical community should occur over time. In addition, we are aware that some physicians have been using Levulan(R) with light devices manufactured by other companies and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called "off-label" uses, these activities could also positively affect the use of our 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 unique therapy, and the related product benefits as 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 that product sales have not reached the levels that were originally expected. While our financial position is strong, we cannot predict when product sales may offset the costs associated with these efforts.

As of December 31, 2003, we had a staff of 50 full-time employees and 1 part-time employee, as compared to 43 full-time employees at the end of 2002, including marketing and sales, production, maintenance, customer support, and financial operations personnel, as well as those who support research and development programs for dermatology and internal indications.

RECENT EVENTS

FEBRUARY 2004 PRIVATE PLACEMENT - On February 27, 2004, DUSA entered into definitive agreements with certain new and existing institutional and other accredited investors for the private placement of 2,250,000 shares of our common stock at a purchase price of $11.00 per share resulting in gross proceeds to DUSA of $24,750,000. DUSA has granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at $11.00 per share. These additional investment rights expire April 14, 2004, or 30 trading days from closing, which occurred on March 2, 2004. The placement agent's commission and non-refundable retainer was paid in 135,000 shares of common stock calculated at the offering price.

DUSA will use the proceeds from the sale of the securities to expand our sales force and for general working capital purposes, including research and development activities.

RE-ACQUISITION OF CANADIAN PRODUCT RIGHTS - On February 24, 2004, DUSA reacquired the rights to the aminolevulinic acid (Levulan(R)) technology for Canada held by Draxis Health Inc. ("Draxis"). These rights were initially assigned to Draxis in 1991 at the time of the original licensing of the patents underlying our Levulan(R) PDT platform from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario. DUSA and Draxis terminated the assignment and DUSA agreed to pay to Draxis an upfront fee and a royalty on sales of the Levulan(R) Kerastick(R) in Canada over a five year term. The commercial launch of our products in Canada is expected to occur in 2004.

MANUFACTURING FACILITY APPROVAL - On July 14, 2003, DUSA received FDA approval to manufacture the Levulan(R) Kerastick(R) at our Wilmington facility, and in February 2004 we commenced manufacturing Kerastick(R) units in support of our plan to maintain an adequate supply of inventory to meet market demand for our products based on sales projections. As of December 31, 2003, we had 30,144 Kerastick(R) units in inventory. This inventory was produced in 2002 by our former third-party manufacturer to meet product demand during the execution of our project to complete construction and gain FDA approval of our new manufacturing facility. The facility will also be utilized in 2004 to produce clinical supplies for our planned DUSA-sponsored studies in addition to investigator studies which DUSA plans to support.

THIRD-PARTY DISTRIBUTION AGREEMENT - Effective December 10, 2003, DUSA amended its agreement with Moore Medical Corporation ("Moore"), a national distributor and marketer of medical and surgical supplies, to eliminate Moore's exclusivity rights and allow DUSA to use other third-party distributors of the Kerastick(R) in the United States. Since that time, two additional distributors have been appointed. In addition, distributors have also been authorized to sell the BLU-U(R) on DUSA's behalf. Distributors have the right to return their inventory of Kerastick(R) units for full credit for a period of time prior to and after the expiration date of their respective agreements.

510(K) FDA FILING - On September 9, 2003, DUSA received market clearance from the FDA to market the BLU-U(R) without Levulan(R) for the treatment of moderate inflammatory acne vulgaris. We initiated the marketing of the BLU-U(R) for this indication in the fourth quarter of 2003. Although direct sales of BLU-U(R) commenced in November 2003, the overall impact that selling the BLU-U(R) for the treatment of acne will have on product sales is uncertain at this time.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Critical accounting policies are 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. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. Since not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We consider the following policies and estimates to be critical to our financial statements.

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REVENUE RECOGNITION - Revenues on product sales 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 previously earned under our collaborative agreement consisted of non-refundable research and development funding from our former dermatology collaboration partner. Research revenue generally compensated us for a portion of our agreed-upon research and development expenses and was recognized as revenue at the time the research and development activities were performed under the terms of the related agreements and when no future performance obligations existed. Milestone or other up-front payments are typically recorded as deferred revenue upon receipt and recognized as earned, generally on a straight-line basis over the term of an agreement. Under the terms of our former dermatology collaboration agreement, we initially estimated a 12 1/2 year life, the term of the agreement. As a result of the termination of that agreement in 2002, the estimated period over which we were recognizing revenue ceased and the unamortized deferred revenue of $20,990,000 was accelerated. Since the termination of the former collaboration agreement, we have been selling our products through distributors who have a general right of return of product and, accordingly, we have deferred such revenue until the product is sold by our distributors to the end user. 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.

In December 2003, the Securities and Exchange Commission released Staff Accounting Bulletin No. 104 ("SAB 104"), Revenue Recognition. SAB 104 clarifies existing guidance regarding revenues for contracts which contain multiple deliverables to make it consistent with Emerging Issues Task Force ("EITF") No. 00-21. The adoption of SAB 104 did not have a material impact on the Company's financial position or results of operations.

INVENTORY - Inventories are stated at the lower of cost or market value. 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. For example, as a result of the termination of the former dermatology collaboration agreement in 2002, we recorded lower of cost or market adjustments of $2,095,000 for excess inventory and commercial light units at that time. We use sales projections to estimate the appropriate level of inventory that should remain on the Consolidated Balance Sheet. Management believes that the recorded inventory value is reasonable in light of our current sales forecasts. Should we be unable to achieve the forecasted sales, additional adjustments may be recorded to cost of goods sold.

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VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS - We review long-lived assets 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. If 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 and again in 2003, we concluded that the termination of our former dermatology collaboration agreement in September 2002 and current business events have not caused any impairment to our manufacturing facility. At December 31, 2003, total property, plant and equipment had a carrying value of $4,251,000, including our manufacturing facility which received FDA approval on July 14, 2003. In September 2002, as a result of the termination of our former dermatology collaboration agreement, we recorded impairment adjustments of $1,182,000 related to certain intangibles assets previously recorded in our financial statements. We had no intangible assets recorded as of December 31, 2003 or 2002.

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, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure". 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, a change in accounting for stock-based compensation could, under certain circumstances, result in an adverse material effect on our results of operations, but would not affect cash flows.

RESULTS OF OPERATIONS

2002 DERMATOLOGY COLLABORATION TERMINATION

On September 1, 2002, DUSA and Schering AG, the Company's former marketing and development partner for Levulan(R) 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, and evaluated certain items on its 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 agreement with Schering AG, and assets including our manufacturing facility, raw material and finished goods inventories, commercial light units, and deferred charges and royalties. As a result of this analysis, in addition to normal amortization recorded prior to the termination of the Schering AG agreement, DUSA recorded the following items in its Consolidated Statements of Operations during September 2002:

STATEMENT OF OPERATIONS ITEM	BALANCE SHEET ITEM
Revenues:	
Research grant and milestone revenue	Deferred revenue (1)
Operating Costs:	
Cost of product sales	Deferred charges (2) Inventory (3) Commercial light sources under or rental (4)
Total cost of product sales	
Research and development costs	Deferred royalty (2)
Total operating cost charges	

1) In 2002, DUSA accelerated the recognition of $20,990,000 of unamortized research grant and milestone revenue, which was previously recorded as deferred revenue.

2) In 2002, DUSA 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(R), (ii) $34,000 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(R), 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 1/2 years.

3) In 2002, DUSA recorded lower of cost or market adjustments for estimated excess BLU-U(R) inventory of $1,594,000, and $111,000 for bulk Levulan(R) 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 expectations at that time of no significant near-term increases in Kerastick(R) sales levels and/or BLU-U(R) placements.

4) In 2002, DUSA recorded an additional $390,000 of depreciation expense reflecting a shortened useful life of our BLU-U(R) units under lease, rental, or trial arrangements to reflect a three-year asset life. This accelerated depreciation policy was attributable to the low level of BLU-U(R) placements at the date of the termination of the collaboration arrangement, and management's expectations at that time that near-term placements would be limited.

YEAR ENDING DECEMBER 31, 2003 AS COMPARED TO 2002

REVENUES - Total revenues for the year ended December 31, 2003 were $970,000, as compared to $25,483,000 in 2002. Revenues for 2002 included research grant and milestone revenues of $22,312,000, comprised of 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 termination of this relationship, and normal amortization of $1,322,000 earned prior to the termination. See section entitled "Results of Operations-2002 Dermatology Collaboration Termination". Revenues for 2002 also included $2,851,000 of research and development reimbursement which we earned from our former marketing partner. Due to the termination of this agreement, we have not received any co-development revenue from Schering AG subsequent to 2002.

Total product sales and rental income for the years ended December 31, 2003 and 2002 were $970,000 and $319,000, respectively, and comprised of the following:

	YEAR ENDED DECEMBER 31,		
	2003	2002	INCREASE (DECREASE)
Kerastick(R)product sales	$ 901,000	$ 209,000	$ 692,000
BLU-U(R)product sales	69,000	--	69,000
BLU-U(R)rental and other sales	--	33,000	(33,000)
Royalty revenues (1)	--	77,000	(77,000)
Total product sales and rental income	$ 970,000	$ 319,000	$ 651,000

(1) Product sales for 2002 included royalty revenues of $77,000 which we previously earned for Kerastick(R) sales by Berlex, the subsidiary of our former marketing partner, to its distributor.

The increase in 2003 Kerastick(R) product sales revenue is due in part to DUSA's receipt of 100% of revenues on units sold to end-users, primarily through its distributors, as compared to approximately 30% of the net sales that we received as a royalty under our former collaboration agreement during 2002. Revenues for 2003 also included BLU-U(R) product sales of $69,000 after receiving FDA clearance to market the BLU-U(R) as a stand alone device for the treatment of moderate inflammatory acne vulgaris.

As of December 31, 2003, 406 BLU-U(R) units were in place in physicians offices, up from 329 units at December 31, 2002. This increase in BLU-U(R) placements included the sale of 21 units following receipt of market clearance from the FDA in September 2003 for acne. Kerastick(R) sales to end-users were

11,172 for 2003, as compared to 7,116 for 2002. Although the level of Kerastick(R) sales to end-users for 2003 is higher than those in the prior year, Kerastick(R) sales must continue to increase significantly to offset the increased costs incurred for marketing and sales activities. See "Results of Operations-Marketing and Sales Costs".

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the year ended December 31, 2003 were $3,481,000, as compared to $5,253,000 in 2002. The components of cost of product sales and royalties for the years ended December 31, 2003 and 2002, including direct and indirect costs to support our product is provided below:

	YEAR E
	2003
COST OF PRODUCT SALES AND ROYALTIES	
Product costs including internal costs (e.g. customer service, quality assurance, purchasing, depreciation, amortization and other product support operations) assigned to support products (1)	$ 2,297,000
Direct Kerastick(R)product costs	381,000
Costs incurred to ship, install and service the BLU-U(R)in physicians offices (2)	729,000
Royalty and supply fees (3)	74,000
Net underutilization costs (4)	-0-
Deferred charges amortization (5)	-0-
Inventory and deferred charge adjustments resulting from collaboration termination (6)	-0-
Total cost of product sales and royalties	$ 3,481,000

1) The increase in product costs for 2003 is primarily attributable to increased costs to support the preparation to manufacture the Kerastick(R), including the submission of an NDA supplement to the FDA for our manufacturing facility, facility depreciation and overhead allocations.

2) Although there were direct BLU-U(R) product sales in 2003, there were no related direct BLU-U(R) product costs in 2003 as these had a zero book value due to inventory impairment charges recorded during 2002 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 at that time of no significant near-term increases in Kerastick(R) sales levels and/or BLU-U(R) placements.

3) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario.

4) Underutilization costs commenced in 2001 and were fully amortized as of December 31, 2002 based on agreements with our third-party manufacturers due to orders falling below certain previously anticipated levels.

5) Deferred charges amortization 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(R). Such deferred charges were fully amortized in 2002.

6) See section entitled "Results of Operations-2002 Dermatology Collaboration Termination".

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the year ended December 31, 2003 were $5,404,000 as compared to $12,122,000 for 2002. The overall lower level of research and development costs in 2003 is attributable, in part, to the absence of co-sponsored project costs that were agreed to under the collaboration termination in 2002, of which approximately two-thirds, or $2,851,000, were previously reimbursed to us by our former marketing partner. Co-sponsored projects included Phase I/II studies using Levulan(R) PDT in the treatment of persistent plantar warts and onychomycosis (nail fungus). These projects have been put on hold as we concentrate on increasing sales, and implementing a new dermatology development program focused on indications that use our approved Kerastick(R). Based on market research that was completed earlier in 2003, we decided to move forward with Phase II studies for use of Levulan(R) PDT in photodamaged skin and acne rather than pursuing a broad area actinic keratoses treatment, as we do not believe the former indication would have a major impact on sales.

In 2003, we also received market clearance from the FDA on a Section 510(k) premarket notification application for use of the BLU-U(R) without Levulan(R) to treat moderate inflammatory acne. This year's development program included the completion of an FDA-mandated Phase IV long-term AK tracking study, which was completed at the end of 2003, with the final report submitted to the FDA in January 2004. DUSA is also funding various investigator studies involving ALA and/or the Kerastick(R).

The decrease in research and development costs in 2003 is also attributable to the assignment of personnel and related costs to marketing and sales functions as of January 1, 2003 that were previously functioning in research and development roles, which totaled $1,310,000 in 2002. In addition, costs incurred in 2002 included 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 in December 2002 between DUSA and Photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company. In addition, we may also be obligated to pay certain regulatory milestones of $1,250,000 upon FDA acceptance of a registration application for a brain cancer product in the United States, and an additional

$1,250,000 upon registration of the product and royalties of 12.5% on net sales under the terms of the License and Development Agreement. This agreement also grants a license of Photonamic's proprietary technology related to ALA 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(R) PDT treatment of Barrett's esophagus with and without dysplasia.

We have also been conducting Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett's esophagus. Results of the high-grade dysplasia (HGD) study as of January 2003, with twelve months of follow-up data in four patients, and six months in one patient, showed a continued complete ablation of HGD. The treatment has been well tolerated, with no occurrence of strictures (circumferential scarring), and no signs of mucosal overgrowth. In addition, in preparation for a Phase II clinical trial, we are planning to carry out a small single-center pilot Phase II clinical trial using DUSA's new proprietary endoscopic light delivery device for the treatment of HGD. However, currently, we do not plan to fund other Phase II or III clinical trials for this indication on our own. Therefore, we are seeking a strategic partner to join in the development, marketing, and distribution of our treatment for Barrett's esophagus dysplasia. While our original goal had been to complete a partnership agreement during 2003, we did not have a partnership in place at the end of 2003. There can be no assurance that we will be able to consummate any collaboration on terms acceptable to us.

We expect research and development costs to increase to approximately $6,500,000 to $7,500,000 during 2004 due primarily to initiating our planned Phase II clinical studies relating to photodamaged skin and moderate to severe acne. Final cost estimates on these Phase II studies are in process as we are working with the FDA to determine the necessary protocols.

MARKETING AND SALES COSTS - Marketing and sales costs for 2003 were $2,494,000, comprised of $924,000 in payroll related costs, including direct and indirect commissions, with the remaining balance in support of such efforts. In the prior year, there were no marketing and sales expenses incurred directly by us as all rights and activities associated with marketing and sales of our products were the sole responsibility of our former partner. In late 2002, following the termination of our collaboration with our former marketing partner, we commenced marketing initiatives associated with having full rights and responsibilities for our products. In addition, as of January 1, 2003, we reassigned resources that were functioning in research and development roles to our marketing and sales function. In August 2003, DUSA hired an Associate Vice President of Sales, and in October 2003 we hired, trained, and deployed a regional sales force, which was initially comprised of six direct representatives, various independent representatives, and an independent sales distributor, to focus on most of our key geographic markets in the United States. At the end of December 2003, we hired our seventh direct representative in a key target market, and in January 2004, we continued to expand our sales capacity by adding one more direct representative and an independent representative in another key target market. We anticipate that the level of marketing and sales expenses and related support functions will continue to increase in 2004 as we seek to expand our sales capacity as a result of the initial success of our sales initiatives.

GENERAL AND ADMINISTRATIVE COSTS - General and administrative expenses for the year ended December 31, 2003 increased to $6,344,000 as compared to $5,591,000 for 2002. This increase is mainly attributable to higher legal expenses incurred in 2003 of $3,253,000 as compared to $1,970,000 in 2002, due primarily to patent defense costs. It is expected that legal expenses will remain at elevated levels as long as the patent dispute continues. These increased legal expenses were offset, in part, by lower staffing related costs of approximately $458,000 in 2003, due primarily to employee separations during 2002.

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 ALA 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 certain activities of PhotoCure and its marketing partner, Galderma S.A, infringe the patent. The case is ongoing and we are unable to predict the outcome at this time. DUSA believes that the final hearing in the Federal Court of Australia will occur in April 2004.

In December 2003, the Company was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging that DUSA's BLU-U(R) caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint names Berlex Laboratories, Inc., a subsidiary of our former marketing partner, as another defendant. The damages are unspecified. The case has been removed to the U.S. District Court, Eastern District of Michigan, Southern Division. While it is not possible to predict or determine the outcome of this action, the Company believes that the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one period to the extent costs are not covered by DUSA's insurance.

OTHER INCOME, NET - Other income for the year ended December 31, 2003 decreased to $1,926,000, as compared to $3,245,000 in 2002. This decrease reflects lower levels of investable cash balances as we used cash to support our operating activities, and a decline in yields. With the addition of the proceeds from the private placement in March 2004, interest income will initially increase and then may decline, dependent on interest rates, as our investable cash balances are used to support our operating activities. In addition, other income in 2002 included $500,000 of gains on the sale of securities to meet planned cash operating requirements. There were no such sales of securities in 2003. During 2003 and 2002, we incurred interest expense of $56,000 and $47,000, respectively, on borrowings associated with the construction of our new Kerastick(R) manufacturing facility. Of these amounts, $36,000 and $47,000 has been currently capitalized in property and equipment in the Consolidated Balance Sheet in 2003 and 2002, respectively.

INCOME TAXES - There is no provision for income taxes due to ongoing operating losses. As of December 31, 2003, we had net operating loss carryforwards of approximately $59,531,000 and tax credit carryforwards of approximately $1,791,000 for Federal reporting purposes. These amounts expire at various times through 2023. See Note 11 to the Notes to the Consolidated Financial Statements. In addition, although we had net income for 2002, there was no income tax expense because 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. The Company has provided a full valuation allowance against the net deferred tax assets at December 31, 2003 and 2002.

NET INCOME (LOSS) - For the year ended December 31, 2003, we recognized a net loss of ($14,827,000), or ($1.06) per share, as compared to net income of $5,763,000, or $0.42 per share, for the year ended 2002. 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 "Results of Operations-2002 Dermatology Collaboration Termination". This one-time recognition resulted in an increase to earnings per share of $1.28 for the 2002 period. Net losses are expected to be incurred until the successful market penetration of our products occurs. Such losses are expected to continue until end-user sales offset the cost of launching our sales force, marketing initiatives, and costs for other business support functions.

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 in 2001, and included the one-time recognition in 2002 of unamortized up-front milestone and unrestricted grant payments previously received from Schering AG totaling $20,990,000 due to the termination 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 "Results of Operations-2002 Dermatology Collaboration Termination". In addition, revenues for 2002 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.

Revenues for 2002 also included product sales and rental income of $319,000, as compared to $515,000 in 2001. This decrease reflected direct Kerastick(R) sales of $209,000 in 2002 from our distributor to physicians subsequent to reacquiring our product rights in September 2002, as compared to $358,000 in 2001 for direct Kerastick(R) sales to Berlex, a subsidiary of our former marketing partner. During 2002, we had no direct Kerastick(R) sales to Berlex as the distribution channel to physicians was filled in late 2001. Also included in 2002 product sales and rental income were royalty revenues of $77,000 which we previously earned for Kerastick(R) sales by Berlex to its distributor, and BLU-U(R) rental and other product sales of $33,000, as compared to royalty revenues of $55,000, and BLU-U(R) rental and other product sales of $102,000 in 2001.

As of December 31, 2002, excluding BLU-U(R) units installed at clinical trial sites or sold to our former partner, 329 BLU-U(R) units were in place, up from the 282 units at December 31, 2001. Kerastick(R) units sold to end-users were 7,116 in 2002 as compared to 7,071 in 2001.

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. This increase was mainly attributable to the recognition of $2,638,000 for lower of cost or market inventory adjustments, increased depreciation taken on BLU-U(R) units, and deferred charges associated with our amended Supply

Agreement with Sochinaz SA. 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:

	YEA
	2002
COST OF PRODUCT SALES AND ROYALTIES	
Recognition for lower of cost or market inventory adjustments, increased depreciation taken on BLU-U(R) units, and deferred charges as a result of the termination of our collaboration agreement with Schering AG	$2,638,000
Internal manufacturing costs (e.g. customer service, quality assurance, purchasing, and other product support operations) assigned to products	1,189,000
Costs incurred to ship, install and service the BLU-U(R)in physicians offices including depreciation	834,000
Royalty and supply fees (1)	64,000
Net underutilization costs (2)	333,000
Amortization of deferred charges (3)	151,000
Direct Kerastick(R)product costs including related testing	44,000
Total cost of product sales and royalties	$5,253,000

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 and were fully amortized as of December 31, 2002 based on agreements with our third-party manufacturers due to orders falling below certain previously anticipated levels.

3) Deferred charges amortization 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(R). Such deferred charges were fully amortized in 2002.

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 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 in December 2002 between DUSA and Photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company. 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(R) PDT treatment of Barrett's esophagus with and without dysplasia. In addition, 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.

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 attributable 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. We also incurred employee separation costs of approximately $395,000 during 2002. There were no employee separation costs in 2001.

OTHER INCOME, NET - 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 attributable 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. Gains on the sale of securities of $500,000 in 2002 in order to meet cash operating requirements, as compared to $92,000 in 2001, partly offset this decline in interest income. During 2002, we incurred interest expense of $47,000 on borrowings associated with the construction of our new Kerastick(R) manufacturing facility, which was 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.

NET INCOME (LOSS) - For the year ended December 31, 2002, we earned net income of $5,763,000, or $0.42 per share, as compared to a net loss of ($7,358,000), or ($0.53) per share, for the year ended 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 "Results of Operations-2002 Dermatology Collaboration Termination".

QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the quarterly results of operations for the years ended December 31, 2003 and 2002, respectively:

	QUARTERLY RESULTS FOR YEAR ENDED DECEMB		
	MARCH 31	JUNE 30	SEPTEMBER 3
Total revenues	$ 143,370	$ 147,275	$ 163,155
Loss from operations	(4,132,108)	(4,338,080)	(4,088,789
Net loss	(3,565,973)	(3,811,116)	(3,679,858
Basic and diluted loss per share	(0.26)	(0.27)	(0.26

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBE		
	MARCH 31	JUNE 30	SEPTEMBER 30
Total revenues	$ 1,325,498	$ 1,429,978	$22,565,754
Income (loss) from operations	(3,641,970)	(4,222,468)	15,065,172
Net income (loss)	(2,867,551)	(3,437,566)	15,760,873
Basic and diluted income (loss) per share	(0.21)	(0.25)	1.13

LIQUIDITY AND CAPITAL RESOURCES

We are in a strong cash position to continue to increase Levulan(R) PDT marketing expenses and to fund our current research and development activities for our Levulan(R) PDT/PD platform. Our primary sources of working capital have been public and private equity financings, as well as research milestone and grant payments from our former marketing and development partner. At December 31, 2003, we had approximately $37,969,000 of cash resources comprised of $4,294,000 of cash and cash equivalents, United States government securities of $33,536,000, and restricted cash of $139,000. All of our United States government securities are classified as available for sale. As of December 31, 2003, these securities had yields ranging from 3.65% to 7.36% and maturity dates ranging from January 15, 2004 to September 24, 2007.

On February 27, 2004, DUSA completed a private placement of 2,250,000 shares of our common stock at a purchase price of $11.00 per share resulting in gross proceeds of $24,750,000. DUSA also granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at $11.00 per share. These additional investment rights expire 30 trading days from closing, which occurred on March 2, 2004.

As of December 31, 2003, our working capital (total current assets minus total current liabilities) was $33,838,000 as compared to $48,891,000 as of December 31, 2002. Total current assets decreased $15,210,000 in 2003 due primarily to a decline in cash, cash equivalents, and United States government securities of $14,846,000 as we use cash to support our operating activities. Total current liabilities decreased $157,000 in 2003 due primarily to a decline in other accrued expenses of $908,000 as higher 2002 accruals for research and development costs, product related costs and license milestone were paid in 2003, offset, in part, by an increase in accounts payable, accrued payroll, and deferred revenue on Kerastick(R) units due to growth in operations and sales,

including an increase in personnel.

During 2003, we used $12,762,000 of cash for operating activities, incurred property, plant, and equipment additions of $633,000, and received $11,000,000 of net proceeds from maturations of United States government securities. During 2003, we also made payments on long-term debt of $270,000, while receiving $33,000 in proceeds from stock option exercises. During the comparable 2002 period, we used $11,786,000 of cash for operating activities, purchased $2,622,000 of property and equipment primarily attributable to the construction of our manufacturing facility, and received net proceeds of $12,115,000 from maturations and purchases of United States government securities. During 2004, we expect to incur capital expenditures of approximately $700,000, which includes upgrades to our computer systems and website, and marketing fixtures, as well as other purchases to support the growth in our business.

In May 2002, we also received $1,900,000 under a secured term loan promissory note ("Note") with Citizens Bank of Massachusetts to fund the construction of our manufacturing facility and made payments on the Note of $113,000 during 2002. As of December 31, 2003, the total outstanding loan balance was $1,518,000, 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. 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. The current interest rate on the Note is 2.755% based on the annual renewal on June 30, 2003. As this rate was lower than the yield being generated by each of our United States government securities at that time, we decided not to repay the loan.

We believe that we have sufficient capital resources to proceed with our current programs for Levulan(R) PDT, and to fund operations and capital expenditures for the foreseeable future. We have invested our funds in liquid investments, so that we have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis.

As a result of the termination of our former dermatology collaboration arrangement, we evaluated our operations during 2003 and minimized research and development and related general and administrative expenditures while we concentrated on implementing new sales, marketing, physician education, and development strategies. Such strategies included the hiring of an Associate Vice President of Sales in August 2003 followed by the October 2003 launch of DUSA's initial sales force, and participation in various medical education events. We anticipate that the level of marketing and sales expenses and related support functions will increase in 2004 as we seek to expand our sales capacity as a result of the initial success of our sales initiatives. We may also 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. For 2004, we are focusing primarily on increasing the sales of the Levulan(R) Kerastick(R) and the BLU-U(R), initiating Phase II studies for use of Levulan(R) PDT in photodamaged skin and acne using our Kerastick(R), and on seeking a partner to help develop and market Levulan(R) 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 products including the success of our marketing programs since reacquiring the rights to the dermatological uses of Levulan(R)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 level of revenues from sales of our products. In order to maintain and continue to expand our sales and marketing endeavors, and to initiate our planned research and development programs, we may need to raise additional funds through future corporate alliances, financings, or other sources, depending upon the amount of sales we receive.

The total capital costs used to develop our manufacturing facility, which was approved to manufacture the Levulan(R) Kerastick(R) by the FDA in July 2003, was approximately $2,665,000, including equipment. We have also incurred certain environmental control costs as part of our development of a production line for Kerastick(R) manufacturing to ensure that our facility complies with environmental standards. However, there can be no assurance 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".

DUSA has no off-sheet balance sheet financing arrangements other than its operating leases.

CONTRACTUAL OBLIGATIONS AND OTHER COMMERCIAL COMMITMENTS

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements, are as follows at December 31, 2003:

OBLIGATIONS DUE BY PERIOD

	TOTAL	1 YEAR OR LESS	2-3 YEARS	4-5 YE
Operating lease obligations	$3,712,000	$ 417,000	$ 865,000	$ 828,
Research and development projects (1, 2)	$1,822,000	$1,822,000	--	
Secured term loan promissory note	$1,517,500	$ 270,000	$ 540,000	$ 540,

1) Research and development projects include various commitments including initial obligations for our planned Phase II clinical studies for photodamaged skin and moderate to severe acne. Final cost estimates on these Phase II studies are in process as we are working with the FDA to determine the necessary protocols.

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

RECENTLY ISSUED ACCOUNTING GUIDANCE

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities, an interpretation of ARB No. 51" ("FIN 46"), which was amended by FIN 46R issued in December 2003. This interpretation of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," addresses consolidation by business enterprises of variable interest entities (VIEs) that either: (1) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or (2) for which the equity investors lack an essential characteristic of a controlling financial interest. This Interpretation applies immediately to VIEs created after January 31, 2003. It also applies in the first fiscal year or interim period ending after March 15, 2004, to VIEs created before February 1, 2003 in which an enterprise holds a variable interest. FIN 46 requires disclosure of VIEs in financial statements issued after January 31, 2003, if it is reasonably possible that as of the transition date: (1) the company will be the primary beneficiary of an existing VIE that will require consolidation or, (2) the company will hold a significant variable interest in, or have significant involvement with, an existing VIE. DUSA has adopted this statement which had no effect on our financial position or results of operations.

INFLATION

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

income by approximately $189,000 based on our December 31, 2003 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 30th 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 of 2.755% is based on a LIBOR-based rate plus 175 basis points at the time of renewal (LIBOR is 1.46% at December 31, 2003). 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 our core objectives for 2004, management's beliefs regarding the unique nature of Levulan(R) and its use and potential use, expectations regarding the timing of results of clinical trials and future development of warts, onychomycosis, psoriasis, molluscum contagioscum, oily skin and acne rosacea, facial photodamaged skin, acne, Barrett's esophagus dysplasia and other potential indications, intention to pursue licensing, marketing, copromotion or acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy and marketing, our intention to develop combination drug and light device systems, our intention to test a new proprietary endoscopic light delivery system, our intention to expand our 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(R) competitive properties, intention to postpone or commence clinical trials and investigator studies in 2004, 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 2004, 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, our manufacturing facilities and its related costs, and potential for additional inspection and testing, beliefs regarding the adequacy of our inventory of Kerastick(R) 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 reimbursement by third-parties for our treatments, the impact

of competitive products and pricing, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, environmental risks relating to 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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2003. There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, DUSA's internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

BOARD OF DIRECTORS

The name, age and current position with the Company of each director is listed below, followed by summaries of their backgrounds and principal occupations.

NAME	AGE	POSITION
D. Geoffrey Shulman, MD, FRCPC.....	49	President, Chief Executive Officer, and Director (principal executive officer)....
John H. Abeles, MD (1) (3).....	59	Director.....
David M. Bartash(1)(2).....	61	Director.....
Jay M. Haft, Esq(1)(2)(3).....	68	Chairman of the Board and Director.....
Richard C. Lufkin (1) (3).....	57	Director.....
Magnus Moliteus (2).....	65	Director.....

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

D. Geoffrey Shulman, MD, FRCPC, is the Company's founder, President and CEO and formerly served as our Chairman. Dr. Shulman, a dermatologist, was the President and a director of Draxis Health Inc. from its founding in October 1987 until May 1990, was Co-Chairman from October 1990 to April 1993, and Chairman of the Board from April 1993 until March 1996. Dr. Shulman also participates, on a limited basis, in a private dermatology practice.

John H. Abeles, MD, is the President and founder of MedVest, Inc. which, since 1980, has provided consulting services to health care and high technology companies. He is also the Chief Executive Officer of UniMedica, Inc., a provider of medical educational services and materials. Dr. Abeles is a member of the Boards of Directors of I-Flow Corporation, Oryx Technology, Inc., Molecular Diagnostics Inc. and Encore Medical Corporation.

David M. Bartash, is the President and founder of Bartash and Company, a consulting company which, since 1990, has been providing consulting services for the healthcare industry, including research for the healthcare investment community and support services for venture start-ups.

Jay M. Haft, Esq., is a strategic and financial consultant for growth-stage companies. He was a senior corporate partner of the law firm of Parker, Duryee, Rosoff & Haft from 1989 to 1994 and was of counsel to Parker, Duryee, Rosoff & Haft and Reed Smith LLP until 2002. Mr. Haft is a member of the Boards of Directors of DCAP Group Inc., Oryx Technology Corporation and Encore Medical Corporation.

Richard C. Lufkin is the principal of Enterprise Development Associates, a proprietorship formed in 1985 which provides consulting and venture support services to early stage technology-based companies, principally in the life sciences. He is also a co-founder, consultant to, and former Chief Financial

Officer of Linguagen Corp., a development-stage, privately-held, biotechnology firm.

Magnus Moliteus is a consultant to the healthcare industry and Chairman of COM Consulting Inc., a privately held firm, which enhances Swedish-American relations particularly between health care companies. From 1995 to 2001, when he became a full-time consultant, Mr. Moliteus served as Executive Director of Invest in Sweden Agency, U.S., a Swedish government agency. From 1977 to 1990, he was Chief Executive Officer of Pharmacia, Inc. (now owned by Pfizer, Inc.)

EXECUTIVE OFFICERS WHO ARE NOT DIRECTORS

The name, age and position with the Company of each executive officer who is not a director of the Company is listed below, followed by summaries of their backgrounds and principal occupations. Executive officers are elected annually, and serve at the discretion of the Board of Directors.

NAME	AGE	TITLE
Mark C. Carota	48	Vice President, Operations
Peter M. Chakoutis	38	Vice President and Chief Financial Off (principal financial and accounting officer
Richard C. Christopher	34	Vice President, Financial Planning Business Analysis
Scott L. Lundahl	45	Vice President, Intellectual Property Regulatory Affairs
Stuart L. Marcus, MD, Ph.D.	57	Vice President, Scientific Affairs; C Medical Officer
David Page	44	Associate Vice President, Sales
Paul A. Sowyrda	42	Vice President, Marketing and Sales

Mark C. Carota has been employed by the Company since October 1999. Prior to joining the Company, Mr. Carota was Director of Operations from November 1998 to October 1999 for Lavelle, Inc., a privately held manufacturer of orthopedic instrumentation. From July 1998 to November 1998, Mr. Carota was employed as Director of Quality Assurance by CGI Inc. Prior to joining CGI Inc., Mr. Carota was employed by Allergan Inc., from February 1997 to July 1998 where he had responsibility for quality assurance, engineering and facilities.

Peter M. Chakoutis has been employed by the Company since December 2000. Prior to his promotion to his current position on January 1, 2004, he held the position of controller. Prior to joining the Company, Mr. Chakoutis was Financial Reporting Manager from December 1996 to December 2000 for State Street Corporation, a publicly traded financial holding company that provides a full range of products and services for sophisticated global investors.

Richard C. Christopher has been employed by the Company since December 2000. Prior to his promotion to his current position on January 1, 2004, he held the position of Director, Financial Analysis. Prior to joining the Company, he was the North American Cost Accounting Manager for Grace Construction Products, a unit of W.R. Grace & Co. from April 1999 to December 2000. Prior to joining Grace Construction Products, Mr. Christopher was employed by the Boston Edison Company from March 1996 until April 1999.

Scott L. Lundahl has been employed by the Company since May 1998. In 1994, Mr. Lundahl co-founded and became Vice President of Lumenetics, Inc., a privately-owned medical device development company, which, prior to May 1998, provided the Company with consulting services in the light device technology area.

Stuart L. Marcus, MD, Ph.D. has been employed by the Company since October 1993. Prior to joining the Company, he was Director of the Hematology/Oncology Department of Daiichi Pharmaceuticals Inc., and prior thereto he held positions in the Medical Research Division of the American Cyanamid Company, directing photodynamic therapy clinical development, among other assignments.

David Page has been employed by the Company since August 2003. Prior to joining the Company, Mr. Page was Vice President of Sales, Aesthetic Division from July 2001 to August 2003 for Lumenis, Inc. From July 1999 to July 2001, Mr. Page was Vice President of Sales for ESC Medical Systems responsible for Aesthetic, Surgical and Veterinary US Markets.

Paul A. Sowyrda, has been employed by the Company since April 2000. From April 1998 to April 2000, Mr. Sowyrda was employed by Aurora Tech, a Division of Carlo Gavazzi, where at the time of his departure he was serving as President and Chief Executive Officer. From October 1997 to February 1998, Mr. Sowyrda was Vice President, Operations of UroMed Corp, Urovation Division.

AUDIT COMMITTEE FINANCIAL EXPERT

Our Board of Directors has determined that Richard Lufkin, the Chairman of our Audit Committee, is an audit committee financial expert, as that term is defined under Regulation S-K, Item 401(h), and that he is independent, as that term is used in Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Under the securities laws of the United States, the Company's directors, officers and any person holding more than ten percent (10%) of our common stock are required to report their ownership of securities and any changes in that ownership to the Securities and Exchange Commission on Forms 3, 4 and 5. Based on our review of the copies of such forms we have received, DUSA believes that all of our officers, directors and shareholders holding ten percent (10%) or more of our common stock complied with all filing requirements applicable to them with respect to their reporting obligations except for a single untimely filing by Peter M. Chakoutis reporting his initial holdings of the Company's securities and one filing by Jay Haft reporting his indirect acquisition of shares through his spouse in three transactions that occurred in 2002. In making these statements, we have relied on the written representations of our directors and officers and copies of the reports that they have filed with the Securities and Exchange Commission.

CODE OF ETHICS

We have adopted a Code of Ethics within the meaning of Item 406(b) of Regulation S-K. This Code of Ethics applies to all our executive officers including our principal executive officer and principal financial officer. If we make substantive amendments to this Code of Ethics or grant any waiver, including any implicit waiver, we will disclose the nature of such amendment in a report on Form 8-K within five days of such amendment or waiver.

ITEM 11. EXECUTIVE COMPENSATION

DIRECTOR COMPENSATION

Directors who are employees of the Company receive no cash compensation for their services as directors or as members of committees. Outside directors receive $25,000 per year, as annual compensation, regardless of the number of Board or Committee meetings they attend. Directors serving on the Audit Committee receive an additional $5,000 per year. Also, directors are paid out-of-pocket expenses related to their attendance. Directors are awarded options to purchase 15,000 shares of common stock on the earlier of thirty (30) days following their date of election or June 30th of their first year of service as a member of the Board of Directors, and options for 10,000 shares of common stock on June 30th of each year following their reelection.

EXECUTIVE COMPENSATION

The following table shows, for the fiscal years ended December 31, 2003, 2002 and 2001, certain compensation paid by DUSA to its executive officers. All amounts are stated in United States dollars unless otherwise indicated.

SUMMARY COMPENSATION TABLE

		ACTUAL COMPENSATION			L	
					AWARDS	
NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)	BONUS ($)	OTHER ANNUAL COMPEN-SATION1 ($)	RESTRICTED STOCK AWARD(S) ($)	
D. Geoffrey Shulman, MD, FRCPC,	2003	340,000	170,000	--	--	
President, Chief Executive Officer	2002	340,000	64,600	--	--	
	2001	340,000	84,460	--	--	
Mark C. Carota, Vice President,	2003	175,000	38,900	--	--	
Operations	2002	157,000	20,300	--	--	
	2001	150,731	26,860	--	--	
Scott Lundahl, Vice President,	2003	182,000	40,400	--	--	
Intellectual Property and Regulatory	2002	168,000	21,700	--	--	
Affairs	2001	134,462	27,060	--	--	

Stuart L. Marcus, MD, Ph.D., Vice President, Scientific Affairs and Chief Medical Officer	2003	250,000	55,500	--	--
	2002	247,520	17,100	--	--
	2001	246,055	34,910	--	--
Paul A. Sowyrda, Vice President, Marketing and Sales	2003	180,000	43,200	--	--
	2002	164,800	21,300	--	--
	2001	154,350	26,550	--	--

Notes:

(1) No officer had perquisites in excess of $50,000 or 10% of salary and bonus reported for 2003, 2002 or 2001.

BOARD COMPENSATION COMMITTEE REPORT ON EXECUTIVE COMPENSATION

The Compensation Committee of the Board of Directors (the "Committee") is composed of three (3) non-employee directors. The Committee is responsible for setting and administering the policies which govern annual executive salaries and cash bonus awards, and recommends participants and amounts of stock option awards to the Company's Board of Directors. The Committee evaluates, on a yearly basis, the performance, and determines the compensation of, the executive officers of DUSA. The Committee evaluates compensation based upon the achievement by the individual of corporate goals, and the performance of individual responsibilities. DUSA's President and Chief Executive Officer, Dr. D. Geoffrey Shulman, is not a member of the Committee, however, the Committee seeks input from Dr. Shulman regarding the performance of DUSA's Vice Presidents, as well as his recommendations for their compensation. Dr. Shulman is present, at the invitation of the Committee, at its meetings, other than during consideration of his own compensation.

DUSA's executive compensation programs consist of base salary, cash bonus incentives, stock option and stock grant awards. The goals of the Company's executive officer compensation policies are to attract, retain, and reward executive officers who contribute to DUSA's success, to align executive officer compensation with DUSA's performance and to motivate executive officers to achieve the Company's business objectives. The executive officers were evaluated by the Committee against established goals for 2003, including corporate goals, the Company's stock performance and individual goals within each executive officer's area of responsibility.

With regard to base salary, the Committee believes that DUSA's officers should be compensated at levels comparable to the base salary of executive officers at similar small public biotechnology or pharmaceutical companies. During 2000, the Committee received survey data reporting the salaries for executives of companies in these groups which was prepared by independent consultants. The Committee intends to obtain an updated report regarding executive compensation for similarly situated companies before the end of 2004 in order to stay apprised of current compensation practices at such companies.

Generally, DUSA's Vice Presidents are eligible to receive up to 30% of their base salary as a cash bonus award. The Committee recognized that these individuals largely achieved their personal goals and corporate goals which had a positive influence on shareholder value for 2003. Therefore, the Committee concluded that DUSA's overall operational performance, particularly with regard

to marketing and sales functions, consolidation of regulatory functions, enhanced medical information functions, and approval of DUSA's manufacturing facility, justified favorable consideration of bonuses for its Vice Presidents. Accordingly, DUSA's Vice Presidents received cash bonus awards ranging from approximately 22% to 24% of their base salaries. These cash awards were paid in March 2004.

The Committee also is using the 2000 survey data from independent consultants to monitor and evaluate the long-term incentive compensation levels of its officers and directors. The Committee believes that a strong stock ownership program is essential to the long-term growth of the Company. In 2004, the Committee granted to DUSA's key executive officers awards of stock options to emphasize the long-term focus required for success in the pharmaceutical industry.

COMPENSATION OF THE PRESIDENT AND CHIEF EXECUTIVE OFFICER

The Committee exercised its subjective judgment and discretion in determining the amounts of Dr. Shulman's base salary, bonus award, and stock option awards for 2003. Dr. Shulman's base salary and cash bonus award for 2003 were determined with reference to the same measures used for all DUSA's executive officers, but with particular emphasis on the maintenance of our financial strength and meeting marketing and sales expectations. Dr. Shulman's base salary for 2003 was $340,000. With regard to a cash bonus award, Dr. Shulman is eligible to receive up to 50% of base salary plus additional amounts for outstanding performance. For 2003, Dr. Shulman's bonus award was 50% of his base salary. Dr. Shulman's bonus award was paid to him in 2004. For 2004, Dr. Shulman proposed that his base salary remain unchanged from that of 2002 and 2003, which proposal was accepted by the Committee.

Jay M. Haft, Esq.
David M. Bartash
Magnus Moliteus

PERFORMANCE GRAPH

COMPARISON OF FIVE YEAR CUMULATIVE SHAREHOLDER TOTAL RETURN
AMONG DUSA PHARMACEUTICALS, INC.,
NASDAQ MARKET INDEX AND MG GROUP INDEX

[GRAPH APPEARS HERE]

1/1/1999	12/31/1999	12/29/2000	12/31/2001	12/31/2002	12/31/

DUSA Pharmaceuticals, Inc.	$ 100.00	$ 386.44	$ 227.97	$ 109.15	$ 22.12	$	6
Drug Manufacturers/Other	100.00	131.60	213.31	189.85	134.88		18
NASDAQ Market Index	100.00	176.37	110.86	88.37	61.64		9

The graph above compares cumulative total shareholder return on our common stock for the five-year period ended December 31, 2003, with the cumulative total return on the Nasdaq Market Index and the Media General Drug Manufacturer Index over the same period. The identity of those corporations included in the Media General Financial Services Drug Manufacturer Index may be obtained by contacting Ms. Shari Lovell, Director of Shareholder Services, DUSA Pharmaceuticals, Inc., 555 Richmond Street West, Suite 300, Toronto, Ontario M5V 3B1 Canada.

The graph assumes $100 was invested in DUSA's common stock on January 1, 1999, and in each of the indices, and that dividends were reinvested. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of DUSA's common stock.

OPTION GRANTS IN 2003

The following grants of stock options were made to the named executive officers during fiscal year 2003.

	INDIVIDUAL GRANTS			
NAME	NUMBER OF SECURITIES UNDERLYING OPTIONS/SARS GRANTED(1)	PERCENT OF TOTAL OPTIONS/SARS GRANTED TO EMPLOYEES IN FISCAL YEAR	EXERCISE OF BASE PRICE ($/SHARE)	EXPIRATION DAT
Dr. D. Geoffrey Shulman	100,000	25.5%	$1.60	3/13/13
	10,000	2.6%	$2.51	6/30/13
Mr. Mark C. Carota	17,500	4.5%	$1.60	3/13/13
Mr. Scott Lundahl	17,500	4.5%	$1.60	3/13/13
Dr. Stuart L. Marcus	17,500	4.5%	$1.60	3/13/13
Mr. Paul A. Sowyrda	17,500	4.5%	$1.60	3/13/13

Notes:

(1) All options in this table have been granted pursuant to the 1996 Omnibus Plan, as amended. The options have exercise prices equal to the fair market value on the date of the grant.

(2) The potential realizable value is calculated based on the fair market value of DUSA's common stock on the date of the grant. These amounts only represent certain assumed rates of appreciation established by the SEC. There can be no assurance that the amounts reflected in this table or the associated rates of appreciation will be achieved.

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

The following table provides certain information as to certain stock options exercisable by the named executive officers for the fiscal year 2003, and the value of such options held by them at December 31, 2003, measured in terms of the closing price of the Company's common stock on The Nasdaq Stock Market on December 31, 2003 which was $5.05 per share.

NAME	SHARES ACQUIRED ON EXERCISE (#)	VALUE REALIZED ($)	NUMBER OF UNEXERCISED OPTIONS AT DECEMBER 31, 2003 EXERCISABLE/ UNEXERCISABLE
Dr. D. Geoffrey Shulman	--	--	671,250/ 193,750
Mr. Mark C. Carota	--	--	35,625/ 36,875
Mr. Scott L. Lundahl	--	--	109,375/ 38,125
Dr. Stuart L. Marcus	--	--	175,625/ 36,875
Mr. Paul A. Sowyrda	--	--	30,625/ 41,875

OTHER COMPENSATION

The Company has employment agreements with each of the executive officers named in the Summary Compensation Table. Pursuant to these agreements, the executive officers are entitled to receive compensation as determined by the Board of Directors and are eligible to receive the benefits generally made

available to employees of the Company. DUSA may terminate any of these agreements at any time, with or without cause on sixty (60) days prior written notice. If employment is terminated without cause, DUSA has agreed to pay a severance allowance equivalent to one year of the executive officer's then-current base salary payable in a lump sum, within sixty (60) days following the date of termination. In addition to the foregoing, Dr. Shulman's employment agreement also provides that he shall have the right to exercise, for a period of one year from the date of termination, all stock options granted to him prior to his termination as to all or any part of the shares covered by such options, including shares with respect to which such options would not otherwise be exercisable, subject to restrictions under U.S. or Canadian law.

In the event an executive officer should die while employed by DUSA, his heirs or beneficiaries will be entitled to any Company paid death benefits in force at the time of such death and will also be entitled to exercise any vested but unexercised stock options which were held by him at the time of his death, within a period of one (1) year from the date of death.

These employment agreements also provide for certain severance benefits following a change in control of the Company and termination of employment. Upon any "change of control," as defined in the agreements, DUSA shall pay to the executive officer a lump sum payment equal to three (3) times his base salary for the last fiscal year within five (5) days after such termination.

Under the Company's 1996 Omnibus Plan, as amended, any and all outstanding options not fully vested shall automatically vest in full and shall be immediately exercisable upon a "change of control," as defined in the grant agreements. The date on which such accelerated vesting and immediate exercisability shall occur, shall be the date of the occurrence of the change of control.

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

The following table sets forth certain information with respect to the beneficial ownership of DUSA's common stock as of March 1, 2004 by: (i) each of our directors; (ii) our named executive officers; (iii) all beneficial owners of greater than 5% of our outstanding common stock; and (iv) all of our directors and executive officers as a group.

NAME(1)	NUMBER OF SHARES BENEFICIALLY OWNED(
John H. Abeles, MD	89,500 (4)
David M. Bartash	50,500 (5)
Mark C. Carota	48,815 (6)
Jay M. Haft, Esq.	103,250 (7)
Richard C. Lufkin	97,100 (8)

Scott L. Lundahl	118,957	(9)
Stuart L. Marcus, MD, Ph.D.	191,250	(10)
Magnus Moliteus	15,000	(11)
D. Geoffrey Shulman, MD, FRCPC	1,107,668	(12)
Paul A. Sowyrda	46,250	(13)
All directors and executive officers as a group (consisting of 14 persons)	1,938,603	(14)
Dimensional Fund Advisors, Inc.	885,800	(15)
Royce & Associates, Inc.	1,225,600	(16)
Mr. Jeffrey Casdin and affiliated entities	2,167,300	(17)
Investors Group Inc. and its affiliated entities	1,120,800	(18)

* Less than 1%.

Notes:

(1) Unless indicated otherwise, the individuals listed herein have a business mailing address of c/o DUSA Pharmaceuticals, Inc., 25 Upton Drive, Wilmington, Massachusetts, 01887.

(2) Unless indicated otherwise, the individuals and entities listed herein have the sole power to both vote and dispose of all securities that they beneficially own.

(3) The percentage of ownership as calculated above includes in the number of shares outstanding for each individual listed those shares that are beneficially, yet not directly, owned. Applicable percentage of ownership is based on 16,391,372 shares of common stock outstanding on March 10, 2004 unless noted as otherwise.

(4) 65,000 of the shares indicated represent shares with respect to which Dr. Abeles has the right to acquire through the exercise of options. Of the shares indicated, Dr. Abeles shares investment and voting power with regard 24,500 shares.

(5) 35,000 of the shares indicated represent shares with respect to which Mr. Bartash has the right to acquire through the exercise of options.

(6) 48,750 of the shares indicated represent shares with respect to which Mr. Carota has the right to acquire through the exercise of options. Under Rule 13d-3 of the Securities and Exchange Act of 1934, as amended, Mr. Carota disclaims, but may be deemed to be the beneficial owner of, 15 shares of common stock that are held by his adult son and 50 shares held by his daughter, both of whom are members of Mr. Carota's household.

(7) 68,750 of the shares indicated represent shares with respect to which Mr.

Haft has the right to acquire through the exercise of options. Under Rule 13d-3 of the Securities and Exchange Act of 1934, as amended, Mr. Haft disclaims, but may be deemed to be the beneficial owner of, 34,500 shares that are held by his spouse.

(8) 95,000 of the shares indicated represent shares with respect to which Mr. Lufkin has the right to acquire through the exercise of options.

(9) 113,750 of the shares indicated represent shares with respect to which Mr. Lundahl has the right to acquire through the exercise of options.

(10) All of the shares indicated represent shares with respect to which Dr. Marcus has the right to acquire through the exercise of options. Dr. Marcus' address is 400 Columbus Avenue, Valhalla, New York, NY 10595.

(11) All of the shares indicated represent shares with respect to which Mr. Moliteus has the right to acquire through the exercise of options.

(12) 300,000 of the shares indicated represent shares with respect to which Dr. Shulman has the right to acquire through the exercise of his Class B Warrants which have an exercise price of CDN $6.79 per Warrant, and 750,000 of such shares represent shares with respect to which Dr. Shulman has the right to acquire through the exercise of options. Dr. Shulman's address is 555 Richmond Street West, Suite 300, Toronto, Ontario M5V 3B1 Canada.

(13) All of the shares indicated represent shares with respect to which Mr. Sowyrda has the right to acquire through the exercise of options.

(14) All of the shares indicated, Class B Warrants and options, as the case may be, as discussed in footnotes (4) through (13) above are included, as well as 1,478,000 shares which may be acquired through the exercise of options.

(15) The number of shares beneficially owned is based upon information disclosed by Dimensional Fund Advisors Inc. on a Schedule 13G/A filed with the Securities and Exchange Commission on February 6, 2004. Dimensional Fund Advisors Inc.'s address is 1299 Ocean Avenue, 11th Floor, Santa Monica, CA 90401.

(16) The number of shares beneficially owned is based upon information disclosed by Royce & Associates, Inc. on a Schedule 13G/A filed with the Securities and Exchange Commission on February 2, 2004. Royce & Associates, Inc.'s address is 1414 Avenue of the Americas, New York, New York 10019.

(17) The number of shares beneficially owned is based upon information disclosed by Jeffrey Casdin and his affiliated entities on a Schedule 13G/A filed with the Securities and Exchange Commission on February 17, 2004. The number of shares includes 567,400 shares beneficially owned by CLSP, L.P., 768,500 shares beneficially owned by CLSP II, L.P., 223,600 shares beneficially owned by CLSP/SBS I, L.P., 65,300 shares beneficially owned by CLSP/SBS II, L.P., 542,500 shares beneficially owned by Cooper Hill Partners, L.P., 1,624,800 shares beneficially owned by Cooper Hill Partners, LLC, 2,167,300 shares beneficially owned by Casdin Capital, L.L.C. and 2,167,300 shares beneficially owned by Jeffrey Casdin. Cooper Hill Partners, LLC is the sole general partner of each entity and has the power to vote and dispose of the securities owned by each entity. Jeffrey Casdin is the managing member of Cooper Hill Partners, LLC. Mr. Casdin is the managing member of Casdin Capital, LLC, the general partner of Cooper Hill Partners, L.P. Mr. Casdin's address is 230 Park Avenue, New York, New York 10169.

(18) The number of shares beneficially owned is based upon information disclosed by Investors Group Inc. and its affiliated entities on a Schedule 13G/A filed with the Securities and Exchange Commission on February 17, 2004. The number of shares listed includes 582,700 shares beneficially owned by Investors Canadian Small Cap Fund, 529,800 shares beneficially owned by Investors Canadian Small Cap Growth Fund, 6,000 shares beneficially owned by Investors Canadian Small Cap Class, 2,300 shares beneficially owned by Investors Canadian Small Cap Growth Class, 1,120,800 beneficially owned by I.G. Investment Management, Ltd., 1,112,500 shares beneficially owned by Investors Group Trust Co. Ltd., 1,112,500 shares beneficially owned by Investors Group Inc., 1,112,500 shares beneficially owned by Investors Group Trustco Inc. and 8,300 shares beneficially owned by Investors Group Corporate Class Inc. Investors Group Inc. owns 100% of the issued and outstanding Class A Common Shares of Investors Group Trustco Inc. Investors Group Trustco Inc. owns 100% of the issued and outstanding Class A Common Shares of the Investors Group Management Ltd. Investors Group Trustco Inc. also owns, directly or indirectly, 100% of the issued and outstanding Common Shares of the Investors Group Trust Co. Ltd. Investors Group Trustco Inc., Investors Group Management Ltd., Investors Group Trust Co. Ltd., Investors Canadian Small Cap Fund and Investors Canadian Small Cap Growth Fund are ultimately controlled by Investors Group Inc. through its ownership of 100% of the issued and outstanding Class A Common Shares of Investors Group Trustco Inc. Power Financial Corporation owns 56.1% of the common stock of Investors Group Inc. Power Corporation of Canada, of which Mr. Paul Desmarais controls 64.7% of the voting power, owns 67.4% of the common stock of Power Financial Corporation. Investors Group Inc.'s address is One Canada Centre, 447 Portage Avenue, Winnipeg, Manitoba R3C 3B6 Canada.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information as of December 31, 2003 with respect to shares of DUSA's common stock that may be issued under our outstanding options, warrants and other rights.

PLAN CATEGORY	(A) NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS OR RIGHTS	(B) WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS	E
Equity compensation plans approved by security holders	2,319,950	$11.656	
Equity compensation plans not approved by security holders	425,000(2)	$6.987	
Total	2,744,950	$10.933	

Note:

(1) The 1996 Omnibus Plan, as amended, provides that the maximum number of shares with respect to which awards may be granted shall not exceed 20% of the Company's common stock outstanding or a maximum of 2,753,328 shares.

(2) This number includes shares that may be issued upon the exercise of the following: (i) A Class B warrant granted to Dr. Shulman, our President, CEO and CFO, for the issuance of 300,000 shares of common stock. The exercise price of the warrant is $6.00 per share. This warrant is exercisable and has an expiration date of January 29, 2007; (ii) Options to purchase a total of 85,000 shares of common stock with an exercise price of $10.875 per share. This option was granted to PARTEQ Research and Development Innovations, the licensor of certain patents underlying our Levulan(R) PDT/PD systems, on October 21, 1997. PARTEQ has subsequently assigned the right to acquire 26,911 shares under this option to certain individuals. These options have ten (10) year terms and vested at the rate of 25% per year beginning on the first anniversary of the date of the original grant; (iii) Options to purchase 15,000 shares of our common stock issued to Therapeutics, Inc., a consultant to the Company, which were granted on March 13, 1997. These options have an exercise price of $6.125 per share, ten (10) year terms and vested 20% per year. These options have been subsequently assigned by Therapeutics, Inc. to its principal; and (iv) Options to purchase 25,000 shares of our common stock with an exercise price of $6.125 per share. These options were granted to Lumenetics, Inc., our former light device consultant, on March 13, 1997. They have been subsequently assigned by Lumenetics, Inc. to its principals. These options have ten (10) year terms and vested at the rate of 25% per year beginning on the date of the original grant.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

None.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

AUDIT FEES

The aggregate fees billed by Deloitte & Touche LLP for professional services rendered for the audit of the Company's annual financial statements for the fiscal years ended December 31, 2003 and 2002, and for the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for fiscal years 2003 and 2002 were $92,000 and $114,000, respectively.

AUDIT RELATED FEES

Other than the fees described under the caption "Audit Fees" above, Deloitte & Touche LLP did not bill any fees for services rendered to us during fiscal years 2003 and 2002 for assurance and related services in connection with the audit or review of our consolidated financial statements.

TAX FEES

The aggregate fees billed by Deloitte & Touche LLP for services rendered to the Company, for tax services for the fiscal years ended December 31, 2003 and 2002, were $20,000 and $14,000, respectively.

ALL OTHER FEES

There were no fees billed by Deloitte & Touche LLP for professional services rendered for the fiscal year ended December 31, 2003 and 2002.

POLICY ON AUDIT COMMITTEE PRE-APPROVAL OF AUDIT AND PERMISSIBLE NON-AUDIT SERVICES OF INDEPENDENT AUDITORS

In considering the nature of the services provided by the independent auditor, which were pre-approved in accordance with procedures required by the Audit Committee Charter, the Audit Committee determined that such services are compatible with the provision of independent audit services. The Audit Committee discussed these services with the independent auditor and Company management to determine that they are permitted under the rules and regulations concerning auditor independence promulgated by the SEC to implement the Sarbanes-Oxley Act of 2002, as well as the American Institute of Certified Public Accountants.

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

A. List of Financial Statements and Schedules

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 27, 2003, announcing that it had hired, trained and deployed an initial sales force.

C. Exhibits filed as part of this Report

3(a.1) 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.2) 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.

4(a) Common Stock specimen, filed as Exhibit 4(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2002, and is incorporated herein by reference;

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

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(b.2) Termination and Transfer Agreement between the Company and Draxis Health Inc. dated as of February 24, 2004, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended;

10(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(h.1) 1996 Omnibus Plan, as amended on May 1, 2003

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) 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(j.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(j.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(k) 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(l) 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(m) Collaboration Termination Agreement, effective September 1, 2002, between the Company 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(n) License and Development Agreement between the Company and Photonamic GmbH & Co. KG dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 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 is incorporated herein by reference; and

10(o) Supply Agreement between the Company and medac GmbH dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 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 is incorporated herein by reference.

10(p) Securities Purchase Agreement dated as of February 27, 2004, by and among the Company and certain investors, filed as Exhibit 10.1 to the Registrant's current report on Form 8-K, filed on March 2, 2004, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(q) Registration Rights Agreement dated as of February 27, 2004 by and among the Company and certain investors, filed as Exhibit 10.2 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;

10(r) Form of Additional Investment Right dated as of February 27, 2004, filed as Exhibit 10.3 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference; and

10(s) Investment Banking Agreement between the Company and Sunrise Securities Corp. entered into February 27, 2004.

14(a) Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers.

21(a)	Subsidiary of Registrant.
23(a)	Independent Auditors' Consent of Deloitte & Touche LLP.
31(a)	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer; and
31(b)	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32(a)	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
32(b)	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99(a)	Press Release dated March 16, 2004.

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, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2003. 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, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 11, 2004

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	DECEMBER 31,	
	2003	2002
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 4,294,482	$ 6,926,713
United States government securities	30,284,841	42,498,617
Accrued interest receivable	533,796	699,664
Accounts receivable	229,483	36,720
Inventory	712,831	1,188,659
Prepaids and other current assets	1,000,413	915,704
TOTAL CURRENT ASSETS	37,055,846	52,266,077
Restricted cash	139,213	137,883
United States government securities	3,250,940	3,316,330
Property, plant and equipment, net	4,251,489	5,229,683
TOTAL ASSETS	44,697,488	$ 60,949,973
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 859,282	$ 552,891
Accrued payroll	796,618	476,602
Other accrued expenses	1,162,139	2,070,150
Current maturities of long-term debt	270,000	270,000
Deferred revenue	129,900	5,100
TOTAL CURRENT LIABILITIES	3,217,939	3,374,743
Long-term debt, net of current	1,247,500	1,517,500
TOTAL LIABILITIES	4,465,439	4,892,243
Commitments and Contingencies (Note 15)		
SHAREHOLDERS' EQUITY		
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. Issued and outstanding: 13,966,247 (2002: 13,887,612) shares of common stock, no par	95,670,554	95,490,561
Additional paid-in capital	2,015,586	2,015,586
Accumulated deficit	(58,909,781)	(44,082,927)
Accumulated other comprehensive income	1,455,690	2,634,510

TOTAL SHAREHOLDERS' EQUITY	40,232,049	56,057,730
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 44,697,488	$ 60,949,973

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	YEAR ENDED	
	2003	
REVENUES		
Product sales and rental income	$ 970,109	$
Research grant and milestone revenue	--	22,
Research revenue earned under collaborative agreement	--	2,
TOTAL REVENUES	970,109	25,
OPERATING COSTS		
Cost of product sales and royalties	3,481,248	5,
Research and development	5,403,961	12,
Marketing and sales	2,494,405	
General and administrative	6,343,680	5,
TOTAL OPERATING COSTS	17,723,294	22,
INCOME (LOSS) FROM OPERATIONS	(16,753,185)	2,
OTHER INCOME, NET		
Interest income, net	1,926,331	2,
Realized gains on sales of United States government securities	--	
TOTAL OTHER INCOME	1,926,331	3,
NET INCOME (LOSS)	$(14,826,854)	$ 5,
BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE	$ (1.06)	$
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	13,936,482	13,

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	COMMON STOCK		ADDITIONAL
	NUMBER OF SHARES	AMOUNT	PAID-IN CAPITAL
BALANCE, JANUARY 1, 2001	13,730,890	$94,757,532	$1,860,519
Comprehensive loss:			
Net loss for period			
Net unrealized gain on United States government securities available for sale (net of realized gains of $91,841)			
Total comprehensive loss			
Issuance of common stock to consultants	5,000	54,750	
Exercises of options	104,500	478,279	
Exercises of warrants	25,000	150,000	
Stock based compensation			155,067
BALANCE, DECEMBER 31, 2001	13,865,390	$95,440,561	$2,015,586
Comprehensive income:			
Net income for period			
Net unrealized gain on United States government securities available for sale (net of realized gains of $500,206)			
Total comprehensive income			
Issuance of common stock to consultants	22,222	50,000	
BALANCE, DECEMBER 31, 2002	13,887,612	$95,490,561	$2,015,586
Comprehensive income:			
Net loss for period			
Net unrealized loss on United States government securities available for sale			
Total comprehensive loss			
Issuance of common stock to consultants	44,416	110,000	
Exercises of options	11,000	32,870	
Issuance of common stock to employee	23,219	37,123	
BALANCE, DECEMBER 31, 2003	13,966,247	$95,670,554	$2,015,586

	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL
BALANCE, JANUARY 1, 2001	$1,179,094	$55,309,796
Comprehensive loss:		
Net loss for period		(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		(6,313,355)
Issuance of common stock to consultants		54,750
Exercises of options		478,279
Exercises of warrants		150,000
Stock based compensation		155,067
BALANCE, DECEMBER 31, 2001	$2,223,835	$49,834,537
Comprehensive income:		
Net income for period		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		6,173,193
Issuance of common stock to consultants		50,000
BALANCE, DECEMBER 31, 2002	$2,634,510	$56,057,730
Comprehensive income:		
Net loss for period		(14,826,854)
Net unrealized loss on United States government securities available for sale	(1,178,820)	(1,178,820)
Total comprehensive loss		(16,005,674)
Issuance of common stock to consultants		110,000
Exercises of options		32,870
Issuance of common stock to employee		37,123
BALANCE, DECEMBER 31, 2003	$1,455,690	$40,232,049

See the accompanying Notes to the Consolidated Financial Statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEAR ENDED DECEMBE	
	2003	2002
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES		
Net income (loss)	$(14,826,854)	$ 5,762,518
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	100,346	(378,089)
Depreciation and amortization	1,610,848	3,247,129
Amortization of deferred revenue	--	(22,312,498)
Stock based compensation	--	--
Issuance of common stock to consultants	110,000	50,000
Changes in other assets and liabilities impacting cash flows from operations:		
Accrued interest receivable	165,868	223,795
Accounts receivable	(192,763)	84,560
Receivable under co-development program	--	864,534
Inventory	475,828	1,144,421
Prepaids and other current assets	(84,709)	(424,779)
Deferred charges	--	(100,000)
Accounts payable	306,391	238,002
Accrued payroll and other accrued expenses	(550,872)	84,477
Deferred revenue	124,800	(268,258)
Restricted cash	(1,330)	(1,865)
NET CASH USED IN OPERATING ACTIVITIES	(12,762,447)	(11,786,053)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES		
Purchases of United States government securities	(4,000,000)	(6,131,356)
Proceeds from maturing and sales of United States government securities	15,000,000	18,246,298
Additions of property, plant and equipment	(632,654)	(2,622,158)
Deposits on equipment	--	--
Payments to licensor	--	--
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	10,367,346	9,492,784
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES		
Proceeds from long-term debt	--	1,900,000
Payment of long-term debt	(270,000)	(112,500)
Proceeds from exercise of options	32,870	--
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	(237,130)	1,787,500
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,632,231)	(505,769)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	6,926,713	7,432,482

CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 4,294,482	$ 6,926,713
Cash paid for interest	$ 58,623	$ 41,066

During 2003, the Company issued 23,219 shares of restricted common stock at a closing price of $1.599 per share to its Chief Executive Officer, reflecting payment of the after-tax portion of his 2002 bonus compensation, which was accrued at December 31, 2002.

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(R)") PDT/PD. The Company's currently marketed products include the Levulan(R) Kerastick(R) 20% Topical Solution and the BLU-U(R) brand light source for the treatment of actinic keratoses (AKs) of the face or scalp. The Company also markets the BLU-U(R) without Levulan for the treatment of moderate inflammatory acne vulgaris.

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(R) manufacturing facility at its Wilmington, Massachusetts location. The cash is held in a separate bank account and is recorded in restricted cash in the Consolidated Balance Sheets. This letter of credit was renewed in December 2003 and has a balance, including interest earned, of $139,213 at December 31, 2003.

E) UNITED STATES GOVERNMENT SECURITIES - The Company classifies all securities as available for sale and records such investments at fair market value and records unrealized gains and losses on available for sale securities as a separate component of shareholders' equity, until realized. The premiums and discounts recorded on the purchase of the securities are amortized into interest income over the life of the securities.

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 securities as current assets, except for those pledged as collateral on the secured term loan promissory note.

F) INVENTORY - Inventory is stated at the lower of cost (first-in, first-out method) or market. Inventory consisting of BLU-U(R) commercial light sources is reclassified to property, plant and equipment when the BLU-U(R) is shipped to physicians for use under demonstration programs, and depreciated over their estimated useful lives. Inventory identified for research and development activities is expensed in the period in which that inventory is designated for such use.

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) 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.

I) REVENUE RECOGNITION - Revenues on product sales are recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred to end-users, and there is reasonable assurance of collection. Research revenue earned under collaborative agreements consisted of non-refundable research and development funding from a corporate partner. Research revenue generally compensated the Company for a portion of agreed-upon research and development expenses and was recognized as revenue at the time the research and development

activities were performed under the terms of the related agreements and when no future performance obligations existed. Milestone or other up-front payments are recorded as deferred revenue upon receipt and are recognized as income on a straight-line basis over the term of the agreement.

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 adopted EITF 00-21 on June 1, 2003 and the adoption had no impact on the Company's financial position or results of operations. In December 2003, the SEC released Staff Accounting Bulletin No. 104, Revenue Recognition ("SAB 104"). SAB 104 clarifies existing guidance regarding revenues for contracts which contain multiple deliverables to make it consistent with EITF No. 00-21. The adoption of SAB 104 did not have a material effect on the Company's financial position or results of operations.

J) 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 that do not have alternative future uses, are expensed at the time the costs are incurred.

K) INCOME TAXES - The Company recognizes deferred income tax assets and liabilities for the expected future tax consequences for events that have been included in the Company's financial statements or tax returns. Deferred tax assets and liabilities are based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which these differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

L) BASIC AND DILUTED NET INCOME (LOSS) 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, 2003, 2002, and 2001, stock options and warrants totaling approximately 2,745,000, 2,553,000, and 2,548,000 shares, respectively, have been excluded from the computation of diluted net income (loss) per share.

M) STOCK-BASED COMPENSATION - SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure," 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, as amended by SFAS No. 148. Under the intrinsic value method, compensation expense, if any, is recognized for the difference between the strike price of the option and the fair value of the underlying common stock as of a measurement date. The measurement date is the time when both the number of shares and the strike price is known. 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, as amended by SFAS No. 148, 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 measurement date, which is generally the grant date. 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:

	2003	2
NET INCOME (LOSS)		
As reported	($ 14,826,854)	$ 5,762,
Effect on net income (loss) if fair value method had been used	(3,445,951)	(3,880,
Proforma	($ 18,272,805)	$ 1,882,
BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE		
As reported	($ 1.06)	$ 0
Effect on net income (loss) per common share if fair value method had been used	(0.25)	(0
Proforma	($ 1.31)	$ 0

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

	2003	2002	2001
Expected life (years)	5	7	7
Risk free interest rate	3.02%	4.89%	4.88%
Expected volatility	80.85%	72.84%	70.87%
Dividend yield	--	--	--

Using these assumptions, the weighted-average fair value per option for the years ended December 31, 2003, 2002, and 2001, was $1.57, $2.53, and $10.29, respectively.

N) COMPREHENSIVE INCOME - The Company has reported comprehensive income (loss) and its components as part of its Consolidated Statement of Shareholders' Equity. Comprehensive income, apart from net income (loss), relates to net unrealized gains or losses on United States government securities.

O) 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.

P) 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 classified as available for sale are carried at fair market value. The fair market value of the Company's long-term debt is currently based on a floating rate based on LIBOR and, accordingly, the carrying value approximates its fair market value.

Q) 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. The Company is exposed to concentration risk related to accounts receivable that is primarily generated from its distributors.

R) RECENTLY ISSUED ACCOUNTING GUIDANCE - In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities, an interpretation of ARB No. 51" ("FIN 46"), which was amended by FIN 46R issued in December 2003. This interpretation of Accounting Research Bulletin No. 51, "Consolidated Financial Statements, " addresses consolidation by business enterprises of variable interest entities (VIEs) that either: (1) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or (2) for which the equity investors lack an essential characteristic of a controlling financial interest. This Interpretation applies immediately to VIEs created after January 31, 2003. It also applies in the first fiscal year or interim period ending after March 15, 2004, to VIEs created before February 1, 2003 in which an enterprise holds a variable interest. FIN 46 requires disclosure of VIEs in financial statements issued after January 31, 2003, if it is reasonably possible that as of the transition date: (1) the company will be the primary beneficiary of an existing VIE that will require consolidation or, (2) the company will hold a significant variable interest in, or have significant involvement with, an existing VIE. The Company has adopted this statement which had no effect on its financial position or results of operations.

3) 2002 DERMATOLOGY COLLABORATION TERMINATION

On September 1, 2002, DUSA and Schering AG, the Company's former marketing

and development partner for Levulan(R) 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, and evaluated certain items on its 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 agreement with Schering AG, and assets including the Company's manufacturing facility, raw material and finished goods inventories, commercial light units, and deferred charges and royalties. As a result of this analysis, in addition to normal amortization recorded prior to the termination of the Schering AG agreement, the Company recorded the following items in its financial statements for the year ended December 31, 2002:

STATEMENT OF OPERATIONS ITEM	BALANCE SHEET ITEM
Revenues:	
Research grant and milestone revenue	Deferred revenue (1)
Operating Costs:	
Cost of product sales	Deferred charges (2) Inventory (3) Commercial light sources under lease or rental (4)
Total cost of product sales	
Research and development costs	Deferred royalty (2)
Total operating cost charges	

1) In 2002, the Company accelerated the recognition of $20,990,000 of previously unamortized research grant and milestone revenue received from Schering AG, which were previously recorded as deferred revenue.

2) In 2002, 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(R), (ii) $34,000 to cost of product sales and royalties for deferred charges associated with underutilization costs paid to National Biological Corporation ("NBC"), the manufacturer of the Company's BLU-U(R), 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 1/2 years.

3) In 2002, the Company recorded lower of cost or market adjustments for estimated excess BLU-U(R) inventory of $1,594,000, and $111,000 for bulk Levulan(R) 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(R) sales levels and/or BLU-U(R) placements.

4) In 2002, the Company recorded an additional $390,000 of depreciation expense reflecting a shortened useful life of its BLU-U(R) units under lease, rental, or trial arrangements to reflect a three-year asset life. This accelerated depreciation policy was attributable to the low level of BLU-U(R) placements to date, the termination of the collaboration arrangement, and management's expectations that near-term placements would be limited.

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 3.65% to 7.36% and maturity dates ranging from January 15, 2004 to September 24, 2007. Securities pledged as collateral on the secured term loan promissory note have been classified as non-current assets. The fair market value and cost basis of such securities were as follows as of December 31:

	2003	2002
Fair market value	$33,535,781	$45,814,947
Cost basis	32,080,091	43,180,437
Gross unrealized gains	$ 1,455,690	$ 2,634,510

The change in net unrealized gains on such securities for the years ended December 31, 2003, 2002 and 2001 was ($1,178,820), $410,675 and $1,044,741, respectively, and has been recorded in accumulated other comprehensive income, which is reported as part of shareholders' equity in the Consolidated Balance Sheets.

5) INVENTORY

Inventory consisted of the following at December 31:

	2003	2002
Finished goods	$ 582,382	$1,047,941
Raw materials	130,449	140,718
	$ 712,831	$1,188,659

6) PROPERTY, PLANT AND EQUIPMENT

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

	USEFUL LIVES (YEARS)	2003
Computer equipment and software	3	$1,971,114
BLU-U(R)units in physicians' offices	3	1,187,875
Furniture, fixtures and equipment	5	542,496
Manufacturing equipment	5	2,096,433
Manufacturing facility	Term of lease	2,204,122
Leasehold improvements	Term of lease	666,344
Construction work-in-progress	--	--
		8,668,384
Accumulated depreciation and amortization		(4,416,895)
		$4,251,489

In July 2003, the Company received FDA approval to manufacture the Levulan(R) Kerastick(R) at its manufacturing facility and accordingly, the Company began to depreciate the facility and related manufacturing equipment over their estimated useful lives. The Company's lease commitment for office space and the manufacturing facility in Wilmington, MA extends through November 2016.

Depreciation and amortization totaled $1,611,000, $1,541,000, and $716,000 for 2003, 2002, and 2001, respectively. Accumulated depreciation and amortization includes $1,016,000 and $473,000 of accumulated depreciation at December 31, 2003 and 2002, respectively, associated with BLU-U(R) units in physicians' offices, which have been transferred to property, plant and equipment from inventory as these units were provided to physicians through former marketing trial programs.

During 2003 and 2002, the Company incurred interest expense of $56,000 and $47,000, respectively, on borrowings associated with the construction of our new Kerastick(R) manufacturing facility. Of these amounts, $36,000 and $47,000 has been currently capitalized in property and equipment in the Consolidated Balance Sheet in 2003 and in 2002, respectively.

7) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following at December 31:

	2003	2002
Accrued research and development costs	$ 184,912	$ 473,543
Accrued marketing and sales costs	113,020	--
Accrued product related costs	144,826	463,340
Accrued license milestone (1)	--	500,000
Accrued legal and other professional fees	359,747	297,966
Accrued employee benefits	189,051	207,833
Other accrued expenses	170,583	127,468
	$1,162,139	$2,070,150

(1) Accrued license milestone at December 31, 2002 represents a one-time $500,000 milestone payment under the Company's license agreement with Photonamic GmbH & Co. KG, which provided the Company with a license to certain proprietary technology related to ALA for use in the field of brain cancer (see Note 15(e)).

8) LONG-TERM DEBT

Long-term debt consisted of the following at December 31:

	2003	2002
Secured term loan promissory note	$ 1,517,500	$ 1,787,500
Less: Current maturities	(270,000)	(270,000)
	$ 1,247,500	$ 1,517,500

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. The Note currently bears interest at a 360-day LIBOR-based rate of 2.755% through June 30, 2004. Based on the terms of the Note, at June 30th of each year 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. Approximately $3,000,000 of the Company's United States government securities are pledged as collateral to secure the loan. The terms of the Note require monthly principal and interest payments through its maturity in June 2009, unless the Company repays the loan balance at the annual renewal date. Annual principal payments due under the Note are as follows:

	PRINCIPAL PAYMENTS
2004	$270,000
2005	270,000
2006	270,000
2007	270,000
2008	270,000
Beyond 2008	167,500
	$1,517,500

9) DEFERRED REVENUE

DUSA engages national distributors and marketers of medical and surgical supplies to act as third-party distributors of the Levulan(R) Kerastick(R) in the United States. The Company has recorded deferred revenue for Kerastick(R) units that have been sold to the distributors but not yet sold to end-users as the price was not fixed and final, since the distributors have a right of return on Kerastick(R) units. Deferred revenue at December 31, 2003 and 2002 was $129,900 and $5,100, respectively.

10) MARKETING AND SALES

As a result of the termination of the Company's marketing and development collaboration with its former marketing partner in September 2002, the Company commenced certain marketing and sales initiatives in 2003 associated with having full rights and responsibilities for its product. In addition, the Company has reassigned personnel and related costs that were previously functioning in research and development roles to its marketing and sales function. Prior to the Company's termination of its marketing and development collaboration, all rights and activities associated with marketing and sales of its approved products were solely the responsibility of its former partner. Activities included in marketing and sales expense for 2003 consist of trade show expenses, advertising, personnel and other resources assigned to marketing and sales activities, and other marketing and promotional activities. All such costs are expensed as incurred.

11) INCOME TAXES

The tax effect of significant temporary differences representing deferred tax assets and liabilities at December 31:

	2003	2002

DEFERRED TAX ASSETS		
Deferred revenue	$ 52,000	$ 2,000
Intangible assets	592,000	588,000
Accrued charges	41,000	46,000
Research and development tax credits carryforwards	2,354,000	2,144,000
Operating loss carryforwards	23,321,000	18,253,000
Capital loss and charitable contribution carryforwards	5,000	5,000
Deferred charges	--	405,000
License fee	181,000	202,000
Reserves	944,000	823,000
Total deferred tax assets	27,490,000	22,468,000
DEFERRED TAX LIABILITIES		
Fixed assets	(8,000)	(8,000
Total deferred tax liabilities	(8,000)	(8,000
Net deferred tax assets before allowance	27,482,000	22,460,000
Valuation allowance	(27,482,000)	(22,460,000
Total deferred tax asset	$ --	$ --

During the years ended December 31, 2003, 2002, and 2001, the valuation allowance was increased by approximately $5,022,000, $191,000, and $4,372,000, respectively, due to the uncertainty of future realization of the net deferred tax assets.

Included in deferred tax assets at December 31, 2003 and 2002 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.

As of December 31, 2003, the Company has Federal net operating loss carryforwards for tax purposes of approximately $59,531,000 and research and development tax credits of approximately $1,791,000, 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
2023	14,406,000	186,000
	$59,531,000	$ 1,791,000

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

	2003		2	
	$	%	$	
Income tax expense (benefit) at statutory rates	(5,041,000)	(34.0)	1,959,000	3
State taxes	(930,000)	(6.3)	371,000	
Tax credit carryforwards	(329,000)	(2.2)	(603,000)	(1
Change in valuation allowance including revisions of prior year estimates	6,268,000	42.3	(1,737,000)	(3
Other	32,000	0.2	10,000	
	--	--	--	--

12) SHAREHOLDERS' EQUITY

COMMON STOCK ISSUANCES - On June 15, 2003, the Company granted compensation of $50,000 to Therapeutics, Inc. ("Therapeutics"), a clinical research organization, pursuant to an agreement for services. This compensation was issued in July 2003 and was comprised of 11,666 shares of common stock valued at $35,000 and $15,000 of cash. On June 15, 2002, the Company granted 22,222 shares of unregistered common stock pursuant to an agreement for services, to Therapeutics. These shares were valued at $50,000 at the time of grant. On October 4, 2001, the Company granted 5,000 shares of unregistered common stock to Therapeutics for services. These shares were valued at approximately $55,000 at the time of grant. Each of these transactions was recorded in research and development expense in the Consolidated Statements of Operations.

On May 2, 2003, the Company granted a total of 32,750 shares of unregistered common stock to two outside consultants as compensation for services rendered. These shares were valued at approximately $75,000 and recorded as part of research and development costs in the Consolidated Statements of Operations.

On March 13, 2003, the Company issued 23,219 shares of restricted common stock at a closing price of $1.599 per share to its Chief Executive

Officer, reflecting payment of the after-tax portion of his 2002 bonus compensation. This amount had been accrued in the December 31, 2002 financial statements.

SHAREHOLDER RIGHTS PLAN - 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 of the Company 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, restricted stock, or other securities determined by the Company, to directors, employees and consultants.

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. NQSO grants to employees 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. In addition, the Company initially grants each individual who agrees to become a director

15,000 NQSO to purchase common stock of the Company. Thereafter, each director reelected at an Annual Meeting of Shareholders will automatically receive an additional 10,000 NQSO on June 30 of each year except for 2001, for which each director received 5,000 NQSO based on an agreement at the June 14, 2001 shareholder meeting. Grants to directors 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, 2003:

	OPTIONS OUTSTANDING			OPT
RANGE OF EXERCISE PRICE	NUMBER OUTSTANDING AT DECEMBER 31, 2003	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	NU EXERCISABL DECE 31,
$1.60 to 3.63	489,700	7.94 years	$2.51	196
3.87 to 7.71	537,250	6.27 years	5.75	338
7.75 to 9.33	495,000	3.03 years	8.10	495
9.69 to 26.19	499,500	5.57 years	14.24	423
27.19 to 31.00	423,500	6.34 years	29.95	317
	2,444,950	5.82 years	$11.50	1,771

Activity under stock option plans during the years ended December 31, 2003, 2002 and 2001 was as follows:

	2003	WEIGHTED AVERAGE EXERCISE PRICE	2002	WEIGH AVER EXERC PR
Options outstanding, beginning of year	2,253,075	$ 12.95	2,197,450	$ 14
Options granted	447,000	2.76	275,000	3

Options exercised	(11,000)	2.99	--	
Options cancelled	(244,125)	11.21	(219,375)	14
Options outstanding, end of year	2,444,950	$ 11.50	2,253,075	$ 12
Options exercisable, end of year	1,771,325	$ 12.59	1,666,826	$ 11

Options that were granted during 2003, 2002 and 2001 have exercise prices ranging from $1.60 to $5.20 per share, $2.90 to $4.01 per share, and $8.05 to $17.63 per share, respectively.

Options which were exercised during 2003 and 2001 were exercised at per share prices ranging from $2.90 to $3.87, and $3.25 to $7.25, respectively. There were no option exercises in 2002.

On October 21, 1997, the Company issued 85,000 options to PARTEQ. In accordance with EITF 96-18, the Company recorded an expense of approximately $155,000 in 2001 as part of research and development costs in the Consolidated Statements of Operations. PARTEQ has subsequently assigned the right to acquire 26,911 shares under this option to certain individuals. In addition, on June 23, 1999, the Company issued 10,000 options to PARTEQ. As of December 31, 2003, all 95,000 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. 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, 2003, 300,000 of the remaining warrants were outstanding. The exercise price of the warrants is CDN $6.79 (U.S. $5.24 at December 31, 2003).

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 $6.00 per share. During 2001 and 2000, the investor relations firm exercised 25,000 shares in each year.

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, 2003, 2002 and 2001, 449 of the warrants were outstanding. These warrants expired on January 14, 2004.

14) RETIREMENT PLAN

Effective January 1, 1996, the Company adopted a tax-qualified employee savings and retirement 401(k) Profit Sharing Plan (the "401(k) Plan"), covering all qualified employees. Participants may elect a salary deferral of at least 1% as a contribution to the 401(k) Plan, up to the statutorily prescribed annual limit for tax-deferred contributions. Effective February 1, 2003, DUSA matches a participant's contribution up to 1.25% of a participant's salary (the "Match"), subject to certain limitations of the

401(k) Plan. Participants will vest in the Match at a rate of 25% for each year of service to DUSA. The Company's matching contribution in 2003 was $33,000.

15) COMMITMENTS AND CONTINGENCIES

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

When the Company is selling its products directly, it has agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where the Company has a sublicensee, 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, 2003, 2002 and 2001, actual royalties based on product sales were approximately $36,000, $12,000, and $3,000, respectively, however, based on the annual minimum royalty requirements, the Company incurred total royalty expense of $74,000, $64,000 and $63,000 in 2003, 2002, and 2001, 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. $77,000 as of December 31, 2003).

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. The Company has the ability to terminate its Wilmington lease after the 10th year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. The minimum lease payments disclosed below include the non-cancelable terms of the leases. Future minimum lease payments related to these agreements for years subsequent to December 31, 2003 are as follows:

	MINIMUM LEASE PAYMENTS
2004	$ 417,000
2005	465,000
2006	400,000
2007	410,000
2008	418,000
Beyond 2008	1,602,000
	$3,712,000

Rent expense incurred under these operating leases was approximately $471,000, $458,000, and $461,000 for the years ended December 31, 2003, 2002, and 2001, respectively.

C) RESEARCH AGREEMENTS - The Company has entered into a series of agreements for research projects and clinical studies. As of December 31, 2003, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $1,822,000 for 2004. 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, with annual renewal periods thereafter, to engage Therapeutics to manage the clinical development of the Company's products in the field of dermatology. The agreement was renewed on June 15, 2003 for a one year period. Minimum payments under this agreement have been included in the total future payments as noted above. Upon execution of this agreement in 2001, Therapeutics received 5,000 shares of the Company's common stock valued at $55,000, and is entitled to receive a bonus, in cash or stock at the Company's discretion, upon each anniversary of the effective date. 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 - On April 12, 2002, the Company received notice that one of the patents licensed to the Company by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario was challenged by PhotoCure ASA. PhotoCure ASA has filed a lawsuit in Australia alleging that Australian Patent No. 624985, which is one of the patents relating to the Company's 5-aminolevulinic acid technology, is invalid. As a consequence of this action, Queen's University has assigned the Australian patent to the Company so that DUSA may participate directly in this litigation. The Company has filed a response setting forth its defenses, in addition to a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A., infringe the patent. The case is ongoing and the Company is unable to predict the outcome at this time. The Company believes that the final hearing in the Federal Court of Australia will occur in April 2004.

In March 2003, the Company received notice that its Netherlands patent was being formally challenged by an anonymous agent, and DUSA filed a formal response to the opposition. The Netherlands Patent Office.

In December 2003, the Company was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging that DUSA's BLU-U(R) caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint names Berlex Laboratories, Inc., a subsidiary of our former marketing partner, as another defendant. The case has been removed to the U.S. District Court for the Eastern District of Michigan Southern Division. The damages are unspecified. The Company is reviewing the complaint with counsel and investigating the matter at this time. While it is not possible to predict or determine the outcome of this action, the Company believes that the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period to the extent costs are not covered by DUSA's insurance.

The Company has not accrued any amounts for settlement at December 31, 2003.

E) LICENSE AND SUPPLY AGREEMENTS - In December 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 made 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 was 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 of $1,250,000 upon FDA acceptance of a registration application for a brain cancer product in the United States, and an additional $1,250,000 upon registration of the product and royalties of 12.5% on net sales under the terms of the License and Development Agreement. The Company 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) SUBSEQUENT EVENTS

A) PRIVATE PLACEMENT - On March 2, 2004, the Company issued 2,250,000 shares of its common stock in a private placement pursuant to Regulation D of the Securities Act of 1933 at $11.00 per share. The Company received gross proceeds of $24,750,000. The Company has also granted the investors the right to purchase up to an aggregate of 337,500 additional shares of common stock at $11.00 per share. These additional investment rights expire April 14, 2004, or 30 trading days from closing, which occurred on March 2, 2004. In addition, 135,000 shares of common stock were issued as commission and non-refundable retainer to the placement agent.

B) REACQUISITION OF CANADIAN RIGHTS - On February 24, 2004, the Company reacquired the rights to the aminolevulinic acid (Levulan(R)) technology for Canada held by Draxis Health Inc. These rights were initially assigned to Draxis in 1991 at the time of the original licensing of the patents underlying our Levulan(R) PDT platform from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario. The Company and Draxis terminated the assignment and DUSA agreed to pay an upfront fee and a royalty on sales of the Levulan(R) Kerastick(R) in Canada over a five year term from the date of the first commercial sale. The commercial launch of the Company's products in Canada is expected to occur in 2004.

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 and Chief Executive Officer

Date: March 16, 2004

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

/s/ D. Geoffrey Shulman D. Geoffrey Shulman, MD, FRCPC	Director, President and Chief Executive Officer (principal executive officer)
/s/Mark C. Carota Mark C. Carota	Vice President, Operations
/s/Peter M. Chakoutis Peter M. Chakoutis	Vice President and Chief Financial Officer (principal financial and accounting officer)
/s/Richard C. Christopher Richard C. Christopher	Vice President, Financial Planning and Business Analysis
/s/Scott L. Lundahl Scott L. Lundahl	Vice President, Intellectual Property and Regulatory Affairs
/s/Stuart L. Marcus Stuart L. Marcus, MD, PhD	Vice President, Scientific Affairs
/s/David Page David Page	Associate Vice President, Sales
/s/Paul A. Sowyrda Paul A. Sowyrda	Vice President, Product Marketing and Sales

/s/John H. Abeles --- John H. Abeles	Director
/s/David Bartash --- David Bartash	Director
/s/Jay M. Haft --- Jay M. Haft, Esq.	Chairman of the Board and Director
/s/Richard C. Lufkin --- Richard C. Lufkin	Director
/s/Magnus Moliteus --- Magnus Moliteus	Director

EXHIBIT INDEX

3(a.1)	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.2)	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.
4(a)	Common Stock specimen, filed as Exhibit 4(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2002, and is incorporated herein by reference;
4(b)	Class B Warrant, filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
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 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(b.2) Termination and Transfer Agreement between the Company and Draxis Health Inc., dated as of February 24, 2004, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended;

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

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

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

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

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

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

10(h.1) 1996 Omnibus Plan, as amended on May 1, 2003;

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

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

10(j.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(j.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(k) 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(l) 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 by reference;

10(m) Collaboration Termination Agreement, effective September 1, 2002, between the Company 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(n) License and Development Agreement between the Company and Photonamic GmbH & Co. KG dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 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 is incorporated herein by reference;

10(o) Supply Agreement between the Company and medac GmbH dated as of December 30, 2002, filed as Exhibit 10(s) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 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 is incorporated herein by reference.

10(p) Securities Purchase Agreement dated as of February 27, 2004, by and among the Company and certain investors, filed as Exhibit 10.1 to the Registrant's current report on Form 8-K, filed on March 2, 2004, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

10(q)	Registration Rights Agreement dated as of February 27, 2004 by and among the Company and certain investors, filed as Exhibit 10.2 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
10(r)	Form of Additional Investment Right dated as of February 27, 2004, filed as Exhibit 10.3 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference; and
10(s)	Investment Banking Agreement between the Company and Sunrise Securities Corp. entered into February 27, 2004.
14(a)	Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers.
21(a)	Subsidiary of Registrant
23(a)	Independent Auditors' Consent of Deloitte & Touche LLP.
31(a)	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer; and
31(b)	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32(a)	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
32(b)	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99(a)	Press Release dated March 16, 2004.