DUSA PHARMACEUTICALS INC
Form 10-K
March 15, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

DUSA Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

NEW JERSEY (State or Other Jurisdiction of Incorporation or Organization)	**22-3103129** (I.R.S. Employer)
25 Upton Drive **Wilmington, Massachusetts** (Address of Principal Executive Offices)	**01887** (Zip Code)

Commission File Number: 0-19777

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

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

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

Common Stock, no par value

(Title of Class)

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

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. ý

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

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 $ 98,901,507.

The number of shares of common stock outstanding of the Registrant as of March 11, 2005 was 16,916,697.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	10-K Part III
Portions of the Registrant s proxy statement to be filed pursuant to Regulation 14A within 120 days after Registrant s fiscal year end of December 31, 2004 are incorporated by reference into Part III of this report.	Items 10, 11, 12, 13 and 14

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, believe 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 30 through 43, 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 engaged primarily in the research, development and marketing of our first drug in combination with light devices to treat or detect a variety of conditions in processes known as photodynamic therapy or photodetection. Our drug, Levulan® brand of aminolevulinic acid HCl, or ALA, is being used with light, for use in a broad range of medical conditions. When we use Levulan® and follow it with exposure to light to treat a medical condition, it is known as Levulan® photodynamic therapy, or Levulan® PDT. When we use Levulan® and follow it with exposure to light to detect medical conditions it is known as Levulan® photodetection, or Levulan® PD.

Our products, the Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® brand light source were launched in the United States, or U.S., in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp under a former dermatology collaboration. 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 U.S. Food and Drug Administration, or FDA, to

market the BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

We are a vertically integrated company, primarily responsible for regulatory, sales, marketing, customer service, manufacturing of our Kerastick®, and other related product activities. We incurred significant marketing and sales expenses in 2004, including the costs associated with increasing the size of our sales force and 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 U.S. and Canada, exploring **partnership opportunities for Levulan® PDT for dermatology in Europe and/or other countries outside of the U.S. and Canada, and** conducting Phase II clinical trials for our facial photodamage and moderate to severe acne indications. We have also signed clinical trial agreements with the National Cancer Institute, or NCI, Division of Cancer Prevention, or DCP, for the clinical development of Levulan® PDT for the treatment of high-grade dysplasia, or HGD, within Barrett s Esophagus, or BE, and oral cavity dysplasia treatment, and are working with the NCI DCP to advance the development of these programs. In addition, we continue to support independent investigator trials to advance research in the use and applicability of Levulan® PDT for other indications in dermatology, and selected internal indications. See section entitled Business Internal Indications .

We are developing Levulan® 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 U.S., DUSA®, DUSA Pharmaceuticals, Inc.®, Levulan®, Kerastick® and BLU-U® are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending. 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:

Expand the Marketing and Sales of our Products. In 2004, DUSA expanded its direct sales force to 22 representatives by year-end and launched various marketing initiatives, which increased revenues. Due to the success of these activities, DUSA is expanding its sales capacity in 2005.

Physician Education Support. DUSA supports various physician education activities, including financial support for independent medical education programs, participation in dermatological conferences, and support for independent investigator studies that could lead to new scientific papers and/or presentations.

Leveraging our Levulan® PDT/PD Platform to Develop Additional Products. In 2004, we initiated Phase II multi-center clinical trials in the U.S. to determine the safety and efficacy of Levulan® PDT in the treatment of facial photodamage and moderate to severe inflammatory acne. If these and subsequent larger Phase III trials are successful and lead to FDA approval, there may be significant additional market opportunities for our products. We are also actively marketing the BLU-U® without Levulan®, to treat moderate inflammatory acne vulgaris, which supports a multi-use capability of our BLU-U®, 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, both independently and in co-operation with the NCI DCP. We are also developing an oral cavity dysplasia program with the NCI DCP. See sections entitled Internal Indications Barrett s Esophagus Dysplasia; and Oral Cavity Dysplasia .

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 exploring opportunities to develop, market, and distribute our **Levulan® PDT platform in Europe and/or other countries outside of the U.S. and Canada**. We are also seeking to acquire and/or license additional dermatology products that complement our Levulan® PDT technology, that would provide our sales force with additional complementary products to sell in the near term.

Use the Results of Independent Researchers to Identify New Applications. We continue to work closely with and 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. We also continue to monitor

independent research in order to identify other potential new indications.

Improve Third-party Reimbursement for our Products. DUSA plans to continue to support activities to improve and/or pursue third-party reimbursement for our products.

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 in the presence of oxygen.

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, so it is generally better suited for treating superficial lesions. However, it is also a potent activator of some photosensitizers, including ours. Red light penetrates more deeply into tissues, and is therefore generally better suited for treating cancers and deeper tissues. However, it is generally not as strong an activator of photosensitizers, including ours. Different photosensitizers do not absorb all wavelengths (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 tissues while minimizing damage to normal surrounding tissues. It also can allow for multiple courses of therapy. The most common side effect of photosensitizers that are taken 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. Unless activated by light, photosensitizers have no direct PDT/PD effects.

Our Levulan® PDT/PD Platform

Our Levulan® Brand of ALA

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

We believe that Levulan® 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® is a small molecule that is easily absorbed whether delivered topically, orally, or intravenously.

Highly Selective. Levulan® 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 in normal surrounding and underlying tissues.

Controlled Activation. Levulan® 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® 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® Brand Applicator

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

Our Light Sources

Customized light sources are critical to successful Levulan® PDT/PD because the effectiveness of Levulan® 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® is a fluorescent light source that can treat the entire face or scalp at one time. The light source is reasonably sized and can be moved from room to room if necessary. 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® 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® is also compliant with CE marking 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® 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. We have also received clearance from the FDA to market the BLU-U® without Levulan® for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. We are also evaluating whether to develop and/or license additional light devices for use with Levulan®.

In 2004, we initiated Part A of a Phase II clinical trial testing the safety and efficacy of two pulsed light sources commonly used in dermatology, the intense pulsed light, or IPL, source used for photorejuvenation, and the long pulsed dye laser, or LPDL, used for treatment of vascular lesions in the repair of facial photodamage. The goal was to determine the maximal tolerated light doses which could be used with IPL and LPDL for the activation of Levulan® PDT. Part A has now been completed. In 2005 DUSA will carry out Part B of this study, which will compare the results of multiple treatments of IPL with or without Levulan®, LPDL with or without Levulan®, and the BLU-U® with or without Levulan® for the repair of facial photodamage. See section entitled Dermatology Indications Facial Photodamaged Skin .

Also in 2004, we began to test our new proprietary endoscopic light delivery system in a small Phase II single-center clinical study of the efficacy and safety of Levulan® 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. See section entitled Internal Indications Barrett s Esophagus Dysplasia .

Our Products

The following table outlines our products and currently planned product candidates. Our product sales for the last three years were $7,987,656 in 2004, $970,109 in 2003, and $319,378 in 2002. Our research and development expenses for the last three years were $6,489,723 in 2004, $5,403,961 in 2003, and $12,121,606 in 2002.

INDICATION/PRODUCT	STATUS OF REGULATORY STUDIES
Dermatology	
Levulan® Kerastick® and BLU-U® for PDT of AKs	Approved; Phase IV(1)
Levulan® PDT for Photodamaged Skin	Phase II(2)
Levulan® PDT for Moderate to Severe Acne Vulgaris	Phase II(3)
BLU-U® Treatment of Moderate Inflammatory Acne Vulgaris and general dermatological conditions Without Levulan®	Market Clearance(4)
Other Indications	
Levulan® PDT for Barrett s Esophagus Dysplasia	Phase I/II (5) (6)
Levulan® Induced Fluorescence Guided Resection for Brain Cancer	European Phase III(7) (8)
DUSA® Endoscopic Light Delivery System	Phase II (9)
Levulan® Oral Cavity Dysplasia	Phase I/II (10)

(1) Phase IV final study report was filed with the FDA in January 2004

(2) Phase II clinical trial was initiated in the second quarter of 2004

(3) Phase II clinical trial was initiated in the fourth quarter of 2004

(4) In September 2003, the FDA provided market clearance

(5) Phase II single-center clinical trial initiated in second quarter 2004 using DUSA s new endoscopic light delivery device

(6) Phase II clinical trial planned to be initiated with the NCI DCP in 2005

(7) Licensed from photonamic GmbH & Co. KG

(8) European Phase III trial results are not expected to be acceptable to the FDA in the U.S.

(9) Phase II pilot clinical trial that commenced in mid 2004

(10) Phase I/II clinical trial planned to be initiated with the NCI DCP in 2005

Dermatology Indications

We have been responsible for our dermatology research and development programs since reacquiring our product rights in late 2002 from a former strategic alliance partner. We have focused on completing our AK post approval development program, and have commenced Phase II clinical programs examining the safety and efficacy of Levulan® PDT for the treatment of photodamaged skin and moderate to severe acne vulgaris which, if successfully developed

through FDA approval, could lead to additional dermatological indications and significant market opportunities. These trials were initiated in 2004 and we expect patient accrual and treatments to be completed in 2005. DUSA also continues to support a wide range of independent investigator studies using the Levulan® Kerastick® that could lead to additional new indications for future development.

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

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®(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® 20% topical solution over the entire area including the photodamaged skin. After 14 to 18 hours, the patients were treated with blue light

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

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® 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 short incubation studies using different light sources: a BLU-U®, pulsed dye lasers, and intense pulsed light sources. Data from some of the independent investigator studies were used to help determine the method of treatment for the current Phase II study. According to peer-reviewed publications, these studies reported that, when Levulan® is applied to the entire face for as little as one hour followed by treatment with the BLU-U®, 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 showed 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. Investigator studies have been published reporting that IPL plus Levulan® results in a photodynamic photorejuvenation which enhances the results of IPL alone. Published investigator studies have also reported that the LPDL together with Levulan® can successfully remove AKs, and improve photodamage as well as treat sebaceous gland hyperplasia (indications which the LPDL alone was unable to treat).

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 initiated a DUSA-sponsored Phase II study in the second quarter of 2004. The first phase of the study which is now complete tested light dose escalation for IPL and LPDL with 32 patients at 4 sites. The second phase of the study will commence in the first quarter of 2005 and will test improvement in photodamage using all 3 light sources.

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®(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

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

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. With Levulan® PDT therapy for moderate to severe acne vulgaris we are seeking to improve or clear patients acne without the need for long-term oral therapy and with fewer side effects than current therapies.

DUSA has clearance from the FDA to market the BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

Based on results of independent investigator studies that were completed during 2003 and 2004, we believe that acne represents a significant potential opportunity for Levulan® PDT. During the fourth quarter of 2004, we initiated a DUSA-sponsored Phase II study that is scheduled to enroll up to 80 patients at 3 sites. The study utilizes the BLU-U®, short drug incubation, and a broad area application of the Levulan® Kerastick® to test whether this combination which was used in the independent investigator studies mentioned above may be safe and effective, while having acceptable treatment-related side effects.

Other Potential Dermatology Indications

We believe that there are numerous other potential uses for Levulan® 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® in dermatology include treatment of skin conditions such as psoriasis, onychomycosis, warts, molluscum contagiosum, oily skin, acne rosacea, cystic acne, inflamed or infected sweat glands (hidradenitis suppurativa), and cancers, such as squamous cell carcinomas and cutaneous T-cell lymphomas. Of these potential indications, we have supported investigator-sponsored studies for psoriasis, onychomycosis, warts, and molluscum contagiosum, and are currently supporting investigator-sponsored studies for psoriasis, basal cell carcinoma, acne rosacea, and cystic acne.

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, the investigators reported that Levulan® PDT allowed the conversion of early-stage Barrett s esophagus with low-grade dysplasia and portions of non-dysplastic Barrett s back to a 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® 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® PDT. Of the 6 patients treated, 5 had complete clearing of their areas of high-grade dysplasia, and 4 of those patients have now been followed for a period greater than 1 year, 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® PDT are still being followed. Complete Barrett s esophagus mucosal ablation after a single Levulan® 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 circumferential esophageal scarring without symptoms. The most common adverse events in both studies were mild to moderate nausea and vomiting. In order to control ongoing research and development costs, we chose not to enroll any additional patients to these studies after 2002, but will continue to follow the patients that have already been treated.

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, utilizing a single insertion. The goal of this device is to allow the

endoscopic light treatment to be performed more rapidly, under direct visualization, and with greater comfort for the patient. In preparation for a larger Phase II clinical trial, in the second quarter of 2004 we initiated a small single-center pilot Phase II clinical trial for enrollment of up to 6 patients at a single site using DUSA s new proprietary endoscopic light delivery device for the treatment of HGD. To date, 3 of 6 patients in this single-center study have been treated. The protocol has been amended to lower the light dosage and to allow in-hospital observation for the remaining 3 patients commencing in March 2005.

In addition, we signed a clinical trial agreement with the National Cancer Institute Division of Cancer Prevention, for the clinical development of Levulan® PDT for the treatment of high-grade dysplasia within Barrett s Esophagus. We will be working together to prepare an overall clinical development plan for Levulan® PDT in this indication, starting with a Phase II trial. The immediate plan is for the NCI DCP to solicit clinical protocols from its extramural expert clinical investigator consortium, after which DUSA and the NCI DCP will finalize the clinical trial design. The NCI DCP will use its resources to file its own Investigational New Drug, or IND, application. DUSA will provide Levulan®, device(s) and the necessary training for the investigators involved in the studies. DUSA will maintain full ownership of its existing intellectual property, has options on new intellectual property, and, subject to successful Phase II and III clinical trial results, intends to seek FDA approval in due course.

Oral Cavity Dysplasia. We have also signed a clinical trial agreement with the NCI DCP for the clinical development of Levulan® PDT for the treatment of oral cavity dysplasia. During 2005, DUSA and the NCI DCP will be collaborating on the formulation of a Levulan® PDT clinical development program including Phase I and possibly Phase II cancer prevention studies in subjects with oral leukoplakia (a premalignant lesion) using NCI s Phase I/II Cancer Prevention Clinical Trials Consortia to perform the studies.

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

In December 2002, we entered into a License and Development Agreement with photonamic GmbH & Co. KG, a 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 be useful and are 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 U.S. and we do not intend, at this time, to repeat this study in the U.S. These clinical trials are expected to continue through late 2005 at a minimum, so future development by DUSA for the brain cancer indication is still to be determined. See section entitled Business Licenses .

Third-party Reimbursement

We have continued to support efforts to improve reimbursement levels to physicians. Such efforts included working with the Centers for Medicare and Medicaid Services, or CMS, on matters related to the PDT procedure fee and the separate drug reimbursement fee. Doctors can also bill for any applicable visit fees. Effective January 1, 2005, the CMS average national reimbursement for the use of Levulan® PDT for AKs was increased, reflecting the cost of additional medical supplies that were not included in the original application. However, the administrative change to a drug reimbursement system based on the average selling price rather than the average wholesale price, which had been used until the end of 2004, caused a decrease in the fee for the Kerastick®. Going forward, reimbursement for the Kerastick® will vary from quarter to quarter, calculated as 106% of the ASP to the end-user during a prior quarter, including all discounts. As DUSA has already started to decrease its Kerastick® volume discount programs, reimbursement is expected to increase in future quarters. Overall, we believe that 2005 reimbursement changes related to treatment of AK are positive for doctors using our therapy. However, we are aware that some physicians still believe that even the new reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices. We believe that the issues related to reimbursement have negatively impacted the economic competitiveness of our therapy with other AK therapies and have hindered its adoption in the past, although it is difficult to predict the effect of the 2005 changes at this time. DUSA continues to support ongoing efforts that might lead to further increases in reimbursement in the future; and intends to support efforts to seek reimbursement for our FDA-cleared use of the BLU-U® alone in the treatment of mild to moderate inflammatory acne of the face.

In addition, we continue to work to educate private insurance carriers so that they will approve our therapy for coverage. As of December 31, 2004, 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.

Supply Partners

National Biological Corporation. In November 1998, we entered into a purchase and supply agreement with National Biological Corporation, or NBC, for the manufacture of some of our light sources, including the BLU-U®. We agreed to order from NBC all of our supply needs of these light sources for the U.S. and Canada, and NBC 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. On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with NBC, which provides for the elimination of certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, grants DUSA an exclusive irrevocable worldwide and fully-paid up license to manufacture, or have the BLU-U® manufactured by any third party subcontractor, and other modifications which provide both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. The agreement maintains the original term, which will expire in November 2008, 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 manufactures and supplies our requirements of Levulan® from its FDA approved facility in Switzerland. The agreement expires on 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 U.S. 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 and 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 (or, in the case of the patents in Australia, were assigned) the patents underlying our Levulan® PDT/PD systems under

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a license agreement with PARTEQ Research and Development Innovations, or 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 U.S. 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. $83,000 as of December 31, 2004) in order to retain the license. For 2004, royalties exceeded this minimum. We have the right to terminate the PARTEQ agreement with or without cause upon 90 days notice. See Note 13(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, known as 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 10% royalty on sales of the Levulan® Kerastick® 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® Kerastick® with PDT for AKs. We also hold Canadian regulatory approval for the BLU-U®. During 2004, we appointed a Canadian distributor who launched our Levulan® Kerastick® and BLU-U® in Canada. See sections entitled Distribution and Note 13(b) to the Company s Notes to the Consolidated Financial Statements .

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

Under the terms of the agreement, we received a license for the U.S. 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. See section entitled Our Products . 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 U.S., 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 U.S. 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.

We have also entered into a clinical trial agreement with photonamic to fund a independent investigator study using oral Levulan® for the treatment of psoriasis. A protocol for this study is expected to be completed in 2005.

Patents and Trademarks

We actively seek, when appropriate, to protect our products and proprietary information through U.S. 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 U.S. Patent and Trademark Office extended the term of U.S Patent No. 5,079,262, with respect to our approved AK indication for Levulan®, until September 29, 2013.

Under the license agreement with PARTEQ, we hold an exclusive worldwide license to certain patent rights in the U.S. and a limited number of foreign countries. See section entitled Business Licenses . All U.S. 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 U.S. 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 U.S., which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counterparts in only six foreign countries, one of which is the subject of legal action, and under the European Patent Convention. 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, as one party has already done, 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 any such additional 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 U.S., and other countries where we may market our products. To date, we have been issued 26 trademark registrations, and other applications are pending.

Manufacturing

On July 14, 2003, we received approval from the FDA to manufacture the Levulan® Kerastick® at our Wilmington, Massachusetts manufacturing facility. In February 2004, we began commercial production of our Levulan® Kerastick® after having terminated the former third-party contract manufacturing arrangement. We plan to maintain a reasonable level of Kerastick® inventory based on sales projections. Our drug, Levulan®, and the BLU-U® brand light source are each manufactured by single third-party suppliers.

Distribution

We have been the direct distributor of the BLU-U® since its launch. During 2004, we decided to shift a portion of the distribution function for our Levulan® Kerastick® in the U.S. from one of our third-party distributors to DUSA personnel. By November 2004 we had increased our own distribution capacity to become the primary distributor. We also maintain a relationship with a third-party, Moore Medical Corporation, or Moore, a national distributor and marketer of medical and surgical supplies, to sell our Kerastick® product. In March 2004, we signed an exclusive Canadian marketing and distribution agreement for the Levulan® Kerastick® and BLU-U® with Coherent-AMT Inc., or Coherent, a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U® in April 2004 and the Kerastick® in June 2004, following receipt of the applicable regulatory approval from Health Canada. The agreement has a three-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. Both distributors have the right for a period of time following termination of their respective agreement, to return their inventory of product.

Marketing and Sales

DUSA markets its approved dermatology products in the U.S. and has appointed Coherent-AMT as marketing partner for our products in Canada.

As a result of reacquiring our product rights in late 2002, we commenced marketing and sales activities for our products in 2003, including the launch of our sales force in October 2003. Initially the sales force was comprised of 6 direct representatives, various independent representatives, and an independent sales distributor, designed to focus on most of our key geographic markets in the U.S. During 2004, we continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. As of December 31, 2004, we also replaced most of our independent representatives with full-time DUSA sales employees providing us with a sales force comprised of 22 sales professionals, including managers and representatives deployed nationally. In 2005, we have further increased the size of our sales force. As 2005 progresses, we will consider whether to hire a contract sales organization or more sales employees.

Following the receipt of marketing approval from the Health Protection Branch Canada in June 2004, we started to market and sell the Levulan® Kerastick® with PDT using the BLU-U® for AKs of the face or scalp in Canada through Coherent-AMT. See sections entitled Business Licenses and Business Distribution .

Competition

Commercial development of PDT agents other than Levulan® is currently being pursued by a number of companies. These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); Pharmacyclics, Inc. (U.S.); PhotoTherapeutics, Inc. (U.K.); 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. In July 2004, PhotoCure received FDA approval in the U.S. for its AK therapy. However, in December 2004 the FDA notified PhotoCure that its new drug application, or NDA, for BCC was not approvable. If PhotoCure enters into the marketplace with its AK therapy, 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, was invalid. As a consequence of this action, Queen s University assigned the Australian patent to us so that we could 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 final hearing in the Federal Court of Australia was held in April 2004, and we expect that the Court s decision, which we are unable to predict, will be rendered in 2005. See section entitled Legal Proceedings .

In August 2003, Axcan Pharma Inc. received FDA approval for the use of its product, PHOTOFRIN®(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 (Efudex®)(4), diclofenac sodium (Solaraze®)(5), and imiquimod

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

(4) Efudex® is a registered trademark of Valeant Pharmaceuticals International.

(5) Solaraze®is a registered trademark of SkyePharma PLC.

(ALDARA)(6), which was approved on or about March 3, 2004. Other AK therapies are also known to be under development, by companies such as Medigene (GmbH), Peplin (Australia) and others. 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.

DUSA also markets the BLU-U® without Levulan® for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. Our competition for the BLU-U® without Levulan® for moderate inflammatory acne vulgaris is primarily oral antibiotics, topical antibiotics and other topical prescription drugs, as well as various laser and non-laser light sources. As blue light alone for acne is still a relatively new therapy compared to existing therapies, reimbursement has not been established by private insurance companies, which may also affect our competitive position versus traditional therapies which are reimbursed.

Our principal method of competition with existing therapies of AKs and moderate inflammatory acne vulgaris is patient benefits, including rapid healing and excellent cosmetic results. See section entitled Business Dermatology Indications, Actinic Keratoses; Acne .

Government Regulation

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

(6) ALDARA is a trademark of 3M Company.

approval of manufacturing facilities, including adherence to current good manufacturing practices, laboratory and clinical practices during production and storage known as cGMP, QSR, GLP and GCP,

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 U.S., 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 is typically 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.

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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 may also 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 must be 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. Safety information collected through this process can result in changes to a product s labeling or withdrawal of a product from the market. 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® Kerastick® 20% Topical Solution with PDT for treatment of AKs of the face or scalp. The commercial version of

our BLU-U®, used together with the Kerastick® to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp, was approved on September 26, 2000. In September 2003, we received clearance from the FDA to market the BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

Other than the FDA-approved use of the Levulan® Kerastick® 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® 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® 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 Medical Device User Fee and Modernization Act, the FDA has 180 days to review a PMA application and respond to the sponsor. The review of PMA applications more often occurs 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 U.S. 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® Kerastick® with PDT for AKs, a combination filing (including a PMA for the BLU-U® light source device and the NDA for the Levulan® Kerastick®) 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® 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® is a new chemical entity and market exclusivity under this law expired on December 3, 2004. During this Hatch-Waxman marketing exclusivity period, the FDA will not approve another application submitted by a third-party for approval of a drug product which has the same reference listed drug as Levulan®, i.e., ALA as its active ingredient. After the expiration of the Hatch-Waxman exclusivity period, any third-party who submits an application for approval for a drug product containing ALA must provide a certification that (i) no patent information has been filed; (ii) that such patent has expired; (iii) marketing will not commence until the patent(s) has expired; or (iv) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the third-party applicant.

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 intend to market our products outside of the U.S. In 2004, DUSA began marketing and selling our products in Canada. 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 U.S. for Levulan® PDT for dermatology uses and did file applications for approval in Austria, Australia, South Africa and Brazil. However, our focus has been primarily on the North American markets initially, and therefore we authorized our former partner to withdraw the applications for regulatory approval of Levulan® PDT in Australia, Austria and South Africa. In 2003, we also advised our former partner to withdraw the applications for the Levulan® Kerastick® and BLU-U® in Brazil, even though the Kerastick® had already been approved, 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, but have not determined if we will reapply in any of the other countries at this time.

With the enactment of the Drug Export Amendments Act of the United States in 1986, products not yet approved in the U.S. may be exported to certain foreign markets if the product is approved by the importing nation and approved for export by the U.S. 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 Kerastick® 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. Furthermore, we cannot assure that current or future environmental laws or regulations will not materially adversely effect our operations, business or assets. Although we believe that our safety procedures for the handling and disposal of such hazardous 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 2004, we had 65 full-time employees and 4 part-time employees, which was a significant increase over the 2003 levels, including 22 employees in our direct sales force. We also retain numerous independent consultants and temporary employees to support our business needs. We expect to add employees during 2005 as business circumstances deem necessary.

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, which will expire on April 28, 2005, having a face value of CDN $2,000,000 on the life of our Chairman and Chief Executive Officer which we do not intend to renew.

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. Please note that our internet address is being provided for reference only and no information contained therein is incorporated by reference into our Exchange Act filings.

RISK FACTORS

You should carefully consider and evaluate all of the information in, or incorporated by reference in, this annual report on Form 10-K. 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 report .

This section of the annual report on Form 10-K 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 report. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report.

Risks Related to DUSA

We are not currently profitable and may not be profitable in the future unless we can successfully market and sell significantly higher quantities of our approved products, the Levulan® Kerastick® with the BLU-U® brand light source for the treatment of AKs of the face or scalp, and the BLU-U® without Levulan® 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 sufficient quantities of our approved products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We are responsible for marketing our approved dermatology products in the U.S. and the rest of the world, except Canada, where we have a distributor. We are 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 we increased the size of our sales force in 2004 to market our products in the U.S. 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 intend to hire additional sales people to penetrate the market. If our sales and marketing efforts fail, then sales of the Kerastick® and the BLU-U® 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® Kerastick® for AKs may suffer.

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan® Kerastick® for AK 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. Overall, we believe that the 2005 reimbursement changes related to AK are a positive for doctors that use the therapy; however, some physicians still believe that even the new reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

Since we now operate the only FDA approved manufacturing facility for the Kerastick® and continue to rely heavily on sole suppliers for the manufacture of Levulan® and the BLU-U®, any supply or manufacturing problems could negatively impact our sales.

If we experience problems producing Kerastick® units in our facility, or if either of our contract suppliers fail to supply DUSA s requirements of Levulan® or the BLU-U®, our business, financial condition and results of operations would suffer. We are not currently approved by the FDA to manufacture the BLU-U® on our own.

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 U.S. and elsewhere will limit our ability to market our products.

Both the manufacture and marketing of our products, the Levulan® Kerastick® with the BLU-U® for AKs and the BLU-U® without Levulan® 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, we 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 U.S.,

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 Good Manufacturing Practice, commonly known as cGMP, and Quality System Regulation, or QSR, 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® Kerastick® for AK, we were required to conduct two Phase IV follow-up studies. We 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 Kerastick® facility, will continue to meet all applicable FDA regulations. 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 our 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, we 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. We 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 2005 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, 2004, our accumulated deficit was $74,539,000. Although sales of the Kerastick® 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 enough 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 compound patent protection for our Levulan® 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 U.S., which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counterparts in only six foreign countries, one of which is the subject of legal action, and certain countries under the European Patent Convention. 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 could participate directly in the litigation. The final hearing in the Federal Court of Australia was held in April 2004, and we expect that the Court s decision will be rendered in 2005. We cannot predict the outcome of this action. 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 wish to enter the Australia market in the future, 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 U.S. 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® 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 U.S., 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 U.S. patent application, or be issued a patent claiming technology also claimed by us in a pending U.S. application(s), we may be required to participate in interference proceedings in the U.S. 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® Kerastick® with the BLU-U® to treat AKs, and the use of the BLU-U® 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®, 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 of our investigational stage products will take or whether they will be medically effective. We cannot be sure that a successful market will continue to develop for our drug technology.

We must receive separate approval for each of our potential products before we can sell them commercially in the U.S. or abroad.

All of our potential Levulan® products will require the approval of the FDA before they can be marketed in the U.S. 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® PDT products are based on relatively new technology. To the best of our knowledge, the FDA has approved only 3 drugs for use in photodynamic therapy, including Levulan®. This factor may lengthen the approval process. We face much trial and error and we may fail at numerous stages along the way.

We cannot predict whether we will obtain approval for any of our potential products. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan® PDT or 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 current sales goals for our products 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 received in connection with a private placement consummated 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 at all or on acceptable terms.

Dependent on the extent of available funding, we may 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 69 employees, including 4 part-time employees as of December 31, 2004. 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 are subject to risk from potential product liability lawsuits which could negatively affect our business.

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. 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®, 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 medical device companies are marketing well-established therapies for the treatment of many of the same conditions that 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 affect the economic competitiveness of our products as compared to other more traditional therapies.

If PhotoCure enters the U.S. marketplace with its PDT product, our sales revenues may decline.

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 products may lose market share if new manufacturers begin producing competing products that are able to penetrate our market.

We have learned that compounding pharmacies are producing a form of aminolevulinic acid HCl and are marketing it to the medical community.

We are aware that there are compounding pharmacies that market compounded versions of aminolevulinic acid HCl as an alternative to our Levulan® product. We have filed lawsuits against 2 compounding pharmacies alleging violations of U.S. patent law. While we believe that certain actions of those pharmacies go beyond the activities which are permitted under the Food, Drug and Cosmetic Act and have advised the FDA and local health authorities of our concerns, we cannot be certain that our lawsuits will be successful in curbing the practices of the 2 pharmacies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

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®. These include: QLT 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); PhotoTherapeutics, Inc. (U.K.) 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. In July 2004, PhotoCure received FDA approval in the U.S. for its AK therapy. If PhotoCure enters into the marketplace based on receiving approval, its product will represent direct competition for our products.

Axcan Pharma Inc. has received FDA approval for the use of its product, PHOTOFRIN®, 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, 2005 there were outstanding options and warrants to purchase 3,083,625 shares of common stock, with exercise prices ranging from U.S. $1.60 to $31.00 per share, and CDN $6.79 per share, respectively. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. 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 specialty pharmaceutical and biotechnology stocks could result in sudden changes in the market value of our stock.

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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, 2004 to March 11, 2005, the price of our stock has ranged from a low of $5.02 to a high of $16.30. Factors that contributed to the volatility of our stock during the last 12 months included:

quarterly 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.

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

Significant fluctuations in orders for our products, on a monthly and quarterly basis, are common based on external factors and sales promotion activities. These fluctuations could increase the volatility of our stock price.

The price of our common stock may be affected by the amount of quarterly shipments of our products to end-users. Since our products are still in the early stages of adoption, and sales volumes are still low, a number of factors could affect product sales levels and growth rates in any period. These could include the timing of medical conferences, sales promotion activities, and large volume purchases by our higher usage customers. In addition, seasonal fluctuations in the number of patients seeking treatment at various times during the year could impact sales volumes. These factors could, in turn, affect the volatility of our stock price.

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.

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 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 office space for our Toronto location which accommodates the

Toronto office of our Chief Executive Officer and shareholder services representative. See Note 13(c) 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 was 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 assigned the Australian patent to us so that we could 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 final hearing in the Federal Court of Australia was held in April 2004, and we expect that the Court s decision will be rendered during 2005. We are unable to predict the outcome at this time. In August 2004, DUSA, PhotoCure and Galderma entered into a Mediation Agreement designed to facilitate resolution of the parties potential patent disputes concerning PhotoCure and Galderma s methyl aminolevulinate product. The parties discussions are on-going.

In December 2004, we filed a lawsuit against New England Compounding Center of Framingham, Massachusetts alleging violations of U.S. patent law in the U.S. District Court in Boston, Massachusetts. In January 2005, we filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law in the U.S. District Court for the District of Arizona. We are seeking injunctive relief, monetary damages and costs in both lawsuits. These cases are in their early stages and we are unable to predict the outcomes at this time. 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, we were served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging, among other things, that our BLU-U® caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint named Berlex Laboratories, Inc., a subsidiary of our former marketing partner, as another defendant. This complaint was dismissed in December 2004.

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

None.

PART II

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

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

Price range per common share by quarter, 2003:

	First	Second	Third	Fourth
NASDAQ				
High	$ 1.78	$ 3.28	$ 6.85	$ 6.75
Low	1.40	1.71	2.45	4.28

Price range per common share by quarter, 2004:

	First	Second	Third	Fourth
NASDAQ				
High	$ 14.87	$ 13.50	$ 12.20	$ 14.41
Low	5.02	8.46	8.23	9.95

On March 11, 2005, the closing price of our common stock was $11.30 per share on the NASDAQ National Market. On March 11, 2005, there were 654 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.

Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
December 31, 2004	30,000	$ 8.00		N/A

In March 2004 we issued 30,000 fully vested stock options as compensation for the services of 3 consultants, valued at $241,000. These options were subsequently repurchased for cash payment of $240,000 in December 2004. We do not plan to repurchase any additional outstanding options at this time.

ITEM 6. SELECTED FINANCIAL DATA

The following information should be read in conjunction with our 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 our audited consolidated financial statements.

Consolidated Statements of Operations Data

	Year ended December 31,				
	2004	**2003**	**2002 (1)**	**2001**	**2000**
Revenues (1)	$ 7,987,656	$ 970,109	$ 25,483,238	$ 5,390,736	$ 2,120,557
Cost of product sales and royalties (1)	3,875,018	3,481,248	5,253,424	2,148,994	1,104,664
Research and development costs (1)	6,489,723	5,403,961	12,121,606	10,789,906	8,163,419
Marketing and sales costs	7,622,106	2,494,405			
General and administrative costs	7,209,536	6,343,680	5,591,039	3,654,792	2,615,502
Income (loss) from operations	(17,208,727)	(16,753,185)	2,517,169	(11,202,956)	(9,763,028)
Other income, net	1,579,747	1,926,331	3,245,349	3,844,860	3,222,273
Net income (loss)	(15,628,980)	(14,826,854)	5,762,518	(7,358,096)	(6,540,755)
Basic and diluted net income (loss) per common share	$ (0.96)	$ (1.06)	$ 0.42	$ (0.53)	$ (0.49)
Weighted average number of shares outstanding	16,317,078	13,936,482	13,877,566	13,791,735	13,285,472

Consolidated Balance Sheets Data

	As of December 31,				
	2004	**2003**	**2002**	**2001**	**2000**
Total assets	$ 56,650,888	$ 44,697,488	$ 60,949,973	$ 75,864,221	$ 82,442,388
Cash and investment securities (2)	49,291,876	37,969,476	52,879,543	64,709,625	74,496,577
Deferred revenue (1)	230,715	129,900	5,100	22,585,856	24,805,041
Long-term debt (3)		1,247,500	1,517,500		
Shareholders equity	52,507,018	40,232,049	56,057,730	49,834,537	55,309,796

(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 Year Ending December 31, 2003 As Compared to 2002 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®. When Levulan® is used and followed with exposure to light to produce a therapeutic effect, the technology is called photodynamic therapy, or PDT. When Levulan® is used and followed with exposure to light to detect medical conditions, the technology is called photodetection, or PD. Our products are Levulan® 20% topical solution using our Kerastick® brand applicator, and our BLU-U® 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, the BLU-U® is used without Levulan® for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. Both products have received approval or market clearance as required from the U.S. Food and Drug Administration (FDA) and regulatory approval from Health Canada.

At this time, our core objectives include (i) focusing on increasing sales in the U.S. which we will do by increasing the size of our force, and (ii) conducting clinical trials to treat moderate to severe acne vulgaris and photodamaged skin, which, if successful, could lead to additional regulatory approvals and ultimately increased revenues. In addition, we continue to advance development of Levulan® PDT for the treatment of dysplasia in patients with Barrett s esophagus, and support independent investigator trials to advance research in the use and applicability of Levulan® PDT for other indications.

We have primarily devoted our resources to fund research and development in order to advance the Levulan® PDT/PD technology platform and, as a result, we have experienced significant operating losses. As of December 31, 2004, we had an accumulated deficit of approximately $74,539,000. We expect to continue to incur operating losses until sales of our products increase substantially. Achieving our goal of becoming a profitable operating company is dependent upon continued acceptance of our therapy by the medical and consumer constituencies, and our ability to develop and/or acquire new products.

We operate in a highly regulated and competitive environment. Our competitors include larger fully integrated pharmaceutical companies and biotechnology companies. Many of the organizations competing with us have substantially greater capital resources, larger research and

development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals, and greater manufacturing and sales and marketing capabilities than we do.

Marketing and sales activities since the October 2003 launch of our sales force have resulted in significant additional revenues as well as expenses. Kerastick® unit sales to end-users were 76,482 for the twelve months ended December 31, 2004, consisting of 69,870 units sold in the U.S., and 6,612 units sold by Coherent-AMT, our Canadian marketing and distribution partner under our License Promotion Distribution and Supply Agreement dated as of March 31, 2004. A summary of quarterly Kerastick® unit sales to end users during the periods ended December 31, 2004 and 2003 is indicated below:

	2004				
	Q1	Q2	Q3	Q4	Total
United States	12,054	16,002	18,870	22,944	**69,870**
Canada		1,908	1,326	3,378	**6,612**
Total	**12,054**	**17,910**	**20,196**	**26,322**	**76,482**

	2003				
	Q1	Q2	Q3	Q4	Total
United States	1,842	1,914	1,938	5,478	**11,172**
Canada					
Total	**1,842**	**1,914**	**1,938**	**5,478**	**11,172**

The net number of BLU-U® units placed in doctors offices during the twelve months ended December 31, 2004 was 508, including 101 placed in Canada. As of December 31, 2004 there were 914 units in doctor s offices, consisting of 813 in the U.S. and 101 in Canada. There were 406 BLU-U® units in doctors offices at December 31, 2003.

Although the costs related to the addition of our sales force and related marketing activities are significant as compared to the revenue generated from the increase in sales, we are encouraged with the quarterly increases in sales. We have continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. See section entitled Results of Operations Marketing and Sales Costs . We have begun to examine the costs and regulatory requirements associated with seeking foreign marketing approvals for our products. If we proceed with this effort without a partner, our operating costs will increase. However, we expect that an important focus during 2005 will include seeking corporate alliances for the marketing and sales of Levulan® PDT outside the U.S. and Canada, subject to appropriate regulatory approvals.

DUSA has continued to support efforts to improve reimbursement levels to physicians. Some physicians have suggested that 2004 reimbursement levels did not fully reflect the required efforts to routinely employ our therapy in their practices. We believe that this issue has adversely affected the economic competitiveness of our products with other AK therapies and has hindered the adoption of our therapy. However, we continue to work to improve reimbursement levels, and have recently been notified of reimbursement changes for 2005 that are expected to be

positive for doctors using our therapy. Several major private insurers have approved coverage. We believe that due to these efforts, along with our education and marketing programs, and increased interest in other potential uses for our products, more widespread adoption by the medical community will occur over time.

We have been encouraged by the positive response from many physicians and patients who have used our therapy, but we recognize that we have to continue 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. While our financial position is strong, we cannot predict when product sales may offset the costs associated with these efforts. We are aware that some physicians have been using Levulan® with the BLU-U®, and with light devices manufactured by other companies, 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 are positively affecting the sales of our products.

We are also aware that some compounding pharmacies may be exceeding the legal limits for their activities, including manufacturing and/or selling quantities of ALA in circumstances which may be inducing purchasers to infringe our intellectual property. These activities may be negatively impacting our sales growth. Therefore in December, 2004 and in January, 2005, we filed lawsuits against 2 compounding pharmacies. See section entitled Legal Proceedings .

As of December 31, 2004, we had a staff of 65 full-time employees and 4 part-time employees, as compared to 50 full-time employees and 1 part-time employee at the end of 2003, 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.

On January 4, 2005, we announced the appointment by DUSA s Board of Directors of Mr. Robert F. Doman as our President and Chief Operating Officer effective January 3, 2005. As a result of Mr. Doman joining DUSA, Dr. D. Geoffrey Shulman resigned his position as President of the Company and Mr. Jay Haft resigned as Chairman of the Board of Directors also effective January 3, 2005. Dr. Shulman remains as DUSA s Chief Executive Officer and has been re-appointed to the position of Chairman of the Board of Directors. Mr. Haft retains his position as Lead Director and has been appointed to the position of Vice Chairman of the Board of Directors.

2004 Transactions

During 2004, DUSA entered into a number of transactions, all designed to foster future growth of its Levulan® PDT platform.

Clinical Trial Agreements signed with the National Cancer Institute To further our objectives concerning treatment of Barrett s esophagus and other internal indications using Levulan® PDT, on September 27, 2004 we signed a clinical trial agreement with the National Cancer Institute, or NCI, Division Of Cancer Prevention, or DCP, for the clinical development of

Levulan® PDT for the treatment of high-grade dysplasia within Barrett s Esophagus. In addition, on November 4, 2004 we signed an additional clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP will be working together to prepare overall clinical development plans for Levulan® PDT in these indications, starting with Phase II BE trials, and Phase I/II oral cavity trials, and continuing through Phase III studies if mutually agreeable. The immediate plan is for the NCI DCP to solicit clinical protocols from its extramural expert clinical investigator consortium, after which time DUSA and the NCI DCP will finalize the clinical trial designs. The NCI DCP will use its resources to file its own Investigational New Drug applications with the FDA. DUSA will provide Levulan®, 10 to 12 laser device(s) and the necessary training for the investigators involved in the studies at an estimated cost during 2005 of approximately $700,000. DUSA will maintain full ownership of its existing intellectual property, has options on new intellectual property and, subject to successful clinical trial results, intends to seek FDA approvals for the indications being studied. See section entitled Results of Operations Year Ending December 31, 2004 As Compared to 2003 Research and Development Costs .

Amended and Restated Purchase and Supply Agreement On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation (NBC), the manufacturer of its BLU-U® light source. This agreement provides for the elimination of certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, and other modifications of the original agreement, providing both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. DUSA paid $110,000 to NBC upon execution of the agreement which will be amortized over the remaining term of the agreement, expiring November 5, 2008.

Third-Party Canadian Marketing and Distribution Agreement On March 31, 2004, DUSA signed an exclusive Canadian marketing and distribution agreement for the Kerastick® and BLU-U® with Coherent-AMT Inc. (Coherent), a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U® for moderate inflammatory acne in April 2004 and the Kerastick® for the treatment of non-hyperkeratotic actinic keratoses, or AKs, in June 2004, following receipt of the applicable regulatory approval from Health Canada. The agreement has a three-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. In addition, during the initial three-year term, either party may terminate the agreement earlier by providing formal written notice of its intention to do so at least 90 days in advance of each anniversary of the effective date, or in the event that the other party shall have materially breached any of its obligations in the agreement.

February 2004 Private Placement On February 27, 2004, DUSA entered into definitive agreements with certain institutional and other accredited investors for the private placement of 2,250,000 shares of its common stock at a purchase price of $11.00 per share, resulting in gross proceeds to DUSA of $24,750,000. The closing date of the private placement was March 2, 2004. DUSA also issued additional investment rights providing the investors with the right to purchase up to an aggregate of an additional 337,500 shares of common stock at

$11.00 per share. All of the additional investment rights were exercised on April 14, 2004, resulting in additional proceeds of $3,712,500. Offering costs incurred in connection with the placement were $1,908,000, of which $1,708,000 consisted of the placement agent s commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price. DUSA will use the proceeds from the sale of the securities to expand its 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®) technology for Canada held by Draxis Health Inc., or Draxis. These rights were initially assigned to Draxis in 1991 at the time of the original licensing of the patents underlying our Levulan® 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 of $150,000 CDN ($114,000 USD at February 24, 2004) and a 10% royalty on sales of the Levulan® Kerastick® in Canada over a five year term commencing in June 2004 based on the first Kerastick® sale in Canada by Coherent, our Canadian marketing and distribution partner.

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.

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. Product sales made through distributors who have a general right of return of product have been recorded as deferred 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.

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. We use sales projections to estimate the appropriate level of inventory that should remain on the Consolidated Balance Sheet. Management believes that the recorded value of Kerastick® inventory is reasonable in light of our current sales forecasts.

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. At December 31, 2004, total property, plant and equipment had a carrying value of $3,482,000, including our manufacturing facility which received FDA approval in July 2003 and began inventory production in February 2004. As of December 31, 2004, we had intangible assets totaling $197,000 recorded in deferred charges and other assets relating to the unamortized balance of payments incurred in 2004 to NBC to amend our agreement to develop and manufacture of light sources and to Draxis to reacquire our product rights in Canada. See sections entitled 2004 Transactions Amended and Restated Purchase and Supply Agreement and 2004 Transactions Re-acquisition of Canadian Product Rights . DUSA had no intangible assets recorded as of December 31, 2003.

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 (APB) 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.

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R), Share-Based Payment, a revision of SFAS No. 123, which will impact the accounting for employee stock options and other equity-based compensation. The standard requires companies to measure and recognize compensation expense for all stock-based payments at fair value. The adoption of SFAS No. 123(R) will not affect our cash flow or financial position, but it will affect

our net income (loss) and earnings per share. In accordance with the revised statement, we will recognize the expense attributable to stock options that are granted or vest in periods ending subsequent to June 30, 2005. As described in Note 2(m) to the Notes to the Consolidated Financial Statements, had the Company expensed its employee stock options under SFAS No. 123 for the year ended December 31, 2004, net loss and net loss per share would have increased by approximately $2,276,000 or $0.14 per share, respectively. As share options are determined each year, the impact to the Company s financial statements of the adoption of SFAS No. 123(R) cannot be predicted with certainty.

Results of Operations

Year Ending December 31, 2004 As Compared to 2003

Revenues Total revenues for the year ended December 31, 2004 were $7,988,000, as compared to $970,000 in 2003 and were comprised of the following:

	2004	2003	Increase
Kerastick® product sales			
United States	$ 5,450,000	$ 901,000	$ 4,549,000
Canada	402,000		402,000
Total	$ 5,852,000	$ 901,000	$ 4,951,000
BLU-U® product sales			
United States	$ 1,795,000	$ 69,000	$ 1,726,000
Canada	341,000		341,000
Total	$ 2,136,000	$ 69,000	$ 2,067,000
Total product sales	$ 7,988,000	$ 970,000	$ 7,018,000

The increase in 2004 product sales reflects sales to physicians of 76,482 Kerastick® units, respectively, as compared to 11,172 Kerastick® units in 2003, and an increase in the BLU-U® units in place in physician s offices of 914 units as of December 31, 2004, up from 406 units at December 31, 2003. With respect to U.S. Kerastick® sales, we have increased our direct selling and distribution efforts, while still maintaining the services of one external distributor. We expect to continue to increase our internal distribution capabilities in order to increase our gross revenue and net profit per unit. Although our costs will also increase to support this function, since we increased our price per Kerastick®in November, 2004, we expect to see a significantly higher average margin per Kerastick® in 2005.

On March 31, 2004, DUSA signed an exclusive marketing and distribution agreement for the Kerastick® and BLU-U® in Canada with Coherent-AMT Inc. (Coherent), a leading Canadian medical device and laser distribution company. Following receipt of regulatory approval from Health Canada, Coherent began marketing the BLU-U® for moderate inflammatory acne in April 2004, and the Kerastick® for the PDT treatment of non-hyperkeratotic actinic keratoses, or AKs, in June 2004. DUSA recognizes product sales when Coherent sells the Kerastick® and/or the BLU-U® to the end-user, as the price is fixed and final at that point. Kerastick® product sales through our Canadian distributor for the year ended December 31, 2004 were 6,612, and there were 101 BLU-U® units in physician s offices as of December 31, 2004.

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The increase of Kerastick® and BLU-U® sales in the U.S. during 2004 is a result of the efforts of our larger sales force, and related marketing and sales activities. In addition, the increase in BLU-U® placements is caused, in part, by our ability to sell the BLU-U® to physicians as a stand alone device for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions following FDA clearance in September 2003. BLU-U® sales during the quarter ended December 31, 2004 decreased as expected, compared with the prior quarter, due to a planned price increase that became effective at the beginning of the fourth quarter, and a decreased emphasis on BLU-U® placements by our sales-force, in light of our shrinking BLU-U® inventory levels at that time. We ordered additional BLU-U® units in the fourth quarter of 2004, and started to be re-supplied during the first quarter of 2005. As we experienced a backlog until the new supply of light sources started to become available, BLU-U® revenues were limited during the fourth quarter of 2004, and have been limited until being re-supplied during the first quarter of 2005. We believe that growth of Kerastick® unit sales were adversely affected during this time by limited BLU-U® sales as it takes some time for a new customer to build up Kerastick® usage levels after initially using the therapy. The temporary shortage of BLU-U® units during that period may have an ongoing effect on the rate of growth in Kerastick® sales levels going forward.

Although the level of Kerastick® sales to end-users for 2004 is substantially higher than the level in the prior year, Kerastick® sales must continue to increase significantly in order for DUSA to become profitable. To reach that goal, we significantly increased the size of our sales force and geographic reach during 2004. In 2005, we plan to continue to increase the capacity of our sales force and continue our participation in many medical conferences. However, should PhotoCure launch its PDT product in the U.S. our sales could be significantly diminished since PhotoCure s marketing partner, Galderma S.A., has a much larger sales force and greater resources than we do. See section entitled Results of Operations Year Ending December 31, 2004 As Compared to 2003 General and Administrative Costs .

Cost of Product Sales and Royalties Cost of product sales and royalties for the year ended December 31, 2004 were $3,875,000, as compared to $3,481,000 in 2003. The components of cost of product sales and royalties for the years ended December 31, 2004 and 2003, including direct and indirect costs to support our product are provided below:

	2004	2003	Increase (Decrease)
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)	$ 1,193,000	$ 2,297,000	$ (1,104,000)
Kerastick® product costs	1,478,000	381,000	1,097,000
Costs incurred to ship, install and service the BLU-U® in physicians offices (2)	919,000	729,000	190,000
Royalty and supply fees (3)	285,000	74,000	211,000
Total cost of product sales and royalties	$ 3,875,000	$ 3,481,000	$ 394,000

1) The decrease in product costs for 2004 primarily reflects the capitalization of labor and overhead associated with the manufacture of Kerastick® units in our facility. These costs were expensed in the prior year due to the absence of production.

2) Although there were direct BLU-U® product sales in 2004 and 2003, there were no related direct BLU-U® product costs as these units had a zero book value due to inventory impairment charges recorded during 2002.

3) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario, and starting in 2004, amortization of an upfront fee and a royalty are paid to Draxis, DUSA s former parent, on sales of the Levulan® Kerastick® in Canada.

Research and Development Costs Research and development costs for the year ended December 31, 2004 were $6,490,000 as compared to $5,404,000 in 2003. This increase reflects the preparation work associated with initiating the Phase II photodamaged skin trial, protocol finalization and initiation of our Phase II acne trial, and the start of our Phase II pilot study for Barrett s esophagus offset, in part, by lower third-party expenditures for our FDA mandated Phase IV clinical study of the long-term efficacy of the Kerastick®. This FDA mandated Phase IV study was completed in late 2003 and we incurred only limited costs to file the final report with the FDA in 2004. We have concentrated our dermatology development program on indications that use our approved Kerastick®. Based on market research that was completed in 2003, we have moved forward with our Phase II clinical studies for use of Levulan® PDT in photodamaged skin and moderate to severe acne vulgaris. We initiated the photodamaged skin study during the second quarter of 2004, and a Phase II study on Levulan® PDT for the treatment of acne vulgaris at the end of October 2004. As our Phase II clinical trials proceed, and especially at such time as we may commence Phase III trials in these indications, research and development expenses are expected to increase significantly. We have also begun to examine the costs and regulatory requirements associated with seeking foreign marketing approvals for our products, which could cause the research and development budget to increase. In addition, 2004 expenses include compensation of $241,000 for the services of 3 consultants. These consultants originally received 30,000 fully vested stock options as compensation which were subsequently repurchased for $240,000 in December 2004 in response to new guidelines of pharmaceutical industry groups that prohibit physicians from having an ownership interest in companies with which they are affiliated. Furthermore, DUSA is also evaluating whether to develop and/or license additional light devices and this cost to develop and/or license has not been determined at this time.

DUSA has also been following patients who completed Phase I/II studies in the treatment of high-grade and low-grade dysplasia associated with Barrett s esophagus. In order to move forward with this indication, on September 27, 2004 DUSA signed a clinical trial agreement with the National Cancer Institute, Division of Cancer Prevention, or NCI DCP, for the clinical development of Levulan® PDT for the treatment of high-grade dysplasia within Barrett s Esophagus. In addition, to further our objectives concerning treatment of internal indications using Levulan® PDT, on November 4, 2004 we signed an additional clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP will be working together to prepare overall clinical development plans for

Levulan® PDT in these indications, starting with Phase II trials, and continuing through Phase III studies, if mutually agreeable. The immediate plan is for the NCI DCP to solicit clinical protocols from its extramural expert clinical investigator consortium, after which time DUSA and the NCI DCP will finalize the clinical trial designs. The NCI DCP will use its resources to file its own Investigational New Drug applications with the FDA. DUSA will provide Levulan®, 10 to 12 laser device(s) and the necessary training for the investigators involved in the studies. DUSA is in the process of estimating its costs of this program. DUSA will maintain full ownership of its existing intellectual property, has options on new intellectual property and, subject to successful Phase II and III clinical trial results, intends to seek FDA approvals in due course. In preparation for new Phase II clinical trials for the treatment of high-grade dysplasia associated Barrett s esophagus, we initiated a small single-center pilot Phase II clinical trial during 2004 using DUSA s new proprietary endoscopic light delivery device.

We have entered into a series of agreements for our research projects and clinical studies. As of December 31, 2004, future payments to be made pursuant to these agreements, under certain terms and conditions, total approximately $2,450,000 for 2005. This amount does not include any amounts which may become due to photonamic GmbH & Co. KG under the terms of our License and Development Agreement. See Note 13(f) to the Notes to the Consolidated Financial Statements. In addition, in connection with the NCI DCP programs mentioned above, we may incur in an additional costs during 2005 of approximately $700,000.

We expect research and development costs to continue to increase as we invest in our clinical programs.

Marketing and Sales Costs Marketing and sales costs for the year ended December 31, 2004 were $7,622,000 as compared to $2,494,000 for 2003. These costs consist of overhead expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling $5,268,000 in 2004 and $1,297,000 in 2003. The remaining expenses consist of tradeshows, miscellaneous marketing expenses and outside consultants totaling $2,354,000 in 2004 and $1,197,000 in 2003. These increases were mainly attributable to the launch of our direct sales force in October 2003 and related marketing and sales activities.

As of December 31, 2004, our sales force was comprised of 22 direct sales professionals, including managers and representatives, and various independent representatives in key target markets. The level of marketing and sales expenses and related support functions will continue to increase in 2005 as we expand our sales capacity with an additional 11 direct representatives during early 2005. We estimate that it takes a sales representative approximately 6 months to break even in comparison to DUSA's investment. In addition, we are considering whether to hire a contract sales force in addition to our direct representatives and we will be evaluating the sales force again in mid - 2005 in light of revenues and customer needs.

General and Administrative Costs General and administrative expenses for the year ended December 31, 2004 increased to $7,210,000 as compared to $6,344,000 for 2003. Other than legal costs as described below, this increase is mainly attributable to a higher level of general corporate expenses to support our expanding business, including an increase in audit and consulting fees primarily related to Sarbanes Oxley compliance work of $285,000, an increase in personnel related costs of $335,000, and an increase in general corporate expenses of $354,000.

General and administrative costs also include legal expenses incurred in 2004 of $3,144,000 and $3,253,000 in 2003, due primarily to the PhotoCure patent litigation costs in Australia. Total patent defense costs in 2004 were $2,150,000 as compared to $2,447,000 in 2003. We expect these patent defense costs to decrease in 2005 even with the current legal disputes in which we are engaged.

In April 2002, PhotoCure ASA filed suit against 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, was invalid. As a consequence of that action, Queen s University assigned the Australian patent to us so that we could 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. We are unable to predict the decision of the Federal Court of Australia, which we expect during 2005. However, should PhotoCure prevail in either part of the case, i.e. the Court finds that (i) our patent is invalid, or (ii) the patent is valid, but PhotoCure s product does not infringe the patent, PhotoCure will be able to market its product in Australia. Each party has the right to appeal within approximately one month of the Court s decision. In August 2004, DUSA, PhotoCure and Galderma entered into a Mediation Agreement designed to facilitate resolution of the parties potential patent disputes concerning PhotoCure and Galderma s methyl aminolevulinate product. The parties discussions are on-going.

In December 2003, DUSA was served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland alleging that DUSA s BLU-U® caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint named Berlex Laboratories, Inc., a subsidiary of our former marketing partner, as another defendant. The case was dismissed in December 2004.

In December 2004, DUSA filed a lawsuit against New England Compounding Center of Framingham, Massachusetts alleging violations of U.S. patent law in the U.S. District Court in Boston, Massachusetts. In January 2005, DUSA filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law in the U.S. District Court for the District of Arizona. DUSA is seeking injunctive relief, monetary damages and costs in both lawsuits. These cases are in their early stages and we are unable to predict the outcomes at this time.

Other Income, net Other income for the year ended December 31, 2004 decreased to $1,580,000, as compared to $1,926,000 in 2003. This decrease reflects a reduction in our average investable cash balances during early 2004 as we used cash to support our operating activities, offset by the additional proceeds received from the private placement in March 2004. Additionally, interest income had been negatively impacted by the general decrease in interest rates which occurred during 2003 and early 2004. During 2004 and 2003, we incurred interest expense of $20,000 and $56,000, respectively, on borrowings associated with the construction of our Kerastick® manufacturing facility. Of these amounts, $36,000 was capitalized in property and equipment in the Consolidated Balance Sheet in 2003. We repaid the outstanding secured term loan promissory note with Citizens Bank of Massachusetts in June 2004.

Income Taxes There is no provision for income taxes due to ongoing operating losses. As of December 31, 2004, we had net operating loss carryforwards of approximately $74,243,000 and tax credit carryforwards of approximately $2,278,000 for Federal reporting purposes. These amounts expire at various times through 2024. See Note 9 to the Notes to the Consolidated Financial Statements. We have provided a full valuation allowance against the net deferred tax assets at December 31, 2004 and 2003.

Net Income (Loss) For the year ended December 31, 2004, we recognized a net loss of ($15,629,000), or ($0.96) per share, as compared to ($14,827,000), or ($1.06) per share, for the year ended 2003. The decrease in net loss per share in 2004 as compared to 2003 is primarily due to an increase in the number of weighted average of common shares outstanding during 2004 as a result of our private placement earlier in 2004. The increase in total net loss in 2004 is due to the increase in operating costs offset, in part, by an increase in revenues. Net losses are expected to continue until product sales to physicians offset the cost of our sales force and marketing initiatives, and the costs for other business support functions.

Year Ending December 31, 2003 As Compared to 2002

2002 Dermatology Collaboration Termination On September 1, 2002, DUSA and Schering AG, the Company s former marketing and development partner for Levulan® 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		Revenue Recognition/ Asset Impairment
Revenues:			
Research grant and milestone revenue	Deferred revenue (1)	$	20,990,000
Operating Costs:			
Cost of product sales	Deferred charges (2)	$	543,000
	Inventory (3)		1,705,000
	Commercial light sources under lease or rental (4)		390,000
Total cost of product sales		$	2,638,000
Research and development costs	Deferred royalty (2)		639,000
Total operating cost charges		$	3,277,000

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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®, (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®, 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 ½ years.

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

4) In 2002, DUSA recorded an additional $390,000 of depreciation expense reflecting a shortened useful life of our BLU-U® 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® 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.

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 Year Ending December 31, 2003 As Compared to 2002 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. We have not received any co-development revenue from Schering AG subsequent to the termination of the agreement in 2002.

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

	2003	2002	Increase (Decrease)
Kerastick® product sales	$ 901,000	$ 209,000	$ 692,000
BLU-U® product sales	69,000		69,000

BLU-U® 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® sales by Berlex, the subsidiary of our former marketing partner, to its distributor.

The increase in 2003 Kerastick® product sales revenue was 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® product sales of $69,000 after receiving FDA clearance to market the BLU-U® as a stand alone device for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

As of December 31, 2003, 406 BLU-U® units were in place in physicians offices, up from 329 units at December 31, 2002. This increase in BLU-U® placements included the sale of 21 units following receipt of market clearance from the FDA in September 2003 for moderate inflammatory acne vulgaris and general dermatological conditions. Kerastick® sales to end-users were 11,172 for 2003, as compared to 7,116 for 2002.

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 are provided below:

	2003	2002	Increase (Decrease)
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	$ 1,189,000	$ 1,108,000
Direct Kerastick® product costs	381,000	44,000	337,000
Costs incurred to ship, install and service the BLU-U® in physicians offices (2)	729,000	834,000	(105,000)
Royalty and supply fees (3)	74,000	64,000	10,000
Net underutilization costs (4)	-0-	333,000	(333,000)
Deferred charges amortization (5)	-0-	151,000	(151,000)
Inventory and deferred charge adjustments resulting from collaboration termination (6)	-0-	2,638,000	(2,638,000)
Total cost of product sales and royalties	$ 3,481,000	$ 5,253,000	$ (1,772,000)

1) The increase in product costs for 2003 is primarily attributable to increased costs to support the preparation to manufacture the Kerastick®, 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® product sales in 2003, there were no related direct BLU-U® 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

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Company s expectation at that time of no significant near-term increases in Kerastick® sales levels and/or BLU-U® 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®. Such deferred charges were fully amortized in 2002.

6) See section entitled Results of Operations Year Ending December 31, 2003 As Compared to 2002 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 was 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. Based on market research that was completed earlier in 2003, we decided to move forward with Phase II studies for use of Levulan® PDT in photodamaged skin and acne.

In 2003, we also received market clearance from the FDA on a Section 510(k) premarket notification application for use of the BLU-U® without Levulan® to treat moderate inflammatory acne. The development program also 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 also funded various investigator studies involving ALA and/or the Kerastick®.

The decrease in research and development costs in 2003 was 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 become obligated to pay certain regulatory milestones of $1,250,000 upon FDA acceptance of a registration application for a brain cancer product in the U.S., 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® PDT treatment of Barrett s esophagus with and without dysplasia.

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 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 U.S.. At the end of December 2003, we hired our seventh direct representative in a key target market.

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 was 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 in the PhotoCure litigation described above. 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.

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 reflected lower levels of investable cash balances as we used cash to support our operating activities, and a decline in yields. 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 Kerastick® manufacturing facility. Of these amounts, $36,000 and $47,000 was 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 $56,562,000 and tax credit carryforwards of approximately $2,032,000 for Federal reporting purposes. These amounts expire at various times through 2023. See Note 9 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. We 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 Year Ending December 31, 2003 As Compared to 2002 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, i.e., until end-user sales offset the cost of launching our sales force, marketing initiatives, and costs for other business support functions.

Quarterly Results of Operations

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2004 and 2003, respectively:

	Quarterly Results For Year Ended December 31, 2004			
	March 31	June 30	September 30	December 31
Total revenues	$ 1,255,685	$ 2,176,028	$ 2,010,619	$ 2,545,324
Loss from operations	(4,800,791)	(4,571,668)	(3,325,565)	(4,510,703)
Net loss	(4,401,654)	(4,196,087)	(2,974,992)	(4,056,247)
Basic and diluted loss per share	(0.30)	(0.25)	(0.18)	(0.24)

	Quarterly Results For Year Ended December 31, 2003			
	March 31	June 30	September 30	December 31
Total revenues	$ 143,370	$ 147,275	$ 163,155	$ 516,309
Loss from operations	(4,132,108)	(4,338,080)	(4,088,789)	(4,194,208)
Net loss	(3,565,973)	(3,811,116)	(3,679,858)	(3,769,907)
Basic and diluted loss per share	(0.26)	(0.27)	(0.26)	(0.27)

Liquidity and Capital Resources

We remain in a strong cash position to continue to fund increased Levulan® PDT sales and marketing expenses and current research and development activities for our Levulan® PDT/PD platform. At December 31, 2004, we had approximately $49,292,000 of total cash resources comprised of $2,928,000 of cash and cash equivalents, marketable securities available for sale totaling $46,223,000, and restricted cash of $141,000. As of December 31, 2004, these securities had yields ranging from 1.25% to 7.75% and maturity dates ranging from January 15, 2005 to February 15, 2007. In August 2004, we changed our investment policy to allow investment of a portion of its securities in high grade corporate bonds in order to improve yields earned on our marketable securities.

On February 27, 2004, we consummated 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. We 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, which were exercised on April 14, 2004, resulting in additional proceeds of $3,712,500. Offering costs incurred in connection with the placement were $1,908,000, of which $1,708,000 consisted of the placement agent s commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price.

As of December 31, 2004, our working capital (total current assets minus total current liabilities) was $48,799,000 as compared to $33,838,000 as of December 31, 2003. Total current assets increased $15,696,000 in 2004 due primarily to the gross proceeds received from the private placement of $28,463,000, offset mainly by the net use of $14,070,000 of cash and cash equivalents to support our operating activities. Total current liabilities increased $735,000 in 2004 due primarily to an increase in other accrued expenses for dermatology consulting fees related to the Phase II clinical studies for use of Levulan® PDT in photodamaged skin and moderate to severe acne vulgaris, and an overall increase in operations. In May 2002, we entered into a secured term loan promissory note with Citizens Bank of Massachusetts to fund the construction of our manufacturing facility and borrowed $1,900,000, and in June 2004 we repaid the outstanding $1,400,000 loan balance.

During 2004, we purchased $530,000 of property, plant, and equipment additions and made payments on long-term debt of $1,518,000. During 2004, we received $28,263,000 in net proceeds from the private placement, $765,000 in proceeds from stock option exercises, and invested $14,037,000 of net proceeds from maturations and sales of marketable securities. During the comparable 2003 period, we used $12,762,000 of cash for operating activities, purchased $633,000 of property, plant and equipment, and received net proceeds of $11,000,000 from maturations and purchases of U.S. government securities.

We believe that we have sufficient capital resources to proceed with our current programs for Levulan® 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 for funding our needs on a short-term and long-term basis.

We are seeking to expand or enhance our business by using resources to acquire by license, purchase or other arrangements, businesses, new technologies, or products, especially in dermatology-related areas in the near term. For 2005, we are focusing primarily on increasing the sales of the Levulan® Kerastick®, acquiring and/or licensing dermatology products that will provide our sales force with additional complementary products to sell, continuing Phase II studies for use of Levulan® PDT in photodamaged skin and acne using our Kerastick®, and exploring corporate alliance opportunities for Levulan® PDT for dermatology in Europe and/or other countries outside of the U.S. and Canada. 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 for the dermatological uses of Levulan® 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.

At this time, 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 generate.

The total capital costs used to develop our manufacturing facility, which was approved to manufacture the Levulan® Kerastick® 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® 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, 2004:

	Obligations Due by Period				
	Total	1 Year or Less	2-3 Years	4-5 Years	After 5 Years
Operating lease obligations	$ 3,295,000	$ 465,000	$ 810,000	$ 850,000	$ 1,170,000
Purchase obligations (1), (2)	$ 2,450,000	$ 2,450,000			
Minimum royalty obligations (3)	$ 726,000	$ 83,000	$ 166,000	$ 166,000	$ 311,000

(1) Research and development projects include various commitments including obligations for our Phase II clinical studies for photodamaged skin and moderate to severe acne.

(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.

(3) Annual minimum royalties to PARTEQ must total at least CDN $100,000 (U.S. $83,000 as of December 31, 2004) through the expiration of the term of the agreement.

In May 2002, we entered into a secured term loan promissory note with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed $1,900,000. We repaid the outstanding loan balance in June 2004. The security interest in approximately $3,000,000 of our U.S. government securities that were being pledged as collateral to secure the loan was released.

Recently Issued Accounting Guidance

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R), Share-Based Payment, a revision of SFAS No. 123, which will impact the accounting for employee stock options and other equity-based compensation. The standard requires companies to measure and recognize compensation expense for all stock-based payments at fair value. The adoption of SFAS No. 123(R) will not affect our cash flow or financial position, but it will affect our net income (loss) and earnings per share. In accordance with the revised statement, we will recognize the expense attributable to stock options that are granted or vest in periods ending subsequent to June 30, 2005. As described in Note 2(m) to the Notes to the Consolidated Financial Statements, had the Company expensed its employee stock options under SFAS No. 123 for the year ended December 31, 2004, net loss and net loss per share would have increased by approximately $2,276,000 or $0.14 per share, respectively. As share options are determined each year, the impact to the Company s financial statements of the adoption of SFAS No. 123(R) cannot be predicted with certainty.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. The amendments made by SFAS No. 151 clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials should be recognized as current-period charges and require the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. The provisions of SFAS No. 151 shall be applied prospectively and are effective for inventory costs incurred during fiscal years beginning after June 15, 2005, with earlier application permitted for inventory costs incurred during fiscal years beginning after the date this Statement was issued. The adoption of SFAS No. 151 is not expected to have a material impact on our financial position and results of

operations.

In March 2004, the FASB issued EITF Issue No. 03-1, The Meaning of Other-Than Temporary Impairment and Its Application to Certain Investments , which provides new guidance for assessing impairment losses on debt and equity investments. Additionally, EITF Issue No. 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. The FASB has delayed the application of the accounting provisions until 2005, but requires new disclosures for annual periods ending after June 15, 2004. Management does not expect the adoption of this new accounting pronouncement to have a material impact on our financial statements upon adoption.

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

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our investments consist of United States government securities and high grade corporate bonds. All investments are carried at market value, which approximates cost.

As of December 31, 2004, the weighted average rate of return on our investments was 5.3%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of December 31, 2004, the fair market value of the portfolio would decline by $356,000. Declines in interest rates could, over time, reduce our interest income.

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 and 21E of the Securities Exchange Act of 1934 which represent our expectations or beliefs concerning future events, including, but not limited to management s goal of becoming profitable, statements regarding our core objectives for 2005, management s beliefs regarding the unique nature of Levulan® and its use and potential use, expectations regarding the timing of results of clinical trials and future development of cancer, warts, onychomycosis, psoriasis, molluscum contagiosum, oily skin and acne rosacea, facial photodamaged skin, cystic acne, acne vulgaris, Barrett s esophagus dysplasia, infected sweat glands (hidradenitis suppurativa) and other potential indications, intention to pursue licensing, marketing, co-promotion 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 continue 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 and market opportunities from approved and potential products and Levulan ® s competitive properties, intention to postpone or commence clinical trials and investigator studies in 2005, expectations of exclusivity under the Hatch-Waxman Act and other patent laws, intentions to seek additional U.S. and foreign regulatory approvals, trademarks, and to market and increase sales outside the U.S., beliefs regarding environmental compliance, beliefs concerning patent disputes, the impact of a third-party s regulatory compliance and fulfillment of contractual obligations, expectations of increases in cost of product sales, expectations to see a significantly higher average margin per Kerastick®, estimations as to the time it takes for a sales representative to break even in comparison to DUSA's investment, expected use of cash resources in 2005, requirements of cash resources for our future liquidity, anticipation of hiring additional personnel, effect of reimbursement policies on revenues and acceptance of our therapies, 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, potential for additional inspection and testing of our manufacturing facilities, beliefs regarding the adequacy of our inventory of Kerastick® and BLU-U® units and the impact of inventories on revenues, belief regarding interest rate risks to our investments and effects of inflation and new accounting standards, beliefs regarding the impact of any current or future legal proceedings, dependence on key personnel, beliefs concerning product liability insurance, intention to continue to develop an alternative BLU-U® light device and integrated drug and light device systems, 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 availability of products for acquisition and/or license on terms agreeable to DUSA, sufficient sources of funds, 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

Conclusion Regarding the Effectiveness of Disclosure 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, 2004. There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, DUSA s internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

DUSA Pharmaceuticals, Inc.

Wilmington, Massachusetts

We have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting included in Item 9A of Form 10-K, that DUSA Pharmaceuticals, Inc. and its subsidiary (the Company) maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or

disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2004 of the Company and our report dated March 14, 2005 expressed an unqualified opinion on those financial statements.

/s/DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 14, 2005

ITEM 9B. **OTHER INFORMATION**

None.

PART III

ITEM 10. **DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information required by Item 10 is hereby incorporated by reference to the sections entitled Nominees, Executive Officers who are not Directors, and Compliance with Section 16(a) of the Exchange Act of the Registrant s 2005 Proxy Statement.

ITEM 11. **EXECUTIVE COMPENSATION**

The information required by Item 11 is hereby incorporated by reference to the sections entitled Director Compensation, Executive Compensation, Board Compensation Committee Report on Executive Compensation, Performance Graph, Option Grants in 2004, Aggregate Option Exercises in 2004 and Option Values at December 31, 2004, and Other Compensation of Registrant s 2005 Proxy Statement.

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

The information required by Item 12 is hereby incorporated by reference to the section entitled Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters of the Registrant s 2005 Proxy Statement.

ITEM 13. **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information required by Item 13 is hereby incorporated by reference to the section entitled Certain Relationships and Related Transactions of the Registrant s 2005 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference to the section entitled Ratification and Selection of Auditors of the Registrant s 2005 Proxy Statement

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

A. *List of Financial Statements and Schedules*

INCLUDED IN ANNUAL REPORT TO SHAREHOLDERS INCORPORATED HEREIN BY REFERENCE:

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

B. *Reports on Form 8-K*

a) Form 8-K, dated and filed October 13, 2004, reporting sales results for the quarter ended September 30, 2004.

b) Form 8-K, dated and filed October 22, 2004, reporting the initiation of a new multi-center Phase II clinical study using the Company s Levulan® Kerastick® and BLU-U® photodynamic therapy for the treatment of moderate to severe acne vulgaris of the face.

c) Form 8-K, dated and filed December 27, 2004, announcing that DUSA had filed a lawsuit against New England Compounding Center of Framingham, Massachusetts alleging violations of U.S. patent law.

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 is incorporated herein by reference; and

3(b) By-laws of the Registrant, filed as Exhibit 3 to the Registrant s current report on Form 8-K, filed on January 4, 2005, and is incorporated herein by reference.

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, filed as Exhibit 10(b.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, 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(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, filed as Exhibit 10(h.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference;

10(h.2) 1996 Omnibus Plan, as amended April 23, 2004, filed as Appendix A to Registrant s Schedule 14A definitive Proxy Statement dated April 28, 2004, and is incorporated herein by reference;

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

10(i.1) Amended and Restated Purchase and Supply Agreement between the Company and National Biological Corporation dated as of June 21, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 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, filed August 11, 2004, 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 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(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;
10(s)	Investment Banking Agreement between the Company and Sunrise Securities Corp. entered into February 27, 2004 filed as Exhibit 10(s) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference;
10(t)	License, Promotion, Distribution and Supply Agreement between the Company and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;
10(u)	Employment Agreement of Scott L. Lundahl, dated as of June 23, 1999;
10(v)	Amended Employment Agreement of Stuart L. Marcus, MD, PhD, dated as of December 9, 1999;
10(w.1)	Employment Agreement of Mark C. Carota, dated as of February 14, 2000;
10(w.2)	First Amendment to Employment Agreement of Mark C. Carota, dated as of October 31, 2001;
10(x)	Employment Agreement of Paul A. Sowyrda, dated as of July 31, 2001;
10(y)	Employment Agreement of Richard Christopher, dated as of January 1, 2004;
10(z)	Employment Agreement of Robert F. Doman, dated as of March 15, 2005;
10(aa)	Employment Agreement of Gary F. Talarico, dated as of February 15, 2005;
10(bb)	Severance Agreement and General Release between the Company and Peter Chakoutis, dated as of February 25, 2005; and
10(cc)	Compensation Policy Applicable to the Company s Non-Employee Directors.
14(a)	Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers.
21(a)	Subsidiary of Registrant.
23(a)	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
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.

Management contract or compensatory plan or arrangement.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2004 and 2003, and the related consolidated statements of operations, shareholders equity and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of December 31, 2004, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2005 expressed an unqualified opinion on management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 14, 2005

DUSA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2004	**2003**
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,928,143	$ 4,294,482
Marketable securities	46,222,969	30,284,841
Accrued interest receivable	641,797	533,796
Accounts receivable	711,016	229,483
Inventory	1,417,160	712,831
Prepaids and other current assets	830,895	1,000,413
Total current assets	52,751,980	37,055,846
Restricted cash	140,764	139,213
Restricted marketable securities		3,250,940
Property, plant and equipment, net	3,481,888	4,251,489
Deferred charges and other assets	276,256	
TOTAL ASSETS	$ 56,650,888	$ 44,697,488
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 857,268	$ 859,282
Accrued compensation	963,607	796,618
Other accrued expenses	1,901,841	1,162,139
Current maturities of long-term debt		270,000
Deferred revenue	230,715	129,900
Total current liabilities	3,953,431	3,217,939
Other liabilities	190,439	
Long-term debt, net of current maturities		1,247,500
TOTAL LIABILITIES	4,143,870	4,465,439
Commitments and Contingencies (Note 13)		
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: 16,876,822 (2003: 13,966,247) shares of common stock, no par.	124,698,059	95,670,554
Additional paid-in capital	2,016,339	2,015,586
Accumulated deficit	(74,538,761)	(58,909,781)
Accumulated other comprehensive income	331,381	1,455,690
TOTAL SHAREHOLDERS EQUITY	52,507,018	40,232,049
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 56,650,888	$ 44,697,488

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2004	**2003**	**2002**
REVENUES			
Product sales, net	$ 7,987,656	$ 970,109	$ 319,378
Research grant and milestone revenue			22,312,498
Research revenue earned under collaborative agreement			2,851,362
TOTAL REVENUES	7,987,656	970,109	25,483,238
OPERATING COSTS			
Cost of product sales and royalties	3,875,018	3,481,248	5,253,424
Research and development	6,489,723	5,403,961	12,121,606
Marketing and sales	7,622,106	2,494,405	
General and administrative	7,209,536	6,343,680	5,591,039
TOTAL OPERATING COSTS	25,196,383	17,723,294	22,966,069
INCOME (LOSS) FROM OPERATIONS	(17,208,727)	(16,753,185)	2,517,169
OTHER INCOME, NET			
Interest income, net	1,568,995	1,926,331	2,745,143
Realized gains on sales of marketable securities	10,752		500,206
TOTAL OTHER INCOME, NET	1,579,747	1,926,331	3,245,349
NET INCOME (LOSS)	$ (15,628,980)	$ (14,826,854)	$ 5,762,518
BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE	$ (0.96)	$ (1.06)	$ 0.42
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	16,317,078	13,936,482	13,877,566

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

	Common Stock		Additional		Accumulated Other	
	Number of Shares	Amount	Paid-in Capital	Accumulated Deficit	Comprehensive Income	Total
BALANCE, JANUARY 1, 2002	**13,865,390**	**$ 95,440,561**	**$ 2,015,586**	**$ (49,845,445)**	**$ 2,223,835**	**$ 49,834,537**
Comprehensive income:						
Net income for period				5,762,518		5,762,518
Net unrealized gain on U.S. government securities available for sale (net of realized gains of $500,206)					410,675	410,675
Total comprehensive income						**6,173,193**
Issuance of common stock to consultants	22,222	50,000				50,000
BALANCE, DECEMBER 31, 2002	**13,887,612**	**$ 95,490,561**	**$ 2,015,586**	**$ (44,082,927)**	**$ 2,634,510**	**$ 56,057,730**
Comprehensive loss:						
Net loss for period				(14,826,854)		(14,826,854)
Net unrealized loss on U.S. government securities available for sale					(1,178,820)	(1,178,820)
Total comprehensive loss						**(16,005,674)**
Issuance of common stock to consultants	44,416	110,000				110,000
Exercises of options	11,000	32,870				32,870
Issuance of common stock to employee	23,219	37,123				37,123
BALANCE, DECEMBER 31, 2003	**13,966,247**	**$ 95,670,554**	**$ 2,015,586**	**$ (58,909,781)**	**$ 1,455,690**	**$ 40,232,049**
Comprehensive loss:						
Net loss for period				(15,628,980)		(15,628,980)
Net unrealized loss on marketable securities available for sale (net of realized gains of $10,752)					(1,124,309)	(1,124,309)
Total comprehensive loss						**(16,753,289)**
Issuance of common stock for cash through a private placement, net of total offering costs of $1,907,952 including 155,250 shares issued to placement agent	2,742,750	28,262,298				28,262,298
Exercises of options	167,825	765,207				765,207
Issuance of options to consultants			240,753			240,753
Repurchase of options issued to consultants			(240,000)			(240,000)
BALANCE, DECEMBER 31, 2004	**16,876,822**	**$ 124,698,059**	**$ 2,016,339**	**$ (74,538,761)**	**$ 331,381**	**$ 52,507,018**

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2004	**2003**	**2002**
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES			
Net income (loss)	$ (15,628,980)	$ (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 marketable securities available for sale, net	225,614	100,346	(378,089)
Depreciation and amortization	1,299,308	1,610,848	3,247,129
Amortization of deferred revenue			(22,312,498)
Issuance of common stock and options to consultants	240,753	110,000	50,000
Changes in other assets and liabilities impacting cash flows from operations:			
Accrued interest receivable	(108,001)	165,868	223,795
Accounts receivable	(481,533)	(192,763)	84,560
Receivable under co-development program			864,534
Inventory	(704,329)	475,828	1,144,421
Prepaids and other current assets	169,518	(84,709)	(424,779)
Restricted cash	(1,551)	(1,330)	(1,865)
Deferred charges and other assets	(276,256)		(100,000)
Accounts payable	(2,014)	306,391	238,002
Accrued compensation and other accrued expenses	906,691	(550,872)	84,477
Deferred revenue	100,815	124,800	(268,258)
Other liabilities	190,439		
Net cash used in operating activities	(14,069,526)	(12,762,447)	(11,786,053)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES			
Purchases of marketable securities	(58,858,323)	(4,000,000)	(6,131,356)
Proceeds from maturing and sales of marketable securities	44,821,212	15,000,000	18,246,298
Purchases of property, plant and equipment	(529,707)	(632,654)	(2,622,158)
Repurchase of options issued to consultants	(240,000)		
Net cash provided by (used in) investing activities	(14,806,818)	10,367,346	9,492,784
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES			
Issuance of common stock (net of stock offering costs of $200,202)	28,262,298		
Proceeds from long-term debt			1,900,000
Payment of long-term debt	(1,517,500)	(270,000)	(112,500)
Proceeds from exercise of options	765,207	32,870	
Net cash provided by (used in) financing activities	27,510,005	(237,130)	1,787,500
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,366,339)	(2,632,231)	(505,769)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	4,294,482	6,926,713	7,432,482
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 2,928,143	$ 4,294,482	$ 6,926,713
Cash paid for interest	$ 20,186	$ 58,623	$ 41,066

Non-Cash Transactions

During 2004, the Company issued 155,250 shares of its common stock in a private placement at $11.00 per share as commission and non-refundable retainer to the placement agent for a total value of $1,707,750 (See Note 10.) Also during 2004, the Company granted 30,000 fully vested options to three consultants. These options were valued at $240,753 (See Note 10.)

During 2003, the Company issued 23,219 shares of restricted common stock at $1.599 per share to its Chief Executive Officer, reflecting payment of the after-tax portion of his 2002 bonus compensation (See Note 10.)

See the accompanying Notes to the Consolidated Financial Statements.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002

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

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) 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 Company s Kerastick® manufacturing facility at its Wilmington, Massachusetts location. The cash in support of the letter of credit is held in a separate bank account and is recorded as restricted cash in the Consolidated Balance Sheets. This letter of credit was renewed in December 2004 and has a balance, including interest earned, of $140,764 at December 31, 2004.

d) Marketable Securities The Company classifies all investment securities as available for sale and records such investments at fair market value. Unrealized gains and losses on available for sale securities are recorded as a separate component of shareholders equity.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

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 marketable securities are available for sale, and as management expects to sell a portion of its marketable securities in the next fiscal year in order to meet its working capital requirements, it has classified marketable securities as current assets, except for those pledged as collateral on the secured term loan promissory note in the Consolidated Balance Sheets as of December 31, 2003, which were released from restriction upon repayment of the note in 2004 (see Note 4).

e) Inventory Inventory is stated at the lower of cost (first-in, first-out method) or market. Inventory consisting of BLU-U® commercial light sources is reclassified to property, plant and equipment when BLU-U® units are 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.

f) Property, Plant and Equipment Property, plant and equipment is carried at cost less accumulated depreciation and amortization. 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.

g) 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 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.

h) 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 reasonableness of collection. Product sales made through distributors who have a general right of return of product have been recorded as deferred revenue until the product is sold by the distributors to the end user. Research revenue earned under collaborative agreements consisted of non-refundable research and development funding from a former 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

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

activities were performed under the terms of the related agreements and when no future performance obligations existed.

i) 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.

j) Marketing and Sales Costs The Company commenced certain marketing and sales initiatives in 2003 including the launch of its direct sales force in October 2003 and related marketing and sales activities. Costs included in marketing and sales expense consist mainly of overhead expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, as well as costs related to tradeshows, miscellaneous marketing and outside consultants. All such costs are expensed as 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 upon 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, 2004, 2003, and 2002, stock options and warrants totaling approximately 3,009,000, 2,745,000, and 2,553,000 shares, respectively, have been excluded from the computation of diluted net income (loss) per share.

m) Stock-based compensation Statement of Financial Accounting Standard (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 (APB) No. 25, Accounting for Stock Issued to

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

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:

		2004	2003	2002
Net income (loss): as reported	$	(15,628,980)	$ (14,826,854)	$ 5,762,518
Deduct: effect on net income (loss) if fair value method had been used		(2,275,678)	(3,445,951)	(3,880,231)
Net income (loss): proforma	$	(17,904,658)	$ (18,272,805)	$ 1,882,287
Basic and diluted net income (loss) per common share: as reported	$	(0.96)	$ (1.06)	$ 0.42
Basic and diluted net income (loss) per common share: proforma	$	(1.10)	$ (1.31)	$ 0.14

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

	2004	2003	2002
Expected life (years)	5	5	7
Risk free interest rate	3.02%	3.02%	4.89%
Expected volatility	76.40%	80.85%	72.84%
Dividend yield			

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

Using these assumptions, the weighted-average fair value per option granted during the years ended December 31, 2004, 2003, and 2002, was $6.34, $1.57, and $2.53, respectively.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS Statement No. 123(R), Share-Based Payment, a revision of SFAS Statement No. 123, which will impact the accounting for employee stock options and other equity-based compensation. The standard requires companies to measure and recognize compensation expense for all stock-based payments at fair value. The adoption of SFAS No. 123(R) will not affect the Company s cash flow or financial position, but it will affect the Company s net income (loss) and earnings per share. In accordance with the revised statement, the Company will recognize the expense attributable to stock options that are granted or vest in periods ending subsequent to June 30, 2005. As noted above, had the Company expensed its employee stock options under SFAS No. 123 for the year ended December 31, 2004, net loss and net loss per share would have increased by approximately $2,276,000 or $0.14 per share, respectively. As share options are determined each year, the impact to the Company s financial statements of the adoption of SFAS No. 123(R) cannot be predicted with certainty.

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 and losses on marketable 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.

During the years ended 2004, 2003 and 2002, the Company derived its sales from the following geographies (as a percentage of net product sales):

	2004	2003	2002
United States	91%	100%	100%
Rest of world	9%		
Total	100%	100%	100%

p) Fair Value of Financial Instruments The carrying value of the Company s financial assets and liabilities approximates their fair values due to their short-term nature. Marketable securities classified as available for sale are carried at fair market value.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

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 U.S. government securities and high grade corporate bonds.

The Company is also exposed to concentration of credit risk related to accounts receivable that are generated from its distributors and customers. To manage credit risk, the Company performs regular credit evaluations of its customers financial condition and provides allowances for potential credit losses, when applicable. Concentrations in the Company s total revenues for the year ended December 31, 2004 and 2003, and accounts receivable as of December 31, 2004 and 2003 were as follows:

	2004		2003	
	% of Revenue	% of Accounts Receivable	% of Revenue	% of Accounts Receivable
Third-party distributor A	31%	27%	89%	86%
Third-party distributor B	17%			5%
Third-party distributor C	5%	34%		
Direct customer distribution	47%	39%	11%	9%
Total	100%	100%	100%	100%

The Company is dependent upon sole-source suppliers for a number of its products. There can be no assurance that these suppliers will be able to meet the Company s future requirements for such products or parts or that they will be available at favorable terms. Any extended interruption in the supply of any such products or parts or any significant price increase could have a material adverse effect on the Company s operating results in any given period.

r) Recently Issued Accounting Guidance In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. The amendments made by SFAS No. 151 clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials should be recognized as current-period charges and require the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Management does not expect the adoption of SFAS No. 151 to have a material impact on the Company s financial position and results of operations upon adoption.

In March 2004, the FASB issued EITF Issue No. 03-1, The Meaning of Other-Than Temporary Impairment and Its Application to Certain Investments which provides new

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

guidance for assessing impairment losses on debt and equity investments. Additionally, EITF Issue No. 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. The FASB has delayed the application of the accounting provisions until 2005, but requires new disclosures for annual periods ending after June 15, 2004. Management does not expect the adoption of this new accounting pronouncement to have a material impact on the Company s financial statements upon adoption.

3) 2002 DERMATOLOGY COLLABORATION TERMINATION

On September 1, 2002, DUSA and Schering AG, the Company s former marketing and development partner for Levulan® 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		Revenue Recognition/ Asset Impairment
Revenues:			
Research grant and milestone revenue	Deferred revenue (1)	$	20,990,000
Operating Costs:			
Cost of product sales	Deferred charges (2)	$	543,000
	Inventory (3)		1,705,000
	Commercial light sources under lease or rental (4)		390,000
Total cost of product sales		$	2,638,000
Research and development costs	Deferred royalty (2)		639,000
Total operating cost charges		$	3,277,000

(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.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

(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®, (ii) $34,000 to cost of product sales and royalties for deferred charges associated with underutilization costs paid to National Biological Corporation, the manufacturer of the Company s BLU-U®, 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 ½ years.

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

(4) In 2002, the Company recorded an additional $390,000 of depreciation expense reflecting a shortened useful life of its BLU-U® 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® placements to date, the termination of the collaboration arrangement, and management s expectations that near-term placements would be limited.

4) MARKETABLE SECURITIES

The Company s investment securities consist of securities of the U.S. government and its agencies, and investment grade corporate bonds, all classified as available for sale. As of December 31, 2004, current yields range from 1.25% to 7.75% and maturity dates range from January 15, 2005 to February 15, 2007. In August 2004, the Company commenced investing in investment grade corporate securities in accordance with the Company s investment policy.

Securities pledged as collateral on the secured term loan promissory note that were classified as non-current assets in the Consolidated Balance Sheets as of December 31, 2003 were released from restriction when the underlying debt was repaid in June 2004.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

The estimated fair value and cost of marketable securities were as follows as of December 31:

	2004			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government securities	$ 27,266,271	$ 389,585	$ (15,315)	$ 27,640,541
Investment grade corporate securities	18,625,317	504	(43,393)	18,582,428
Total marketable securities available for sale	$ 45,891,588	$ 390,089	$ (58,708)	$ 46,222,969

	2003			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government securities	$ 32,080,091	$ 1,455,690		$ 33,535,781
Investment grade corporate securities				
Total marketable securities available for sale	$ 32,080,091	$ 1,455,690		$ 33,535,781

The change in net unrealized gains and losses on such securities for the years ended December 31, 2004, 2003 and 2002 was ($1,124,309), ($1,178,820) and $410,675, 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:

	2004	2003
Finished goods	$ 1,226,071	$ 582,382
Work in process	85,910	
Raw materials	105,179	130,449
	$ 1,417,160	$ 712,831

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

6) PROPERTY, PLANT AND EQUIPMENT

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

	Useful Lives (Years)	2004	2003
Computer equipment and software	3	$ 2,226,646	$ 1,971,114
BLU-U® units in physicians offices	3	700,043	1,187,875
Furniture, fixtures and equipment	5	726,069	542,496
Manufacturing facility	Term of lease	2,204,122	2,204,122
Manufacturing equipment	5	2,153,485	2,096,433
Leasehold improvements	Lesser of their useful lives or term of lease	699,892	666,344
		8,710,257	8,668,384
Accumulated depreciation and amortization		(5,228,369)	(4,416,895)
		$ 3,481,888	$ 4,251,489

In July 2003, the Company received FDA approval to manufacture the Levulan® Kerastick® 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 $1,299,000, $1,611,000, and $1,541,000 for 2004, 2003, and 2002, respectively. Accumulated depreciation and amortization at December 31, 2004 and 2003 includes $700,000 and $1,016,000, respectively, of accumulated depreciation associated with BLU-U® units in physicians offices, which had been transferred to property, plant and equipment from inventory as these units were provided to physicians through former marketing trial programs. As of December 31, 2004, these units have been fully depreciated, and ownership of a portion of these units has been transferred to physicians through sales or transfer agreements during 2004 and therefore are excluded from property, plant and equipment.

During 2003, the Company incurred interest expense of $56,000 on borrowings associated with the construction of its Kerastick® manufacturing facility. Of this amount, $36,000 of interest expense was capitalized in property and equipment during construction of the facility.

7) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following at December 31:

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

	2004	2003
Research and development costs	$ 778,926	$ 184,912
Marketing and sales costs	153,167	113,020
Product related costs	261,444	144,826
Legal and other professional fees	374,142	359,747
Employee benefits	229,304	189,051
Other expenses	104,858	170,583
	$ 1,901,841	$ 1,162,139

8) LONG-TERM DEBT

In May 2002, DUSA entered into a secured term loan promissory note with Citizens Bank of Massachusetts to fund the construction of its manufacturing facility and borrowed $1,900,000. DUSA repaid the outstanding loan balance in June 2004 without premium or penalty. The security interest in approximately $3,000,000 of the Company s U.S. government securities that were pledged as collateral to secure the loan was released upon repayment.

9) INCOME TAXES

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

	2004	2003
Deferred Tax Assets		
Deferred revenue	$ 93,000	$ 52,000
Intangible assets	632,000	592,000
Accrued charges	51,000	41,000
Research and development tax credits carryforwards	2,593,000	2,354,000
Operating loss carryforwards	29,463,000	23,326,000
License fee	161,000	181,000
Reserves		944,000
Total deferred tax assets	32,993,000	27,490,000
Deferred Tax Liabilities		
Fixed assets	(8,000)	(8,000)
Total deferred tax liabilities	(8,000)	(8,000)
Net deferred tax assets before allowance	32,985,000	27,482,000
Valuation allowance	(32,985,000)	(27,482,000)
Total deferred tax asset	$	$

During the years ended December 31, 2004, 2003, and 2002, the valuation allowance was increased by approximately $5,503,000, $5,022,000, and $191,000, respectively, due to the uncertainty of future realization of the net deferred tax assets which were increasing.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

Included in deferred tax assets at December 31, 2004 and 2003 is $1,600,000 in both years of future benefits attributable to the exercise of stock options which, if realized, will be credited to additional paid in capital rather than results of operations.

As of December 31, 2004, the Company has Federal net operating loss carryforwards for tax purposes of approximately $74,243,000 and research and development tax credits of approximately $2,278,000, both of which, if not utilized, will expire for Federal tax purposes as follows:

	Operating loss carryforwards	Research and development tax credits
2011	$	$ 7,000
2012		57,000
2013		66,000
2014		84,000
2015	2,325,000	44,000
2016	6,638,000	102,000
2017	6,841,000	235,000
2018	5,738,000	145,000
2019		81,000
2020		159,000
2021	8,394,000	343,000
2022	14,646,000	477,000
2023	11,980,000	232,000
2024	17,681,000	246,000
	$ 74,243,000	$ 2,278,000

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

	2004		2003		2002	
	$	%	$	%	$	%
Income tax expense (benefit) at statutory rates	(5,314,000)	(34.0)	(5,041,000)	(34.0)	1,959,000	34.0
State taxes	(979,000)	(6.3)	(930,000)	(6.3)	371,000	6.4
Tax credit carryforwards	(435,000)	(2.8)	(329,000)	(2.2)	(603,000)	(10.5)
Change in valuation allowance including revisions of prior year estimates	6,676,000	42.7	6,268,000	42.3	(1,737,000)	(30.1)
Other	52,000	0.4	32,000	0.2	10,000	0.2

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

10) SHAREHOLDERS EQUITY

Common Stock Issuances **-** On February 27, 2004, the Company completed a private placement of 2,250,000 shares of its common stock at a purchase price of $11.00 per share, resulting in gross proceeds of $24,750,000. The closing date of the private placement was March 2, 2004. The Company 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 were exercised on April 14, 2004, resulting in additional gross proceeds of $3,712,500. Offering costs incurred in connection with the placement were $1,907,952, of which $1,707,750 consisted of the placement agent s commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price.

On March 18, 2004, the Company granted a total of 30,000 fully vested options to three consultants on its Medical Advisory Board as compensation for services. These options were valued at $240,753 and recorded as part of research and development costs in the Condensed Consolidated Statement of Operations. On December 30, 2004 the Company repurchased these options for a total cash payment of $240,000.

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. Both of these transactions were recorded in research and development expense in the Consolidated Statements of Operations. There was no equity issued as compensation in 2004.

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

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

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.

11) 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 3,343,874 shares. 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

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

will automatically receive an additional 10,000 NQSO on June 30 of each year. 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, 2004:

	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
Range of exercise price	Number outstanding at December 31, 2004	Weighted average remaining contractual life	Weighted average exercise price	Number exercisable at December 31, 2004	Weighted average exercise price
$1.60 to 5.10	600,250	7.96 years	$ 3.02	255,125	$ 3.02
5.20 to 7.75	591,250	2.07 years	7.44	591,250	7.44
8.49 to 9.92	658,750	7.19 years	9.60	305,000	9.32
9.99 to 27.31	554,500	5.56 years	17.17	469,250	18.03
31.00 to 31.00	304,000	5.18 years	31.00	304,000	31.00
	2,708,750	5.69 years	$ 11.62	1,924,625	$ 13.46

Activity under stock option plans during the years ended December 31, 2004, 2003 and 2002 was as follows:

	2004	Weighted average exercise price	2003	Weighted average exercise price	2002	Weighted average exercise price
Options outstanding, beginning of year	2,444,950	$ 11.50	2,253,075	$ 12.95	2,197,450	$ 14.30
Options granted	512,250	9.97	447,000	2.76	275,000	3.65
Options exercised	(167,825)	4.50	(11,000)	2.99		
Options cancelled	(80,625)	12.28	(244,125)	11.21	(219,375)	14.67
Options outstanding, end of year	2,708,750	$ 11.62	2,444,950	$ 11.50	2,253,075	$ 12.95
Options exercisable, end of year	1,924,625	$ 13.46	1,771,325	$ 12.59	1,666,826	$ 11.75

Options that were granted during 2004, 2003 and 2002 have exercise prices ranging from $9.05 to $12.87 per share, $1.60 to $5.20 per share, and $2.90 to $4.01 per share, respectively.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

Options which were exercised during 2004 and 2003 were exercised at per share prices ranging from $1.60 to $7.44, and $2.90 to $3.87, respectively. There were no option exercises in 2002.

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, 2004, 300,000 of the remaining warrants were outstanding. The exercise price of the warrants is CDN $6.79 (U.S. $5.64 at December 31, 2004).

12) 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 contributions in 2004 and 2003 were $39,000 and $33,000, respectively.

13) COMMITMENTS AND CONTINGENCIES

a) PARTEQ Agreement The Company licenses certain patents underlying its Levulan® 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.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

For the years ended December 31, 2004, 2003 and 2002, actual royalties based on product sales were approximately $229,000, $36,000, and $12,000, respectively. However, based on the annual minimum royalty requirements, the Company incurred total royalty expense of $74,000 and $64,000 in 2003 and 2002, 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. $83,000 as of December 31, 2004).

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

b) Draxis Termination and Transfer Agreement - On February 24, 2004, the Company reacquired the rights to the aminolevulinic acid (Levulan®) technology for Canada held by Draxis Health Inc. (Draxis). These rights were initially assigned to Draxis in 1991. The Company and Draxis terminated the assignment and DUSA agreed to pay to Draxis an upfront fee of $150,000 CDN ($114,000 USD at February 24, 2004) and a 10% royalty on sales of the Levulan® Kerastick® in Canada over a five year term commencing in June 2004 based on the first Kerastick® sale in Canada by Coherent, our Canadian marketing and distribution partner. The upfront fee was capitalized and is being amortized over the five year term of the arrangement. At December 31, 2004, the remaining unamortized balance of $101,000 is included in deferred charges and other assets. The Company incurred total royalty expense of $56,000 in 2004 which has been recorded in cost of product sales and royalties.

c) Lease Agreements The Company has entered into lease commitments for office space in Wilmington, Massachusetts, Valhalla, New York, and Toronto, Ontario. These leases generally have five or ten year terms. 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, 2004 are as follows:

	Minimum Lease Payments
2005	$ 465,000
2006	400,000
2007	410,000
2008	418,000
2009	432,000
Beyond 2009	1,170,000
	$ 3,295,000

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

Rent expense incurred under these operating leases was approximately $472,000, $471,000, and $458,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

d) Research Agreements The Company has entered into various agreements for research projects and clinical studies. As of December 31, 2004, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $2,450,000 for 2005. Included in this future payment is 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, 2004 for a one year period. Therapeutics is entitled to receive a bonus valued at $50,000, 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.

e) 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 being challenged by PhotoCure ASA. PhotoCure ASA 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, was invalid. As a consequence of this action, Queen s University assigned the Australian patent to the Company so that DUSA could participate directly in this litigation. The Company filed a response setting forth its defenses, and a related countersuit alleging that certain activities of PhotoCure and its marketing partner, Galderma S.A., infringe the patent. The final hearing in the Federal Court of Australia was held in April 2004, and a decision is expected in 2005. Each party has the right to appeal within approximately one month following the Court s decision. In August 2004, DUSA, Queen s, PhotoCure and Galderma entered into a Mediation Agreement designed to facilitate resolution of the parties potential patent disputes concerning PhotoCure and Galderma s methyl aminolevulinate product. The parties discussions are on-going. The Company is unable to predict the outcome of the case at this time.

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® caused the plaintiff to suffer a seizure during the performance of her duties as an office assistant. The complaint named Berlex Laboratories, Inc., a subsidiary of the Company s former marketing partner, as another defendant. This case was dismissed in December 2004.

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002 (continued)

In December 2004, the Company filed a lawsuit against New England Compounding Center of Framingham, Massachusetts alleging violations of U.S. patent law in the U.S. District Court in Boston, Massachusetts. In January 2005, the Company filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law in the U.S. District Court for the District of Arizona. The Company is seeking injunctive relief, monetary damages and costs in both lawsuits. These cases are in their early stages and the Company is unable to predict the outcomes at this time.

The Company has not accrued any amounts for settlement at December 31, 2004.

f) 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 had been charged to research and development costs in the Consolidated Statement of Operations in 2002, and had been included in other accrued expenses in the Consolidated Balance Sheet at December 31, 2002 since the contract was executed prior to year end. The Company may also be obligated to pay certain regulatory milestones including $1,250,000 upon FDA acceptance of a registration application for a brain cancer product in the U.S., 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 also 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 U.S. in order to retain the license for the use of the technology to treat brain cancer. Such additional obligations are undeterminable at this time.

g) Amended and Restated Purchase and Supply Agreement On June 21, 2004, the Company signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation (NBC), the manufacturer of its BLU® light source. This agreement provides for the elimination of certain exclusivity clauses, permits the Company to order on a purchase order basis without minimums, and other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources and the associated technology within the field of PDT. The Company paid $110,000 to NBC upon execution of the agreement which will be amortized over the remaining term of the agreement, expiring November 5, 2008.

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
Chairman and Chief Executive Officer

Date: March 15, 2005

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

/s/D. Geoffrey Shulman D. Geoffrey Shulman, MD, FRCPC	Director, Chairman and Chief Executive Officer (principal executive officer)	March 15, 2005 Date
/s/Robert F. Doman Robert F. Doman	President, Chief Operating Officer	March 15, 2005
/s/Mark C. Carota Mark C. Carota	Vice President, Operations	March 15, 2005
/s/Peter M. Chakoutis Peter M. Chakoutis	Vice President (principal accounting officer)	March 15, 2005
/s/Richard C. Christopher Richard C. Christopher	Vice President, Finance and Chief Financial Officer (principal financial officer)	March 15, 2005
/s/Scott L. Lundahl Scott L. Lundahl	Vice President, Intellectual Property and Regulatory Affairs	March 15, 2005
/s/Stuart L. Marcus Stuart L. Marcus, MD, PhD	Vice President, Scientific Affairs	March 15, 2005
/s/Paul A. Sowyrda Paul A. Sowyrda	Vice President, Marketing	March 15, 2005
/s/Gary F. Talarico Gary F. Talarico	Vice President, Sales	March 15, 2005

/s/John H. Abeles John H. Abeles	Director	March 15, 2005
/s/David Bartash David Bartash	Director	March 15, 2005
/s/Jay M. Haft Jay M. Haft, Esq.	Vice Chairman of the Board and Lead Director	March 15, 2005
/s/Richard C. Lufkin Richard C. Lufkin	Director	March 15, 2005
/s/Magnus Moliteus Magnus Moliteus	Director	March 15, 2005

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 is incorporated herein by reference; and
3(b)	By-laws of the Registrant, filed as Exhibit 3 to the Registrant s current report on Form 8-K, filed on January 4, 2005, and is incorporated herein by reference.
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, filed as Exhibit 10(b.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, 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(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, filed as Exhibit 10(h.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference;

10(h.2) 1996 Omnibus Plan, as amended April 23, 2004, filed as Appendix A to Registrant s Schedule 14A definitive Proxy Statement dated April 28, 2004, and is incorporated herein by reference;

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

10(i.1) Amended and Restated Purchase and Supply Agreement between the Company and National Biological Corporation dated as of June 21, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004, filed August 11, 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, 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;
10(s)	Investment Banking Agreement between the Company and Sunrise Securities Corp. entered into February 27, 2004, filed as Exhibit 10(s) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference; and
10(t)	License, Promotion, Distribution and Supply Agreement between the Company and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;
10(u)	Employment Agreement of Scott L. Lundahl, dated as of June 23, 1999;
10(v)	Amended Employment Agreement of Stuart L. Marcus, MD, PhD, dated as of December 9, 1999;
10(w.1)	Employment Agreement of Mark C. Carota, dated as of February 14, 2000;
10(w.2)	First Amendment to Employment Agreement of Mark C. Carota, dated as of October 31, 2001;

10(x)	Employment Agreement of Paul A. Sowyrda, dated as of July 31, 2001;
10(y)	Employment Agreement of Richard Christopher, dated as of January 1, 2004;
10(z)	Employment Agreement of Robert F. Doman, dated as of March 15, 2005;
10(aa)	Employment Agreement of Gary F. Talarico, dated as of February 15, 2005;
10(bb)	Severance Agreement and General Release between the Company and Peter Chakoutis, dated as of February 25, 2005; and
10(cc)	Compensation Policy Applicable to the Company s Non-Employee Directors.
14(a)	Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers.
21(a)	Subsidiary of Registrant
23(a)	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
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.

Management Contract or compensatory plan or arrangement.