

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

DUSA PHARMACEUTICALS INC
Form 10-K
March 10, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO
SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(MARK ONE)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2005

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 001-31533

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
Identification No.)

25 Upton Drive, Wilmington, MA

(Address of principal executive offices) 01887
(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE:
(978) 657-7500

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:
(TITLE OF CLASS)
NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
(TITLE OF CLASS)
COMMON STOCK, NO PAR VALUE

Indicate by check mark if the registrant is a well-known seasoned issuer,
as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports
pursuant to Section 13 or Section 15(d) of the Act Yes No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Act).

Large Accelerated Filer [] Accelerated Filer [X] Non-accelerated Filer []

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X]

As of March 6, 2006, the registrant had 17,046,197 shares of Common Stock, no par value, outstanding.

Based on the last reported sale price of the Company's common stock on the NASDAQ National Market on June 30, 2005 (\$9.30) (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$100,843,825.

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, 2005 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," "believes," "seeks," "estimates," or variations of such words and similar expressions, are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict particularly in the highly regulated pharmaceutical industry in which we operate. Therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include those set forth herein under "Risk Factors" on pages 26 through 38, 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 Pharmaceuticals, Inc. (referred to as "DUSA," "we," and "us") 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(R) 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(R) and follow it with exposure to light to treat a medical condition, it is known as Levulan(R) photodynamic therapy, or Levulan(R) PDT. When we use Levulan(R) and follow it with exposure to light to detect medical conditions it is known as Levulan(R) photodetection, or Levulan(R) PD.

Our products, the Levulan(R) Kerastick(R) 20% Topical Solution with PDT and the BLU-U(R) brand light source were launched in the United States, or U.S., in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003 we received clearance from the U.S. Food and Drug Administration, or FDA, to market the BLU-U(R) without Levulan(R) 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(R), and other related product activities. Our objectives include increasing the sales of our approved products in the U.S. and Canada, continuing our efforts of exploring partnership opportunities for Levulan(R) PDT for dermatology in Europe and/or other countries outside of the U.S., Canada and Latin America, and continuing our clinical development programs for our facial photodamage and moderate to severe acne indications. In January 2006, we entered into a marketing and distribution agreement with Stiefel Laboratories, Inc. granting Stiefel an exclusive right to distribute the Levulan(R) Kerastick(R) in Mexico, Central and South America.

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(R) 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(R) PDT for other indications in dermatology, and selected internal indications. See sections entitled "Business - Internal Indications" and "Business - Distribution".

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

On December 30, 2005, we entered into a merger agreement, (the "Merger Agreement"), to acquire all of the common stock of Sirius Laboratories, Inc. of Vernon Hills, Illinois in exchange for cash and common stock of DUSA worth up to \$30,000,000. Of the up to \$30,000,000, \$8,000,000 less certain expenses will be paid in cash upon closing, \$17,000,000 will be paid in shares of DUSA's common stock

3

also upon closing, and up to \$5,000,000 in cash or common stock may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. The products acquired in this transaction, called the Sirius Merger, focus primarily on the treatment of acne vulgaris and acne rosacea. We expect that the DUSA shares will be issued pursuant to Regulation D.

Further, the Merger Agreement provides for certain conditions precedent to closing, including, but not limited to, (i) the approval of the transaction and the terms and conditions of the Merger Agreement by the Sirius shareholders, (ii) the receipt by DUSA of audited financial statements of Sirius for the fiscal years ended 2003, 2004 and 2005, and (iii) the determination by DUSA that the third party manufacturing and distribution facilities used by Sirius to manufacture or distribute its products, as the case may be, are in material compliance with all applicable legal requirements and that the third party manufacturing facilities have the reasonable capability of continuing to manufacture Sirius' products in compliance with cGMP. In addition, the Merger Agreement provides DUSA, Sirius and certain Sirius shareholders with the right to terminate the Merger Agreement under certain circumstances. The parties have also made customary representations, warranties and covenants in the Merger Agreement. The closing of the transaction is expected during the first quarter of 2006, subject to the terms and conditions in the Merger Agreement.

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 our products, 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:

- o Expand the Marketing and Sales of our Products. In 2005, DUSA expanded its direct sales force to 24 representatives by year-end and launched various marketing initiatives, which increased revenues.
- o 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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- o Leveraging our Levulan(R) PDT/PD Platform to Develop Additional Products. During 2005, we conducted Phase II multi-center clinical trials in the United States to determine the safety and efficacy of Levulan(R) PDT in the treatment of facial photodamage and moderate to severe inflammatory acne. If we are able to obtain FDA approval, there may be significant additional market opportunities for our products. We are also actively marketing the BLU-U(R) without Levulan(R), to treat moderate inflammatory acne vulgaris, which supports a multi-use capability of our BLU-U(R), in addition to its use in our

4

approved AK therapy. Outside of dermatology, we are developing Levulan(R) products for the treatment of high-grade dysplasia in patients with Barrett's esophagus, both independently and in co-operation with the NCI DCP, and for oral cavity dysplasia treatment (with the NCI DCP) See sections entitled "Internal Indications - Barrett's Esophagus Dysplasia; and - Oral Cavity Dysplasia".

- o 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(R) PDT platform in Europe and/or other countries outside of the United States, Canada and Latin America following our recently completed agreement with Stiefel Laboratories, Inc. We are also continuing to seek to acquire and/or license additional dermatology products that complement our current products, that would provide our sales force with additional synergistic products to sell in the near term.
- o 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.
- o 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:

- o 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.
- o 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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:

- o the desired depth of penetration of the light into the target tissue, and
- o the efficiency of the light in activating the photosensitizer.

5

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 applied topically or taken systemically is temporary skin sensitivity to bright light. Patients undergoing PDT and PD treatments are usually advised to avoid direct sunlight and/or to wear protective clothing during this period. Patients' indoor activities are generally unrestricted except that they are told to avoid bright lights. The degree of selectivity and period of skin photosensitivity varies among different photosensitizers and is also related to the drug dose given. Unless activated by light, photosensitizers have no direct PDT/PD effects.

OUR LEVULAN(R) PDT/PD PLATFORM

OUR LEVULAN(R) BRAND OF ALA

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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

- o Naturally Occurring. ALA is a naturally occurring substance found in virtually all living human cells.
- o Small Molecule. Levulan(R) is a small molecule that is easily absorbed whether delivered topically, orally, or intravenously.
- o Highly Selective. Levulan(R) is not itself a photosensitizer, but is a pro-drug that is converted through a cell-based process into the photosensitizer PpIX. The combination of topical application, tissue specific uptake, conversion into PpIX and targeted light delivery make this a highly selective process. Therefore, under appropriate conditions, we can achieve selective clinical effects in targeted tissues with minimal effects in normal surrounding and underlying tissues.
- o Controlled Activation. Levulan(R) has no PDT effect without exposure to light at specific wavelengths, so the therapy is easily controlled.

6

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

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

OUR KERASTICK(R) BRAND APPLICATOR

We designed our proprietary Kerastick(R) specifically for use with Levulan(R). It is a single-use, disposable applicator, which allows for the rapid preparation and uniform application of Levulan(R) topical solution in standardized doses. The Kerastick(R) has two separate glass ampoules, one containing Levulan(R) powder and one containing a liquid vehicle, both enclosed within a single plastic tube and an outer cardboard sleeve. There is a filter and a metered dosing tip at one end. Prior to application, the doctor or nurse crushes the ampoules and shakes the Kerastick(R) according to directions to mix the contents into a solution. The Kerastick(R) tip is then dabbed onto the individual AK lesions, releasing a predetermined amount of Levulan(R) 20% topical solution.

OUR LIGHT SOURCES

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

- o are compact and tailored to fit specific medical needs,
- o are pre-programmed and easy to use, and

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- o provide cost-effective therapy.

Our proprietary BLU-U(R) is a continuous-wave (non-pulsed) 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(R) also incorporates a proprietary regulator that controls the optical power of the light source to within specified limits. It has a simple control panel consisting of an on-off key switch and digital timer which turns off the light automatically at the end of the treatment. The BLU-U(R) is also compliant with CE marking requirements.

We believe non-laser, non-pulsed light sources in comparison to lasers and high-intensity pulsed light sources, are:

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

7

For treatment of AKs, our BLU-U(R) uses blue light which is a potent activator of PpIX and does not penetrate deeply into the skin. 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 our relatively low intensity, non-laser, non-pulsed BLU-U, which is designed to treat areas such as the face or scalp. 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(R) without Levulan(R) 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(R).

During 2005, we studied the use of Levulan(R) with three different light devices, including our BLU-U for the repair of facial photodamage. Also in 2005, we continued the study of our new proprietary endoscopic light delivery system in a small Phase II single-center clinical study of the efficacy and safety of Levulan(R) PDT for the treatment of high grade dysplasia in patients with Barrett's esophagus. Our new system is designed to ease the process by which physicians place fiber optics used for endoscopic light delivery within hollow target organs such as the esophagus. See sections entitled "Business-Dermatology Indications, Facial Photodamage and Internal Indications, Barrett's Esophagus Dysplasia".

OUR PRODUCTS

The following table outlines our Levulan(R) and BLU-U(R) products and currently planned product candidates. Our product sales for the last three years were \$11,337,461 in 2005, \$7,987,656 in 2004, and \$970,109 in 2003. Our research and development expenses for the last three years were \$5,587,599 in 2005, \$6,489,723 in 2004, and \$5,403,961 in 2003.

STATUS OF

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| INDICATION/PRODUCT ----- | REGULATORY STUDIES ----- |
|---|--------------------------------|
| DERMATOLOGY | |
| Levulan(R) Kerastick(R) and BLU-U(R) for PDT of AKs | Approved |
| Levulan(R) PDT for Photodamaged Skin | Phase II(1) |
| Levulan(R) PDT for Moderate to Severe Acne Vulgaris | Phase II(2) |
| BLU-U(R) Treatment of Moderate Inflammatory Acne Vulgaris and general dermatological conditions Without Levulan(R) | Market Clearance(3) |
| OTHER INDICATIONS | |
| Levulan(R) PDT for Barrett's Esophagus Dysplasia using DUSA(R) Endoscopic Light Delivery System | Phase I/II(4), (5) |
| Levulan(R) Induced Fluorescence Guided Resection for Brain Cancer | European Phase III(6), (7) |
| Levulan(R) Oral Cavity Dysplasia | Phase I/II(8) |

-
- 1 Phase II clinical trial interim results were released in the first quarter of 2006
 - 2 Phase II clinical trial results were released in the first quarter of 2006
 - 3 In September 2003, the FDA provided market clearance
 - 4 Phase II single-center clinical trial initiated in second quarter 2004 using DUSA's new endoscopic light delivery device. All patients have been accrued and treated and follow-up is continuing.
 - 5 Phase II clinical trial planned to be initiated with the NCI DCP in 2005 is still in process of protocol finalization. Initiation is expected in 2006.
 - 6 Licensed from photonamic GmbH & Co. KG
 - 7 European Phase III clinical trial results are not expected to be suitable for NDA filing in the United States.

8

- 8 Phase I/II clinical trial planned to be initiated with the NCI DCP in 2005. Protocol finalization continuing and initiation is expected during 2006.

DERMATOLOGY INDICATIONS

We have been responsible for our Levulan(R) 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(R) 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. The results of our Phase II trials were announced in early 2006. DUSA also continues to support a wide range of independent investigator studies using the Levulan(R) Kerastick(R) that could lead to additional new indications for future development.

Actinic Keratoses. AKs are superficial precancerous skin lesions usually

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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 deep freezing of skin, using liquid nitrogen; 5-fluorouracil cream, or 5-FU; and surgery, for especially thick or suspicious lesions. In recent years, imiquimod and diclofenac have also been used for the treatment of AKs. Although any of these 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 permanent 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. Surgery is generally most useful for one or a few individual lesions, but not large numbers of lesions, and leaves permanent scars. Imiquimod or diclofenac require extended applications of cream, lasting up to 3 or 4 months, during which the skin is often very red and inflamed. Our approved treatment method involves applying Levulan(R) 20% topical solution using the Kerastick(R) to individual AK lesions, followed 14 to 18 hours later with exposure to our BLU-U(R) for approximately 17 minutes. In our Phase III trials, using this overnight drug application, our treatment was painful, but generally well tolerated. Resulting redness and/or inflammation generally resolved within days without any change in pigmentation.

Facial Photodamaged Skin. Photodamaged skin, which is skin damaged by the sun, occurs primarily in fair-skinned individuals after many years of sun exposure. Signs of photodamaged skin include roughness, wrinkles and brown spots. AKs also occur frequently in areas of photodamaged skin. There are numerous consumer cosmetic and herbal products which claim to lessen or relieve the symptoms of photodamaged skin. In most cases, there is little scientific data to support these claims. The FDA has approved only one prescription drug, Renova(R) (1), to treat this common skin condition. Patients generally use the product for between six 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

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

9

investigators applied Levulan(R) 20% topical solution over the entire area including the photodamaged skin. After 14 to 18 hours, the patients were treated with blue light at differing light doses. Investigators noted marked improvement in skin roughness in the treated areas in two-thirds of the patients after treatment with Levulan(R) PDT as well as some degree of improvement of wrinkles and brown spots. However, 10 of the 64 patients found that the burning and stinging of the PDT therapy was too uncomfortable and as a result the treatment was either terminated early or the light power was reduced. No patients reported a serious treatment-related adverse event.

During 2003, DUSA-supported independent investigator studies for photodamaged skin were completed, including short incubation studies using different light sources: a BLU-U(R), 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 Phase II study mentioned below. According to peer-reviewed publications, these studies reported that, when Levulan(R) is applied to the entire face for as little as one hour followed by

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

treatment with the BLU-U(R), or pulsed light sources, efficacy in removing AKs is similar to that of our Phase III trials, which used spot application on each AK and overnight incubation. Additionally, these studies report that patients' skin have 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(R) results in a "photodynamic photorejuvenation" which enhances the results of IPL alone. Published investigator studies have also reported that the LPDL together with Levulan(R) can successfully remove AKs, and improve photodamage as well as treat sebaceous gland hyperplasia (indications which the LPDL alone was unable to treat). The positive results of an independent investigator prospective, randomized, controlled split face clinical study using Levulan(R) photodynamic therapy, together with intense pulsed light for the treatment of photodamaged skin, were published in the October 2005 issue of the American Medical Association Journal Archives of Dermatology.

In February, 2006 we reported the interim analysis results from our 80 patient, multi-center Phase II split-face clinical study of photodynamic therapy (PDT) in the treatment of photodamaged skin using the Levulan(R) (aminolevulinic acid HCl, ALA) Kerastick(R) in combination with either the Company's BLU-U(R), an Intense Pulsed Light ('IPL'), or a Long Pulsed Dye Laser ('LPDL'). Each patient served as his or her own control, using a 'split-face' design. Following skin cleansing with an acetone solution, and approximately 60 minutes of drug and/or vehicle incubation, light treatment with a fixed dose was given using one of the three light sources. Up to 3 treatments were given, 3 weeks apart. Interim results were assessed at Weeks 9 and 12. The protocol includes additional follow-up visits scheduled for Weeks 26 and 52.

The goal of the study was to guide selection of light source(s) for future development in the treatment of photodamaged skin, using the Company's proprietary Levulan PDT technology. The study was not designed to detect differences between the light sources.

At Week 12, Levulan PDT with BLU-U light demonstrated material improvement in photodamaged skin, in comparison to BLU-U and vehicle. Statistical significance in net changes from baseline scores was achieved in 2 parameters of photodamage, namely mottled pigmentation ($p=0.0348$) and tactile roughness ($p=0.0455$). In addition, the trend toward improvement in a number of parameters was notably greater at Week 12 than Week 9, without any additional treatments with Levulan, which suggests that other parameters may also reach statistical significance over time. Specifically, Levulan with BLU-U showed greater improvements in mottled pigmentation, tactile roughness, fine wrinkling, sallowness and Global Photodamage Score (i.e. all the parameters that were measured except for telangiectasia (small blood vessels in the skin)), compared with areas treated with BLU-U and vehicle. BLU-U by itself is not known to have any effects on photodamaged skin.

10

These results support the conclusions of a prior independent study by Touma et al (2004), using Levulan with BLU-U versus BLU-U alone, that achieved statistical significance with the addition of Levulan in all photodamage parameters measured, other than deep wrinkles. In that study, the investigators treated more severely sun-damaged patients, each with a minimum of 4 actinic keratoses. They also used twice the dose of blue light compared to the current study (10 vs. 5 Joules/cm²), and drug incubation times ranging from 1-3 hours.

IPL by itself has previously been shown in independent studies to significantly improve photodamage, predominantly by targeting brown discoloration and red blood vessels. Therefore, as would be expected, at Week

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

12, significant improvement in photodamage was seen with IPL and vehicle, especially with respect to mottled pigmentation and telangiectasia. With the addition of Levulan, there was a trend toward even greater improvement in all parameters of photodamage except for mottled pigmentation, although these trends did not achieve statistical significance. However, similar to the BLU-U results, the trend toward improvement was notably greater at Week 12 than Week 9 without any additional treatments with Levulan, and additional follow up is scheduled at weeks 26 and 52.

These results support the conclusions of prior independent studies by Dover et al (2005), Alster et al (2005), and Gold et al (in press) using Levulan with IPL versus IPL alone for photodamage. All of these studies reported significant benefits from the addition of Levulan to IPL, especially in patients with significant photodamage. In addition, although IPL itself does not treat pre-cancerous cell damage, such as actinic keratoses, when combined with Levulan (ALA) to produce a PDT effect, IPL has been reported to effectively remove these lesions (Avram and Goldman, 2004, Ruiz-Rodrigues, 2002).

With LPDL, as would be expected, there was significant improvement in photodamaged skin with LPDL and vehicle, especially with respect to telangiectasia, the primary target of this device. However, with LPDL, the addition of Levulan for the treatment of photodamage did not lead to any discernable differences in photodamage parameters between the two groups, as suggested by the results of an earlier study (Smith et al, 2004).

In general, safety was excellent in all groups, but treatment using Levulan with BLU-U was better tolerated than treatment with IPL or LPDL (with or without Levulan) i.e. the frequency and severity of stinging and burning during treatment was greater with IPL and LPDL (with or without Levulan) compared to Levulan with BLU-U, and for BLU-U with vehicle. Levulan with BLU-U was also easy to use and less operator dependent.

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 nodulo-cystic acne, an oral retinoid drug called Accutane(R) (2) is the most commonly prescribed treatment. It is also commonly used for moderate to severe inflammatory acne. Over-the-counter treatments are not effective for many patients and can result in side effects including drying, flaking and redness of the skin. Prescription antibiotics lead to improvement in many cases, but patients must often take them on a long-term basis, with the associated risks of increased antibiotic resistance. With Levulan(R) 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.

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

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

During the fourth quarter of 2004, we initiated a DUSA-sponsored Phase II study which we recently completed. This 72 patient, investigator blinded study was designed to examine various safety and efficacy parameters as a function of varying Levulan/vehicle incubation times, namely 15, 60 and 120 minutes.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Patients were randomized within each incubation group so that 18 subjects received `Levulan BLU-U' and six received `BLU-U alone'. There were no formal placebo arms in this study. Up to four PDT treatments were given at 2-week intervals. The primary efficacy parameters were the percent change in total acne lesion count for inflammatory, non-inflammatory, and total lesions at 4 and 8 weeks after the final PDT session. Acne severity scores (grades 0 - 4) were also assessed. Safety and tolerability were also followed throughout the study. The results of the study indicate that both `Levulan BLU-U' and `BLU-U alone' appear to effectively reduce the number of both inflammatory and non-inflammatory acne lesions. Given the higher than anticipated `BLU-U alone' response rate using this protocol, the study was not powered (sized) to discern differences between these arms. Using an intent-to-treat analysis, at the Week 8 time point, the median percent decrease in total lesion count, (inflammatory plus non-inflammatory) for `Levulan BLU-U' and `BLU-U alone' was 61% and 80%, respectively. In the overall `Acne Severity Assessment' at the Week 8 time point, the `Levulan BLU-U' group showed 7/18 (39%) of subjects had at least 2 grades of improvement in their acne, compared with 4/6 (67%) in the `BLU-U alone' group. In the group of 28 patients with the most severe (Grade 4) acne, which included those with the highest number of inflammatory lesions at baseline (> or = 60 lesions), the total lesion count at Week 8 decreased in the `Levulan BLU-U' group, whereas total lesion count at Week 8 increased in the `BLU-U alone' group. Treatment was well tolerated in both arms of the study with no unanticipated adverse events being reported. Side effects were minimal. In the 15-minute Levulan BLU-U group, no PDT treatments were discontinued due to pain, and at the Week 8 time-point, there were no significant differences between the groups in erythema, edema or hyperpigmentation. The results of this study suggest that for future development of the acne indication for Levulan PDT, those patients with the most severe form(s) of acne should receive the greatest benefit.

During September 2005, the FDA issued draft guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. As a result of this newly issued guidance in combination with the results of our own Phase II clinical study on inflammatory acne, additional Phase II work will definitely be required before we commence Phase III acne trials.

OTHER POTENTIAL DERMATOLOGY INDICATIONS

We believe that there are numerous other potential uses for Levulan(R) PDT/PD in dermatology, and we continue to support, research in several of these areas, with corporate-sponsored trials, pilot trials, and/or investigator-sponsored studies, based on pre-clinical, clinical, regulatory and marketing criteria we have established through our strategic planning processes. Some of the additional potential uses for Levulan(R) in dermatology include treatment of skin conditions such as psoriasis, onychomycosis, warts, molluscum contagiosum, oily skin, acne rosacea, 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, hidradenitis suppurativa, acne vulgaris, basal cell carcinoma, and acne rosacea and are currently supporting investigator-sponsored studies for psoriasis, non-melanoma skin cancer, and inflammatory acne.

12

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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(R) 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(R) followed by red laser light in varying light doses. Patients were randomized to receive various light doses, with retreatment if required, and follow-up for 24 months after the initial treatment. In our clinical trial in which the primary efficacy goal was the ablation of high-grade dysplasia, or HGD, in Barrett's esophagus (late stage Barrett's esophagus), six patients with HGD were treated with Levulan(R) PDT. Of the six patients treated, 5 had complete clearing of their areas of high-grade dysplasia, and 4 of those patients have now been followed for 24 months and remain free of HGD, 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, 11 patients were treated with Levulan(R) PDT, and 4 were followed for 12 months while six were followed for 24 months (n=6). Complete Barrett's esophagus mucosal ablation after one or two Levulan(R) PDT treatment remained stable in 5/10 (50%) of patients for up to 2 years. Of those patients followed for 2 years, 4/6 (67%) remained clear for that time. 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 continued to follow the patients that have already been treated.

Currently, for the treatment of HGD in BE, 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 six patients at a single site using DUSA's proprietary endoscopic light delivery device

for the treatment of HGD. The protocol was amended to lower the light dosage and to allow in-hospital observation for the remaining 3 patients commencing in March 2005. As of the end of 2005, six patients received at least one Levulan(R) PDT treatment in this single-center study, and 5 are evaluable for acute efficacy. Four out of five (4/5, 80%) are currently free of HGD after treatment and continue to be followed.

In addition, we are working with the National Cancer Institute Division of Cancer Prevention (NCI DCP), for the clinical development of Levulan(R) PDT for the treatment of high-grade dysplasia within Barrett's Esophagus. The Phase I/II trial design is being finalized and the NCI DCP has identified two clinical sites from its extramural expert clinical investigator consortium. The NCI DCP will use its resources to file its own Investigational New Drug, or IND, application. DUSA will provide Levulan(R), 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. DUSA anticipates that the NCI DCP will begin the clinical trial during 2006.

Oral Cavity Dysplasia. We have also signed a clinical trial agreement with the NCI DCP for the clinical development of Levulan(R) PDT for the treatment of oral cavity dysplasia. During 2005, DUSA and the NCI DCP collaborated to develop the protocol for a Phase I study in subjects with oral leukoplakia (a premalignant lesion) using NCI's Phase I/II Cancer Prevention Clinical Trials Consortia to perform the studies. As of the end of 2005, the NCI DCP had selected consortia for consideration as clinical trial sites. DUSA also expects this study to begin during 2006.

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 completed its European Phase III clinical trial in which ALA-induced fluorescence was used to guide surgical tumor resection in patients suffering from glioblastoma multiforme. DUSA believes that the European Phase III clinical trial results, although they might meet the primary efficacy parameters of the protocol as written, might require the support of additional clinical trials which would take years to complete in order to meet the regulatory requirements for approval in the United States. We do not intend, at this time, to repeat this study or to carry out additional studies in this indication in the United States. However, we have agreed to accompany photonamics to the FDA should it wish to request a Pre-IND meeting with the FDA for this indication. See section entitled "Business - Licenses".

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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, and the American

14

Academy of Dermatology Association, or AADA, 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, 2006, the CMS average national reimbursement for the use of Levulan(R) PDT for AKs' Ambulatory Patient Classifications code ("APC code") was increased. The APC code is used by many hospitals. The CMS Current Procedural Terminology code ("CPT code"), which is used by private physician clinics using Levulan(R) PDT for treating AKs was not increased for 2006 (i.e. it will be unchanged from 2005 levels). DUSA had expected reimbursement under the CPT code to increase on January 1, 2006; however, we now believe that the increase will not be effective until January 1, 2007 based on information from CMS and the AADA. We are aware that some physicians believe that 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. DUSA continues to support ongoing efforts that might lead to further increases in reimbursement in the future; and intends to continue supporting efforts to seek reimbursement for our FDA-cleared use of the BLU-U(R) alone in the treatment of mild to moderate inflammatory acne of the face.

Most 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(R). We agreed to order from NBC all of our supply needs of these light sources for the United States 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(R) 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(R) from its FDA approved facility in Switzerland. The agreement expires on December 31, 2009. 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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

15

LICENSES

PARTEQ Research and Development Innovations. We license (or, in the case of the patents in Australia, were assigned) the patents underlying our Levulan(R) PDT/PD systems under 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 United States patents and becomes perpetual and royalty-free when no United States patent subsists. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$85,793 as of December 31, 2005) in order to retain the license. For 2005, 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(R) Kerastick(R) in Canada over a five-year term following the first commercial sale in Canada. We are now responsible for any royalties which would be due to PARTEQ for Canadian sales. Draxis also agreed to assign to us the Canadian regulatory approvals for the Levulan(R) Kerastick(R) with PDT for AKs. We also hold Canadian regulatory approval for the BLU-U(R). During 2004, we appointed a Canadian distributor who launched our Levulan(R) Kerastick(R) and BLU-U(R) in Canada. See sections entitled "Distribution" and "Note 13(b) to the Company's Notes to the Consolidated Financial Statements".

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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(R) PDT and photodetection (PD).

Under the terms of the agreement, we received a license for the United States and several other countries, to use photonamic's technology, including pre-clinical and clinical data, related to ALA for systemic dosing in the field of brain cancer, and for indications which the parties may jointly develop during the term of their collaboration. Additionally, we are entitled to use the pre-clinical data for indications which we may develop on our own. 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 United States, an additional

16

\$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. Although we do not believe that the results from medac's European Phase III clinical study will be acceptable to the FDA, we have agreed to ask FDA for a pre-IND meeting if medac determines that it wishes to proceed. Should photonamic's clinical study be acceptable to the FDA, we will be obligated to proceed with development of the product in the United States in order to retain the license for the use of the technology in the treatment of brain cancer. The agreement has a term of 10 years from the date of first approval of a product using photonamic's technology, subject to earlier termination rights, as well as one-year renewal terms.

We have also entered into a clinical trial agreement with photonamic to fund an independent investigator study using oral Levulan(R) for the treatment of psoriasis. A protocol for this study was established in 2005.

Stiefel Laboratories, Inc. On January 12, 2006, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc. The agreement covers current and future uses of our Levulan(R) Kerastick(R) PDT in dermatology. The agreement, which has an initial term of ten years, grants Stiefel the right to market and distribute our product in Mexico, Central and South America. We have completed the portion of the Brazilian regulatory submission for the use of Levulan PDT for actinic keratoses. Stiefel will complete final integration and submission of the data to the Brazilian regulatory agency with market launch expected in late 2006 or early 2007. Stiefel will prepare and file the regulatory applications in other countries in the territory subject to the terms of the Agreement, perhaps first launching in a country other than Brazil. All regulatory filings and registrations for approval will be owned by DUSA, unless otherwise agreed by DUSA. Stiefel will make up to \$3,000,000 in milestone payments, based upon receipt of final pricing approval of the product from Brazilian regulatory authorities and achievement of certain minimum purchase levels in the territory, subject to certain terms and conditions. We will manufacture the Kerastick(R) for Stiefel in our manufacturing facility in Wilmington, Massachusetts. Stiefel will pay to DUSA a percentage of Stiefel's final selling price to third-parties subject to a certain minimum purchase price per unit and to other terms and conditions. Stiefel has certain minimum purchase obligations. The parties have certain rights to terminate the Agreement prior to the end of the initial term, and Stiefel has an option to extend the term for an additional ten years on mutually agreeable terms and conditions.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

PATENTS AND TRADEMARKS

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

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

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

17

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

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

We have limited patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counterparts in only six foreign countries 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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

18

Regulation". Effective patent protection also depends on many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of the new drug provisions of the Food, Drug and Cosmetic Act, or similar laws and regulations in other countries.

We seek registration of trademarks in the United States, and other countries where we may market our products. To date, we have been issued 27 trademark registrations, and other applications are pending.

MANUFACTURING

On July 14, 2003, we received approval from the FDA to manufacture the Levulan(R) Kerastick(R) at our Wilmington, Massachusetts manufacturing facility. In February 2004, we began commercial production of our Levulan(R) Kerastick(R) after having terminated the former third-party contract manufacturing arrangement. We plan to maintain a reasonable level of Kerastick(R) inventory based on sales projections. During the third quarter of 2005, we received FDA approval to manufacture our BLU-U(R) brand light source in our Wilmington, Massachusetts facility. However, at this time, we expect to utilize our own facility only as a back-up to our current third-party manufacturer or for repairs. Our drug, Levulan(R), and the BLU-U(R) brand light source are each manufactured by single third-party suppliers.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

DISTRIBUTION

We have been a direct distributor of the BLU-U(R) since its launch. Effective January 1, 2006, we have increased our own distribution capacity and have become the sole distributor for our Levulan(R) Kerastick(R) in the United States. In March 2004, we signed an exclusive Canadian marketing and distribution agreement for the Levulan(R) Kerastick(R) and BLU-U(R) with Coherent-AMT Inc., or Coherent, a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U(R) in April 2004 and the Kerastick(R) 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. Coherent has the right for a period of time following termination of its agreement to return inventory of product.

In January 2006, we entered into a marketing and distribution agreement for the Levulan(R) Kerastick(R) with Stiefel Laboratories, Inc. Under the agreement, Stiefel was granted an exclusive right to distribute Levulan(R) Kerastick(R) in Mexico, Central and South America. The Agreement has an initial term of ten years. DUSA has completed its portion of the Brazilian regulatory submission for the use of Levulan PDT for actinic keratoses. Effective with the signing of the Agreement, Stiefel will complete final integration and submission of the data to the Brazilian regulatory agency with market launch expected in late 2006 or early 2007. Stiefel may launch the product in Mexico or other countries in the territory prior to a launch in Brazil. See section entitled "Business - Licenses, Stiefel Laboratories, Inc."

MARKETING AND SALES

DUSA markets its approved dermatology products in the United States. We have appointed Coherent-AMT as marketing partner for our products in Canada and Stiefel for our Levulan(R) Kerastick(R) in Mexico, Central and South America.

As a result of reacquiring our product rights in late 2002 from a former marketing partner, 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 six direct representatives, various

19

independent representatives, and an independent sales distributor, designed to focus on most of our key geographic markets in the United States. During 2005, we continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. As of December 31, 2005, we have further increased the size of our sales force to 24 sales representatives deployed nationally.

Following the receipt of marketing approval from the Health Protection Branch - Canada in June 2004, we started to market and sell the Levulan(R) Kerastick(R) with PDT using the BLU-U(R) for AKs of the face or scalp in Canada through Coherent-AMT. We anticipate that Stiefel will complete final integration and submission of the data to the Brazilian regulatory agency with market launch expected in late 2006 or early 2007 and perhaps sooner in other countries in its territory. See sections entitled "Business - Licenses and Distribution".

COMPETITION

Commercial development of PDT agents other than Levulan(R) is currently being pursued by a number of companies. These include: QLT Inc. (Canada); Axcan Pharma Inc. (United States); Miravant, Inc. (United States); Pharmacyclics, Inc.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

(United States); 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 United States 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. In April 2005, the Federal Court of Australia ruled that the Australian patent assigned to DUSA by Queen's University which relates to DUSA's aminolevulinic acid photodynamic therapy is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product, Metvix, does not infringe the claims in the Australian patent. We have been negotiating a settlement with PhotoCure pertaining to certain of our patents and we expect the agreement to be finalized in the first half of 2006. See section entitled "Legal Proceedings".

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

There are also non-PDT products for the treatment of AKs, including cryotherapy with liquid nitrogen, 5-fluorouracil (Efudex(R)) (4), diclofenac sodium (Solaraze(R)) (5), and imiquimod (ALDARA(TM)) (6). Other

-
- (3) PHOTOFRIN(R) is a registered trademark of Axcan Pharma Inc.
 - (4) Efudex(R) is a registered trademark of Valeant Pharmaceuticals International.
 - (5) Solaraze(R) is a registered trademark of SkyePharma PLC.
 - (6) ALDARA(TM) is a trademark of 3M Company.

20

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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(R) without Levulan(R) for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. Our competition for the BLU-U(R) without Levulan(R) 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 United States are governed by a variety of statutes and regulations. These laws require, among other things:

- o 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,
- o controlled research and testing of products,
- o applications for marketing approval containing manufacturing, preclinical and clinical data to establish the safety and efficacy of the product, and
- o control of marketing activities, including advertising and labeling.

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

21

- o preclinical studies
- o the filing of an Investigational New Drug, or IND, application,

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- o human clinical trials, and
- o 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. 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 six months to four years to complete, but can take longer, depending on the drug and the nature of the study.

Data from Phase I, II and III trials are submitted to the FDA with the NDA. The NDA involves considerable data collection, verification and analysis, as well as the preparation of summaries of the manufacturing and testing processes and preclinical and clinical trials. Submission of an NDA does not assure FDA approval for marketing. The application review process generally takes 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(R) Kerastick(R) 20% Topical Solution with PDT for treatment of AKs of the face or scalp. The commercial version of our BLU-U(R), used together with the Kerastick(R) to provide PDT for the treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp, was approved on September 26, 2000. In September 2003, we received clearance from the FDA to market the BLU-U(R) without Levulan(R) PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

Other than the FDA-approved use of the Levulan(R) Kerastick(R) with PDT for treatment of AKs, and the FDA clearance to market the BLU-U for moderate inflammatory acne and other dermatologic conditions, our other potential products still require significant development, including additional preclinical and/or clinical testing, and regulatory marketing approval prior to commercialization. The process of obtaining required approvals can be costly and time consuming and there can be no guarantee that the use of Levulan(R) in any future products will be successfully developed, prove to be safe and effective in clinical trials, or receive applicable regulatory marketing approvals.

Medical devices, such as our light source device, are also subject to the FDA's rules and regulations. These products are required to be tested, developed, manufactured and distributed in accordance with FDA regulations, including good manufacturing, laboratory and clinical practices. Under the Food, Drug & Cosmetic Act, all medical devices are classified as Class I, II or III devices. The classification of a device affects the degree and extent of the FDA's regulatory requirements, with Class III devices subject to the most stringent requirements and FDA review. Generally, Class I devices are subject to general controls (for example, labeling and adherence to the cGMP requirement for medical devices), and Class II devices are subject to general controls and special controls (for example, performance standards, postmarket surveillance, patient registries and FDA guidelines). Class III devices, which typically are life-sustaining or life-supporting and implantable devices, or new devices that have been found not to be substantially equivalent to a legally marketed Class I or Class II "predicate device," are subject to general controls and also require clinical testing to assure safety and effectiveness before FDA approval is obtained. The FDA also has the authority to require clinical testing of Class I and II devices. The BLU-U(R) is part of a combination product as defined by FDA and therefore has been classified as a Class III device. We are developing an endoscopic device for the Barrett's esophagus indication which we believe will also be classified as Class III and be subject to the highest level of FDA regulation. Approval of Class III devices require the filing of a premarket approval, or PMA, application supported by extensive data, including preclinical and clinical trial data, to demonstrate the safety and effectiveness of the device. If human clinical trials of a device are required and the device presents a "significant risk," the manufacturer of the device must file an

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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

23

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

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

The United States Drug Price Competition and Patent Term Restoration Act of 1984 known as the Hatch-Waxman Act establishes a 5-year period of marketing exclusivity from the date of NDA approval for new chemical entities approved after September 24, 1984. Levulan(R) is a new chemical entity and market exclusivity under this law 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(R), 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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.

24

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 United States for Levulan(R) 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(R) PDT in Australia, Austria and South Africa. In 2003, we also advised our former partner to withdraw the applications for the Levulan(R) Kerastick(R) and BLU-U(R) in Brazil, even though the Kerastick(R) had already been approved, as it was determined that such rights cannot be transferred to us. We, together with Stiefel under our recently completed agreement, are in the process of reapplying for approval 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 by the FDA may be exported to certain foreign markets if the product is approved by the importing nation and approved for export by the United States government. We can provide no assurance that we will be able to get approval for any of our potential products from any importing nations' regulatory authorities or be able to participate in the foreign pharmaceutical market.

Our research and development activities have involved the controlled use of certain hazardous materials, such as mercury in fluorescent tubes. We are subject to various laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products. During the design, construction and validation phases of our Kerastick(R) facility, we have taken steps to ensure that appropriate environmental controls associated with the facility comply with environmental laws and standards. We can provide no assurance that we will not have to make significant additional expenditures in order to comply with environmental laws and regulations in the future. 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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 2005, we had 64 full-time employees and two part-time employees, which was an increase over the 2004 levels. We also retain numerous independent consultants and temporary employees to support our business needs.

We have employment agreements with all of our key executive officers.

25

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.

ITEM 1A. 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(R) KERASTICK(R) WITH THE BLU-U(R) BRAND LIGHT SOURCE FOR THE TREATMENT OF AKS OF THE FACE OR SCALP, AND THE BLU-U(R) WITHOUT LEVULAN(R) FOR THE TREATMENT OF MODERATE INFLAMMATORY ACNE.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

If we are unable to successfully market and sell sufficient quantities of our 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 United States and the rest of the world, except Canada, and Mexico and Central and South America, where we have distributors. We are doing so without the experience of having marketed pharmaceutical products prior to 2000. In October 2003, DUSA began hiring a small direct sales force and we increased the size of our sales force to market our products in the United States. Acquiring and retaining marketing and sales force capabilities involves significant expense, and current sales levels are not offsetting the expenses related to these efforts. If our sales and marketing efforts fail, then sales of the Kerastick(R) and the BLU-U(R) will be adversely affected.

26

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

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan(R) Kerastick(R) for 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. Although 2005 reimbursement changes related to AK were made, some physicians still believe that 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(R) AND CONTINUE TO RELY HEAVILY ON SOLE SUPPLIERS FOR THE MANUFACTURE OF LEVULAN(R) AND THE BLU-U(R), ANY SUPPLY OR MANUFACTURING PROBLEMS COULD NEGATIVELY IMPACT OUR SALES.

If we experience problems producing Kerastick(R) units in our facility, or if either of our contract suppliers fail to supply DUSA's requirements of Levulan(R) or the BLU-U(R), our business, financial condition and results of operations would suffer. Although we have received approval by the FDA to manufacture the BLU-U(R) in our Wilmington, Massachusetts facility, at this time we expect to utilize our own facility only as a back-up to our current third party manufacturer or for repairs.

Manufacturers and their subcontractors often encounter difficulties when commercial quantities of products are manufactured for the first time, or large quantities of new products are manufactured, including problems involving:

- o product yields,
- o quality control,
- o component and service availability,
- o compliance with FDA regulations, and
- o 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,

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

costs or quality as we and our suppliers seek to 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 manufacture our products, we may not be able to quickly remedy the problem(s). Any of these problems could cause our sales to suffer.

27

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

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

- o approval of manufacturing facilities, including adherence to good manufacturing and laboratory practices during production and storage,
- o controlled research and testing of products even after approval, and
- o 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:

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

with cGMP and foreign regulatory requirements, we and our third-party manufacturers will be obligated to expend time, money and effort in production, record keeping and quality control to assure that our products meet applicable specifications and other requirements.

As part of our FDA approval for the Levulan(R) Kerastick(R) for AK, we were required to conduct two Phase IV follow-up studies. We successfully completed the first study; and submitted our final report on the second study to the FDA in January 2004. The FDA could request additional information and/or studies. Additionally, if previously unknown problems with the product, a manufacturer or its facility are

28

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(R) 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 available to research and development of such products and we may not have sufficient funds to complete all or any of our development programs.

THE COMMERCIAL SUCCESS OF ANY PRODUCTS THAT WE MAY DEVELOP WILL DEPEND UPON THE DEGREE OF MARKET ACCEPTANCE OF OUR PRODUCTS AMONG PHYSICIANS, PATIENTS, HEALTH CARE PAYORS, PRIVATE HEALTH INSURERS AND THE MEDICAL COMMUNITY.

Our ability to commercialize any products that we may develop will be highly dependent upon the extent to which these products gain market acceptance among physicians, patients, health care payors, such as Medicare and Medicaid, private health insurers, including managed care organizations and group purchasing organizations, and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- o the effectiveness, or perceived effectiveness, of our products in comparison to competing products;
- o the existence of any significant side effects, as well as their severity in comparison to any competing products;

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- o potential advantages over alternative treatments;
- o the ability to offer our products for sale at competitive prices;
- o relative convenience and ease of administration;
- o the strength of marketing and distribution support; and
- o sufficient third-party coverage or reimbursement.

29

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 2006 as we attempt to increase sales of our approved products in the marketplace and continue research and development of potential new products. We incurred net losses of \$15,628,980 for the year ended December 31, 2004 and net losses of \$14,998,709 for the year ended December 31, 2005. As of December 31, 2005, our accumulated deficit was approximately \$89,537,000. 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(R) brand of the compound ALA. Our basic patents are for methods of detecting and treating various diseased tissues using ALA (or related compounds called precursors), in combination with light. We own or exclusively license patents and patent applications related to the following:

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

We have limited patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counterparts in only six foreign countries, 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.

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 to us by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario, 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. On April 6, 2005, the Federal Court of Australia ruled that the patent is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product does not infringe the claims in the Australian patent. The parties signed a Mediation Agreement in August 2004 to attempt to settle their disputes and those discussions are ongoing. If the parties are unable to amicably resolve matters, patent litigation could ensue in the United States and there can be no guarantee that we would prevail.

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

30

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

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

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

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

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

Additionally, if a third-party were to file a United States patent application in the United States, or be issued a patent claiming technology also claimed by us in a pending United States application(s), we may be required to participate in interference proceedings in the United States Patent and Trademark Office to determine the priority of the invention. A third-party could

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

also request the declaration of a patent interference between one of our issued United States 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.

During 2005 and into 2006, we filed several lawsuits against compounding pharmacies and physicians alleging violations of patent law. While we have been successful in obtaining a default judgment against one compounding pharmacy and have obtained consent judgments from several physicians, we do not know whether these lawsuits will prevent others from infringing our patents or whether we will be successful in stopping these activities which we believe are negatively affecting our revenues.

31

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

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

We do not know if the Levulan(R) Kerastick(R) or the BLU-U(R) products will ever be commercially successful. 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 Levulan(R) and BLU-U(R) 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:

- o delays in product development, clinical testing or manufacturing,
- o unplanned expenditures in product development, clinical testing or manufacturing,
- o failure in clinical trials or failure to receive regulatory approvals,
- o emergence of superior or equivalent products,
- o inability to market products due to third-party proprietary rights, and
- o 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 Levulan(R) drug technology.

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

All of our potential Levulan(R) products will require the approval of the FDA before they can be marketed in the United States. If we fail to obtain the required approvals for these products our revenues will be limited. Before an application to the FDA seeking approval to market a new drug, called an NDA, can

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

be filed, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually 1 to 3 years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan(R) PDT products are based on relatively new technology. To the best of our knowledge, the FDA has approved only 3 drugs for use in photodynamic therapy, including Levulan(R). This factor may lengthen the approval process. We face much trial and error and we may fail at numerous stages along the way.

We cannot predict whether we will obtain approval for any of our potential products. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan(R) PDT or photodetection, known as PD, is safe and effective for any new use we are studying. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy. During September 2005, the FDA issued

32

guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. As a result, it is likely that the costs and time to approval associated with seeking regulatory approval of this indication will be increased. The FDA may issue additional guidance in the future, which may result on additional costs and delays. 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. 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. 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.

WE ARE EXPOSED TO RISKS ASSOCIATED WITH ACQUISITIONS.

On December 30, 2005 we entered into a Merger Agreement with Sirius Laboratories, Inc. The transaction is expected to close during the first quarter of 2006, subject to the terms and conditions in the Merger Agreement. We may in the future make other acquisitions of, or significant investments in, businesses with complementary products, services and/or technologies. Acquisitions involve numerous risks, including, but not limited to:

- o difficulties and increased costs in connection with integration of the personnel, operations, technologies and products of acquired companies;

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- o diversion of management's attention from other operational matters;
- o the potential loss of key employees;
- o the potential loss of key collaborators;
- o lack of synergy, or the inability to realize expected synergies, resulting from the acquisition;
- o acquired intangible assets becoming impaired as a result of technological advancements or worse-than-expected performance of the acquired company;
- o the potential for unexpected liabilities; and
- o use of cash which could be difficult to replace on reasonable terms.

Mergers and acquisitions are inherently risky, and the inability to effectively manage these risks could materially and adversely affect our business, financial condition and results of operations.

33

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 66 employees, including 2 part-time employees as of December 31, 2005. 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.

OUR COLLABORATIONS WITH OUTSIDE SCIENTISTS MAY BE SUBJECT TO RESTRICTION AND CHANGE.

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These scientists and advisors are not our employees and may have other commitments that limit their availability to us. Although our advisors and collaborators generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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(R), we are subject to additional environmental laws and regulations. We believe that we are in compliance in all material respects with currently applicable environmental laws and regulations. However, we cannot guarantee that we will not incur significant costs to comply with environmental laws and regulations in the future. We also cannot guarantee that current or future environmental laws or regulations will not materially adversely affect our operations, business or assets. In addition, although we believe our safety

34

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 United States 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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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:

- o price reductions,
- o lower levels of third-party reimbursements,
- o failure to achieve market acceptance, and
- o 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(R) product. On January 31, 2005, we filed a

35

lawsuit in the United States District Court for the District of Arizona against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement and of United States patent law. A motion for default judgment was granted on July 25, 2005 in our favor for failure of The Cosmetic Pharmacy of Tucson to appear, together with injunctive relief and attorney fees and costs in the amount of approximately \$20,700. Also, on December 27, 2004, we filed a lawsuit in United States District Court for the District of Massachusetts against New England Compounding Pharmacy, Inc. of Framingham, Massachusetts alleging violations of United States patent law. New England Compounding Pharmacy has filed an answer, including a defense alleging invalidity of our patents, and several counterclaims against us, and we have filed our response. The parties are now in the discovery stage of this litigation and we have been unable to predict the outcome of the lawsuit at this time. A tentative trial date has been set by the court for January 2007. We cannot be certain whether we will be successful in defending such counterclaims, however, we have not accrued any amounts for settlement at this time. While we believe that certain actions of these 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 these 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(R). These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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 United States 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(R), for PDT in the treatment of high grade dysplasia associated with Barrett's esophagus. Axcan is the first company to market a PDT therapy for this indication, which we are also pursuing.

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

- o the ease of administration of our method of PDT,
- o the degree of generalized skin sensitivity to light,
- o the number of required doses,

36

- o the selectivity of our drug for the target lesion or tissue of interest, and
- o 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, 2006 there were outstanding options and warrants to purchase 2,867,875 shares of common stock, with exercise prices ranging from U.S. \$1.60 to \$31.00 per share, and of 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.

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, 2005 to March 1, 2006, the price of our stock has ranged from a low of \$6.57 to a high of \$16.30. Factors that contributed to the volatility of our stock during the last 12 months included:

- o quarterly levels of product sales;

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- o clinical trial results;
- o general market conditions;
- o increased marketing activities; and
- o changes in third-party payor reimbursement for our therapy.

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.

37

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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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 1B. UNRESOLVED STAFF COMMENTS

None.

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. In December 2001 we entered into 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 sq. ft., for our wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., replacing the space DUSA previously occupied.

38

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 12(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. On April 6, 2005, the Federal Court of Australia ruled that the patent is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product does not infringe the claims in the Australian patent. Since these claims are unique to the Australian patent and Australian law differs from patent law in other jurisdictions, we do not expect that this decision is determinative of the validity of any other patents licensed by us from Queen's University or of whether PhotoCure's product infringes claims in such other patents, including the United States patent. None of the parties have appealed the decision and the date to do so has expired. The parties, including PhotoCure's marketing partner, Galderma S.A., signed a Mediation Agreement in August 2004 to attempt to settle their disputes. The parties are negotiating a settlement agreement which is expected to be finalized in the first half of 2006.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

In December 2004, we filed a lawsuit against New England Compounding Center of Framingham, Massachusetts alleging violations of United States patent law in the United States Federal District Court in Boston, Massachusetts. On March 17, 2005, New England Compounding Pharmacy filed an answer against us, including a defense that our patents are invalid and several counterclaims against us, and we filed our response on April 5, 2005. The parties are now in the discovery stage of this litigation. A tentative trial date has been set by the court for January 2007. We are seeking injunctive relief, monetary damages and costs.

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 United States patent law in the United States District Court for the District of Arizona. A motion for default judgment was granted on July 25, 2005 in our favor for failure of The Cosmetic Pharmacy of Tucson to appear, together with injunctive relief and attorney fees and costs in the amount of approximately \$20,700.

In November of 2005 and January of 2006, we filed lawsuits against physicians in several states to prevent their continued use of versions of our Levulan (R) brand of aminolevulinic acid HCl (ALA) produced by compounding pharmacies, for use in our patented photodynamic therapy (PDT) treatment for actinic keratosis, basal cell carcinoma, acne and other dermatological conditions. The suits allege that ALA obtained from sources other than DUSA is being used by these physicians for patient treatments that are covered under patents exclusively licensed by DUSA, resulting in direct infringement of these patent(s). Additionally, some doctors are also being sued for misuse of DUSA's trademarks and for violations of the Lanham Act for using the Levulan (R) brand name on their web sites and promotional materials, but performing patient treatments with ALA obtained from other sources. Most of the physicians have entered Consent Judgments in which they admit the infringement and provide DUSA with the right to review their books and records. Two lawsuits are currently on-going.

39

For other patent matters, see section entitled "Risk Factors - If we are unable to protect our proprietary technology, trade secrets or know-how, we may not be able to operate our business profitably".

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

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, 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 sales prices for the common stock reported for the quarterly periods shown.

Price range per common share by quarter, 2004:

| First | Second | Third | Fourth |
|-------|--------|-------|--------|
| ----- | ----- | ----- | ----- |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | | | | |
|--------|----------|----------|----------|----------|
| NASDAQ | | | | |
| High | \$ 14.87 | \$ 13.50 | \$ 12.20 | \$ 14.41 |
| Low | 5.02 | 8.46 | 8.23 | 9.95 |

Price range per common share by quarter, 2005:

| | First ----- | Second ----- | Third ----- | Fourth ----- |
|--------|----------------|-----------------|----------------|-----------------|
| NASDAQ | | | | |
| High | \$ 16.30 | \$ 11.68 | \$ 11.33 | \$ 10.80 |
| Low | 8.70 | 8.33 | 8.50 | 8.67 |

On March 1, 2006, the closing price of our common stock was \$7.42 per share on the NASDAQ National Market. On March 1, 2006, there were 634 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.

40

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 | | |
|--|---------------------|---------------|---------------|
| | 2005 ----- | 2004 ----- | 2003 ----- |
| Revenues (1) | \$ 11,337,461 | \$ 7,987,656 | \$ 970,1 |
| Net income (loss) | (14,998,709) | (15,628,980) | (14,826,8 |
| Basic and diluted net income (loss) per common share | \$ (0.89) | \$ (0.96) | \$ (1. |

CONSOLIDATED BALANCE SHEETS DATA

| | AS OF DECEMBER | | |
|--------------|----------------|---------------|---------------|
| | 2005 ----- | 2004 ----- | 2003 ----- |
| Total assets | \$ 42,330,631 | \$ 56,650,888 | \$ 44,697, |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | | | |
|-----------------------|------------|------------|---------|
| Long-term obligations | - | - | 1,247, |
| Shareholders' equity | 38,028,728 | 52,507,018 | 40,232, |

- (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. These amounts were previously deferred and were being amortized into operations over periods ranging from 1 to 12.5 years.

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 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(R) 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(R) and follow it with exposure to light to treat a medical condition, it is known as Levulan(R) photodynamic therapy, or Levulan(R) PDT. When we use Levulan(R) and follow it with exposure to light to detect medical conditions it is known as Levulan(R) photodetection, or Levulan(R) PD.

Our products, the Levulan(R) Kerastick(R) 20% Topical Solution with PDT and the BLU-U(R) brand light source were launched in the United States, 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 United States Food and Drug Administration, or FDA, to market the BLU-U(R) without Levulan(R) 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(R), and other related product activities. Our objectives include increasing the sales of our products in the United States and Canada, continuing our efforts of exploring partnership opportunities for Levulan(R) PDT for dermatology in Europe and/or other countries outside of the United States and Canada and Latin America and continuing our clinical development programs for our facial photodamage and moderate to severe acne indications. To further these objectives, we entered into a marketing and distribution agreement with Stiefel Laboratories, Inc. in January 2006 granting Stiefel an exclusive right to distribute the Levulan(R) Kerastick(R) in Mexico, Central and South America. During 2004 we signed clinical trial agreements with the National Cancer Institute, or NCI, Division of Cancer Prevention, or DCP, for the clinical

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

development of Levulan(R) 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(R) PDT for other indications in dermatology, and selected internal indications. See sections entitled "Business - Internal Indications" and "Business - Distribution".

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

On December 30, 2005, we entered into a merger agreement to acquire all of the common stock of Sirius Laboratories, Inc. of Vernon Hills, Illinois in exchange for cash and common stock of DUSA worth up to \$30,000,000. The transaction is expected to close during the first quarter of 2006, subject to the terms and conditions in the Merger Agreement. Of the up to \$30,000,000, \$8,000,000 less certain expenses will be paid in cash upon closing, \$17,000,000 was paid in shares of DUSA's common stock also upon closing, and up to \$5,000,000 in cash or common stock, as DUSA determines, may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. The products acquired in this transaction, called the Sirius Merger, focus primarily on the treatment of acne vulgaris and acne rosacea. The DUSA shares are expected to be issued pursuant to Regulation D. The number of shares to be paid will be equal to \$17,000,000 divided by the lesser of \$10.10 or the average closing price of DUSA's shares on the NASDAQ Stock Market for the twenty (20) trading days prior to closing date.

The closing is subject to certain closing conditions as previously disclosed which if not met, would provide a party the right to terminate the Merger Agreement. See section entitled "Business - General." If the Merger Agreement is terminated, a break-up fee in the amount of \$250,000 might be due from one party to the other. In addition, DUSA has incurred approximately \$800,000 of direct acquisition related costs which will affect the statement of operations if the transaction does not close. We cannot be certain that the merger will close.

Historically, we devoted most of our resources to fund research and development efforts in order to advance the Levulan(R) PDT/PD technology platform. More recently, we have also devoted significant

resources to our sales and marketing efforts. As a result, we have experienced significant operating losses. During the quarter ended September 30, 2005, the Company eliminated 14 staff positions, representing 16% of the workforce, to align headcount more closely with management's assessment of its resource requirements at that time. These workforce reductions were made across all functions of the Company. As a result of these actions the Company recorded a restructuring charge of approximately \$150,000. As of December 31, 2005, the Company had paid all of its obligations under the restructuring plan. As of December 31, 2005, we had an accumulated deficit of approximately \$89,537,000. We expect to continue to incur operating losses until sales of our products

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

increase substantially. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our therapy by the medical and consumer constituencies, and our ability to develop and/or acquire new profitable 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(R) unit sales to end-users were 100,668 and 76,482 for the twelve months ended December 31, 2005 and 2004, respectively, consisting of 87,210 and 69,870 units sold in the U.S., and 13,458 and 6,612 units sold in Canada, in 2005 and 2004 respectively. A summary of quarterly Kerastick(R) unit sales to end users during the periods ended December 31, 2005 and 2004 is indicated below:

| | 2005 | | | | |
|---------------|--------|--------|--------|--------|---------|
| | Q1 | Q2 | Q3 | Q4 | TOTAL |
| UNITED STATES | 24,900 | 16,506 | 17,766 | 28,038 | 87,210 |
| CANADA | 3,804 | 3,666 | 2,520 | 3,468 | 13,458 |
| TOTAL | 28,704 | 20,172 | 20,286 | 31,506 | 100,668 |
| | ===== | ===== | ===== | ===== | ===== |

| | 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 |
| | ===== | ===== | ===== | ===== | ===== |

The net number of BLU-U(R) units placed in doctors' offices during the twelve months ended December 31, 2005 and 2004 was 423 and 508, respectively, including 94 and 101 placed in Canada in 2005 and 2004, respectively. As of December 31, 2005 and 2004 there were 1,337 and 914 units in doctor's offices, consisting of 1,142 and 813 in the U.S. and 195 and 101 in Canada in 2005 and 2004,

respectively. In addition, during 2005 we began a BLU-U marketing effort to allow prospective customers to evaluate a BLU-U for a short period of time prior to making a purchase decision. BLU-U(R) commercial light sources placed in physicians' offices pursuant to the Company's BLU-U(R) evaluation program are classified as inventory in the accompanying Consolidated Balance Sheets. The Company amortizes the cost of the evaluation units during the evaluation period to cost of goods sold using an estimated useful life for the equipment of 3 years.

We have continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. See section entitled "Management's Discussion and Analysis - Results of Operations, Marketing and Sales Costs". We are encouraged with the year-over-year increase in sales, as well as the positive feedback we continue to receive from physicians across the country that believe Levulan PDT should become a routine part of standard dermatological practice. We are currently exploring opportunities to develop, market, and distribute our Levulan(R) PDT platform in Europe and/or other countries outside of the United States and Canada following our recently completed agreement with Stiefel Laboratories, Inc. We are also continuing to seek to acquire and/or license additional dermatology products that complement our current product portfolio that would provide our sales force with additional complementary products to sell in the near term.

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. 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, and the American Academy of Dermatology, or AAD, 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, 2006, the CMS average national reimbursement for the use of Levulan(R) PDT for AK's Ambulatory Patient Classifications code ("APC code") was increased. The APC code is used by many hospitals. The CMS Current Procedural Terminology code ("CPT code"), which is used by private physician clinics using Levulan(R) PDT for treating AKs was not increased for 2006 (i.e. it will be unchanged from 2005 levels). DUSA had expected reimbursement under the CPT code to increase on January 1, 2006; however, we now believe that the increase will not be effective until January 1, 2007 based on information from CMS and the AAD. We are aware that some physicians believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices. We continue to support ongoing efforts that might lead to further increases in reimbursement in the future; and intend to continue supporting efforts to seek reimbursement for our FDA-cleared use of the BLU-U(R) alone in the treatment of mild to moderate inflammatory acne of the face.

Most 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.

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 physicians have been using Levulan(R) with the BLU-U(R) using short incubation, and with light

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

devices manufactured by other companies, and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called 'off-label' uses, we believe that these activities are positively affecting the sales of our products.

44

We believe that some compounding pharmacies are 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. We believe that these activities are negatively impacting our sales growth. Therefore in December 2004 and in January 2005, we filed lawsuits against two compounding pharmacies and several physicians. See section entitled "Legal Proceedings".

As of December 31, 2005, we had a staff of 64 full-time employees and 2 part-time employee, as compared to 65 full-time employees and 4 part-time employees at the end of 2004, 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. During 2005, we increased the size of our sales force to 26 from 22 at the end of 2004. During 2005 we eliminated 14 positions through a restructuring action, representing 16% of our workforce, to align headcount more closely with our assessment of our resource requirements at this time. These workforce reductions were made across all functions of the Company. We anticipate that this reduction in staff will reduce our future operating costs by \$1,400,000 on an annualized basis. We may add and/or replace employees during 2006 as business circumstances deem necessary.

2005 TRANSACTIONS

During 2005 and early 2006, DUSA entered into a number of transactions, all designed to foster future growth of its Levulan(R) PDT and early 2006 platform.

ENTERED INTO EXCLUSIVE MARKETING, DISTRIBUTION AND SUPPLY AGREEMENT WITH STIEFEL LABORATORIES - In January, 2006, we announced that we had entered into an exclusive Marketing, Distribution and Supply Agreement (the "Agreement") with Stiefel Laboratories, Inc. ("Stiefel") covering current and future uses of DUSA's proprietary Levulan(R) Kerastick(R) for photodynamic therapy (PDT) in dermatology. The Agreement, grants Stiefel an exclusive right to distribute, promote and sell the Levulan(R) Kerastick(R) in the western hemisphere from south of and including Mexico and all other countries in the Caribbean, excluding United States territories (collectively, the "Territory"). DUSA will manufacture and supply to Stiefel on an exclusive basis in the Territory all of Stiefel's reasonable requirements for the product. The Agreement, which has an initial term of ten years, will expand the distribution of Levulan(R) beyond the North American market for the first time into Mexico, Central and South America. DUSA has completed its portion of the Brazilian regulatory submission for the use of Levulan PDT for actinic keratoses. Effective with the signing of the Agreement, Stiefel will complete final integration and submission of the data to the Brazilian regulatory agency with market launch expected in late 2006 or early 2007. Stiefel will prepare and file the regulatory applications in other countries in the Territory subject to the terms of the Agreement. The parties have certain rights to terminate the Agreement prior to the end of the initial term, and Stiefel has an option to extend the term for an additional ten years on mutually agreeable terms and conditions.

SIGNED MERGER AGREEMENT TO ACQUIRE SIRIUS LABORATORIES, INC. - In December, 2005, we signed a definitive Merger Agreement to acquire all of the common stock of Sirius Laboratories Inc. of Vernon Hills, Illinois in exchange

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

for cash and common stock worth up to \$30,000,000. Sirius is a privately held dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Closing of the transaction is expected in the first quarter of 2006, subject to the terms and conditions in the Merger Agreement. Of the up to \$30,000,000, \$8,000,000 less certain expenses will be paid in cash upon closing, \$17,000,000 will be paid in shares of DUSA's common stock also upon closing in a private placement, and up to \$5,000,000 in cash or common stock may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products.

45

LAWSUITS FILED FOR INFRINGEMENT OF OUR LEVULAN(R) PHOTODYNAMIC THERAPY PATENTS- In November 2005, we filed lawsuits against physicians in California, Florida, and Tennessee to prevent their continued use of versions of its Levulan(R) brand of aminolevulinic acid HCl (ALA) produced by compounding pharmacies, for use in DUSA's patented photodynamic therapy (PDT) treatment for actinic keratosis, basal cell carcinoma, acne and other dermatological conditions. Additionally, some doctors were sued for misuse of DUSA's trademarks and for violations of the Latham Act for using the Levulan(R) brand name on their web sites and promotional materials, but performing patient treatments with ALA obtained from other sources. We also sued two compounding pharmacies.

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 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 reasonable expectation of collection. Product sales made through distributors 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 reserves, if any, that are necessary at each balance sheet date.

VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS - We review long-lived

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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, the asset is written down to its estimated fair value on a discounted cash flow basis. At December 31, 2005 and 2004, respectively, total property, plant and equipment had a net carrying value of \$2,972,000 and \$3,482,000 including \$2,233,000 at December 31, 2005 associated with our manufacturing facility. As of December 31, 2005 and 2004, respectively, we had intangible assets totaling \$150,000 and \$197,000 recorded in deferred charges and other assets

46

relating to the unamortized balance of payments made in 2004 to a light source supplier related to an amendment to our agreement and to a licensor related to the reacquisition of our product rights in Canada.

STOCK-BASED COMPENSATION - Prior to January 1, 2006, we used 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. 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 ("FASB") issued SFAS No. 123(R), "Share-Based Payment," a revision of SFAS Statement No. 123. The Company adopted SFAS 123(R) effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006 will be required to measure all employee share-based compensation awards using a fair value based method and record share-based compensation expense in its financial statements if the requisite service to earn the award is provided. The pro forma results and assumptions used in fiscal years 2005, 2004 and 2003 were based solely on historical volatility of our common stock over the most recent period commensurate with the estimated expected life of our stock options. The adoption of SFAS No. 123(R) will not affect the Company's cash flow, but it will materially increase the Company's net loss and basic and diluted loss per common share. In accordance with SFAS 123R, the Company will recognize the expense attributable to stock awards that are granted or vest in periods ending subsequent to December 31, 2005.

For 2006, total stock-based compensation expense is estimated to be in the range of \$1,500,000 to \$2,500,000. In order to develop the fiscal 2006 stock-based compensation expense estimate, we utilized assumptions including, among other items, projected option grants, volatility measures using a combination of historical and current and historical implied volatility, and expected life estimates for officer and non-officer employee groups. The amount

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

of the 2006 grants, if any, have not yet been determined and could result in a change to the amounts included in the range reflected above. Total unrecognized stock-based compensation expense related to unvested stock options, expected to be recognized over approximately two years, amounted to \$3,300,000 at December 31, 2005 net of forfeitures.

47

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2005 AS COMPARED TO 2004

REVENUES - Total revenues for the year ended December 31, 2005 were \$11,337,000, as compared to \$7,988,000 in 2004 and were comprised of the following:

| | 2005 | 2004 | INCREASE |
|-----------------------|---------------|--------------|--------------|
| | ----- | ----- | ----- |
| KERASTICK(R) REVENUES | | | |
| United States | \$ 7,957,000 | \$ 5,450,000 | \$ 2,507,000 |
| Canada | 935,000 | 401,000 | 534,000 |
| | ----- | ----- | ----- |
| Total | \$ 8,892,000 | \$ 5,851,000 | \$ 3,041,000 |
| BLU-U(R) REVENUES | | | |
| United States | \$ 1,930,000 | \$ 1,795,000 | \$ 135,000 |
| Canada | 515,000 | 342,000 | 173,000 |
| | ----- | ----- | ----- |
| Total | \$ 2,445,000 | \$ 2,137,000 | \$ 308,000 |
| | ----- | ----- | ----- |
| Total product sales | \$ 11,337,000 | \$ 7,988,000 | \$ 3,349,000 |
| | ===== | ===== | ===== |

For the year ended December 31, 2005, overall Kerastick(R) unit sales to end-users were 100,668, including 87,210 sold in the United States and 13,458 sold in Canada by Coherent-AMT, our Canadian marketing and distribution partner. This represents an increase from 76,482 Kerastick(R) units sold in the year ended December 31, 2004, including 69,870 sold in the United States, and 6,612 sold in Canada by Coherent-AMT. The increase in Kerastick(R) revenues for 2005 compared with 2004 is attributable to increased sales volumes, an increase in our average unit selling price, increased levels of our direct distribution to customers and a reduction in our overall sales volume discount programs. Our average net selling price for the Kerastick(R) increased to \$88.33 for 2005 from \$76.50 in 2004. Our average net selling price for the Kerastick(R) includes sales made directly to our end-user customers, as well as sales made to our distributors, both in the United States and Canada.

The increase in 2005 BLU-U(R) revenue was driven by an increase in our average selling price, which increased to \$6,542 in 2005 from \$4,368 in 2004. During 2005, there were 368 units sold versus 489 units in 2004. The 2005 total consists of 276 units sold in the United States and 92 units sold in Canada by Coherent-AMT. The 2004 total consists of 398 sold in the United States and 91 sold in Canada. The decrease in BLU-U(R) units sold in 2005 compared to 2004 is due primarily to the implementation of a more focused sales strategy aimed at increasing Kerastick(R) sales volumes in existing accounts; as well as a decrease in BLU-U(R) discounting programs. During the fourth quarter of 2005, we

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

introduced a BLU-U(R) evaluation program, which, for a limited number of BLU-U(R) units, allows customers to take delivery of a unit for a period of up to 4 months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At December 31, 2005, there were 80 units in the field pursuant to this evaluation program. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of 3 years. Revenues pursuant to the evaluation program were not significant in 2005.

The increase of both Kerastick(R) and BLU-U(R) revenues during 2005 is a result of the increased efforts of our sales force and related marketing and sales activities. With respect to United States sales, we increased our average selling prices, increased our direct selling and distribution efforts, while still maintaining the services of one external distributor, and reduced our overall sales volume discount programs, all of which have had a positive impact on our average selling prices during 2005. Sales must increase significantly from these levels in order for us to become profitable. We remain confident that we

48

are in a good position to exploit our therapy and that sales will continue to increase through increased consumption of the Kerastick(R) by our existing customers as well as the addition of new customers.

COST OF PRODUCT SALES AND ROYALTIES - Cost of product sales and royalties for the year ended December 31, 2005 were \$6,214,000, as compared to \$3,875,000 in 2004. The components of cost of product sales and royalties for the years ended December 31, 2005 and 2004, including direct and indirect costs to support our product are provided below:

| | |
|---|---------|
| KERASTICK(R) COST OF PRODUCT REVENUES AND ROYALTIES | 200 |
| | ----- |
| Direct Kerastick Product Costs | \$1,771 |
| Other Kerastick(R) Product costs including internal costs assigned to support products | 1,357 |
| Royalty and Supply fees (1) | 456 |
| | ----- |
| Total Kerastick(R) cost of product revenues and royalties | \$3,584 |
| | ===== |
| | |
| BLU-U(R) COST OF PRODUCT REVENUES | 200 |
| | ----- |
| Direct BLU-U(R) Product costs (2) | \$1,249 |
| Other BLU-U(R) Product costs including internal costs assigned to support products; as well as costs incurred to ship, install and service the BLU-U(R) in physicians offices | 1,381 |
| | ----- |
| Total BLU-U(R) cost of product revenues | \$2,630 |
| | ----- |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

TOTAL COST OF PRODUCT REVENUES AND ROYALTIES

\$6,214
=====

-
- 1) 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(R) Kerastick(R) in Canada.
 - 2) Although there were direct BLU-U(R) product revenues in 2004, there were no related direct BLU-U(R) product costs as these units had a zero book value due to inventory impairment charges recorded during 2002.

MARGINS - Total product margins for the year ended December 31, 2005, were \$5,124,000 as compared to \$4,113,000 for the year ended December 31, 2004, as shown below:

| | 2005 | | 2004 | | INCREASE/ (DECREASE) |
|--------------|--------------|------|--------------|-----|-------------------------|
| Kerastick(R) | \$ 5,308,000 | 60% | \$ 3,827,000 | 65% | \$ 1,481,000 |
| BLU-U(R) | (184,000) | (8)% | 286,000 | 13% | (470,000) |
| Total Margin | \$ 5,124,000 | 45% | \$ 4,113,000 | 51% | \$ 1,011,000 |

49

Kerastick(R) margins for the year ended December 31, 2005, were 60% compared to 65% for the year ended December 31, 2004. The decrease in the Kerastick(R) margin percentage for the year ended December 31, 2005 is due primarily to an increase in unabsorbed manufacturing expenses incurred in 2005. In general, we have been operating our Kerastick(R) manufacturing plant well below capacity, resulting in underutilization charges, which have negatively impacted margins. Due to this situation, we are realizing fluctuations in our margins as a result of both the timing of production and unabsorbed expenses. This has been somewhat offset by an increase in the overall selling price per unit. Our long-term goal is to achieve higher margins on Kerastick(R) sales, which is significantly dependent on increased volume.

BLU-U(R) margins for the year ended December 31, 2005, were (8)% compared with 13% for the year ended December 31, 2004. The erosion on margin is directly attributable to the fact that in 2005 we sold newly purchased units with an associated production cost, whereas during 2004 period, we sold units which had a zero net book value due to inventory impairment charges recorded during 2002 following termination of an agreement with a marketing partner. The margin erosion is somewhat offset by an increase in the overall selling price per unit and a decrease in Other BLU-U(R) Product costs. Our short-term strategy is to break-even on device sales in an effort to drive Kerastick(R) sales volumes. However, our longer term goal is to move towards a reasonable profit margin on all device sales.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs for the year ended December 31, 2005 and 2004 were \$5,588,000 as compared to \$6,490,000 in 2004.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Contributing to the decrease in spending in 2005 compared with 2004 is the receipt of a refund from the FDA for our 2003 and 2004 product and registration fees in the amount of approximately \$530,000.

| | 2005 | 2004 | INCRE (DECRE |
|---|--------------|--------------|-----------------|
| | ----- | ----- | ----- |
| Research & Development costs incurred | \$ 6,118,000 | \$ 6,490,000 | \$ (372 |
| Refund of FDA product and registration fees | (530,000) | - | (530 |
| | ----- | ----- | ----- |
| Total Research and Development Expense | \$ 5,588,000 | \$ 6,490,000 | \$ (902 |
| | ===== | ===== | ===== |

During the fourth quarter of 2004, we initiated a DUSA-sponsored Phase II study which we recently completed. This 72 patient, investigator blinded study was designed to examine various safety and efficacy parameters as a function of varying Levulan/vehicle incubation times, namely 15, 60 and 120 minutes. Patients were randomized within each incubation group so that 18 subjects received 'Levulan BLU-U' and six received 'BLU-U alone'. There were no formal placebo arms in this study. Up to four PDT treatments were given at 2-week intervals. The primary efficacy parameters were the percent change in total acne lesion count for inflammatory, non-inflammatory, and total lesions at 4 and 8 weeks after the final PDT session. Acne severity scores (grades 0 - 4) were also assessed. Safety and tolerability were also followed throughout the study. The results of the study indicate that both 'Levulan BLU-U' and 'BLU-U alone' appear to effectively reduce the number of both inflammatory and non-inflammatory acne lesions. Given the higher than anticipated 'BLU-U alone' response rate using this protocol, the study was not powered (sized) to discern differences between these arms. Using an intent-to-treat analysis, at the Week 8 time point, the median percent decrease in total lesion count, (inflammatory plus non-inflammatory) for Levulan BLU-U and BU-U alone was 61% and 80%, respectively. In the overall Acne Severity Assessment at the Week 8 time point, the Levulan BLU-U group showed 7/18 (39%) of subjects had at least 2 grades of improvement in their acne, compared with 4/6 (67%) in the BLU-U alone group.

50

In the group of 28 patients with the most severe (Grade 4) acne, which included those with the highest number of inflammatory lesions at baseline (> or = 60 lesions), the total lesion count at Week 8 decreased in the Levulan BLU-U group, whereas total lesion count at Week 8 increased in the BLU-U alone group. Treatment was well tolerated in both arms of the study with no unanticipated adverse events being reported. Side effects were minimal. In the 15-minute Levulan BLU-U group, no PDT treatments were discontinued due to pain, and at the Week 8 time-point, there were no significant differences between the groups in erythema, edema or hyperpigmentation. The results of this study suggest that for future development of the acne indication for Levulan PDT, those patients with the most severe form(s) of acne should receive the greatest benefit.

In February 2006, we reported the interim analysis results from our 80 patient, multi-center Phase II split-face clinical study of PDT in the treatment of photodamaged skin using the Levulan(R) (aminolevulinic acid HCl, ALA) Kerastick(R) in combination with either the Company's BLU-U(R), an Intense Pulsed Light, or IPL, or a Long Pulsed Dye Laser, or LPDL. Each patient served

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

as his or her own control, using a 'split-face' design. Following skin cleansing with an acetone solution, and approximately 60 minutes of drug and/or vehicle incubation, light treatment with a fixed dose was given using one of the three light sources. Up to 3 treatments were given, 3 weeks apart. Interim results were assessed at Weeks 9 and 12. The protocol includes additional follow-up visits scheduled for Weeks 26 and 52.

The goal of the study was to guide selection of light source(s) for future development in the treatment of photodamaged skin, using the Company's proprietary Levulan PDT technology. The study was not designed to detect differences between the light sources.

At Week 12, Levulan PDT with BLU-U light demonstrated material improvement in photodamaged skin, in comparison to BLU-U and vehicle. Statistical significance in net changes from baseline scores was achieved in 2 parameters of photodamage, namely mottled pigmentation ($p=0.0348$) and tactile roughness ($p=0.0455$). In addition, the trend toward improvement in a number of parameters was notably greater at Week 12 than Week 9, without any additional treatments with Levulan, which suggests that other parameters may also reach statistical significance over time. Specifically, Levulan with BLU-U showed greater improvements in mottled pigmentation, tactile roughness, fine wrinkling, sallowness and Global Photodamage Score (i.e. all the parameters that were measured except for telangiectasia (small blood vessels in the skin)), compared with areas treated with BLU-U and vehicle. BLU-U by itself is not known to have any effects on photodamaged skin.

These results support the conclusions of a prior independent study by Touma et al (2004), using Levulan with BLU-U versus BLU-U alone, that achieved statistical significance with the addition of Levulan in all photodamage parameters measured, other than deep wrinkles. In that study, the investigators treated more severely sun-damaged patients, each with a minimum of 4 actinic keratoses. They also used twice the dose of blue light compared to the current study (10 vs. 5 Joules/cm²), and drug incubation times ranging from 1-3 hours.

IPL by itself has previously been shown in independent studies to significantly improve photodamage, predominantly by targeting brown discoloration and red blood vessels. Therefore, as would be expected, at Week 12, significant improvement in photodamage was seen with IPL and vehicle, especially with respect to mottled pigmentation and telangiectasia. With the addition of Levulan, there was a trend toward even greater improvement in all parameters of photodamage except for mottled pigmentation, although these trends did not achieve statistical significance. However, similar to the BLU-U results, the trend toward improvement was notably greater at Week 12 than Week 9 without any additional treatments with Levulan, and additional follow up is scheduled at weeks 26 and 52.

51

These results support the conclusions of prior independent studies by Dover et al (2005), Alster et al (2005), and Gold et al (in press) using Levulan with IPL versus IPL alone for photodamage. All of these studies reported significant benefits from the addition of Levulan to IPL, especially in patients with significant photodamage. In addition, although IPL itself does not treat pre-cancerous cell damage, such as actinic keratoses, when combined with Levulan (ALA) to produce a PDT effect, IPL has been reported to effectively remove these lesions (Avram and Goldman, 2004, Ruiz-Rodrigues, 2002).

With LPDL, as would be expected, there was significant improvement in photodamaged skin with LPDL and vehicle, especially with respect to telangiectasia, the primary target of this device. However, with LPDL, the addition of Levulan for the treatment of photodamage did not lead to any

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

discernable differences in photodamage parameters between the two groups, as suggested by the results of an earlier study (Smith et al, 2004).

In general, safety was excellent in all groups, but treatment using Levulan with BLU-U was better tolerated than treatment with IPL or LPDL (with or without Levulan) i.e. the frequency and severity of stinging and burning during treatment was greater with IPL and LPDL (with or without Levulan) compared to Levulan with BLU-U, and for BLU-U with vehicle. Levulan with BLU-U was also easy to use and less operator dependent.

During September 2005, the FDA issued a new draft guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. As a result of the issuance of this guidance, in combination with the results of our Phase II study, we believe that additional Phase II work will be required before we commence Phase III acne trials. 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 retained the services of a regulatory consultant to assist us with seeking foreign marketing approvals for our products, which could cause research and development expenses to increase.

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(R) 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(R) photodynamic therapy ("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 are working together to prepare overall clinical development plans for Levulan(R) PDT in these indications, starting with Phase I/II trials, and continuing through Phase III studies, if appropriate. DUSA and the NCI DCP have prepared outlines of clinical studies in both indications. The NCI DCP is currently working with, DUSA and investigators to finalize the clinical trial designs. The NCI DCP will use its resources to file its own Investigational New Drug applications with the FDA. Our costs related to these studies will be limited to providing Levulan(R), device(s) and the necessary training for the investigators involved. All other costs of these studies will be the responsibility of the NCI DCP. We will maintain full ownership of our existing intellectual property, have options on new intellectual property and, subject to successful Phase II and III clinical trial results, intend 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, our small single-center pilot Phase II clinical trial using our new proprietary endoscopic light delivery device is continuing.

We have entered into a series of agreements for our research projects and clinical studies. As of December 31, 2005, future payments to be made pursuant to these agreements, under certain terms and conditions, total approximately \$1,775,000 for 2006. 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. We expect research

52

and development costs to increase in 2006 as compared to 2005 as we continue to invest in our clinical programs.

MARKETING AND SALES COSTS -- Marketing and sales costs for the year ended December 31, 2005 were \$9,069,000 as compared to \$7,622,000 for 2004. These costs consist of overhead expenses such as salaries and benefits for the

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$6,934,000 in 2005 and \$5,268,000 in 2004. These increases were mainly attributable to the expansion of our sales force during 2005 and related marketing activities. The remaining expenses consist of trade shows, miscellaneous marketing expenses and outside consultants totaling \$2,135,000 in 2005 and \$2,354,000 in 2004. For 2006, we expect marketing and sales costs will increase from 2005 levels reflecting our increased efforts to generate higher sales volumes; as well as, a full year impact of our sales force expansion that took place during 2005.

GENERAL AND ADMINISTRATIVE COSTS -- General and administrative expenses for the year ended December 31, 2005, decreased to \$6,703,000 as compared to \$7,210,000 for 2004. The increase/decrease is mainly attributable to lower legal expenses of \$1,902,000 as compared to \$3,144,000 in the comparable period in 2004, due to the absence of patent litigation costs in Australia as the final hearing in the PhotoCure litigation described below was held in 2004. The savings related to the Australian litigation is partially offset by patent litigation costs against compounding pharmacies and physicians, as described below. Additionally, general corporate expenses, including increased personnel related costs, have increased as our business has expanded. For 2006, we expect general and administrative costs to be relatively consistent with 2005 levels. General and administrative costs are highly dependent on our legal expenses, which are difficult to predict.

OTHER INCOME, NET -- Other income for the year ended December 31, 2005, decreased to \$1,388,000, as compared to \$1,580,000 in 2004. This decrease reflects a reduction in our average investable cash balances during 2005 as we used cash to support our operating activities. We expect other income, net will decrease in 2006 as we continue to use cash in support of our operations, our capital requirements and corporate transactions, particularly upon the expected closing of the merger with Sirius Laboratories, Inc.

INCOME TAXES -- There is no provision for income taxes due to ongoing operating losses. As of December 31, 2005, we had net operating loss carryforwards of approximately \$79,261,000 and tax credit carryforwards of approximately \$2,521,000 for Federal reporting purposes. These amounts expire at various times through 2024. See Note 8 to the Notes to the Consolidated Financial Statements. We have provided a full valuation allowance against the net deferred tax assets at December 31, 2005 and 2004.

NET LOSS -- For the year ended December 31, 2005, we recognized a net loss of \$14,999,000, or \$0.89 per share, as compared to \$15,629,000, or \$0.96 per share, for the year ended 2004. 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 ENDED 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 (R) PRODUCT REVENUES | | | |
| United States | \$5,450,000 | \$901,000 | \$4,549,000 |
| Canada | 401,000 | - | 401,000 |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | | | |
|---------------------------|-------------------------------|-----------------------------|-------------------------------|
| Total | ----- \$5,851,000 | ----- \$901,000 | ----- \$4,950,000 |
| BLU-U(R) PRODUCT REVENUES | | | |
| United States | \$1,795,000 | \$ 69,000 | \$1,726,000 |
| Canada | 342,000 | - | 342,000 |
| Total | ----- \$2,137,000 | ----- \$ 69,000 | ----- \$2,068,000 |
| Total Product Revenues | ----- \$7,988,000 ===== | ----- \$970,000 ===== | ----- \$7,018,000 ===== |

The increase in 2004 product revenues reflects sales to physicians of 76,482 Kerastick(R) units, as compared to 11,172 Kerastick(R) units in 2003, and an increase in the BLU-U(R) units in place in physician's offices of 914 units as of December 31, 2004, up from 406 units at December 31, 2004. With respect to U.S. Kerastick(R) sales, we increased our direct selling and distribution efforts, while still maintaining the services of one external distributor.

On March 31, 2004, DUSA signed an exclusive marketing and distribution agreement for the Kerastick(R) and BLU-U(R) 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(R) for moderate inflammatory acne in April 2004, and the Kerastick(R) for the PDT treatment of non-hyperkeratotic actinic keratoses, or AKs, in June 2004. DUSA recognizes product sales when Coherent sells the Kerastick(R) and/or the BLU-U(R) to the end-user, as the price is fixed and final at that point. Kerastick(R) product sales through our Canadian distributor for the year ended December 31, 2004 were 6,612, and there were 101 BLU-U(R) units in physician's offices as of December 31, 2004.

The increase of Kerastick(R) and BLU-U(R) revenues in the U.S. during 2004 is a result of the efforts of a larger sales force, and related marketing and sales activities. In addition, the increase in BLU-U(R) placements was caused, in part, by our ability to sell the BLU-U(R) 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(R) 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(R) placements by our sales-force, in light of diminishing BLU-U(R) inventory levels at that time. We ordered additional BLU-U(R) 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(R) revenues were limited during the fourth quarter of 2004, and were limited until being re-supplied during the first quarter of 2005.

Although the level of Kerastick(R) sales to end-users for 2004 was substantially higher than the level in the prior year, we significantly increased the size of our sales force and geographic reach during 2004.

COST OF PRODUCT REVENUES AND ROYALTIES -- Cost of product revenues 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 revenues and royalties for the years ended December 31, 2004 and 2003, including direct and indirect costs to support our product are provided below:

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

KERASTICK(R) COST OF PRODUCT REVENUES AND ROYALTIES

| | 2004 | |
|---|-------------|---------|
| | ----- | ----- |
| Direct Kerastick(R) Product Costs(1) | \$1,478,000 | \$2,000 |
| Other Kerastick Product costs including internal costs assigned to support products | 261,000 | 1,900 |
| Royalty and supply fees (3) | 285,000 | 2,000 |
| | ----- | ----- |
| Total Kerastick(R) cost of product revenues and royalties | \$2,024,000 | \$2,000 |
| | ===== | ===== |

BLU-U(R) COST OF PRODUCT REVENUES

| | 2004 | |
|---|-------------|---------|
| | ----- | ----- |
| Other BLU-U(R) Product costs including internal costs assigned to support products; as well as costs incurred to ship, install and service the BLU-U(R) in physicians offices (2) | 1,851,000 | 1,200 |
| | ----- | ----- |
| Total BLU-U(R) cost of product revenues | \$1,851,000 | \$1,200 |
| | ----- | ----- |
| TOTAL COST OF PRODUCT REVENUES AND ROYALTIES | \$3,875,000 | \$3,400 |
| | ===== | ===== |

(1)The decrease in product costs for 2004 primarily reflects the capitalization of labor and overhead associated with the manufacture of Kerastick(R) 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(R) product sales in 2004 and 2003, there were no related direct BLU-U(R) 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(R) Kerastick(R) in Canada.

MARGINS -- Total product margins for the year ended December 31, 2004, were \$4,113,000 as compared to \$(2,511,000) for the year ended December 31, 2003, as shown below:

| | 2004 | 2003 | | INCREASE/ (DECREASE) |
|--------------|-------------|-------|---------------|-------------------------|
| | ----- | ----- | | ----- |
| Kerastick(R) | \$3,827,100 | 65% | \$(1,361,000) | (151)% |
| | | | | \$5,188,000 |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | | | | | |
|--------------|-------------|-----|---------------|----------|-------------|
| BLU-U(R) | 286,000 | 13% | \$(1,150,000) | (1,660)% | 1,436,000 |
| | ----- | | ----- | | ----- |
| Total Margin | \$4,113,000 | 51% | \$(2,511,000) | (259)% | \$6,624,000 |
| | ===== | | ===== | | ===== |

Kerastick(R) margins for the year ended December 31, 2004, were 65% compared to (151)% for the year ended December 31, 2004. The increase in the Kerastick(R) margins, in terms of both dollars and percentages, for the year ended December 31, 2004 is due primarily to the capitalization of labor and overhead associated with the manufacture of Kerastick(R) units in our facility in 2004. These costs were expensed in 2003 due to the absence of production.

55

BLU-U(R) margins for the year ended December 31, 2004, were 13% compared with (1,660) % for the year ended December 31, 2003. The increase in margin is directly attributable to increased BLU-U(R) revenues during 2004 with no associated direct costs, since the units being sold in both 2003 and 2004 had a zero book value due to an inventory impairment charge recorded in 2002.

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(R). 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 concentrated our dermatology development program on indications that use our approved Kerastick(R). Based on market research that was completed in 2003, we moved forward with our Phase II clinical studies for use of Levulan(R) 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(R) PDT for the treatment of acne vulgaris at the end of October 2004. In addition, 2004 expenses included 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.

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 consisted 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 consisted of trade shows, 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.

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 was mainly attributable to a higher level of general corporate expenses to support our expanding business, including an increase in audit and consulting

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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 included 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.

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(R) manufacturing facility. Of these amounts,

56

\$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 was 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 8 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 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 was 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 was 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.

57

QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2005 and 2004, respectively:

| | QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2005 | | | |
|----------------------|--|-------------|--------------|-------------|
| | MARCH 31 | JUNE 30 | SEPTEMBER 30 | DECEMBER 31 |
| Total revenues | \$3,368,614 | \$2,228,116 | \$2,392,244 | \$3,348,414 |
| Loss from operations | (4,698,611) | (5,178,714) | (3,948,670) | (2,560,611) |
| Net loss | (4,331,614) | (4,826,118) | (3,608,281) | (2,232,611) |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Basic and diluted loss per share \$ (0.26) \$ (0.29) \$ (0.21) \$ (0.21)

| 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 | \$2,545,300 |
| Loss from operations | (4,800,791) | (4,571,668) | (3,325,565) | (4,510,700) |
| Net loss | (4,401,654) | (4,196,087) | (2,974,992) | (4,056,200) |
| Basic and diluted loss per share | (0.30) | (0.25) | (0.18) | (0.21) |

LIQUIDITY AND CAPITAL RESOURCES

We remain in a strong cash position to continue to fund increased Levulan(R) PDT sales and marketing expenses and current research and development activities for our Levulan(R) PDT/PD platform. At February 28, 2006, we had approximately \$31,147,000 of total cash resources comprised of \$11,681,000 of cash and cash equivalents, \$19,466,000 of marketable securities.

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' and provides allowances for potential credit losses, when applicable.

On December 30, 2005, we signed a definitive Merger Agreement to acquire all of the common stock of Sirius Laboratories Inc. of Vernon Hills, Illinois in exchange for cash and common stock worth up to \$30,000,000. Sirius is a privately held dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Closing of the transaction is expected in the first quarter of 2006, subject to the terms and conditions in the Merger Agreement. Of the up to \$30,000,000, \$8,000,000 less certain expenses will be paid in cash upon closing, \$17,000,000 will be paid in shares of DUSA's common stock also upon closing in a private placement, and up to \$5,000,000 in cash or common stock may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. As part of the Sirius Merger, we also expect to pay at closing certain expenses incurred by Sirius related to the acquisition and Sirius' balance on their bank line of credit, if any. We believe we have sufficient resources to finance the acquisition utilizing our existing resources.

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.

58

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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

As of December 31, 2005, our working capital (total current assets minus total current liabilities) was \$34,889,000 as compared to \$48,799,000 as of December 31, 2004. Total current assets decreased \$13,766,000 in 2005 due primarily to a decrease in marketable securities, which was used to fund our loss from operations. Total current liabilities increased \$143,000 in 2005 due to an increase in accounts payable and other accrued expenses, partially offset by a decrease in deferred revenue.

During 2005, we used \$14,101,000 of cash to support our operating activities, purchased \$415,000 of property, plant, and equipment, received \$928,000 in exercises of stock options and received \$14,874,000 of net proceeds from maturations and sales of marketable securities. During the comparable 2004 period, we used \$14,070,000 of cash for operating activities, purchased \$530,000 of property, plant and equipment, received \$765,000 in proceeds from exercises of stock options and invested \$14,037,000 of net proceeds from maturations and sales of marketable securities.

We believe that we have sufficient capital resources to proceed with our current programs for Levulan(R) PDT, and to fund operations and capital expenditures for approximately 2 years. 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. However, upon the closing of the Sirius Merger we will deplete a significant amount of our liquid assets and if product revenues do not meet our expectations, we will need to raise capital in order to continue our research and development activities as planned.

In addition to the contemplated merger with Sirius Laboratories, Inc., we continue to seek opportunities to 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 2006, we are focusing primarily on increasing the sales of our approved products in the U.S. and Canada, continuing our efforts of exploring partnership opportunities for Levulan(R) PDT for dermatology in Europe and/or other countries outside of the United States, Canada and Latin America, and continuing our clinical development programs for our facial photodamage and moderate to severe acne indications. In January 2006, we entered into a marketing and distribution agreement with Stiefel Laboratories, Inc. granting Stiefel an exclusive right to distribute the Levulan(R) Kerastick(R) in Mexico, Central and South America. 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(R) 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(R) PDT for other indications in dermatology, and selected internal indications. We and the NCI DCP have prepared outlines of clinical studies in both indications. The NCI DCP is currently working with us and investigators to finalize the clinical trial designs. The NCI DCP will use its resources to file its own Investigational New Drug applications with the FDA. Our costs related to these studies will be limited to providing Levulan(R), device(s) and the necessary training for the investigators involved. All other costs of these studies will be the responsibility of the NCI DCP.

Full development and testing of the use of Levulan PDT for treatment of acne and facial photodamage would require additional funding. The timing of expenditures will be dependent on various factors, including:

59

- the level of sales of our products including the success of our

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

marketing programs for the dermatological uses of Levulan(R) PDT,

- progress of our research and development programs,
- the results of preclinical and clinical trials,
- the timing of regulatory marketing approvals,
- competitive developments,
- the results of patent disputes,
- any new additional collaborative arrangements, if any, we may enter, and
- the availability of other financing.

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.

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, 2005:

| | OBLIGATIONS DUE BY PERIOD | | | | AFTER 1 YEAR |
|---------------------------------|---------------------------|-------------------|------------|------------|-----------------|
| | TOTAL | 1 YEAR OR LESS | 2-3 YEARS | 4-5 YEARS | |
| Operating lease obligations | \$2,959,000 | \$ 470,000 | \$ 887,000 | \$ 880,000 | \$72,000 |
| Purchase obligations (1, 2) | \$1,934,000 | \$1,934,000 | - | - | - |
| Minimum royalty obligations (3) | \$667,000 | \$ 86,000 | \$ 172,000 | \$ 172,000 | \$23,000 |

-
- 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. \$86,000 as of December 31, 2005) through the expiration of the term of the

agreement.

RECENTLY ISSUED ACCOUNTING GUIDANCE

60

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. We have adopted this standard beginning the first quarter of 2006 and do not believe the adoption will have a material impact on our results of operations or financial position as such costs have historically been expensed as incurred.

In November 2005, FASB issued FASB Staff Position FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP FAS 115-1"), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP FAS 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP FAS 115-1 is required to be applied to reporting periods beginning after December 15, 2005. We are required to adopt FSP FAS 115-1 in the first quarter of 2006. We do not expect that the adoption of this statement will have a material impact on our results of operations or financial condition. The unrealized losses on the Company's investments in U.S. Treasury obligations, and direct obligations of U.S. government agencies and investment grade corporate securities were caused by interest rate increases. It is expected that these securities would not be settled at a price less than the amortized cost of the Company's investment. Because the Company has the ability and

61

intent to hold these investments until a recovery of fair value, which may be maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2005.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

United States government securities and high grade corporate bonds. All investments are carried at market value, which approximates cost.

As of December 31, 2005, the weighted average rate of return on our investments was 4.08%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of December 31, 2005, the fair market value of the portfolio would decline by \$259,000. 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 strategies and core objectives for 2006, our expectations regarding our proposed merger with Sirius Laboratories, Inc. and matters relating thereto, management's beliefs regarding the unique nature of Levulan(R) and its use and potential use, expectations regarding the timing of results of clinical trials, future development of Levulan(R) and our other products for cancer, warts, onychomycosis, psoriasis, molluscum contagiosum, oily skin and acne rosacea, facial photodamaged skin, cystic acne, acne vulgaris, Barrett's esophagus, high-grade dysplasia, infected sweat glands (hidradenitis suppurativa) and other potential indications, intention to pursue licensing, marketing, co-promotion, collaboration 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 expectations regarding new proprietary endoscopic light delivery systems and the potential use of other light devices, our beliefs regarding the safety, simplicity, reliability and cost-effectiveness of certain light sources, our expectations regarding product launches, our intention to expand our sales force, hope that our products will be an AK therapy of choice and barriers to achieving that status, our beliefs regarding revenues and market opportunities from approved and potential products and Levulan's(R) competitive properties, our intention to postpone or commence clinical trials and investigator studies in 2006, beliefs regarding the clinical benefit of Levulan(R) PDT for acne and other indications, beliefs regarding the suitability of clinical data, expectations of exclusivity under the Hatch-Waxman Act and other patent laws and the potential benefits thereof, expectations regarding the confidentiality of our proprietary information, intentions to seek additional U.S. and foreign regulatory approvals, trademarks, and to

62

market and increase sales outside the U.S., beliefs regarding regulatory classifications, filings, timelines, off-label use and environmental compliance, beliefs concerning patent disputes and litigation, the impact of a third-party's regulatory compliance and fulfillment of contractual obligations, expectations of increases in cost of product sales, expectations regarding margins on Kerastick(R) and other products, 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 2006, requirements of cash resources for our future liquidity, beliefs regarding investments and economic conditions, beliefs regarding accounting policies and practices, expectations regarding outstanding options and warrants and our dividend policy, anticipation of increases or decreases in 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 and competition, expectations regarding the adequacy and availability of insurance, expectations regarding stable general and administrative costs, expectations

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

regarding the status of research and development costs and our efforts with respect thereto, expectations regarding increased sales and marketing 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(R) and BLU-U(R) units, our manufacturing capabilities and the impact of inventories on revenues, belief regarding interest rate risks to our investments and effects of inflation and new and existing accounting standards and policies, 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(R) light device and integrated drug and light device systems, our principal methods of competition, competition in general and competitive developments. 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

| | |
|--|-----|
| Report of Independent Registered Public Accounting Firm..... | F-1 |
| Consolidated Balance Sheets..... | F-2 |
| Consolidated Statements of Operations..... | F-3 |
| Consolidated Statements of Shareholders' Equity..... | F-4 |
| Consolidated Statements of Cash Flows..... | F-5 |
| Notes to the Consolidated Financial Statements..... | F-6 |

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

None.

63

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to our (including our subsidiaries) required to be included in our periodic Securities and Exchange Commission filings. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

Changes in Internal Control Over Financial Reporting. There was no change in our internal control over financial reporting that occurred during the period

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

covered by this Report that has materially affected, or is reasonably likely to materially affect, our 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 Chief Executive Officer and Chief 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, 2005.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

64

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders 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 that DUSA Pharmaceuticals, Inc. and its subsidiary (the "Company") maintained effective internal control over financial reporting as of December 31, 2005, 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 opinions.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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, 2005, is fairly stated, in all material respects, based on the criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring

65

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, 2005, 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, 2005, of the Company and our report dated March 10, 2006, expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 10, 2006

66

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 2006 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

the sections entitled "Director Compensation," "Executive Compensation," "Board Compensation Committee Report on Executive Compensation," "Performance Graph," "Option Grants in 2005," "Aggregate Option Exercises in 2006 and Option Values at December 31, 2005," and "Other Compensation" of Registrant's 2006 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 2006 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 2006 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 2006 Proxy Statement.

67

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

A. List of Financial Statements and Schedules

| | |
|--|-----|
| Report of Independent Registered Public Accounting Firm..... | F-1 |
| Consolidated Balance Sheets..... | F-2 |
| Consolidated Statements of Operations..... | F-3 |
| Consolidated Statements of Shareholders' Equity..... | F-4 |
| Consolidated Statements of Cash Flows..... | F-5 |
| Notes to the Consolidated Financial Statements..... | F-6 |

B. Exhibits filed as part of this Report

- 2(a.1)* Merger Agreement by and among the Company, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005; and
- 2(a.2) First Amendment to Merger Agreement by and among the Company, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006.
- 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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- 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 herein 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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(j.3) Third Amendment to Supply Agreement between the Company and Sochinaz SA dated July 29, 2005, filed as Exhibit 10.1 to the Registrant's Form 10-Q filed on August 3, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(k) Master Service Agreement between the Company and Therapeutics, Inc.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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) 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(m) 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(n) 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(o) 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(p) 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(q) 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

70

Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;

- 10(r) Employment Agreement of Scott L. Lundahl dated as of June 23, 1999 filed as Exhibit 10(u) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(s) Amended Employment Agreement of Stuart L. Marcus, MD, PhD dated December 9, 1999 filed as Exhibit 10(v) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(t) Employment Agreement of Mark C. Carota dated as of February 14, 2000 filed as Exhibit 10(w.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- 10(t.1) First Amendment to Employment Agreement of Mark C. Carota dated October 31, 2001 filed as Exhibit 10(w.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(u) Employment Agreement of Paul A. Sowyrda dated as of July 31, 2001 filed as Exhibit 10(x) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(v) Employment Agreement of Richard Christopher dated as of January 1, 2004 filed as Exhibit 10(y) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(w) Employment Agreement of Robert F. Doman dated as of March 15, 2005 filed as Exhibit 10(z) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(x) Employment Agreement of Gary F. Talarico dated as of February 15, 2005 filed as Exhibit 10(aa) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y) Severance Agreement and General Release between the Company and Peter Chakoutis dated as of February 25, 2005 filed as Exhibit 10(bb) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y.1) Final Agreement and General Release, between the Company and Peter Chakoutis, dated as of April 4, 2005, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 4, 2005, and is incorporated herein by reference; +
- 10(z) Compensation Policy Applicable to the Company's Non-Employee Directors filed as Exhibit 10(cc) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; and +
- 10(aa) Marketing, Distribution and Supply Agreement between the Company and Stiefel Laboratories, Inc., dated as of January 12, 2006, 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.
- 14(a) Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers, filed as Exhibit 14(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference.
- 21(a) Subsidiaries of the 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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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.

71

* Schedules and exhibits omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Commission upon request.

72

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
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, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. 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 Dusa Pharmaceuticals, Inc. and subsidiaries as of December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, 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, 2005, 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 10, 2006, 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Boston, Massachusetts
March 10, 2006

F-1

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

| | DECEMBER |
|---|---------------------|
| | 2005 |
| | ----- |
| ASSETS | |
| CURRENT ASSETS | |
| Cash and cash equivalents | \$ 4,210,675 |
| Marketable securities | 30,579,486 |
| Accrued interest receivable | 353,449 |
| Accounts receivable, net | 373,130 |
| Inventory | 1,860,793 |
| Deferred acquisition costs | 831,875 |
| Prepays and other current assets | 776,293 |
| TOTAL CURRENT ASSETS | 38,985,701 |
| Restricted cash | 144,541 |
| Property, plant and equipment, net | 2,971,869 |
| Deferred charges and other assets | 228,520 |
| TOTAL ASSETS | \$42,330,631 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | |
| CURRENT LIABILITIES | |
| Accounts payable | \$ 934,694 |
| Accrued compensation | 1,071,677 |
| Other accrued expenses | 1,995,679 |
| Deferred revenue | 94,283 |
| TOTAL CURRENT LIABILITIES | 4,096,333 |
| Other liabilities | 205,570 |
| TOTAL LIABILITIES | 4,301,903 |
| COMMITMENTS AND CONTINGENCIES (NOTE 12) | |
| 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. Common stock shares issued and outstanding: 17,041,197 in 2005 and 16,876,822 in 2004, no par | 125,626,163 |
| Additional paid-in capital | 2,035,783 |
| Accumulated deficit | (89,537,470) |
| Accumulated other comprehensive (loss) income | (95,748) |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | |
|--|--------------|
| TOTAL SHAREHOLDERS' EQUITY | 38,028,728 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$42,330,631 |

See the accompanying Notes to the Consolidated Financial Statements.

F-2

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

| | YEAR ENDED DECEMBER 31, | | |
|--|-------------------------|-----------------|---------|
| | 2005 | 2004 | |
| REVENUES | | | |
| Kerastick(R) Product Revenues | \$ 8,891,565 | \$ 5,850,835 | \$ |
| BLU-U(R) Product Revenues | 2,445,896 | 2,136,821 | |
| PRODUCT REVENUES | 11,337,461 | 7,987,656 | |
| COST OF PRODUCT REVENUES | | | |
| Kerastick(R) Cost of Product Revenues and Royalties | 3,583,650 | 2,023,685 | 2, |
| BLU-U(R) Cost of Product Revenues | 2,629,951 | 1,851,333 | 1, |
| COST OF PRODUCT REVENUES AND ROYALTIES | 6,213,601 | 3,875,018 | 3, |
| GROSS MARGIN | 5,123,860 | 4,112,638 | (2, |
| OPERATING COSTS | | | |
| Research and Development | 5,587,599 | 6,489,723 | 5, |
| Marketing and sales | 9,068,984 | 7,622,106 | 2, |
| General and administrative | 6,703,047 | 7,209,536 | 6, |
| Restructuring | 150,917 | - | |
| TOTAL OPERATING COSTS | 21,510,547 | 21,321,365 | 14, |
| LOSS FROM OPERATIONS | (16,386,687) | (17,208,727) | (16, |
| OTHER INCOME | | | |
| Interest income | 1,387,978 | 1,579,747 | 1, |
| NET LOSS | \$ (14,998,709) | \$ (15,628,980) | \$ (14, |
| BASIC AND DILUTED NET LOSS PER COMMON SHARE | \$ (0.89) | \$ (0.96) | \$ |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 16,932,138 | 16,317,078 | 13, |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

See the accompanying Notes to the Consolidated Financial Statements.

F-3

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

| | COMMON STOCK | | ADDITIONAL | ACCUMULATED |
|--|--------------|---------------|--------------|--------------|
| | NUMBER OF | AMOUNT | PAID-IN | DEFICIT |
| | SHARES | | CAPITAL | |
| BALANCE, JANUARY 1, 2003 | 13,887,612 | \$ 95,490,561 | \$ 2,015,586 | \$ (44,082,9 |
| Comprehensive loss: | | | | |
| Net loss for period | | | | (14,826,8 |
| Net unrealized loss on marketable securities available for sale | | | | |
| Total comprehensive loss | | | | |
| Issuance of common stock to consultants | 44,416 | 110,000 | | |
| Exercises of options | 11,000 | 32,870 | | |
| Issuance of common stock to employee | 23,219 | 37,123 | | |
| BALANCE, DECEMBER 31, 2003 | 13,966,247 | \$ 95,670,554 | \$ 2,015,586 | \$ (58,909,7 |
| Comprehensive loss: | | | | |
| Net loss for period | | | | (15,628,9 |
| Net unrealized loss on marketable securities available for sale | | | | |
| Total comprehensive loss | | | | |
| 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 | | |
| Exercises of options | 167,825 | 765,207 | | |
| Issuance of options to consultants | | | 240,753 | |
| Repurchase of options issued to consultants | | | (240,000) | |
| BALANCE, DECEMBER 31, 2004 | 16,876,822 | 124,698,059 | 2,016,339 | (74,538,7 |
| Comprehensive loss | | | | |
| Net loss for period | | | | (14,998,7 |
| Net unrealized loss on marketable securities available for sale | | | | |
| Total comprehensive loss | | | | |
| Exercises of options | 164,375 | 928,104 | | |
| Acceleration of vesting of stock options | | | 19,444 | |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | | | | |
|----------------------------|------------|----------------|--------------|--------------|
| BALANCE, DECEMBER 31, 2005 | 17,041,197 | \$ 125,626,163 | \$ 2,035,783 | \$ (89,537,4 |
| | ===== | ===== | ===== | ===== |

See the accompanying Notes to the Consolidated Financial Statements.

F-4

DUSA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | YEAR ENDED |
|---|-----------------|
| | 2005 |
| | ----- |
| CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES | |
| Net (loss) | \$ (14,998,709) |
| Adjustments to reconcile net loss to net cash used in operating activities: | |
| Amortization of premiums and accretion of discounts on debt securities, net | 416,550 |
| Realized gain on sale of marketable securities | (74,512) |
| Depreciation and amortization | 925,185 |
| Stock-based compensation | 19,444 |
| Changes in other assets and liabilities impacting cash flows from operating activities: | |
| Accrued interest receivable | 288,348 |
| Accounts receivable | 337,886 |
| Inventory | (443,632) |
| Prepaid and other current assets | (729,537) |
| Deferred charges and other assets | - |
| Accounts payable | 77,426 |
| Accrued compensation and other accrued expenses | 201,907 |
| Deferred revenue | (136,432) |
| Other liabilities-non current | 15,131 |
| | ----- |
| NET CASH USED IN OPERATING ACTIVITIES | (14,100,945) |
| | ----- |
| CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES | |
| Purchases of marketable securities | (58,850,356) |
| Proceeds from maturities and sales of marketable securities | 73,724,674 |
| Restricted cash | (3,777) |
| Purchases of property, plant and equipment | (415,168) |
| Repurchase of options issued to consultants | - |
| | ----- |
| NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES | 14,455,373 |
| | ----- |
| CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES | |
| Issuance of common stock (net of stock offering costs of \$200,202) | - |
| Payment of long-term debt | - |
| Proceeds from exercise of options | 928,104 |
| | ----- |
| NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES | 928,104 |
| | ----- |
| NET DECREASE IN CASH AND CASH EQUIVALENTS | 1,282,532 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 2,928,143 |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

CASH AND CASH EQUIVALENTS AT END OF PERIOD

\$ 4,210,675
=====

Cash paid for interest

=====

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.

F-5

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

1) NATURE OF BUSINESS

DUSA Pharmaceuticals, Inc. ("DUSA" or the "Company") is a pharmaceutical company engaged primarily in the research, development and marketing of a drug named 5-aminoluvulinic acid, or ALA, which is used in combination with light devices to treat or detect a variety of conditions in processes known as photodynamic therapy or photodetection. Our drug, Levulan(R) 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(R) and follow it with exposure to light to treat a medical condition, it is known as Levulan(R) photodynamic therapy, or Levulan(R) PDT. When we use Levulan(R) and follow it with exposure to light to detect medical conditions it is known as Levulan(R) photodetection, or Levulan(R) PD.

The Company's products, the Levulan(R) Kerastick(R) 20% Topical Solution with PDT and the BLU-U(R) brand light source were launched in the United States of America, or U.S., in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003 we received clearance from the U.S. Food and Drug Administration, or FDA, to market the BLU-U(R) without Levulan(R) PDT 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. All intercompany balances and transactions have been eliminated.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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. 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 money market funds. All other investments are classified as marketable securities. In December 2001, the Company executed a short-term, renewable, irrevocable and unconditional letter of credit in lieu of a security deposit for the Company's Kerastick(R) 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. At December 31, 2005, the amount of the letter of credit was \$136,018, and the restricted cash balance was \$144,541.

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. The premiums and discounts recorded on the purchase of the debt securities are amortized into interest income over the life of the securities. As the Company's marketable securities are available to fund operations 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, all marketable securities are classified as current assets.

F-6

DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

e) INVENTORY - Inventory is stated at the lower of cost (first-in, first-out method) or market. Inventory identified for research and development activities is expensed in the period in which that inventory is designated for such use. BLU-U(R) commercial light sources placed in physicians' offices for an initial evaluation period are included in inventory in the accompanying Consolidated Balance Sheets until all revenue recognition criteria are met.

f) DEFERRED ACQUISITION COSTS - Deferred acquisition costs are direct costs incurred by the Company through December 31, 2005, related to a pending acquisition (see Note 13). If the negotiations are unsuccessful and a determination is made that the acquisition is not likely to be consummated, the deferred acquisition costs will be expensed in the period such a determination is made.

g) 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.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

h) VALUATION 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 or that the useful lives of these assets are no longer appropriate. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. When it is determined that the carrying value of a long-lived asset is not recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis.

i) REVENUE RECOGNITION - Revenues on product sales are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred to end-users, and there is collection is probable. Product sales made through distributors have been recorded as deferred revenue until the product is sold by the distributors to the end user. The Company has certain units held by physicians for a trial period. No revenue is recognized until the physician elects to purchase the equipment and all other revenue recognition criteria are met.

j) RESEARCH AND DEVELOPMENT COSTS - Costs related to the conceptual formulation and design of products and processes are expensed as research and development costs as they are incurred. Purchased technology, including the costs of licensed technology for a particular research project that do not have alternative future uses, are expensed at the time the costs are incurred.

k) 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 trade shows, miscellaneous marketing and outside consultants. All such costs are expensed as incurred.

l) 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.

F-7

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

m) BASIC AND DILUTED NET LOSS PER COMMON SHARE - Basic net 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 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, 2005, 2004,

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

and 2003, stock options and warrants totaling approximately 3,150,000, 3,009,000, and 2,745,000 shares, respectively, have been excluded from the computation of diluted net loss per share.

n) STOCK-BASED COMPENSATION - Statement of Financial Accounting Standard ("SFAS") No. 123, "Accounting for Stock-Based Compensation," as amended, addresses the financial accounting and reporting standards for stock or other equity-based compensation arrangements. The Company 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 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. Under the intrinsic value method, compensation expense, if any, is recognized for the difference between the exercise 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 exercise 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, 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, prior to January 1, 2006 the Company used the intrinsic value method to measure compensation expense associated with grants of stock options to employees. Had the Company used the fair value method to measure compensation, the net loss and net loss per share would have been reported as follows for the years ended December 31:

F-8

DUSA PHARMACEUTICALS, INC.
 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
 DECEMBER 31, 2005, 2004, AND 2003

| | 2005 | 2004 | 2003 |
|---|-----------------|-----------------|-----------------|
| | ----- | ----- | ----- |
| Net loss: as reported | \$ (14,998,709) | \$ (15,628,980) | \$ (14,826,854) |
| | ----- | ----- | ----- |
| Add: stock-based compensation expense included in reported net loss | 19,444 | - | - |
| Deduct: effect on net loss if fair value method had been used | (1,738,275) | (2,275,678) | (3,445,951) |
| | ----- | ----- | ----- |
| Net loss: pro forma | \$ (16,717,540) | \$ (17,904,658) | \$ (18,272,805) |
| | ===== | ===== | ===== |
| Basic and diluted net loss per common share: as reported | \$ (0.89) | \$ (0.96) | \$ (1.06) |
| | ----- | ----- | ----- |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | | | | | | |
|----------------------------|----|--------|----|--------|----|--------|
| Basic and diluted net loss | \$ | (0.99) | \$ | (1.10) | \$ | (1.31) |
| per common share: proforma | | ===== | | ===== | | ===== |

The fair value of the options at the date of grant was estimated using the Black-Scholes model with the following weighted average assumptions for the years ended December 31:

| | 2005 | 2004 | 2003 |
|-------------------------|--------|--------|--------|
| | ----- | ----- | ----- |
| Expected life (years) | 5 | 5 | 5 |
| Risk free interest rate | 3.97% | 3.02% | 3.02% |
| Expected volatility | 72.05% | 76.40% | 80.85% |
| Dividend yield | - | - | - |

Using these assumptions, the weighted-average fair value per option granted during the years ended December 31, 2005, 2004, and 2003, was \$6.71, \$6.34, and \$1.57, respectively.

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123(R), "Share-Based Payment," a revision of SFAS Statement No. 123. The Company adopted SFAS 123(R) effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006 will be required to measure all employee share-based compensation awards using a fair value based method and record share-based compensation expense in its financial statements if the requisite service to earn the award is provided. The above disclosed pro forma results and assumptions used in fiscal years 2005, 2004 and 2003 were based solely on historical volatility of our common stock over the most recent period commensurate with the estimated expected life of our stock options. The adoption of SFAS No. 123(R) will not affect the Company's cash flow, but it will materially increase the Company's net loss and basic and diluted loss per common share. In accordance with SFAS 123R, the Company will recognize the expense attributable to stock awards that are granted or vest in periods ending subsequent to December 31, 2005.

For 2006, total stock-based compensation expense is estimated to be in a range of \$1,500,000 to \$2,500,000. In order to develop the fiscal 2006 stock-based compensation expense estimate, we utilized assumptions including, among other items, projected option grants, volatility measures using a combination of historical and current and historical implied volatility, and expected life estimates for officer and non-officer employee groups. The amount of the 2006 grants, if any, have not yet been determined and could result in a change to the amounts included in the range reflected above. Total unrecognized stock-based compensation expense related to unvested stock options, expected to be recognized over approximately two years, amounted to \$3,300,000 at December 31, 2005, net of forfeitures.

F-9

DUSA PHARMACEUTICALS, INC.
 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
 DECEMBER 31, 2005, 2004, AND 2003

o) COMPREHENSIVE LOSS - The Company has reported comprehensive loss and

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

its components as part of its Consolidated Statements of Shareholders' Equity. Comprehensive loss, apart from net loss, relates to net unrealized gains and losses on marketable securities.

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

During the years ended 2005, 2004 and 2003, the Company derived revenues from the following geographies (as a percentage of product revenues):

| | 2005 | 2004 | 2003 |
|---------------|-------|-------|-------|
| | ---- | ---- | ---- |
| UNITED STATES | 87% | 91% | 100% |
| CANADA | 13% | 9% | - |
| | ---- | ---- | ---- |
| TOTAL | 100% | 100% | 100% |
| | ===== | ===== | ===== |

q) 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.

r) CONCENTRATION OF CREDIT RISK - The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company manages the credit risk associated with its investments in marketable securities by investing in U.S. government securities and investment 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' and provides allowances for potential credit losses, when applicable. Concentrations in the Company's accounts receivable as of December 31, 2005 and 2004 and in the Company's revenues for the years ended December 31, 2005, 2004, and 2003, were as follows:

| | 2005 | | 2004 | | 2003 |
|------------------|-----------------|--------------------------------|-----------------|--------------------------------|-----------------|
| | % OF REVENUE | % OF ACCOUNTS RECEIVABLE | % OF REVENUE | % OF ACCOUNTS RECEIVABLE | % OF REVENUE |
| | ----- | ----- | ----- | ----- | ----- |
| Distributor A | 16% | - | 31% | 27% | 89% |
| Distributor B | - | - | 17% | - | - |
| Distributor C | 13% | 6% | 5% | 34% | - |
| Direct Customers | 71% | 94% | 47% | 39% | 11% |
| | ---- | ---- | ---- | ---- | ---- |
| Total | 100% | 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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.

s) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

F-10

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

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. The Company has adopted this standard beginning the first quarter of 2006 and does not believe the adoption will have a material impact on its results of operations or financial position as such costs have historically been expensed as incurred.

In November 2005, FASB issued FASB Staff Position FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP FAS 115-1"), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP FAS 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP FAS 115-1 is required to be applied to reporting periods beginning after December 15, 2005. We

F-11

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

are required to adopt FSP FAS 115-1 in the first quarter of 2006. We do not expect the adoption of this statement will have a material impact on our results of operations or financial condition.

3) 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, 2005, current yields range from 2.36% to 7.38% and maturity dates range from January 17, 2006 to June 15, 2008.

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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | 2005 | | | |
|--|-------------------|------------------------------|-------------------------------|---------------|
| | AMORTIZED COST | GROSS UNREALIZED GAINS | GROSS UNREALIZED LOSSES | FAIR VALUE |
| United States government debt securities | \$ 19,857,171 | \$ 3,732 | \$ (72,243) | \$ 19,788,660 |
| Investment grade corporate debt securities | 10,818,063 | 15,136 | (42,373) | 10,790,826 |
| Total marketable debt securities available for sale | \$ 30,675,234 | \$ 18,868 | (\$114,616) | \$ 30,579,486 |

| | 2004 | | | |
|--|-------------------|------------------------------|-------------------------------|--------------|
| | AMORTIZED COST | GROSS UNREALIZED GAINS | GROSS UNREALIZED LOSSES | FAIR VALUE |
| United States government debt securities | \$ 27,266,271 | \$ 389,585 | (\$ 15,315) | \$27,640,541 |
| Investment grade corporate debt securities | 18,625,317 | 504 | (43,393) | 18,582,428 |
| Total marketable debt securities available for sale | \$ 45,891,588 | \$ 390,089 | (\$ 58,708) | \$46,222,969 |

The change in net unrealized gains and losses on such securities for the years ended December 31, 2005, 2004 and 2003 was (\$427,129), (\$1,124,309) and (\$1,178,820), respectively, and has been recorded in accumulated other comprehensive income, which is reported as part of shareholders' equity in the Consolidated Balance Sheets. Realized gains on sales of marketable securities were \$75,000 in 2005. There were no realized gains or losses in 2004 or 2003.

F-12

DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

Because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2005.

F-13

DUSA PHARMACEUTICALS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

4) INVENTORY

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Inventory consisted of the following at December 31:

| | 2005 | 2004 |
|---------------------------|--------------|--------------|
| | ----- | ----- |
| Finished goods | \$ 1,004,772 | \$ 1,226,071 |
| BLU-U(R) evaluation units | 292,129 | - |
| Work in process | 60,805 | 85,910 |
| Raw materials | 503,087 | 105,179 |
| | ----- | ----- |
| | \$ 1,860,793 | \$ 1,417,160 |
| | ===== | ===== |

BLU-U(R) commercial light sources placed in physicians' offices pursuant to the Company's BLU-U(R) evaluation program are classified as inventory in the accompanying Consolidated Balance Sheets.

5) RESTRUCTURING CHARGE

During the quarter ended September 30, 2005, the Company eliminated 14 staff positions, representing 16% of the workforce, to align headcount more closely with management's assessment of its resource requirements at that time. These workforce reductions were made across all functions of the Company. As a result of these actions the Company recorded a restructuring charge of approximately \$150,000. As of December 31, 2005, the Company had paid all of its obligations under the restructuring plan.

F-14

DUSA PHARMACEUTICALS, INC.
 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
 DECEMBER 31, 2005, 2004, AND 2003

6) PROPERTY, PLANT AND EQUIPMENT

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

| | USEFUL LIVES (YEARS) | 2005 | 2004 |
|------------------------------------|--|--------------|--------------|
| | ----- | ----- | ----- |
| Computer equipment and software | 3 | \$ 2,389,562 | \$ 2,226,646 |
| BLU-U units in physicians' offices | 3 | - | 700,043 |
| Furniture, fixtures and equipment | 5 | 810,488 | 726,069 |
| Manufacturing facility | Term of lease | 2,204,122 | 2,204,122 |
| Manufacturing equipment | 5 | 2,187,244 | 2,153,485 |
| Leasehold improvements | Lesser of their useful Lives or term of lease | 833,967 | 699,892 |
| | | ----- | ----- |
| | | 8,425,383 | 8,710,257 |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

| | | |
|---|--------------|--------------|
| Accumulated depreciation and amortization | (5,453,514) | (5,228,369) |
| | \$ 2,971,869 | \$ 3,481,888 |
| | ===== | ===== |

Depreciation and amortization totaled \$925,000, \$1,299,000, and \$1,611,000 for 2005, 2004, and 2003, respectively.

7) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following at December 31:

| | 2005 | 2004 |
|-----------------------------------|--------------|--------------|
| | ----- | ----- |
| Research and development costs | \$ 347,220 | \$ 778,926 |
| Marketing and sales costs | 173,092 | 153,167 |
| Product related costs | 667,388 | 261,444 |
| Legal and other professional fees | 488,401 | 374,142 |
| Employee benefits | 225,628 | 229,304 |
| Other expenses | 93,950 | 104,858 |
| | ----- | ----- |
| | \$ 1,995,679 | \$ 1,901,841 |
| | ===== | ===== |

8) INCOME TAXES

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

| | 2005 | 2004 |
|---|------------|------------|
| | ----- | ----- |
| DEFERRED TAX ASSETS | | |
| Deferred revenue | \$ 19,000 | \$ 93,000 |
| Intangible assets | 917,000 | 632,000 |
| Accrued charges | 60,000 | 51,000 |
| Research and development tax credit carryforwards | 2,720,000 | 2,593,000 |
| Capitalized R&D | 3,571,000 | - |
| Operating loss carryforwards | 31,916,000 | 29,463,000 |
| License fee | 141,000 | 161,000 |
| Reserves | - | - |
| | ----- | ----- |

F-15

DUSA PHARMACEUTICALS, INC.
 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
 DECEMBER 31, 2005, 2004, AND 2003

| | | |
|---------------------------|------------|------------|
| | 102,000 | |
| | ----- | |
| Total deferred tax assets | 39,446,000 | 32,993,000 |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

DEFERRED TAX LIABILITIES

| | | |
|--|--------------|--------------|
| Fixed assets | (8,000) | (8,000) |
| Total deferred tax liabilities | (8,000) | (8,000) |
| Net deferred tax assets before allowance | 39,438,000 | 32,985,000 |
| Valuation allowance | (39,438,000) | (32,985,000) |
| Total | \$ - | \$ - |

During the years ended December 31, 2005, 2004, and 2003, the valuation allowance was increased by approximately \$6,453,000, \$5,503,000, and \$5,022,000, respectively, due to the uncertainty of future realization of the net deferred tax assets which were increasing.

Included in deferred tax assets at December 31, 2005 and 2004 is \$1,817,000 and \$1,600,000 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, 2005, the Company has Federal net operating loss carryforwards for tax purposes of approximately \$79,261,000 and research and development tax credits of approximately \$2,521,000, both of which, if not utilized, will expire for Federal tax purposes as follows:

| | OPERATING LOSS CARRYFORWARDS | RESEARCH AND DEVELOPMENT TAX CREDITS |
|------|---------------------------------|--|
| | ----- | ----- |
| 2010 | \$ 2,325,000 | \$ - |
| 2011 | 6,638,000 | 7,000 |
| 2012 | 6,841,000 | 57,000 |
| 2013 | - | 66,000 |
| 2014 | - | 84,000 |
| 2015 | - | 44,000 |
| 2016 | - | 102,000 |
| 2017 | - | 235,000 |
| 2018 | 5,738,000 | 145,000 |
| 2019 | - | 81,000 |
| 2020 | - | 159,000 |
| 2021 | 1,772,000 | 343,000 |
| 2022 | 15,382,000 | 477,000 |
| 2023 | 12,716,000 | 232,000 |
| 2024 | 9,913,000 | 282,000 |
| 2025 | 17,936,000 | 207,000 |
| | ----- | ----- |
| | \$ 79,261,000 | \$ 2,521,000 |
| | ===== | ===== |

The tax loss carryforwards of the Company and its subsidiaries may be subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. The amount of the limitation, if any, has not been quantified by the Company.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

F-16

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

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

| | 2005 | | 2004 | |
|---|---------------|--------|---------------|--------|
| | | % | | % |
| Income tax benefit at statutory rate | (\$5,100,000) | (34.0) | (\$5,314,000) | (34.0) |
| State taxes | (939,000) | (6.3) | (979,000) | (6.3) |
| Tax credit carryforwards | (234,000) | (1.6) | (435,000) | (2.8) |
| Change in valuation allowance including revisions of prior year estimates | 6,233,000 | 41.6 | 6,676,000 | 42.7 |
| Other | 40,000 | 0.3 | 52,000 | 0.4 |
| | ----- | ---- | ----- | ---- |
| | \$ - | - | \$ - | - |
| | ===== | ==== | ===== | ==== |

9) SHAREHOLDERS' EQUITY

COMMON STOCK ISSUANCES -

In March 2005, the vesting period for 18,875 options to purchase shares of common stock was extended beyond the original terms and the vesting of 1,250 options was accelerated upon an employee's termination. As a result of this stock option modification, the Company recorded compensation expense of approximately \$19,000 during 2005. The compensation expense was calculated using the intrinsic value method, which compares the common stock option exercise price to the fair market value of the underlying common stock on the date of modification. The stock compensation expense was recorded as part of general and administrative costs in the Consolidated Statement of Operations.

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 Consolidated Statement of Operations. On December 30, 2004 the Company repurchased these options for

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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. The transaction was recorded in research and development expense in the Consolidated Statements of Operations.

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

F-17

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

On March 13, 2003, the Company issued 23,219 shares of restricted common stock at the grant date fair value 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.

10) 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 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

outstanding at December 31, 2005:

| RANGE OF EXERCISE PRICE | OPTIONS OUTSTANDING | | | OPTIONS EXERCISABLE | |
|-------------------------|--|---|--|--|--|
| | NUMBER OUTSTANDING AT DECEMBER 31, 2005 | WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE | WEIGHTED AVERAGE EXERCISE PRICE | NUMBER EXERCISABLE AT DECEMBER 31, 2005 | WEIGHTED AVERAGE EXERCISE PRICE |
| \$1.60 to 5.10 | 461,625 | 6.85 years | \$ 2.86 | 303,625 | \$ 2.96 |
| 5.11 to 7.75 | 503,750 | 1.15 years | 7.41 | 503,750 | 7.41 |
| 7.76 to 9.92 | 681,125 | 6.39 years | 9.55 | 445,939 | 9.42 |
| 9.93 to 27.31 | 899,750 | 6.60 years | 14.22 | 456,000 | 17.15 |
| 31.00 to 31.00 | 304,000 | 4.18 years | 31.00 | 304,000 | 31.00 |
| | 2,850,250 | 5.37 years | \$ 11.85 | 2,013,314 | \$ 12.95 |
| | ===== | | | ===== | |

F-18

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

Activity under stock option plans during the years ended December
31, 2005, 2004 and 2003 was as follows:

| | 2005 | WEIGHTED AVERAGE EXERCISE PRICE | 2004 | WEIGHTED AVERAGE EXERCISE PRICE | 2003 |
|--|-----------|--|-----------|--|-----------|
| Options outstanding, beginning of year | 2,708,750 | \$ 11.62 | 2,444,950 | \$ 11.50 | 2,253,070 |
| Options granted | 598,750 | 11.00 | 512,250 | 9.97 | 447,000 |
| Options exercised | (164,375) | 5.65 | (167,825) | 4.50 | (11,000) |
| Options cancelled | (292,875) | 11.46 | (80,625) | 12.28 | (244,125) |
| Options outstanding, end of year | 2,850,250 | \$ 11.85 | 2,708,750 | \$ 11.62 | 2,444,950 |
| Options exercisable, end of year | 2,013,314 | \$ 12.95 | 1,924,625 | \$ 13.46 | 1,771,320 |
| | ===== | ===== | ===== | ===== | ===== |

Options that were granted during 2005, 2004 and 2003 have exercise prices ranging from \$9.04 to \$15.90 per share, \$9.05 to \$12.87 per share, and \$1.60 to \$5.20 per share, respectively.

Options which were exercised during 2005, 2004 and 2003 were exercised at per share prices ranging from \$1.60 to \$9.92, \$1.60 to \$7.44, and \$2.90 to \$3.87, respectively.

b) WARRANTS - On January, 17, 2002, the Company extended the term of 300,000 warrants, which were previously issued to the Chief Executive

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Officer of the Company, from January 29, 2002 to January 29, 2007. The warrants are convertible on a one-for-one basis into Shares of Common Stock. 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, 2005, all of these warrants were outstanding. The exercise price of the warrants is CDN \$6.79 (U.S. \$5.82 at December 31, 2005).

11) 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 2005, 2004 and 2003 were \$42,000, \$39,000 and \$33,000, respectively.

12) COMMITMENTS AND CONTINGENCIES

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

F-19

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

When the Company is selling its products directly, it has agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where the Company has a sublicensee, it will pay 6% and 4% when patent rights do and do not exist, respectively, on its net selling price less the cost of goods for products sold to the sublicensee, and 6% of payments the Company receives on sales of products by the sublicensee.

For the years ended December 31, 2005, 2004 and 2003, actual royalties based on product sales were approximately \$340,000, \$229,000, and \$36,000, respectively. However, based on the annual minimum royalty requirements, the Company incurred total royalty expense of \$74,000 in 2003, 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. \$86,000 as of December 31, 2005).

The Company is also obligated to pay to PARTEQ 5% of any lump sum sublicense fees received, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts. No amounts have been paid to PARTEQ as a result of sublicense fees received.

b) DRAXIS TERMINATION AND TRANSFER AGREEMENT - On February 24, 2004, the Company reacquired the rights to the aminolevulinic acid (Levulan(R))

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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(R) Kerastick(R) in Canada over a five year term commencing in June 2004 based on the first Kerastick(R) 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, 2005, the remaining unamortized balance of \$78,000 is included in deferred charges and other assets. The Company incurred total royalty expense of \$116,000 and \$56,000 in 2005 and 2004, respectively, 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 are as follows:

| | MINIMUM LEASE PAYMENTS |
|-------------|---------------------------|
| | ----- |
| 2006 | \$ 470,000 |
| 2007 | 469,000 |
| 2008 | 418,000 |
| 2009 | 432,000 |
| 2010 | 448,000 |
| Beyond 2010 | 722,000 |
| | ----- |
| | \$ 2,959,000 |
| | ===== |

Rent expense incurred under these operating leases was approximately \$477,000, \$472,000, and \$471,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

d) RESEARCH AGREEMENTS - The Company has entered into various agreements for research projects and clinical studies. As of December 31, 2005, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$1,775,000 for 2006. Included in this future payment is a master service agreement, effective June 15, 2001, with

F-20

DUSA PHARMACEUTICALS, INC.
 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
 DECEMBER 31, 2005, 2004, AND 2003

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, 2005 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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 - 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. On April 6, 2005, the Federal Court of Australia ruled that the patent is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product does not infringe the claims in the Australian patent. Since these claims are unique to the Australian patent and Australian law differs from patent law in other jurisdictions, we do not expect that this decision is determinative of the validity of any other patents licensed by us from Queen's University or of whether PhotoCure's product infringes claims in such other patents, including the United States patent. None of the parties have appealed the decision and the date to do so has expired. The parties, including PhotoCure's marketing partner, Galderma S.A., signed a Mediation Agreement in August 2004 to attempt to settle their disputes and negotiations 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. On March 17, 2005, New England Compounding Pharmacy filed an answer against us, including a defense that our patents are invalid and several counterclaims against us, and we filed our response on April 5, 2005. The parties are now in the discovery stage of this litigation. A tentative trial date has been set by the court for January 2007. We are seeking injunctive relief, monetary damages and costs.

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. A motion for default judgment was granted on July 25, 2005 in our favor for failure of The Cosmetic Pharmacy of Tucson to appear, together with injunctive relief and attorney fees and costs in the amount of \$20,668.

In November, 2005 and January, 2006 we filed lawsuits against physicians in several states to prevent their continued use of versions of our Levulan (R) brand of aminolevulinic acid HCl (ALA) produced, by third-parties for use in our patented photodynamic therapy (PDT) treatment for actinic keratosis, basal cell carcinoma, acne and other dermatological conditions. The suits allege that ALA obtained from sources other than DUSA is being used by physicians for patient treatments that are covered under patents exclusively licensed by DUSA, resulting in direct infringement of these patent(s). Additionally, some doctors are also being sued for misuse of DUSA's trademarks and for violations of the Lanham Act for using the Levulan (R) brand name on their web sites and promotional materials, but performing patient treatments with ALA obtained from other sources. Most of the physicians have entered Consent Judgments in which

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED
DECEMBER 31, 2005, 2004, AND 2003

they admit the infringement and provide DUSA with the right to review their books and records. Two lawsuits are currently on-going.

The Company has not accrued any amounts for these contingencies as of December 31, 2005, as these amounts are neither probable nor estimable.

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. 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-U(R) 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.

13) PENDING TRANSACTION

In December, 2005, we signed a definitive Merger Agreement to acquire all of the common stock of Sirius Laboratories Inc. of Vernon Hills, Illinois in exchange for cash and common stock worth up to \$30,000,000. Sirius is a privately held dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Closing of the transaction is expected in the first quarter of 2006, subject to the terms and conditions in the Merger Agreement. Of the potential \$30,000,000 consideration, \$8,000,000 less certain expenses will be paid in cash upon closing, \$17,000,000 will be paid in shares of DUSA's common stock also upon closing in a private placement, and up to \$5,000,000 in cash or common stock may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. The amount of DUSA common stock to be issued in the merger agreement will depend upon the average trading price of DUSA's common stock during a 20 trading-day period just prior to the closing.

Included in the accompanying Consolidated Balance Sheets as of December 31, 2005 are deferred acquisition costs of approximately \$830,000

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

related to the Sirius acquisition. If the negotiations are unsuccessful and a determination is made that the acquisition is not likely to close, the deferred acquisition costs will be expensed in the period such a determination is made.

F-22

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 of the Board and Chief Executive Officer

Date: March 10, 2006

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

| | | |
|---|---|----------------|
| /s/ D. Geoffrey Shulman ----- D. Geoffrey Shulman, MD, FRCPC | Director, Chairman of the Board and Chief Executive Officer (principal executive officer) | March 10, 2006 |
| /s/ Robert F. Doman ----- Robert F. Doman | President, Chief Operating Officer | March 10, 2006 |
| /s/ Richard C. Christopher ----- Richard C. Christopher | Vice President, Finance and Chief Financial Officer (principal financial officer and principal accounting officer) | March 10, 2006 |
| /s/ John H. Abeles ----- John H. Abeles | Director | March 10, 2006 |
| /s/ David Bartash ----- David Bartash | Director | March 10, 2006 |
| /s/ Jay M. Haft ----- Jay M. Haft, Esq. | Vice Chairman of the Board and Lead Director | March 10, 2006 |
| /s/ Richard C. Lufkin ----- Richard C. Lufkin | Director | March 10, 2006 |
| /s/ Magnus Moliteus ----- Magnus Moliteus | Director | March 10, 2006 |

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

EXHIBIT INDEX

- 2(a.1)* Merger Agreement by and among the Company, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005; and
- 2(a.2) First Amendment to Merger Agreement by and among the Company, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006.
- 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

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

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 herein 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;

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- 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(j.3) Third Amendment to Supply Agreement between the Company and Sochinaz SA dated July 29, 2005, filed as Exhibit 10.1 to the Registrant's Form 10-Q filed on August 3, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(k) 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) 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(m) 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(n) 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(o) 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(p) 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(q) License, Promotion, Distribution and Supply Agreement between the Company and Coherent-AMT dated as of March 31, 2004 filed as Exhibit

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

- 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(r) Employment Agreement of Scott L. Lundahl dated as of June 23, 1999 filed as Exhibit 10(u) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(s) Amended Employment Agreement of Stuart L. Marcus, MD, PhD dated December 9, 1999 filed as Exhibit 10(v) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(t) Employment Agreement of Mark C. Carota dated as of February 14, 2000 filed as Exhibit 10(w.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(t.1) First Amendment to Employment Agreement of Mark C. Carota dated October 31, 2001 filed as Exhibit 10(w.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(u) Employment Agreement of Paul A. Sowyrda dated as of July 31, 2001 filed as Exhibit 10(x) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(v) Employment Agreement of Richard Christopher dated as of January 1, 2004 filed as Exhibit 10(y) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(w) Employment Agreement of Robert F. Doman dated as of March 15, 2005 filed as Exhibit 10(z) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(x) Employment Agreement of Gary F. Talarico dated as of February 15, 2005 filed as Exhibit 10(aa) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y) Severance Agreement and General Release between the Company and Peter Chakoutis dated as of February 25, 2005 filed as Exhibit 10(bb) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y.1) Final Agreement and General Release, between the Company and Peter Chakoutis, dated as of April 4, 2005, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 4, 2005, and is incorporated herein by reference; +
- 10(z) Compensation Policy Applicable to the Company's Non-Employee Directors filed as Exhibit 10(cc) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; and +
- 10(aa) Marketing, Distribution and Supply Agreement between the Company and Stiefel Laboratories, Inc., dated as of January 12, 2006, 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.
- 14(a) Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers filed as Exhibit 14(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

reference.

- 21(a) Subsidiaries of the 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.

* Schedules and exhibits omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Commission upon request.