

DUSA PHARMACEUTICALS INC

Form 10-K

March 11, 2008

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549  
FORM 10-K**

(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, 2007**

**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 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 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

**Large Accelerated Filer**

**Accelerated Filer**

**Non-accelerated Filer**

**Smaller reporting company**

**(Do not check if a smaller reporting company)**

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

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As of March 7, 2008, the registrant had 24,078,610 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, 2007 (\$3.08) (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 \$59,400,000.

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, 2007 are incorporated by reference into Part III of this report.	Items 10, 11, 12, 13 and 14

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**PART I**

This Annual Report on Form 10-K and certain written and oral statements incorporated herein by reference of DUSA Pharmaceuticals, Inc. and subsidiaries (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 41, as well as those noted in the documents incorporated herein by reference. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. However, readers should carefully review the statements set forth in other reports or documents we file from time to time with the Securities and Exchange Commission, particularly the Quarterly Reports on Form 10-Q and any Current Reports on Form 8-K.

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**ITEM 1. BUSINESS**

**General**

DUSA is a vertically integrated dermatology company that is developing and marketing Levulan PDT and other products for common skin conditions. Our currently marketed products include among others Levulan® Kerastick® 20% Topical Solution with photodynamic therapy, the BLU-U® brand light source, certain products acquired in the March 10, 2006 merger with Sirius Laboratories, Inc., including, Nicomide®, Nicomide-T®, and the newly launched product, ClindaReach .

Historically, we devoted most of our resources to advancing the development and marketing of our Levulan® PDT/PD technology platform. In addition to our marketed products, our drug, Levulan® brand of aminolevulinic acid HCl, or ALA, in combination with light, has been studied in a broad range of medical conditions. When Levulan® is used and followed with exposure to light to treat a medical condition, it is known as Levulan® PDT. When Levulan® is used and followed with exposure to light to detect medical conditions, it is known as Levulan® photodetection, or Levulan® PD. Our Kerastick® is the proprietary applicator that delivers Levulan®.

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® brand light source were launched in the United States, or U.S., in September 2000 for the treatment of non-hyperkeratotic 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® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

Sirius Laboratories, Inc., or Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Nicomide®, its key product, is an oral prescription vitamin supplement which targets the market for inflammatory skin conditions such as acne. The merger has allowed us to expand our product portfolio, capitalize on cross-selling and marketing opportunities, increase our sales force size, as well as provide us with the opportunity to launch ClindaReach in March 2007.

We are responsible for manufacturing of our Levulan® Kerastick® and for the regulatory, sales, marketing, and customer service of our Levulan® Kerastick®, and other related activities for all of our products. Our current objectives include increasing the sales of our products in the United States, Canada, Latin America, and Korea, launching Levulan® with our partners in Brazil and other Latin American countries and Asia, continuing our efforts of exploring partnership opportunities for Levulan® PDT for dermatology in Europe and Japan, and continuing our Levulan® PDT clinical development program for the moderate to severe acne indication.

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® Kerastick® in Mexico, Central and South America. We have been actively working with Stiefel to obtain acceptable final pricing from the Brazilian regulatory authorities. In light of the unexpected delay in receiving acceptable final pricing in Brazil, in 2007 we amended certain terms of the original Stiefel agreement to reflect our plans to launch in other Latin American countries prior to Brazil. The product was launched in Argentina, Chile, Colombia and Mexico during the fourth quarter of 2007. On March 5, 2008 Stiefel notified us that the Brazilian

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authorities had published the final pricing for the product which is acceptable to Stiefel and to us. We expect Stiefel to launch the product in Brazil shortly. Similarly, in January 2007, we entered into a marketing and distribution agreement with Daewoong Pharmaceutical Co., Ltd. and Daewoong's wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, together referred to as Daewoong, granting Daewoong exclusive rights to distribute the Levulan<sup>®</sup> Kerastick<sup>®</sup> in certain Asian countries. Subsequent to September 30, 2007 the Korean Food and Drug Administration, or KFDA, approved Levulan<sup>®</sup> Kerastick<sup>®</sup> for PDT for the treatment of actinic keratosis. Daewoong launched our product in Korea during the fourth quarter of 2007.

We are developing Levulan<sup>®</sup> PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA<sup>®</sup>, DUSA Pharmaceuticals, Inc.<sup>®</sup>, Levulan<sup>®</sup>, Kerastick<sup>®</sup>, BLU-U<sup>®</sup> Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup>, Meted<sup>®</sup>, Psoriacap<sup>®</sup> and Psoriatec<sup>®</sup> 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.

As of December 31, 2007, we had an accumulated deficit of approximately \$135,600,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis. We expect to continue to incur operating losses until sales of our products increase substantially. We recorded a significant impairment charge of goodwill during the fourth quarter of 2007. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our PDT therapy by the medical and consumer constituencies, increased sales of our products and other factors contained in this report and in the filings we make with the Securities and Exchange Commission, or SEC.

On October 29, 2007, we entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement with several investors for the private placement of 4,581,043 shares of our common stock at a purchase price of \$2.40 per share which resulted in gross proceeds to us of \$11,000,000, and warrants to purchase an additional 1,145,259 shares of common stock. The warrants become exercisable on April 30, 2008, have a term of five years from the initial exercise date, and have an exercise price of \$2.85 per share. On November 26, 2007, we registered the shares of common stock issued in the transaction and the shares underlying the warrants with the Securities and Exchange Commission for resale on a registration statement on Form S-3. On January 22, 2008, we filed an amended registration statement on Form S-3/A. This registration statement was declared effective by the Securities and Exchange Commission on January 24, 2008.

Unless the context otherwise requires, the terms we, our, us, the Company and DUSA refer to DUSA Pharmaceuticals, Inc., a New Jersey corporation.

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) (web address: www.dusapharma.com). On February 29, 1994, we formed DUSA Pharmaceuticals New York, Inc., a wholly owned subsidiary located in Valhalla, New York, to coordinate our research and development efforts. DUSA Acquisition Corp., now known as Sirius Laboratories, Inc., also a wholly-owned subsidiary of DUSA, was formed on January 26, 2006, in connection with the Sirius merger. We have financed our operations to date,

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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, or the Act, including private placements under Regulation D of the Act, and from payments received from marketing collaborators. See the sections entitled Management's Discussion and Analysis of Financial Condition Overview; Results of Operations; and Liquidity and Capital Resources .

**Business Strategy**

The key elements of our strategy include the following:

*Expand the Marketing and Sales of our Products.* Continue to drive PDT growth, domestically through a concerted focus on medical dermatology practices, and internationally through leveraging our partnerships with Stiefel Laboratories and Daewoong. Increase our Non-PDT revenues through regaining Nicomide® market share following our settlement with River's Edge, and establishing and growing the market for our new product, ClindaReach™.

*Leverage our Levulan® PDT/PD Platform to Develop Additional Products.* During 2007, we began enrollment of our Phase IIb multi-center clinical trials in the United States using Levulan® PDT in the treatment of moderate to severe inflammatory acne. If we are able to obtain FDA approval, there may be significant additional market opportunities for Levulan® and the BLU-U®. We are also actively marketing the BLU-U® without Levulan®, to treat moderate inflammatory acne vulgaris, which supports a multi-use capability of our BLU-U®, in addition to its use in our approved AK therapy.

*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 exploring opportunities to develop, market, and distribute our Levulan® PDT platform in Europe and Japan following our completed distribution agreements with Stiefel Laboratories, Inc. for Latin America, and Daewoong for certain Asian countries. We are also continuing to seek to acquire and/or license additional dermatology products that complement our current products, and that would provide our sales force with additional synergistic products to sell in the near term.

*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.

*Enhance Physician Education Support.* We support 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.

*Use the Results of Independent Researchers to Identify New Applications.* We continue to work closely with and support research by independent



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investigators so that we have the benefit of the resulting anecdotal human data for use in evaluating potential Levulan® indications for corporate development. We also continue to monitor independent research in order to identify other potential new indications

### **PDT/PD Overview**

In general, both photodynamic therapy, or PDT, and photodetection, or PD, are two-step processes:

The first step is the application of a drug known as a photosensitizer, or a pre-cursor of this type of drug, which tends to collect in specific cells.

The second step is activation of the photosensitizer by controlled exposure to a selective light source in the presence of oxygen.

During this process, energy from the light activates the photosensitizer. In PDT, the activated photosensitizer transfers energy to oxygen molecules found in cells, converting the oxygen into a highly energized form known as singlet oxygen, which destroys or alters the sensitized cells. In PD, the activated photosensitizer emits energy in the form of light, making the sensitized cells fluoresce, or glow .

The longer the wavelength of visible light, the deeper into tissue it penetrates. Different wavelengths, or colors of light, including red and blue light, may be used to activate photosensitizers. The selection of the appropriate color of light for a given indication is primarily based on two criteria:

the desired depth of penetration of the light into the target tissue, and

the efficiency of the light in activating the photosensitizer.

Blue light does not penetrate deeply into tissues, so it is generally better suited for treating superficial lesions. However, it is also a potent activator of some photosensitizers, including ours. Red light penetrates more deeply into tissues, and is therefore generally better suited for treating cancers and deeper tissues. However, it is generally not as strong an activator of photosensitizers, including ours. Different photosensitizers do not absorb all wavelengths (colors) of visible light in the same manner. For any given photosensitizer, some colors are more strongly absorbed than others.

Another consideration in selecting a light source is the location of the target tissue. Lesions on the skin which are easily accessible can be treated with either laser or non-laser light sources. Internal indications, which are often more difficult to access, usually require lasers in order to focus light into small fiber optic delivery systems that can be passed through an endoscope or into hollow organs.

PDT can be a highly selective treatment that targets specific tissues while minimizing damage to normal surrounding tissues. It also can allow for multiple courses of therapy. The most common side effect of photosensitizers that are 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.

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### **Our Levulan® PDT/PD Platform**

#### **Our Levulan® Brand of ALA**

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

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

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

*Small Molecule.* Levulan® is a small molecule that is easily absorbed whether delivered topically, orally, or intravenously.

*Highly Selective.* Levulan® is not itself a photosensitizer, but is a pro-drug that is converted through a cell-based process into the photosensitizer PpIX. The combination of topical application, tissue specific uptake, conversion into PpIX and targeted light delivery make this a highly selective process. Therefore, under appropriate conditions, we can achieve selective clinical effects in targeted tissues with minimal effects in normal surrounding and underlying tissues.

*Controlled Activation.* Levulan® has no PDT effect without exposure to light at specific wavelengths, so the therapy is easily controlled.

Scientists believe that the accumulation of PpIX following the application of Levulan® is more pronounced in: rapidly growing diseased tissues, such as precancerous and cancerous lesions,

conditions characterized by rapidly proliferating cells such as those found in psoriasis and certain microbes, and

in certain normally fast-growing tissues, such as hair follicles, sebaceous glands, esophageal mucosa and the lining of the uterus.

#### **Our Kerastick® Brand Applicator**

We designed our proprietary Kerastick® specifically for use with Levulan® and sometimes refer to it as the Levulan® Kerastick®. It is a single-use, disposable applicator, which allows for the rapid preparation and uniform application of Levulan® topical solution in standardized doses. The Kerastick® has two separate glass ampoules, one containing Levulan® powder and one containing a liquid vehicle, both enclosed within a single plastic tube and an outer cardboard sleeve. There is a filter and a metered dosing tip at one end. Prior to application,

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the doctor or nurse crushes the ampoules and shakes the Kerastick® according to directions to mix the contents into a solution. The Kerastick® tip is then dabbed onto the individual AK lesions, releasing a predetermined amount of Levulan® 20% topical solution.

### **Our Light Sources**

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

are compact and tailored to fit specific medical needs,

are pre-programmed and easy to use, and

provide cost-effective therapy.

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

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

safer,

simpler to use,

more reliable, and

far less expensive.

For treatment of AKs, our BLU-U® 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® without Levulan® for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions and we are using the BLU-U in our Phase IIb Levulan PDT study of moderate to severe acne. We are also evaluating whether to develop and/or license additional light devices for use with Levulan®.

### **Our Products**

The following table outlines the development status of our products and planned product candidates. Our product sales for the last three years were \$27,663,000 in 2007, \$25,583,000 in 2006, and \$11,337,000 in 2005. Our research and development expenses for the last three years were \$5,977,000 in 2007, \$6,214,000 in 2006, and \$5,588,000 in 2005.

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Indication/Product	Regulatory status
<b>Dermatology</b>	
Levulan® Kerastick® and BLU-U® for PDT of AKs	Approved
BLU-U® Treatment of Moderate Inflammatory Acne Vulgaris and general dermatological conditions Without Levulan®	Market Clearance (1)
Levulan® PDT for Moderate to Severe Acne Vulgaris	Phase II (2)
Nicomide®, Nicomide-T®, and Psoriatec®	Marketed Unapproved Drugs
ClindaReach	sANDA (3)
Meted® Shampoo	OTC
Nicomide-T®	Cosmetic
Psoriacap®	Dietary Supplement
AVAR® products	Marketed Unapproved Drugs (4)
<b>Other Indications</b>	
Levulan® Oral Cavity Dysplasia	Phase I/II (5)
<ol style="list-style-type: none"> <li>1 In September 2003, the FDA provided market clearance</li> <li>2 Phase II clinical trial results were released in the first quarter of 2006. A new Phase II studies was initiated in the first quarter of 2007.</li> <li>3 sANDA owned by L. Perrigo Company.</li> <li>4 AVAR products were licensed to River s Edge as part of the settlement of our litigation.</li> <li>5 Phase I/II clinical trial planned to be initiated with the NCI DCP in the first quarter</li> </ol>	

of 2008.

### **Dermatology Indications**

Our current Levulan<sup>®</sup> research and development efforts focus on supporting our approved AK product and a Phase IIb clinical program examining the safety and efficacy of Levulan<sup>®</sup> PDT for the treatment of moderate to severe acne vulgaris which, if successfully developed through FDA approval, could lead to an additional dermatological indication and significant market opportunities. The results of our initial Phase II trials examining acne and facial photodamage were announced in early 2006 and indicated that more work was required before advancing to Phase III trials. Initiation of the Phase IIb trial on acne started in February 2007. Due to strategic and financial considerations, we have decided not to continue to advance development of the photodamage indication at this time. DUSA also continues to support a wide range of independent investigator studies using the Levulan<sup>®</sup> Kerastick<sup>®</sup> to explore the potential for additional new indications for future development. Following the completion of the Sirius merger, we continued two development efforts for products aimed at the acne and rosacea markets. The first of these pipeline products, ClindaReach was launched in March 2007. During the fourth quarter of 2007, the Company decided that it would not pursue the second, as well as a third potential new product related to the Sirius merger. In such circumstances, the merger agreement obligates us to pay \$250,000 in lieu of a \$500,000 milestone. The first of the two \$250,000 payments was made in December 2007 and the second was made in January 2008, which together relieved us of all of our obligations with respect to such milestones. See the section below entitled Business Licenses; Altana, Inc.

#### *Actinic Keratoses.*

AKs are superficial precancerous skin lesions usually appearing in sun-exposed areas as rough, scaly patches of skin with some underlying redness. The traditional methods of treating

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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<sup>®</sup> 20% topical solution using the Kerastick<sup>®</sup> to individual AK lesions, followed 14 to 18 hours later with exposure to our BLU-U<sup>®</sup> for approximately 17 minutes. In our Phase III trials, using this overnight drug application, our treatment produced varying degrees of pain during light treatment, but the therapy was generally well tolerated. The resulting redness and/or inflammation generally resolved within days without any change in pigmentation.

*Acne and Rosacea.*

Acne is a common skin condition caused in part 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<sup>®1</sup> 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 including increased antibiotic resistance. Blue light alone has been shown to improve mild to moderate inflammatory acne, in part by targeting the bacterium *Propionibacterium acnes* (*P. acnes*), which accumulates its own photosensitizer much like that produced by Levulan<sup>®</sup> in the skin, and possibly by other anti-inflammatory actions. With Levulan<sup>®</sup> PDT therapy for moderate to severe acne vulgaris an independent investigator study using Levulan<sup>®</sup> Kerastick<sup>®</sup> under occlusion for 3 hours followed by red light (Hongcharu et al, 2000) reported that Levulan<sup>®</sup> can be taken up by the sebaceous glands, decrease their activity and result in long-term clearance of acne.

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

We are currently conducting a Phase IIb study examining the use of Levulan<sup>®</sup> PDT for the treatment of moderate to severe acne. We currently expect results from this study by the end of 2008, depending upon how quickly we complete enrollment of patients. We have received comments on our acne development program from the FDA statistical reviewer assigned to our investigational new drug application, or IND. In this letter, the reviewer stated concern about whether we will have sufficient data to select an appropriate dosing regimen for Phase III trials. We believe that we have the data to indicate that sufficient drug dose ranging has been done;

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

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however, if the FDA does not accept our rationale, additional clinical trials and/or formulation development work may be required for the acne development program, which may extend the expected development time lines for such program.

Nicomide<sup>®</sup>, which we acquired in the Sirius merger, is an anti-inflammatory being marketed for patients with acne and acne rosacea. Acne rosacea is a condition that primarily affects the skin of the face and typically first appears between the ages of 30 and 60 as a transient flushing or blushing on the nose, cheeks, chin or forehead, progressing in many patients to a papulopustular form clinically similar to acne vulgaris (inflammatory acne). Given its resemblance to inflammatory acne, and the general public's limited knowledge of rosacea, the condition is frequently mistaken by patients as adult acne. If untreated, rosacea has the tendency to worsen over time, although it can also wax and wane.

### **Other Potential Levulan<sup>®</sup> Indications**

We are currently planning to initiate, in 2008, a DUSA-sponsored clinical trial, which we expect will include 30 to 40 patients, for the chemoprevention of squamous cell carcinoma in immunosuppressed solid organ transplant patients who are at risk of developing multiple skin cancers annually. A protocol outline has been prepared and reviewed, and we are expecting to file an Orphan Drug Designation Application during the first quarter of 2008.

We believe that there are numerous other potential uses for Levulan<sup>®</sup> 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<sup>®</sup> 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 are supporting investigator-sponsored studies for hidradenitis suppurativa, acne vulgaris, non-melanoma skin cancer, and inflammatory acne. Other potential indications that we could pursue are facial photodamaged skin, Barrett's Esophagus dysplasia and brain cancer.

### **Internal Indications**

#### *Oral Cavity Dysplasia.*

We have entered into a clinical trial agreement with the NCI DCP for the clinical development of Levulan<sup>®</sup> 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. The NCI DCP finalized a clinical protocol and submitted its IND to the FDA before the end of 2006. An IND was approved, and the NCI DCP has notified us that the clinical protocol is currently scheduled to be initiated and to begin accruing patients in the first quarter of 2008. DUSA is providing Levulan, lasers, and training in PDT.

### **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<sup>®</sup>. We agreed to order from NBC all of our supply needs of these light sources for the

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United States and Canada, and NBC agreed to supply us with the quantities we ordered. On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with NBC, which provides for the elimination of certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, grants DUSA an exclusive irrevocable worldwide and fully-paid up license to manufacture, or have the BLU-U® manufactured by any third party subcontractor, and other modifications which provide both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. The agreement maintains the original term, which will expire in November 2008, subject to earlier termination for breach or insolvency or for convenience. However, a termination for convenience requires 12 months prior written notice.

*Sochinaz SA.*

Under an agreement dated December 24, 1993, Sochinaz SA manufactures and supplies our requirements of Levulan® from its FDA approved facility in Switzerland. The agreement expires on December 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.

*Actavis Totowa, LLC.*

Under an agreement dated May 18, 2001, and amended on February 8, 2006, Sirius entered into an arrangement for the supply of Nicomide® with Amide Pharmaceuticals, Inc., now Actavis Totowa, LLC. Currently, Actavis Totowa supplies all of our requirements of Nicomide®; however, we have the right to use a second source for a significant portion of our needs if we choose to do so. The agreement expires on February 8, 2009. The agreement was assigned to us as part of the Sirius merger. Actavis Totowa has received several warning letters from the FDA regarding certain regulatory observations including certain comments about Nicomide relating to the compliance policy entitled,

Marketed New Drugs without Approved NDAs or ANDAs. The FDA may take further action against Actavis Totowa and DUSA is evaluating its options in case of such action occurring. See also the section entitled Business Marketing and Sales.

*L. Perrigo Company.*

On October 25, 2005, Sirius entered into a supply agreement with L. Perrigo Company for the exclusive manufacture and supply of the ClindaReach proprietary device/drug kit designed by Sirius pursuant to an approved ANDA owned by Perrigo. The agreement was assigned to us as part of the Sirius merger. Perrigo is entitled to royalties on net sales of the product, including certain minimum royalties which began on May 1, 2006. The initial term of the agreement expires in July 2011 and may be renewed based on certain minimum purchase levels and other terms and conditions. Minimum royalties to Perrigo are \$250,000 per year.

*Medac/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, and a supply agreement with medac discussed below. These agreements provided for the licensing to DUSA of photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. Since we did not believe that the results from medac's European Phase III clinical study would be acceptable to the FDA and we do not intend to conduct additional clinical trials in the brain cancer field, on August 7, 2007 we terminated the license and development agreement with photonamic and the supply agreement with medac. We mutually terminated these agreements, without penalty, relinquishing our rights to the technology for fluorescent-guided resection of brain cancer. However, certain provisions of



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these agreements survive the termination. We entered a new license and supply agreement as of August 7, 2007 among photonamic, medac and us confirming our rights to use certain pre-clinical data and licensed technology on a non-exclusive basis outside of this field, in the U.S., and other territories and providing for a supply of medac's oral and intravenous formulation of ALA on terms to be mutually agreed upon. The term of the agreement is five years, subject to rights to earlier termination and automatic renewals. No additional royalties or payments for the license are due to photonamic.

**Licenses***PARTEQ*

We license (or, in the case of the patents in Australia, were assigned) the patents underlying our Levulan® 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. \$102,000 as of December 31, 2007) in order to retain the license. For 2007, royalties exceeded this minimum. We have the right to terminate the PARTEQ agreement with or without cause upon 90 days notice.

Together with PARTEQ and Draxis Health, Inc., our former parent, we entered into an agreement, known as the ALA Assignment Agreement, effective October 7, 1991. According to the terms of this agreement we assigned to Draxis our rights and obligations under the PARTEQ license agreement to the extent they relate to Canada. On February 24, 2004, we reacquired these rights and agreed to pay an upfront fee and a 10% royalty on sales of the Levulan® Kerastick® in Canada over a five-year term following the first commercial sale in Canada, which ends in the second quarter of 2009. 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® Kerastick® with PDT for AKs. We also hold Canadian regulatory approval for the BLU-U®. During 2004, we appointed a Canadian distributor who launched our Levulan® Kerastick® and BLU-U® in Canada. See the section entitled *Distribution*.

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*Altana, Inc.*

In June 2005, Sirius entered into a development and product license agreement with Altana, Inc. relating to a reformulated dermatology product. According to the agreement, Sirius pays for all development costs. The agreement was assigned to us by virtue of the Sirius merger. In January 2008, Altana received a non-approvable letter from the FDA with respect to its ANDA supplement for this product. Based on the FDA action which required Altana to withdraw the ANDA supplement, we will not receive pre-market approval to launch this product as previously anticipated. Furthermore, in light of preliminary market research data which was equivocal as to the potential acceptability of the product due to the changing competitive environment, we have decided not to launch this product.

*Winston Laboratories, Inc.*

On or about January 30, 2006, Winston Laboratories, Inc., or Winston, and the former Sirius entered into a license agreement relating to a Sirius product, Psoriatec<sup>®</sup> (known by Winston as Micanol) revising a former agreement. The original 2006 Micanol License Agreement granted an exclusive license, with limitation on rights to sublicense, to all property rights, including all intellectual property and improvements, owned or controlled by Winston to manufacture, sell and distribute products containing anthralin, in the United States. On January 29, 2008, our wholly-owned subsidiary, Sirius, entered into the 2006 Micanol Transition License Agreement with Winston. The Transition License Agreement amends the original 2006 Micanol License Agreement which was due to expire pursuant to its terms on January 31, 2008. The parties entered into the Transition License Agreement to extend the term of the 2006 Micanol License Agreement to September 30, 2008 in order to allow DUSA to sell its last batch of product, to reduce the period of time that Sirius is required to maintain product liability insurance with respect to its distribution and sale of products containing anthralin after the termination of the Transition License Agreement and to confirm the allocation of certain costs and expenses relating to the product during and after the transition period. We will pay royalties on net sales of Psoriatec<sup>®</sup>, but we are no longer required to pay Winston a minimum royalty to maintain the license.

*PhotoCure ASA*

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby we granted a non-exclusive license to PhotoCure under the patents we license from PARTEQ, for esters of ALA. Furthermore, we granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any DUSA patents that may issue or be licensed by us in the future. PhotoCure received FDA approval to market Metvixia for treatment of AKs in July 2004 and it would be directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product should PhotoCure decide to begin marketing this product. While we are entitled to royalties from PhotoCure on its net sales of Metvixia, this product may adversely affect our ability to maintain or increase our market.

*River s Edge*

As part of the settlement with River s Edge, we have entered into a license agreement, dated October 28, 2007, whereby we granted River s Edge a perpetual, exclusive license to River s Edge to manufacture and sell four of products from the AVAR<sup>®</sup> line, including AVAR cleanser, AVAR gel, AVAR E-emollient cream and AVAR E-green in exchange for a royalty on net sales of these products, including a guaranteed minimum royalty of \$300,000, payable in equal annual installments of \$100,000 for three years. DUSA provided its on-hand inventory of these products to River s Edge for no cost. DUSA acquired the AVAR products from Sirius as a

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result of the merger which closed on March 10, 2006. In connection with the license agreement, DUSA requested and received a waiver to certain obligations to promote the AVAR products being licensed to River s Edge from the Sirius shareholder representatives acting on behalf of all of the former shareholders of Sirius. As consideration for the waiver, we and the Sirius shareholder representatives agreed to amend the merger agreement to extend the milestone termination date provided in the merger agreement by eight additional months and agreed that for the balance of the 50 month period prior to the milestone termination date (as amended), DUSA will credit the cumulative net sales milestone amounts under the merger agreement with a monthly amount equal to the average of the last 12-months of net sales by DUSA of the four products licensed to River s Edge. See Item 3. Legal Proceedings.

**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. 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 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. We own or exclusively license patents and patent applications related to the following:

methods of using ALA and its unique physical forms in combination with light,

compositions and apparatus for those methods, and

unique physical forms of ALA.

These patents expire no earlier than 2009, and certain patents are entitled to terms beyond that date. Effective September 29, 2003, the United States Patent and Trademark Office extended the term of U.S. Patent No. 5,079,262, with respect to our approved AK indication for Levulan<sup>®</sup>, 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 the 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 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, including our BLU-U<sup>®</sup> light device, and other technology. We cannot guarantee that any pending patent applications will mature into issued patents.

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We also own patents covering Nicomide<sup>®</sup> and the AVAR<sup>®</sup> products, and have patent applications pending that will cover other products, if those applications issue as patents, including an application on the design of the applicator wand for ClindaReach pledgets. The Nicomide<sup>®</sup> patent expires in 2025. For more information concerning our Nicomide<sup>®</sup> patent, see the section entitled Legal Proceedings . The AVAR<sup>®</sup> patent expires in 2021.

We have limited patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic ALA method of treatment patents and applications have counterparts in only six foreign countries and under the European Patent Convention. See the section entitled Risk Factors Risks Related to DUSA .

We can provide no assurance that a third-party or parties will not claim, with or without merit, that we have infringed or misappropriated their proprietary rights. A number of entities have obtained, and are attempting to obtain patent protection for various uses of ALA. We can provide no assurance as to whether any issued patents, or patents that may later issue to third-parties, may affect the uses on which we are working or whether such patents can be avoided, invalidated or licensed if they cannot be avoided or invalidated. If any third-party were to assert a claim for infringement, as one party has already done, we can provide no assurance that we would be successful in the litigation or that such litigation would not have a material adverse effect on our business, financial condition and results of operation. Furthermore, we may not be able to afford the expense of defending against any such additional claim.

In addition, we cannot guarantee that our patents, whether owned or licensed, or any future patents that may issue, will prevent other companies from developing similar or functionally equivalent products. Further, we cannot guarantee that we will continue to develop our own patentable technologies or that our products or methods will not infringe upon the patents of third-parties. In addition, we cannot guarantee that any of the patents that may be issued to us will effectively protect our technology or provide a competitive advantage for our products or will not be challenged, invalidated, or circumvented in the future.

We also attempt to protect our proprietary information as trade secrets. Generally, agreements with employees, licensing partners, consultants, universities, pharmaceutical companies and agents contain provisions designed to protect the confidentiality of our proprietary information. However, we can provide no assurance that these agreements will provide effective protection for our proprietary information in the event of unauthorized use or disclosure of such information. Furthermore, we can provide no assurance that our competitors will not independently develop substantially equivalent proprietary information or otherwise gain access to our proprietary information, or that we can meaningfully protect our rights in unpatentable proprietary information.

Even in the absence of composition of matter patent protection for ALA, we may receive financial benefits from: (i) patents relating to the use of such products (like PARTEQ s patents); (ii) patents relating to special compositions and formulations (like the Nicomide<sup>®</sup> and AVAR<sup>®</sup> patents); (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 the section entitled Business Government Regulation . Effective patent protection also depends on many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of the new drug provisions of the Food, Drug and Cosmetic Act, or similar laws and regulations in other countries.

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We seek registration of trademarks in the United States, and other countries where we may market our products. To date, we have been issued more than 75 trademark registrations, including trademarks for DUSA® DUSA Pharmaceuticals, Inc.®, Levulan®, Kerastick®, BLU-U®, Nicomide®, Nicomide-T®, Meted®, Psoriacap®, and Psoriatec®, and other applications are pending.

**Manufacturing**

We manufacture our Levulan® Kerastick® at our Wilmington, Massachusetts facility and we maintain a reasonable level of Kerastick® inventory based on our internal sales projections. During the third quarter of 2005, we received FDA approval to manufacture our BLU-U® 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®, and the BLU-U® brand light source are each manufactured by single third-party suppliers. In connection with our merger with Sirius, we assumed a number of key agreements relating to the supply of our Non-PDT current products, and relating to the development of certain product candidates. We intend to continue to use third-party manufacturers for these products. See the section entitled Business Supply Partners.

**Distribution**

We have been a direct distributor of the BLU-U® since its launch. Effective January 1, 2006, we increased our own distribution capacity and have become the sole distributor for our Levulan® Kerastick® in the United States. In March 2004, we signed an exclusive Canadian marketing and distribution agreement for the Levulan® Kerastick® and BLU-U® with Coherent-AMT Inc., or Coherent, a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U® in April 2004 and the Kerastick® in June 2004, following receipt of the applicable regulatory approval from Health Protection Branch Canada. The agreement is automatically renewed for 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.

On January 12, 2006, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc., or Stiefel, covering current and future uses of our proprietary Levulan® Kerastick® for PDT in dermatology. The agreement, grants Stiefel an exclusive right to distribute, promote and sell the Levulan® Kerastick® in the western hemisphere from and including Mexico south, and all other countries in the Caribbean, excluding United States territories. We will manufacture and supply to Stiefel on an exclusive basis in the territory all of Stiefel's reasonable requirements for the product. The agreement has an initial term of ten years. The launch of the product in Brazil is dependent upon receipt of acceptable final pricing approval from Brazilian government regulators at CMED. In September 2007, in light of the unexpected delay in receiving acceptable final pricing in Brazil, we amended certain terms of the original Stiefel agreement to reflect our plans to launch in other Latin American countries prior to Brazil. Pursuant to the amendment, Stiefel will make aggregate milestone payments to us of up to \$2,250,000, rather than up to \$3,000,000 under the Agreement as follows: (i) \$375,000 upon launch of the product in either Mexico or Argentina; (ii) \$375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of \$375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of \$375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. In addition, the transfer price for the product was amended to set a fixed price plus a royalty on net sales, rather than a revenue-sharing arrangement as under the Agreement. We

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believe that the amended transfer price reduces some of the risk related to currency and market price fluctuations during the ten-year term 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. In 2007, the product was launched in Argentina, Chile, Colombia, and Mexico, and we began recognizing revenue under the agreement in the fourth quarter of 2007. On March 5, 2008 Stiefel notified us that the Brazilian authorities had published the final pricing for the product which is acceptable to Stiefel and to us. We expect Stiefel to launch the product in Brazil shortly.

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong covering current and future uses of the Levulan® Kerastick® for PDT in dermatology. The agreement grants Daewoong exclusive rights to distribute, promote and sell the Levulan® Kerastick® in Korea, Taiwan, China, including without limitation Hong Kong, India, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. We will manufacture and supply the product to Daewoong on certain terms and conditions. The agreement has an initial term of ten years (subject to earlier termination and extension provisions). Daewoong will complete final integration and submission on our behalf of all registrations and regulatory filings for the product in the territory. Under the terms of the agreement, Daewoong will make up to \$3,500,000 in milestone payments to us, \$1,000,000 of which was paid on signing, and \$1,000,000 of which was paid upon receipt of Korean regulatory approval of the product. The remaining milestones consist of two installments of \$750,000 each for cumulative end-user sales totaling 200,000 units and 500,000 units. In order to maintain its exclusive rights, Daewoong is obligated to purchase a certain number of units of the product and meet certain regulatory timelines. We will manufacture the product in our facility in Wilmington, Massachusetts. We will also receive a minimum transfer price per unit plus a percentage of Daewoong's end-user price above a certain level. In 2007, the product was launched Korea, and we began recognizing revenue under the agreement in the fourth quarter of 2007.

Our Non-PDT products are distributed through several major wholesalers in the United States pursuant to customary industry arrangements.

**Marketing and Sales**

DUSA markets its products in the United States. We have appointed Coherent-AMT as our marketing partner for our products in Canada, Stiefel for our Levulan® Kerastick® in Mexico, Central and South America and Daewoong for our Levulan® Kerastick® in several Asian countries. Both Stiefel and Daewoong launched the Levulan® Kerastick® in Latin American and Korea, respectively, during the fourth quarter of 2007. See the section entitled Business Distribution.

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 independent representatives, and an independent sales distributor, designed to focus on most of our key geographic markets in the United States. As of December 31, 2007 and 2006, we had 35 and 37, respectively, sales representatives deployed nationally, including sales management.

Following the receipt of marketing approval from the Health Protection Branch Canada in June 2004, we started to market and sell the Levulan® Kerastick® with PDT using the BLU-U® for AKs of the face or scalp in Canada through Coherent-AMT. Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and

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labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. The FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with the FDA to begin that process. The FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide® could not be marketed as a dietary supplement with its current labeling. If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide® as an over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market these products and could therefore, negatively affect our revenues and profits.

**Competition**

The pharmaceutical industry is highly competitive, and many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care. Our competitors may succeed in developing products that are safer or more effective than ours and in obtaining regulatory marketing approval of future products before we do. Our competitiveness may also be affected by our ability to manufacture and market our products and by the level of reimbursement for the cost of our drug and treatment by third-party payors, such as insurance companies, health maintenance organizations and government agencies.

A number of companies are pursuing commercial development of PDT agents other than Levulan®. These include: QLT Inc. (Canada); Axcan Pharma Inc. (United States); Miravant, Inc. (United States); and Pharmacyclics, Inc. (United States). Several companies are also commercializing and/or conducting research with ALA or ALA-related compounds. These include: medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera PhotoTherapeutics, Inc. (U.K.) and PhotoCure ASA (Norway) who entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications. There are many pharmaceutical companies that compete with us in the field of dermatology, particularly in the acne and rosacea markets.

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. 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,

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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. On May 30, 2006, we entered into a patent license agreement under which we granted PhotoCure ASA a non-exclusive license under the patents we license from PARTEQ for ALA esters. In addition, we granted a non-exclusive license to PhotoCure for its existing formulations of Hexvix® and Metvix® (known in the U.S. as Metvixia®) for any patent we own now or in the future. PhotoCure is obligated to pay us royalties on sales of its ester products to the extent they are covered by our patents in the U.S. and certain other territories. As part of the agreement, PhotoCure paid us a prepaid royalty in the amount of \$1 million.

In August 2003, Axcan Pharma Inc. received FDA approval for the use of its product, PHOTOFRIN®<sup>2</sup>, 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, for which we designed our proprietary sheath device and have conducted pilot clinical trials.

There are also non-PDT products for the treatment of AKs, including cryotherapy with liquid nitrogen, 5-fluorouracil (Efudex®)<sup>3</sup>, diclofenac sodium (Solaraze®)<sup>4</sup>, and imiquimod (ALDARA<sup>5</sup>) Other AK therapies are also known to be under development by companies such as Medigene (GmbH), Peplin (Australia) and others.

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. We believe that with increased reimbursement for our PDT-related procedure fee, including an 18% increase in January 2008, our treatment is increasingly financially viable for practitioners, and more competitive with alternative AK therapies from a practice management perspective. However, assurance can be given that developments by other parties will not render our products uncompetitive or obsolete.

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

2 PHOTOFRIN® is a registered trademark of Axcan Pharma Inc.

3 Efudex® is a registered trademark of Valeant Pharmaceuticals International.

4



Solaraze® is a registered trademark of SkyePharma PLC.

<sup>5</sup> ALDARA® is a registered trademark of Graceway Pharmaceuticals, LLC.

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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 the section entitled Business Dermatology Indications, Actinic Keratoses; Acne .

Our Non-PDT Drug Products compete in the field of acne and rosacea with well-established therapies, such as over-the-counter topical medications for mild cases, and prescription topical medications or oral antibiotics for mild to moderate cases, as well as various laser and non-laser light sources. In addition, generic companies may decide to enter the market. The entry of new products from time to time would likely cause us to lose market share and cause fluctuations in our product revenues in this market.

**Government Regulation**

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

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

controlled research and testing of products,

applications for marketing approval containing manufacturing, preclinical and clinical data to establish the safety and efficacy of the product, and

control of marketing activities, including advertising and labeling.

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

preclinical studies

the filing of an Investigational New Drug, or IND, application,

human clinical trials, and

the approval of a New Drug Application, or NDA.

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

The human clinical testing program involves three phases. Each clinical study 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,

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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® Kerastick® 20% Topical Solution with PDT for treatment of AKs of the face or scalp. The commercial version of our BLU-U®, used together with the Kerastick® to provide PDT for the treatment of non-

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

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

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

Following receipt of the PMA application, if the FDA determines that the application is sufficiently complete to permit a substantive review, the agency will accept it for filing and further review. Once the submission is filed, the FDA begins a review of the PMA application. Under the Medical Device User Fee and Modernization Act, the FDA has 180 days to review a PMA application and respond to the sponsor. The review of PMA applications more often occurs over a significantly protracted time period, and the FDA may take up to 2 years or more from the date of filing to complete its review. In addition, a PMA for a device which forms part of a combination product will not be approved unless and until the NDA for the corresponding drug is also approved.

The PMA process can be expensive, uncertain and lengthy. A number of other companies have sought premarket approval for devices that have never been approved for marketing. The review time is often significantly extended by the FDA, which may require more information or clarification of information already provided in the submission. During the review period, an advisory committee likely will be convened to review and evaluate the PMA application and

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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. The Medical Device Reporting regulations require that we provide information to the FDA whenever there is evidence to reasonably suggest that one of our devices may have caused or contributed to a death or serious injury or, if a malfunction were to recur, could cause or contribute to a death or serious injury. Under FDA regulations, we are required to submit reports of certain voluntary recalls and corrections to the FDA. If the FDA believes that a company is not in compliance with applicable regulations, it can institute proceedings to detain or seize products, issue a warning letter, issue a recall order, impose operating restrictions, enjoin future violations and assess civil penalties against that company, its officers or its employees and can recommend criminal prosecution to the Department of Justice.

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

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

The United States Drug Price Competition and Patent Term Restoration Act of 1984 known as the Hatch-Waxman Act establishes a 5-year period of marketing exclusivity from the date of NDA approval for new chemical entities approved after September 24, 1984. Levulan<sup>®</sup> is a new chemical entity and market exclusivity under this law expired on December 3, 2004. After the expiration of the Hatch-Waxman exclusivity period, any third-party who submits an application for approval for a drug product containing ALA must provide a certification that (i) no patent information has been filed; (ii) that such patent has expired; (iii) marketing will not commence until the patent(s) has expired; or (iv) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the third-party applicant.

Any abbreviated or paper NDA applicant will be subject to the notification provisions of the Hatch-Waxman Act, which should facilitate our notification about potential infringement of our patent rights. The abbreviated or paper NDA applicant must notify the NDA holder and the owner of any patent applicable to the abbreviated or paper NDA product, of the application and intent to market the drug that is the subject of the NDA.

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.

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For Levulan® PDT, we have received such approval in Canada, and together with Stiefel under our agreement for Latin America are in the process of securing acceptable pricing approval in Brazil, having received regulatory approval in Argentina, Brazil, Chile, Colombia and Mexico Also, together with Daewoong, we have received approval in Korea, and expect to apply for approvals in additional territories with Stiefel and Daewoong.

Medical device regulations also are in effect in many of the countries outside the United States in which we do business. These laws range from comprehensive device approval and quality system requirements for some or all of our medical device products to simpler requests for product data or certifications. The number and scope of these requirements are increasing. Under the European Union Medical Device Directive, all medical devices must meet the Medical Device Directive standards and receive CE Mark certification. CE Mark certification requires a comprehensive quality system program and submission of data on a product to a Notified Body in Europe. The Medical Device Directive, ISO 9000 series and ISO 13485 are recognized international quality standards that are designed to ensure that we develop and manufacture quality medical devices. A recognized Notified Body (an organization designated by the national governments of the European Union member states to make independent judgments about whether or not a product complies with the protection requirements established by each CE marking directive) audits our facilities annually to verify our compliance with these standards. We will be required to meet these standards should we decide to sell our devices outside of the United States.

We are subject to laws and regulations that regulate the means by which companies in the health care industry may market their products to hospitals and health care professionals and may compete by discounting the prices of their products. This requires that we exercise care in structuring our sales and marketing practices and customer discount arrangements.

Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export and other laws regarding transactions in foreign countries. Among other things, these laws restrict, and in some cases prohibit, United States companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices in foreign countries.

Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by the controlling laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of this type of an accident, we could be held liable for any damages that result and any liability could exceed our resources. Although we believe that we are in compliance in all material respects with applicable environmental laws and regulations, we could incur significant costs to comply with environmental laws and regulations in the future, and our operations, business or assets could be materially adversely affected by current or future environmental laws or regulations.

In addition to the above regulations, we are and may be subject to regulation under federal and state laws, including, but not limited to, requirements regarding occupational health and safety, laboratory practices and the maintenance of personal health information. As a public company, we are subject to the securities laws and regulations, including the Sarbanes-Oxley Act

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of 2002. We may also be subject to other present and possible future local, state, federal and foreign regulations.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide® could not be marketed as a dietary supplement with its current labeling. If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide® as an over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market these products and could therefore, negatively affect our revenues and profits.

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® manufacturing 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.

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**Product Liability and Insurance**

We are subject to the inherent business risk of product liability claims in the event that the use of our technology or any prospective product is alleged to have resulted in adverse effects during testing or following marketing approval of any such product for commercial sale. We maintain product liability insurance for coverage of our clinical trial activities and for our commercial supplies. There can be no assurance that such insurance will continue to be available on commercially reasonable terms or that it will provide adequate coverage against all potential claims.

**Employees**

At the end of 2007, we had 83 employees, including 4 part-time employees. 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.

**Internet Information**

Our Internet site is located at [www.dusapharma.com](http://www.dusapharma.com). Copies of our reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or 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 SEC. 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. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, including DUSA, that file electronically with the SEC. The address of that site is [www.sec.gov](http://www.sec.gov).

**ITEM 1A. RISK FACTORS**

Investing in our common stock is very speculative and involves a high degree of risk. You should carefully consider and evaluate all of the information in, or incorporated by reference in, this report. 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 trading price of our common stock and you might lose all or part of your investment.

This report contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. We use words such as "anticipate", "believe", "expect", "future" and "intend" and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the factors described below and elsewhere in this report. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report.



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**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 Products.**

*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 would need alternative sources of 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, including our acne program.

*Nicomide® Will Likely Lose Significant Market Share If Another Generic Product Enters the Market And Our Ability To Become Profitable Will Be More Difficult.*

In March 2006, we acquired Nicomide®, in connection with our merger with Sirius Laboratories, Inc. Shortly after the closing of the merger, we became engaged in patent litigation with River s Edge Pharmaceuticals, LLC, or River s Edge, a company that launched a niacinamide-based product in competition with our Nicomide® product. River s Edge had also requested that the United States Patent and Trademark Office reexamine the Nicomide® patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties submitted their responses to the first office action. Nicomide® sales were adversely impacted throughout the litigation process and had a material negative impact on our revenues, results of operations and liquidity. On October 28, 2007, we entered into a settlement agreement and mutual release, or settlement agreement, to dismiss the lawsuit brought by DUSA against River s Edge, asserting a number of claims arising out of River s Edge s alleged infringement of U.S. Patent No. 6,979,468 under which DUSA has marketed, distributed and sold Nicomide®. Under the terms of the settlement agreement, River s Edge unconditionally acknowledges the validity and enforceability of the Nicomide® patent. River s Edge has made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and will pay to DUSA \$25.00 for every bottle of NIC 750 above 5,000 bottles that is substituted for Nicomide® after September 30, 2007. River s Edge is responsible for all returns of NIC 750 from the distribution chain and/or order its destruction and will immediately cease the manufacture, distribution and sale of NIC 750. River s Edge was obligated to withdraw and cease participating in the re-examination of the Nicomide® patent and consented to the return to us of the \$750,000 bond that was held by the court with all accrued interest. On November 19, 2007, the USPTO issued an Order to Show Cause providing River s Edge with one month or 30 days, whichever is longer, to demonstrate to the USPTO why it should not terminate the reexamination process in light of the dismissal of the patent litigation. River s Edge did not respond. On March 6, 2008, the USPTO vacated the reexamination.

If another company launches a substitutable niacinamide product, our revenues from sales of Nicomide® will decrease, perhaps permanently, and our ability to become profitable will be more difficult.

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***Any Failure To Comply With Ongoing Governmental Regulations In The United States And Elsewhere Will Limit Our Ability To Market Our Products.***

The manufacture and marketing of our products are subject to continuing FDA review as well as comprehensive regulation by the FDA and by state and local regulatory authorities. These laws require, among other things:

approval of manufacturing facilities, including adherence to good manufacturing and laboratory practices during production and storage,

controlled research and testing of some of these products even after approval, and

control of marketing activities, including advertising and labeling.

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

send us warning letters,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products,

refuse to approve pending applications or supplements to approved applications filed by us,

refuse to permit exports of our products from the United States,

require us to recall products,

require us to notify physicians of labeling changes and/or product related problems,

impose restrictions on our operations, and/or

criminally prosecute us.

We and our manufacturers must continue to comply with cGMP and Quality System Regulation, or QSR, and equivalent foreign regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. In complying with cGMP and foreign regulatory requirements, we and our third-party manufacturers will be obligated to expend time, money and effort in production, record keeping and quality control to assure that our products meet applicable specifications and other requirements.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to

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products marketed without approved marketing applications including Nicomide®. The FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, *Marketed New Drugs without Approved NDAs or ANDAs*. Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with the FDA to begin that process. The FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide® could not be marketed as a dietary supplement with its current labeling. If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide® as an over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market these products and could therefore, negatively affect our revenues and profits.

Manufacturing facilities are subject to ongoing periodic inspection by the FDA, including unannounced inspections. We cannot guarantee that our third-party supply sources, or our own Kerastick® facility, will continue to meet all applicable FDA regulations. If we, or any of our manufacturers, including without limitation, the manufacturer of Nicomide®, who has received warning letters from the FDA, 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 a significant adverse effect on our financial condition and operations.

As part of our FDA approval for the Levulan® Kerastick® for AK, we were required to conduct two Phase IV follow-up studies. We successfully completed the first study; and submitted our final report on the second study to the FDA in January 2004. The FDA could request additional information and/or studies. Additionally, if previously unknown problems with the product, a manufacturer or its facility are discovered in the future, changes in product labeling restrictions or withdrawal of the product from the market may occur. We have implemented changes in our marketing materials due to the warning letter we received from the FDA in early 2007. This letter caused us to cease using a good portion of our marketing materials which made the selling effort of our Levulan® Kerastick® more difficult. If we receive other warning letters, our revenues may suffer.

***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-parties may infringe one or more of our patents, and cause us to spend significant resources to enforce our patent rights. Also, in a lawsuit against a third-party for infringement of our patents in the United States, that third-party may challenge the validity of our patent(s). We cannot guarantee that a third-party will not claim, with or without merit, that our patents are not valid, as in the case described below, or that we have infringed their patent(s) or misappropriated

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their proprietary material. Defending these types of legal actions involve 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 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.

On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that River's Edge's niacinamide-based product infringed our United States Patent No. 6,979,468. River's Edge requested that the United States Patent and Trademark Office reexamine the patent. We have now settled the litigation. On November 19, 2007, the USPTO issued an Order to Show Cause providing River's Edge with one month or 30 days, whichever is longer, to demonstrate to the USPTO why it should not terminate the reexamination process in light of the dismissal of the patent litigation. River's Edge did not respond. On March 6, 2008, the USPTO vacated the reexamination.

During 2005 and 2006, we filed several lawsuits against chemical suppliers, compounding pharmacies, a light device company, its distributor and a sales representative, and physicians alleging violations of patent law. While we have been successful in obtaining a default judgment against one compounding pharmacy, and settled other suits favorably to us, 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.

***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.***

While we recently completed a private placement raising net proceeds of approximately \$10.3 million, 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 additional financing will be available at all or on acceptable terms. Depending 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.

The availability of additional capital to us is uncertain. There can be no assurance that additional funding will be available to us on favorable terms, if at all. Any equity financing, if needed, would likely result in dilution to our existing shareholders and debt financing, if available, would likely involve significant cash payment obligations and include restrictive covenants that restrict our ability to operate our business. Failure to raise capital if needed could materially adversely impact our business, our financial condition, results of operations and cash flows.

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***Since We Now Operate The Only FDA Approved Manufacturing Facility For The Kerastick<sup>®</sup> And Continue To Rely Heavily On Sole Suppliers For The Manufacture Of Levulan<sup>®</sup>, The BLU-U<sup>®</sup>, Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup>, Meted<sup>®</sup>, Psoriacap<sup>®</sup> And Psoriatec<sup>®</sup>, Any Supply Or Manufacturing Problems Could Negatively Impact Our Sales.***

If we experience problems producing Levulan<sup>®</sup> Kerastick<sup>®</sup> units in our facility, or if any of our contract suppliers fail to supply our requirements for products, our business, financial condition and results of operations would suffer. Although we have received approval by the FDA to manufacture the BLU-U<sup>®</sup> and the Levulan<sup>®</sup> Kerastick<sup>®</sup> in our Wilmington, Massachusetts facility, at this time, with respect to the BLU-U<sup>®</sup>, we expect to utilize our own facility only as a back-up to our current third party manufacturer or for repairs.

The sole supplier of Nicomide<sup>®</sup> has received warning letters from the FDA regarding certain regulatory observations. The primary observations noted in the warning letters were not related to Nicomide<sup>®</sup>. However, with respect to Nicomide<sup>®</sup> and certain other products manufactured by this supplier, the FDA also notified the manufacturer that the FDA believes that Nicomide<sup>®</sup> could not be marketed as a dietary supplement with its current labeling. The FDA regulates such products under the compliance policy guide described above entitled, Marketed New Drugs without Approved NDAs or ANDAs.

Nicomide<sup>®</sup> is the key product we acquired from Sirius in connection with our merger completed in March, 2006. Nicomide<sup>®</sup> is an oral prescription vitamin supplement. If the FDA is not satisfied with the response to the warning letters issued to the manufacturer of Nicomide<sup>®</sup> and causes the manufacturer to cease operations, our revenues will be significantly negatively affected.

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:

product yields,

quality control,

component and service availability,

compliance with FDA regulations, and

the need for further FDA approval if manufacturers make material changes to manufacturing processes and/or facilities.

We cannot guarantee that problems will not arise with production yields, costs or quality as we and our suppliers seek to increase production. Any manufacturing problems could delay or limit our supplies which would hinder our marketing and sales efforts. If our facility, any facility of our contract manufacturers, or any equipment in those facilities is damaged or destroyed, we may not be able to quickly or inexpensively replace it. Likewise, if there are any quality or supply problems with any components or materials needed to manufacturer our products, we may not be able to quickly remedy the problem(s). Any of these problems could cause our sales to suffer.

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***We Have Only Limited Experience Marketing And Selling Pharmaceutical Products And, As A Result, Our Revenues From Product Sales May Suffer.***

If we are unable to successfully market and sell sufficient quantities of our products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We are responsible for marketing our products in the United States and the rest of the world, except Canada, Latin America and parts of Asia, 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. If our sales and marketing efforts fail, then sales of the Levulan<sup>®</sup> Kerastick<sup>®</sup>, the BLU-U<sup>®</sup>, Nicomide<sup>®</sup> and other products will be adversely affected.

***If We Cannot Improve Physician Reimbursement And/Or Convince More Private Insurance Carriers To Adequately Reimburse Physicians For Our Product Sales May Suffer.***

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan<sup>®</sup> Kerastick<sup>®</sup> 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, a broader adoption of our therapy and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK were made in 2005, 2007 and again in 2008, some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

If insurance companies do not cover, or stop covering products which are covered, including Nicomide<sup>®</sup>, our sales could be dramatically reduced.

***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:

the effectiveness, or perceived effectiveness, of our products in comparison to competing products;

the existence of any significant side effects, as well as their severity in comparison to any competing products;

potential advantages over alternative treatments;

the ability to offer our products for sale at competitive prices;

relative convenience and ease of administration;

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the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

***We Have Significant Losses And Anticipate Continued Losses***

We have a history of operating losses. We expect to have continued losses until sales of our products increase substantially. We incurred net losses of \$14,714,000 and \$31,350,000 for the years ended December 31, 2007 and 2006, respectively. As of December 31, 2007, our accumulated deficit was approximately \$135,600,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis.

***We Have Limited Patent Protection, And If We Are Unable To Protect Our Proprietary Rights, Competitors Might Be Able To Develop Similar Products To Compete With Our Products And Technology.***

Our ability to compete successfully depends, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We have no compound patent protection for our Levulan® brand of the compound ALA. Our basic ALA 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 ALA patents and patent applications related to the following:

methods of using ALA and its unique physical forms in combination with light,

compositions and apparatus for those methods, and

unique physical forms of ALA.

We have limited ALA 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.

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

Nicomide® is covered by a United States patent which issued in December 2005. River s Edge Pharmaceuticals, LLC filed an application with the

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USPTO for the reexamination of the patent. The USPTO accepted the application for reexamination of the patent and the parties submitted their responses to the first office action. On October 28, 2007, we entered into a settlement agreement and mutual release to dismiss the lawsuit brought by DUSA against River's Edge, asserting a number of claims arising out of River's Edge's alleged infringement of U.S. Patent No. 6,979,468 under which DUSA has marketed, distributed and sold Nicomide®. Under the terms of the settlement agreement, River's Edge unconditionally acknowledges the validity and enforceability of the Nicomide® patent. On November 19, 2007, the USPTO issued an Order to Show Cause providing River's Edge with one month or 30 days, whichever is longer, to demonstrate to the USPTO why it should not terminate the reexamination process in light of the dismissal of the patent litigation. River's Edge did not respond. On March 6, 2008, the USPTO vacated the reexamination. Also, recently two new products have been launched that could compete with Nicomide®. These events could cause us to lose significant revenues and put our ability to be profitable at risk.

Furthermore, PhotoCure received FDA approval to market Metvixia® for treatment of AKs in July 2004 and this product, which would be directly competitive with our Levulan®Kerastick® product, could be launched at any time. While we are entitled to royalties from PhotoCure on its net sales of Metvixia®, this product which will be marketed in the U.S. by a large dermatology company, may adversely affect our ability to maintain or increase our Levulan® market.

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

these persons or entities might breach the agreements,

we might not have adequate remedies for a breach, and/or

our competitors will independently develop or otherwise discover our trade secrets;  
all of which could negatively impact our ability to be profitable.

**We Have Only Three Therapies That Have Received Regulatory Approval Or Clearance, And We Cannot Predict Whether We Will Ever Develop Or Commercialize Any Other Levulan® Products.**

***Our Potential Products Are In Early Stages Of Development And May Never Result In Any Commercially Successful Products.***

To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products. Except for Levulan® PDT for AKs, the BLU-U® for acne, the ClindaReach pledget and the currently marketed products we acquired in our merger with Sirius, all of our other potential Levulan® and other potential product candidates are at an early stage of development and subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

delays in product development, clinical testing or manufacturing,



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unplanned expenditures in product development, clinical testing or manufacturing,

failure in clinical trials or failure to receive regulatory approvals,

emergence of superior or equivalent products,

inability to market products due to third-party proprietary rights, and

failure to achieve market acceptance.

We cannot predict how long the development of our investigational stage products will take or whether they will be medically effective. We cannot be sure that a successful market will continue to develop for our Levulan<sup>®</sup> drug technology.

***We Must Receive Separate Approval For Each Of Our Potential Products Before We Can Sell Them Commercially In The United States Or Abroad.***

All of our potential Levulan<sup>®</sup> 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 (as we did for the product we were developing with Altana discussed in the sections entitled Business General and Management's Discussion and Analysis of Financial Condition and Results of Operations Contractual Obligations and Other Commercial Commitments and in the Form 8-K we filed on January 18, 2008) for these products our revenues will be limited. Before an application to the FDA seeking approval to market a new drug, called an NDA, can be filed, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually one to three years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan<sup>®</sup> PDT products are based on relatively new technology. To the best of our knowledge, the FDA has approved only three drugs for use in photodynamic therapy, including Levulan<sup>®</sup>. 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<sup>®</sup> 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 guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. We are developing Levulan<sup>®</sup> PDT for acne. We have received comments on our acne development program from the FDA statistical reviewer assigned to our investigational new drug application or IND. In this letter, the reviewer stated concern about whether we will have sufficient data to select an appropriate dosing regimen for Phase III trials. We believe that we have the data to indicate that sufficient drug dose ranging has been done; however, if the FDA does not accept our rationale, additional clinical trials and/or formulation development work may be required for the acne development program, which may extend the expected development time lines for such program. 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

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risks associated with obtaining FDA marketing approval and may impose substantial additional costs.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. The FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with the FDA to begin that process. The FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide® could not be marketed as a dietary supplement with its current labeling. If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide® as over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval.

In December 2007, we decided not to develop a third product from the list of potential products we acquired from Sirius because these products would have either been classified as unapproved drug products or had development timeframes and costs which were greater than would have been justified by the products' market potential. As a result, we made a payment to the former Sirius shareholders as provided in the merger agreement. If FDA takes action against Nicomide, or other unapproved marketed drugs we sell which we acquired from Sirius, our revenues will be significantly negatively impacted.

***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 83 employees, including 4 part-time employees, as of December 31, 2007. 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, especially in the photodynamic therapy portion of our business. 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.

***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

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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 expose us to product liability claims related to the use or misuse of our products. Product liability claims can be expensive to defend and may result in significant judgments against us. A successful claim in excess of our insurance coverage could materially harm our business, financial condition and results of operations. Additionally, we cannot guarantee that continued product liability insurance coverage will be available in the future at acceptable costs. If the cost is too high, we may have to self-insure.

***Our Business Involves Environmental Risks And We May Incur Significant Costs Complying With Environmental Laws And Regulations.***

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

**We May Not Be Able To Compete Against Traditional Treatment Methods Or Keep Up With Rapid Changes In The Biotechnology And Pharmaceutical Industries That Could Make Some Or All Of Our Products Non-Competitive Or Obsolete.**

***Competing Products And Technologies Based On Traditional Treatment Methods May Make Some Or All Of Our Programs Or Potential Products Noncompetitive Or Obsolete.***

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of many of the same conditions that we are seeking to treat, including AKs, acne and rosacea. 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.

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Many companies are also seeking to develop new products and technologies, and receiving approval for medical conditions for which we are developing treatments. Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Our competitors may succeed in developing products that are safer or more effective than ours. Many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing and obtaining regulatory approvals to market products for health care.

We cannot guarantee that new drugs or future developments in drug technologies will not have a material adverse effect on our business. Increased competition could result in:

price reductions,

lower levels of third-party reimbursements,

failure to achieve market acceptance, and

loss of market share, any of which could adversely affect our business. Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technology obsolete

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby DUSA granted a non-exclusive license to PhotoCure under the patents DUSA licenses from PARTEQ, for esters of ALA. Furthermore, DUSA granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any DUSA patents that may issue or be licensed by DUSA in the future. PhotoCure received FDA approval to market Metvixia for treatment of AKs in July 2004 and it would be directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product should PhotoCure decide to begin marketing this product. While we are entitled to royalties from PhotoCure on its net sales of Metvixia, this product, which will be marketed in the U.S. by a large dermatology company which may start to market Metvixia at any time, would adversely affect our ability to maintain or increase our market.

***We Have Learned That Some 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<sup>®</sup> product. Since December 2004, we have filed lawsuits against some compounding pharmacies and physicians alleging violations of the Lanham Act for false advertising and trademark infringement, and of United States patent law. All of the lawsuits have been settled favorably to us. More recently, we have sued chemical suppliers, and a light device company, its distributor and a sales representative, alleging that they induced physicians to infringe patents licensed to us, among other things. While we believe that certain actions of compounding pharmacies and others 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 companies 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.

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***Generic Manufacturers May Launch Products at Risk of Patent Infringement.***

If generic manufacturers, like River s Edge, launch products to compete with Nicomide® in spite of our patent position these manufacturers may erode our market and negatively impact our sales revenues, liquidity and operations. ***Our Competitors In The Biotechnology And Pharmaceutical Industries May Have Better Products, Manufacturing Capabilities Or Marketing Expertise.***

We are aware of several companies commercializing and/or conducting research with ALA or ALA-related compounds, including: medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera, 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. We also anticipate that we will face increased competition as the scientific development of PDT and PD advances and new companies enter our markets. Several companies are developing PDT agents other than Levulan®. These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and Pharmacyclics, Inc. (U.S.). There are many pharmaceutical companies that compete with us in the field of dermatology, particularly in the acne and rosacea markets.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AKs and basal cell carcinoma in the European Union, New Zealand, Australia and countries in Scandinavia. PhotoCure s marketing partner, a large dermatology company, could begin to market its product in direct competition with Levulan® in the U.S., at any time, under the terms of our patent license agreement and we may lose market share.

Axcan Pharma Inc. has received FDA approval for the use of its product, PHOTOFRIN®, for PDT in the treatment of high grade dysplasia associated with Barrett s Esophagus. Axcan is the first company to market a PDT therapy for this indication for which we designed our proprietary sheath device and have conducted pilot clinical trials.

We expect that our principal methods of competition with other PDT products will be based upon such factors as:  
the ease of administration of our method of PDT,

the degree of generalized skin sensitivity to light,

the number of required doses,

the selectivity of our drug for the target lesion or tissue of interest, and

the type and cost of our light systems.

Our primary competition in the acne and rosacea markets include oral and topical antibiotics, other topical prescription and over-the-counter products, as well as various laser and non-laser light treatments. The market is highly competitive and other large and small companies have more experience than we do which could make it difficult for us to penetrate the market. We are also aware of new products that were launched recently which will compete with Nicomide® which could negatively impact our market share. The entry of new products from time to time would likely cause us to lose market share.

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**Risks Related To Our Stock**

***If The Shares Of Common Stock Held By Former Sirius Shareholders or our new Investors Are Sold, The Price Of The Shares Could Become Depressed.***

All of the shares of DUSA's common stock which were issued to the former Sirius shareholders were subject to a lock-up provision under the terms of the merger agreement. On March 10, 2007, the lock-up provision on 1,380,151 shares was lifted and the lock-up on the remaining 1,016,094 shares will be lifted on March 10, 2008. These shares have been registered and are freely tradable. In addition, in October 2007 we privately placed 4,581,043 shares of DUSA's common stock with several investors. These shares have been registered and are freely tradable. If any of these shareholders decide to sell their shares, the price of our common stock on NASDAQ could be depressed.

***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 February 29, 2008 there were outstanding options and warrants to purchase 4,250,384 shares of common stock, with exercise prices ranging from \$1.60 to \$31.00 per share, and from \$2.85 to \$6.00 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.

***Our Results Of 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, 2006 to March 10, 2008, the price of our stock has ranged from a low of \$1.63 to a high of \$11.12. Factors that contributed to the volatility of our stock during this period included:

quarterly levels of product sales;

clinical trial results;

general market conditions;

patent litigation;

increased marketing activities or press releases; and

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.

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**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 PDT products are still in the early stages of adoption, and sales volumes are still low, a number of factors could affect product sales levels and growth rates in any period. These could include the timing of medical conferences, sales promotion activities, and large volume purchases by our higher usage customers. In addition, seasonal fluctuations in the number of patients seeking treatment at various times during the year could impact sales volumes. These factors could, in turn, affect the volatility of our stock price.

***Effecting A Change Of Control Of DUSA Would Be Difficult, Which May Discourage Offers For Shares Of Our Common Stock.***

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

On September 27, 2002, we adopted a shareholder rights plan at a special meeting of DUSA's board of directors. The rights plan could discourage, delay or prevent a person or group from acquiring 15% or more 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 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 more, as the case may be, of DUSA, or until such later date as may be determined by the our board of directors.

Under the rights plan, if a person or group acquires the threshold amount of common stock, all holders of rights (other than the acquiring person or group) may, upon payment of the purchase price then in effect, purchase shares of common stock of DUSA having a value of twice the purchase price. In the event that we are involved in a merger or other similar transaction where DUSA is not the surviving corporation, all holders of rights (other than the acquiring person or group) shall be entitled, upon payment of the purchase price then in effect, to purchase common stock of the surviving corporation having a value of twice the purchase price. The rights will expire on October 10, 2012, unless previously redeemed. Our board of directors has also adopted certain amendments to DUSA's certificate of incorporation consistent with the terms of the rights plan.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

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**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 10<sup>th</sup> year (2011) of the lease by providing the landlord with notice at least 7 and one-half months prior to the date on which the termination would be effective. In October 2002, we entered into a five-year lease commitment for approximately 2,000 sq. ft., for our wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., replacing the space DUSA previously occupied. In October 2007, we entered into a 14 month lease extension for the New York office space, extending the lease through December 2008, with a renewal option for an additional year. 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 Chairman of the Board and shareholder services representative. In December 2006, we extended the Toronto lease for an additional five year term through August 2012.

We also leased office space in Vernon Hills, Illinois as a result of our acquisition of Sirius. This lease terminated in November 2007.

**ITEM 3. LEGAL PROCEEDINGS**

***LEVULAN® SUITS***

Since December 2004, we have filed lawsuits against physicians in several states to prevent their unlicensed use of versions of our Levulan<sup>®</sup> brand of aminolevulinic acid HCl (ALA) produced, by third-parties for use in our patented PDT treatment for actinic keratosis, basal cell carcinoma, or acne. The suits alleged that these physicians performed patient treatments that are covered under patents exclusively licensed by DUSA, resulting in direct infringement of these patent(s). Additionally, some physicians were sued for infringement of DUSA's trademarks and for violations of the Lanham Act for using the Levulan<sup>®</sup> brand name on their web sites and promotional materials, but performing patient treatments with ALA obtained from other sources. All of the lawsuits against physicians have settled favorably to us and DUSA has the right to review the physician's books and records to verify ongoing compliance.

We have also sued two compounding pharmacies which we believed were inducing physicians to infringe our patents on the photodynamic treatment of acne or actinic keratosis. These compounding pharmacies were selling ALA to those physicians. Both of the suits against the compounding pharmacies have been resolved in DUSA's favor, and DUSA has the right to review their books and records to verify ongoing compliance.

More recently, we sued chemical suppliers in United States District Court for the District of Arizona and the District of Utah, and a light device manufacturer, a distributor, and a sales representative in United States District Court for the Southern District of Ohio, Eastern Division, alleging that these defendants induce physicians to infringe patents licensed to us, among other things. These cases, have also been resolved in DUSA's favor, with DUSA having the right to review their books and records to verify ongoing compliance.

While we believe that certain actions of compounding pharmacies and others 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 companies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies



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which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

***RIVER S EDGE***

On March 28, 2006, a lawsuit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division by River s Edge Pharmaceuticals, LLC, or River s Edge, against us alleging, among other things, that, prior to the merger with DUSA, Sirius agreed to authorize River s Edge to market a generic version of Nicomide<sup>®</sup>, and that the United States patent covering Nicomide<sup>®</sup> issued to Sirius in December 2005 is invalid. Nicomide<sup>®</sup> is the key product DUSA acquired from Sirius in its merger. River s Edge has also filed an application with the U.S. Patent and Trademark Office requesting reexamination of the Nicomide<sup>®</sup> patent. On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that the River s Edge niacinamide product infringes U.S. Patent No. 6,979,468.

On October 28, 2007, we entered into a Settlement Agreement and Mutual Release to resolve all claims arising out of the litigation. Under the terms of the Settlement Agreement, River s Edge unconditionally acknowledged the validity and enforceability of the Nicomide<sup>®</sup> patent, made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and agreed to pay to DUSA \$25.00 for every bottle of NIC 750 above 5,000 bottles that is substituted for Nicomide<sup>®</sup> after September 30, 2007. River s Edge is responsible for all returns of NIC 750 from the distribution chain and/or order its destruction and immediately ceased the manufacture, distribution and sale of NIC 750. River s Edge withdrew from and ceased participating in the re-examination of our Nicomide<sup>®</sup> patent and consented to the return to us of the \$750,000 bond, which we received from the courts during the fourth quarter of 2007. On March 6, 2008, the USPTO vacated the reexamination.

As part of the settlement, DUSA and River s Edge have also entered into a license agreement, dated October 28, 2007 whereby DUSA granted a perpetual, exclusive license to River s Edge to manufacture and sell four of products from the AVAR<sup>®</sup> line, including AVAR cleanser, AVAR gel, AVAR E-emollient cream and AVAR E-green in exchange for a royalty on net sales of these products, including a guaranteed minimum royalty of \$300,000, payable in equal annual installments of \$100,000 for three years. DUSA provided its on-hand inventory of these products to River s Edge for no cost. DUSA acquired the AVAR products from Sirius Laboratories, Inc., the Illinois corporation, as a result of the merger which closed on March 10, 2006. In connection with the License Agreement, DUSA requested and received a waiver to certain obligations to promote the AVAR products being licensed to River s Edge from the Sirius shareholder representatives acting on behalf of all of the former shareholders of Sirius Laboratories, Inc. As consideration for the waiver, we and the Sirius shareholder representatives agreed to amend the merger agreement to extend the milestone termination date provided in the merger agreement by 8 additional months and agreed that for the balance of the 50 month period prior to the milestone termination date (as amended), DUSA will credit the cumulative net sales milestone amounts under the merger agreement with a monthly amount equal to the average of the last 12-months of net sales by DUSA of the four products licensed to River s Edge.

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

None.

**Table of Contents****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 Global 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, 2007:

	First	Second	Third	Fourth
NASDAQ				
High	\$4.53	\$5.00	\$3.15	\$3.30
Low	\$3.15	\$2.75	\$1.63	\$1.94

Price range per common share by quarter, 2006:

	First	Second	Third	Fourth
NASDAQ				
High	\$11.12	\$7.25	\$5.93	\$5.89
Low	\$ 6.57	\$3.87	\$3.85	\$3.52

On March 7, 2008, the closing price of our common stock was \$2.40 per share on the NASDAQ Global Market. On March 7, 2008, there were 830 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.

**RELATIVE STOCK PERFORMANCE**

The graph below compares DUSA Pharmaceuticals, Inc.'s cumulative 5-year total stockholder return on common stock with the cumulative total returns of the NASDAQ Market index and the Hemsco Group index. The graph tracks the performance of a \$100 investment in our common stock and in each of the indexes (with the reinvestment of all dividends) from December 31, 2002 to December 31, 2007. The comparisons in this graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

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**COMPARE 5-YEAR CUMULATIVE TOTAL RETURN  
AMONG DUSA PHARMACEUTICALS, INC.,  
NASDAQ MARKET INDEX AND HEMSCOTT GROUP INDEX  
ASSUMES \$100 INVESTED ON DECEMBER 31, 2002  
ASSUMES DIVIDEND REINVESTED  
FISCAL YEAR ENDING DEC. 31, 2007**

	Cumulative Return Total					
	12/31/02	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07
DUSA PHARMACEUTICALS, INC.	\$ 100.00	\$ 309.63	\$ 876.76	\$ 660.33	\$ 263.64	\$ 126.92
HEMSCOTT GROUP INDEX	\$ 100.00	\$ 138.99	\$ 147.38	\$ 163.55	\$ 182.68	\$ 207.46
NASDAQ MARKET INDEX	\$ 100.00	\$ 150.36	\$ 163.00	\$ 166.58	\$ 183.68	\$ 201.91

**ITEM 6. SELECTED FINANCIAL DATA**

The following information should be read in conjunction with our Consolidated Financial Statements and the Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report. The selected financial data set forth below has been derived from our audited consolidated financial statements.

**CONSOLIDATED STATEMENTS OF OPERATIONS DATA**

	YEAR ENDED DECEMBER 31,				
	2007	2006(4)	2005	2004	2003
Revenues	\$ 27,662,598	25,582,986	\$ 11,337,461	\$ 7,987,656	\$ 970,109
Net income (loss)	(14,713,507)(1)	(31,349,507)(2)	(14,998,709)	(15,628,980)	(14,826,854)
Basic and diluted net income (loss) per common share	\$ (0.73)	(1.65)	(0.89)	(0.96)	(1.06)

**CONSOLIDATED BALANCE SHEET DATA**

	YEAR ENDED DECEMBER 31,				
	2007	2006	2005	2004	2003
Total Assets	\$32,892,240	\$33,755,813	\$42,330,631	\$56,650,888	\$44,697,488
Long-term obligations (3)	4,501,186	1,199,086			1,247,500
Shareholders' equity	22,106,522	26,333,573	38,028,728	\$52,507,018	40,232,049

(1) Includes an impairment charge of \$6,773,000 resulting from our review of the carrying amount of our goodwill.



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- (2) Includes an impairment charge of \$15,740,000 resulting from our review of the carrying amount of our intangible assets.
- (3) Primarily comprised of deferred revenues related to milestone payments received under distribution agreements and the fair value of the warrants issued in connection with our October 29, 2007 private placement.
- (4) The results of operations include operations of Sirius Laboratories, Inc. from the date of acquisition, March 10, 2006.

**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 the section entitled "Risk Factors" .

**Overview**

DUSA is a vertically integrated dermatology company that is developing and marketing Levulan<sup>®</sup> PDT and other products for common skin conditions. The products we currently market include, among others Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with photodynamic therapy, the BLU-U<sup>®</sup> brand light source, certain products acquired in the March 10, 2006 merger with Sirius including, Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup>, and ClindaReach .

Historically, we devoted most of our resources to advancing the development and marketing of our Levulan<sup>®</sup> PDT/PD technology platform. In addition to our marketed products, our drug, Levulan<sup>®</sup> brand of aminolevulinic acid HCl, or ALA, in combination with light, has been studied in a broad range of medical conditions. When Levulan<sup>®</sup> is used and followed with exposure to light to treat a medical condition, it is known as Levulan<sup>®</sup> PDT. When Levulan<sup>®</sup> is used and followed with exposure to light to detect medical conditions, it is known as Levulan<sup>®</sup> photodetection, or Levulan<sup>®</sup> PD. Our Kerastick<sup>®</sup> is the proprietary applicator that delivers Levulan<sup>®</sup>.

The Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT and the BLU-U<sup>®</sup> brand light source were launched in the U.S. in September 2000 for the treatment of non-hyperkeratotic 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 FDA to market the BLU-U<sup>®</sup> without Levulan<sup>®</sup> PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Nicomide<sup>®</sup>, its key product, is an oral prescription vitamin supplement which is targeted to the market for inflammatory skin conditions such as acne. The merger has allowed us to expand our product portfolio with the launch of ClindaReach<sup>®</sup> in March 2007, capitalize on cross-selling and marketing opportunities, and increase the size of our sales force.

During the fourth quarter of 2007, we performed our annual test for goodwill impairment as required by Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets (SFAS 142). We use December 1st as the date of our annual goodwill impairment test. Based on the review, we have recorded an impairment charge to goodwill of \$6.8 million. The impairment charge is primarily driven by our revised estimate of cash flows

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associated with the Sirius products and product pipeline. Decisions related to the product pipeline were based on a number of factors, most importantly, DUSA's development partner's, Altana, Inc.'s, recent receipt of a non-approvable letter from the FDA with respect to its ANDA supplement covering one of the potential products we acquired from Sirius. We no longer expect to launch this product.

We manufacture our Levulan® Kerastick® in our own facility, while our other products are manufactured by third parties. We are responsible for the regulatory, sales, marketing, and customer service and other related product activities for our Levulan® Kerastick® and for all of our products. Our current objectives include increasing the sales of our products in the United States, Canada, Latin America, and Korea, launching Levulan® with our partners in Brazil and other Latin American countries and Asia, continuing to explore partnership opportunities for Levulan® PDT for dermatology in Europe and Japan, continuing our Levulan® PDT clinical development program for the moderate to severe acne indication. We are working toward having a distribution agreement in place for Japan by the end of the second quarter of 2008.

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® Kerastick® in Mexico, Central and South America. We have been actively working with Stiefel to obtain acceptable final pricing from the Brazilian regulatory authorities. In light of the unexpected delay in receiving acceptable final pricing in Brazil, in 2007 we amended certain terms of the original Stiefel agreement to reflect our plans to launch in other Latin American countries prior to Brazil. The product was launched in Argentina, Chile, Colombia, and Mexico during the fourth quarter of 2007. On March 5, 2008 Stiefel notified us that the Brazilian authorities had published the final pricing for the product which is acceptable to Stiefel and to us. We expect Stiefel to launch the product in Brazil shortly. Similarly, we entered into a marketing and distribution agreement with Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Company, or together, Daewoong, granting Daewoong exclusive rights to distribute the Levulan® Kerastick® in certain Asian countries. In the fourth quarter of 2007 the Korean Food and Drug Administration, or KFDA, approved Levulan® Kerastick® for PDT for the treatment of actinic keratosis and Daewoong launched our product.

We are developing Levulan® PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA®, DUSA Pharmaceuticals, Inc.®, Levulan®, Kerastick®, BLU-U® Nicomide®, Nicomide-T®, Meted®, Psoriacap®, Psoriatec®, AVAR®, AVAR Green®, AVAR-e®, AVAR-e Green®, and AVAR Cleanser® are registered trademarks we own or license. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

As of December 31, 2007, we had an accumulated deficit of approximately \$135,600,000. We believe that if operations continue as planned, we may be able to achieve profitability and be cash-flow positive on a quarterly basis by the fourth quarter of 2008. Achieving profitability in 2008 is dependent on our ability to continue to grow our PDT segment revenues, both internationally and domestically, our ability to regain the level of Nicomide® revenues we had attained without generic competition beginning in the second quarter of 2008, and our ability to sustain that level of revenues for the remainder of the year.

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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.

Net revenues generated by the products acquired as part of our acquisition of Sirius totaled \$9,388,000 for the twelve-month period ended December 31, 2007 and \$9,486,000 for the period from March 10, 2006 (date of acquisition) through December 31, 2006. The substantial majority of these revenues were from sales of Nicomide®. With the settlement of the River s Edge litigation in 2007, we expect moderate growth in our Non-PDT Drug Products revenues in 2008, primarily due to the belief that existing quantities of NIC 750 in the distribution channel should be substantially depleted by the end of March 2008 and we should regain our market share beginning in the second quarter of 2008. Our expectations for growth assume that there are no other products successfully introduced into the marketplace which would be substitutable for Nicomide® and that the FDA does not take enforcement action against Nicomide® as a marketed unapproved drug. We are pursuing an alternative labeling and distribution strategy that we believe we could deploy if the FDA takes such action.

We have continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. See the section entitled Management s Discussion and Analysis Results of Operations, Marketing and Sales Costs. We are encouraged with the year-over-year increase in PDT 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 continuing to explore opportunities to develop, market, and distribute our Levulan® PDT platform in Europe and expect that our distribution partners, Stiefel for Latin America and Daewoong for Asia will give the product increased visibility in the market and thereby advance our international strategy. 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.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. The FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with the FDA to begin that process. The FDA s enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide® could not be marketed as a dietary supplement with its current labeling. If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide® as an over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA would have a material impact on our Non-PDT Drug Product revenues.



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Label changes eliminating claims of certain medicinal benefits could make it more difficult to market Nicomide® and could therefore, negatively affect our revenues and profits.

Shortly after the closing of the merger with Sirius, we became engaged in patent litigation with River's Edge Pharmaceuticals LLC, or River's Edge, a company that launched a niacinamide-based product. River's Edge also requested that the United States Patent and Trademark Office, or USPTO, reexamine the Nicomide® patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties submitted their responses to the first office action. Although the court issued a preliminary injunction against sales of River's Edge's product in May 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process by the USPTO presented sufficient changed circumstances to warrant the dissolution of the injunction. On October 28, 2007, we entered into a settlement agreement and mutual release, or Settlement Agreement, and a license agreement with River's Edge ending the litigation. On March 6, 2008, the USPTO vacated the reexamination. See the section entitled Legal Proceedings-River's Edge. Nicomide® sales were adversely impacted throughout the litigation process and had a material negative impact on our revenues, results of operations and liquidity. With the settlement of the River's Edge litigation in 2007, we expect moderate growth in our Non-PDT Drug Products revenues in 2008.

We believe that issues related to reimbursement negatively impacted the economic competitiveness of our therapy with other AK therapies and 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 and the American Academy of Dermatology Association on matters related to PDT-related procedure fee and the separate drug reimbursement. In addition, in many cases, physicians can also bill for any applicable office visit reimbursements. 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® alone in the treatment of mild to moderate inflammatory acne of the face. Effective in January 2008, the national Medicare average reimbursement amount for our PDT-related procedure fee increased by approximately 18%. We believe that with increased reimbursement for our PDT-related procedure fee, including the 18% increase in January 2008, our treatment is increasingly financially viable for practitioners, and more competitive with alternative AK therapies from a practice management perspective. Most major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, plus potential future improvements, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time.

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. Since we cannot predict when product sales may offset the costs associated with these efforts, we expect that we will continue to generate operating losses through 2008. We are aware that physicians have been using Levulan® with the BLU-U® using short incubation times, and with light devices manufactured by other companies, and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called off-label uses, we believe that these activities are positively affecting the sales of our products.

As of December 31, 2007, we had a staff of 83 employees, including 4 part-time employees, as compared to 85 full-time employees, including 2 part-time employees, at the end of 2006, 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. At December 31, 2007, our sales force was comprised

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of 35 employees. During 2006, with the addition of the sales force from Sirius we increased the size of our sales force to 37 from 26 at the end of 2005. We may add and/or replace employees during 2008 as business circumstances deem necessary.

**2007 TRANSACTIONS**

During 2007, DUSA entered into a number of transactions:

*Winston Laboratories, Inc.*

On or about January 30, 2006, Winston Laboratories, Inc., or Winston, and the former Sirius entered into a license agreement relating to a Sirius product, Psoriatec® (known by Winston as Micanol) revising a former agreement. The original 2006 Micanol License Agreement granted an exclusive license, with limitation on rights to sublicense, to all property rights, including all intellectual property and improvements, owned or controlled by Winston to manufacture, sell and distribute products containing anthralin, in the United States. On January 29, 2008, our wholly-owned subsidiary, Sirius, entered into the 2006 Micanol Transition License Agreement with Winston. The Transition License Agreement amends the original 2006 Micanol License Agreement which was due to expire pursuant to its terms on January 31, 2008. The parties entered into the Transition License Agreement to extend the term of the 2006 Micanol License Agreement to September 30, 2008 in order to allow DUSA to sell its last batch of product, to reduce the period of time that we are required to maintain product liability insurance with respect to its distribution and sale of products containing anthralin after the termination of the Transition License Agreement and to confirm the allocation of certain costs and expenses relating to the product during and after the transition period. We will pay royalties on net sales of Psoriatec®, but we are no longer required to pay Winston a minimum royalty to maintain the license.

*Private Placement*

On October 29, 2007, we entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement with several investors for the private placement of 4,581,043 shares of our common stock at a purchase price of \$2.40 per share which resulted in gross proceeds to us of \$11,000,000, and warrants to purchase an additional 1,145,259 shares of common stock. The warrants become exercisable on April 30, 2008, have a term of five years from the initial exercise date, and have an exercise price of \$2.85 per share. On November 26, 2007, we registered the shares of common stock issued in the transaction and the shares underlying the warrants with the Securities and Exchange Commission for resale on a registration statement on Form S-3. On January 22, 2008, we filed an amended registration statement on Form S-3/A. This registration statement was declared effective by the Securities and Exchange Commission on January 24, 2008. The warrants are accounted for as a derivative liability at fair value on the Consolidated Balance Sheet.

*River s Edge*

On March 28, 2006, a lawsuit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division by River s Edge Pharmaceuticals, LLC, or River s Edge, against us alleging, among other things, that, prior to the merger with DUSA, Sirius agreed to authorize River s Edge to market a generic version of Nicomide®, and that the United States patent covering Nicomide® issued to Sirius in December 2005 is invalid. Nicomide® is the key product DUSA acquired from Sirius in its merger. River s Edge also filed an application with the U.S. Patent and Trademark Office requesting reexamination of the Nicomide® patent. On April 20, 2006, we filed a patent infringement suit in the United States

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District Court in Trenton, New Jersey alleging that the River s Edge niacinamide product infringes U.S. Patent No. 6,979,468.

On October 28, 2007, we entered into a Settlement Agreement and Mutual Release to resolve all claims arising out of the litigation. Under the terms of the Settlement Agreement, River s Edge unconditionally acknowledged the validity and enforceability of the Nicomide® patent, made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and agreed to pay to DUSA \$25.00 for every bottle of NIC 750 above 5,000 bottles that is substituted for Nicomide® after September 30, 2007. River s Edge is responsible for all returns of NIC 750 from the distribution chain and/or order its destruction and will immediately cease the manufacture, distribution and sale of NIC 750. River s Edge withdrew from and ceased participating in the re-examination of our Nicomide® patent and consented to the return to us of the \$750,000 bond, which was received by us during the fourth quarter of 2007. On March 6, 2008, the U.S. Patent and Trademark Office vacated the reexamination of the Nicomide® patent.

As part of the settlement, DUSA and River s Edge have also entered into a license agreement, dated October 28, 2007, whereby DUSA granted a perpetual, exclusive license to River s Edge to manufacture and sell four of products from the AVAR® line, including AVAR cleanser, AVAR gel, AVAR E-emollient cream and AVAR E-green in exchange for a royalty on net sales of these products, including a guaranteed minimum royalty of \$300,000, payable in equal annual installments of \$100,000 for three years. DUSA provided its on-hand inventory of these products to River s Edge for no cost. We recorded a gain of \$583,000 shown as Net gain from settlement of litigation, and will record royalties, as earned, in Product revenues in the Consolidated Statements of Operations.

*Stiefel Laboratories, Inc.*

In January, 2006, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc., or Stiefel, covering current and future uses of our proprietary Levulan® Kerastick® for PDT in dermatology. The agreement, grants Stiefel an exclusive right to distribute, promote and sell the Levulan® Kerastick® in the western hemisphere from and including Mexico south, and all other countries in the Caribbean, excluding United States territories. We will manufacture and supply to Stiefel on an exclusive basis in the territory all of Stiefel s reasonable requirements for the product. The agreement has an initial term of ten years. The Mexican, Argentinean, Colombian, and on March 5, 2008 the Brazilian regulatory authorities have granted their respective approvals to market the product. In September 2007, in light of the unexpected delay in receiving acceptable final pricing in Brazil, we amended certain terms of the original Stiefel agreement to reflect our plans to launch in other Latin American countries prior to Brazil. During the third quarter of 2007, our first shipments were released to Argentina and Mexico. Pursuant to the amendment, Stiefel will make aggregate milestone payments to us of up to \$2,250,000, rather than up to \$3,000,000 under the Agreement based upon: (i) launch of the product in either Mexico or Argentina which has been paid; (ii) upon receipt of acceptable pricing approval in Brazil; and (iii) achievement of pre-determined minimum purchase levels in the territory. In addition, the transfer price for the product was amended to set a fixed price plus a royalty on net sales, rather than a revenue-sharing arrangement as under the agreement. We believe that the amended transfer price reduces some of the risk related to currency and market price fluctuations during the ten-year term 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. Revenues associated with this agreement are recorded in accordance with Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue arrangements with Multiple Deliverables* (EITF 00-21).

*Daewoong Pharmaceutical Co., Ltd.*

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong covering current and future uses of the Levulan® Kerastick® for PDT

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in dermatology. The agreement grants Daewoong exclusive rights to distribute, promote and sell the Levulan® Kerastick® in Korea, Taiwan, China, including without limitation Hong Kong, India, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. We will manufacture and supply the product to Daewoong on certain terms and conditions.

The agreement has an initial term of ten years (subject to earlier termination and extension provisions). Daewoong will complete final integration and submission on our behalf of all registrations and regulatory filings for the product in the territory.

Under the terms of the agreement, Daewoong will make up to \$3,500,000 in milestone payments to us, \$1,000,000 of which was paid on signing, and \$1,000,000 of which was paid upon receipt of Korean regulatory approval of the product. The remaining milestones are based upon achievement of pre-determined cumulative sales targets in the territory subject to certain terms and conditions. In order to maintain its exclusive rights, Daewoong is obligated to purchase a certain number of units of the product and meet certain regulatory timelines. We will manufacture the product in our facility in Wilmington, Massachusetts. We will also receive a minimum transfer price per unit plus a percentage of Daewoong's end-user price above a certain level. Revenues associated with this agreement are recorded in accordance with EITF 00-21.

*Levulan® Lawsuits Filed*

Since December 2004, we have filed lawsuits against physicians in several states to prevent their unlicensed use of versions of our Levulan® brand of ALA produced, by third-parties for use in our patented PDT treatment for actinic keratosis, basal cell carcinoma, or acne. The suits alleged that these physicians performed patient treatments that are covered under patents exclusively licensed by DUSA, resulting in direct infringement of these patent(s). Additionally, some physicians were sued for infringement of DUSA's trademarks and for violations of the Lanham Act for using the Levulan® brand name on their web sites and promotional materials, but performing patient treatments with ALA obtained from other sources. As of the end of 2007, all of the lawsuits against physicians have settled favorably to us and DUSA has the right to review the physician's books and records to verify ongoing compliance.

We have also sued two compounding pharmacies which we believed were inducing physicians to infringe our patents on the photodynamic treatment of acne or actinic keratosis. These compounding pharmacies were selling ALA to those physicians. Both of the suits against the compounding pharmacies have been resolved in DUSA's favor, and DUSA has the right to review their books and records to verify ongoing compliance.

During 2006, we sued chemical suppliers in United States District Court for the District of Arizona and the District of Utah, and a light device manufacturer, a distributor, and a sales representative in United States District Court for the Southern District of Ohio, Eastern Division, alleging that these defendants induced physicians to infringe patents licensed to us, among other things. During 2007, these cases have been resolved in DUSA's favor, with DUSA having the right to review their books and records to verify ongoing compliance.

While we believe that certain actions of compounding pharmacies and others 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 companies 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.

**Table of Contents****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 and Provisions for Estimated Reductions to Gross Revenues*** We recognize revenues in accordance with Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*. Accounting for revenue transactions relies on certain estimates that require difficult, subjective and complex judgments on the part of management.

For revenues associated with contractual agreements with multiple deliverables, we apply the revenue recognition criteria outlined in SEC Staff Accounting Bulletin Topic 13, *Revenue Recognition* (SAB Topic 13) and EITF 00-21, *Revenue Arrangements with Multiple Deliverables*. Accordingly, revenues from contractual agreements are recognized based on the performance requirements of those agreements. As prescribed by EITF 00-21, we analyze each contract in order to separate each deliverable into separate units of accounting and then recognize revenue for those separated units at their fair values as earned in accordance with the SAB Topic 13 or other applicable revenue recognition guidance.

***PHOTODYNAMIC THERAPY (PDT) DRUG AND DEVICE PRODUCTS***

Revenues on the Kerastick<sup>®</sup> and BLU-U<sup>®</sup> product sales in the U.S. and Canada are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is probable. Product sales made through distributors, historically, have been recorded as deferred revenue until the product was sold by the distributors to the end users because we did not have sufficient history with our distributors to be able to reliably estimate returns. Beginning in the first quarter of 2006, we began recognizing revenue as product is sold to distributors because we believe we have sufficient history to reliably estimate returns from distributors beginning January 1, 2006. This change in estimate was not material to our revenues or results of operations. We offer programs that allow physicians access to our BLU-U<sup>®</sup> device for a trial period. No revenue is recognized on these units until the physician elects to purchase the equipment and all other revenue recognition criteria are met.

We have entered into exclusive marketing, distribution and supply agreements with distributors in Latin America and Korea that contain multiple deliverables. Revenues on the Kerastick<sup>®</sup> product sales made under these agreements are recorded in accordance with EITF 00-21 as described below.

*Stiefel Laboratories Agreement.* In January 2006, as amended in September 2007, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc. for Levulan<sup>®</sup> PDT in Latin America. Under the agreement, Stiefel is required to purchase Levulan<sup>®</sup> Kerastick<sup>®</sup> from us and make up front, milestone and royalty payments. Stiefel may cancel the agreement if there is a breach of contract, if either party files for bankruptcy, if its

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sales during any year are less than its minimum purchase obligations, or, as to Brazil only, if acceptable pricing approval, as defined in the agreement, is not obtained. No upfront or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications. We are obligated under the agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. The agreement establishes a fixed supply price per unit, as well as a royalty based on a percentage of the net sales price to end-users. Under EITF 00-21 the deliverables under the agreement are treated as a single unit of accounting. We determine attribution methods for each of the separate payment streams. Revenues from unit sales of Levulan® Kerastick® are recognized based on end-user demand as we do not have sufficient data to determine product acceptance in the marketplace and therefore do not have the ability to estimate product returns. Royalty revenues are recorded each quarter based on Stiefel's reported net sales for that quarter and are included in product revenues. The agreement also establishes minimum purchase quantities over the first five years following regulatory approval.

The non-refundable up-front payments are being recognized into revenues on a straight-line basis commencing upon the first product shipments in a country over the remaining contractual term of the agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2007, in accordance with our policy of deferring revenues on new product launches, we have deferred revenues of \$206,000 related to product shipments of Levulan® Kerastick® into Mexico and Argentina that have not yet been sold through to the end user customers. Deferred revenues at December 31, 2007 associated with milestone payments received from Stiefel are \$345,000.

*Daewoong Agreement.* On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement (the Agreement) with Daewoong for Levulan® PDT in Korea (see Note 13 to the Consolidated Financial Statements). Under the agreement, Daewoong is required to purchase Levulan® Kerastick® from us and make up-front and milestone payments. Daewoong may cancel the agreement only if there is a breach of contract or if either party files for bankruptcy. Under the terms of the agreement, Daewoong will make up to \$3.5 million in milestone payments to us, \$1.0 million of which was paid upon contract execution during the first quarter of 2007 and another \$1.0 million of which was paid during the fourth quarter of 2007 upon achieving regulatory approval in Korea. The milestone payments are non-refundable. Product shipments are subject to return and refund only if the product does not comply with technical specifications. We are obligated under the agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. The agreement establishes a fixed supply price per unit, as well as an excess purchase price component if the average selling price to end-users exceeds a certain threshold. Under EITF 00-21 the deliverables under the agreement are treated as a single unit of accounting. We determine attribution methods for each of the separate payment streams. Revenues from unit sales of Levulan® are recognized based on end-user demand as we do not have sufficient data to determine product acceptance in the marketplace and therefore do not have the ability to estimate product returns. Excess purchase price revenues are recorded each quarter based on Daewoong's reported net sales for that quarter and are included in product revenues. The agreement also establishes minimum purchase quantities over the first five years following regulatory approval in Korea.

The non-refundable up-front payments are recognized into revenues on a straight-line basis commencing upon the first product shipment in the territory over the remaining contractual

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term of the agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2007, in accordance with our policy of deferring revenues on new product launches, we have deferred revenues of \$762,000 related to product shipments of Levulan® Kerastick® into Korea that have not yet been sold through to the end user customers. Deferred revenues at December 31, 2007 associated with milestone payments received from Daewoong are \$1,848,000.

*Photocure Agreement.* On May 30, 2006, we entered into a patent license agreement under which we granted PhotoCure ASA a non-exclusive license under the patents we license from PARTEQ for ALA esters. In addition, we granted a non-exclusive license to PhotoCure for its existing formulations of Hexvix® and Metvix® (known in the U.S. as Metvixia®) for any patent we own now or in the future. PhotoCure is obligated to pay us royalties on sales of its ester products to the extent they are covered by our patents in the U.S. and certain other territories. As part of the agreement, PhotoCure paid us a prepaid royalty in the amount of \$1 million. Revenues recognized pursuant to the Photocure agreement have not been material to date. The balance of the prepaid royalty under the Photocure Agreement is included in deferred revenues in the accompanying Consolidated Balance Sheets.

***NON-PDT DRUG PRODUCTS***

We recognize revenue for sales of Non-PDT Drug Products when substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment to wholesale customers, with the exceptions described below. Revenue is recognized net of revenue reserves, which consist of allowances for discounts, returns, rebates, chargebacks and fees paid to wholesalers under distribution service agreements.

In the case of sales made to wholesalers as a result of incentives and that are in excess of the wholesaler's ordinary course of business inventory level, substantially all the risks and rewards of ownership do not transfer upon shipment and, accordingly, such sales are recorded as deferred revenue and the related costs as deferred cost of revenue until the product is sold through to the wholesalers' customers on a first in, first out basis.

We evaluate inventory levels at our wholesaler customers, which account for the vast majority of its sales in the Non-PDT Drug Products segment, through an analysis that considers, among other things, wholesaler purchases, wholesaler shipments to retailers, available end-user prescription data obtained from third parties and on-hand inventory data received directly from our three largest wholesaler customers. We believe that this evaluation of wholesaler inventory levels, allows us to make reasonable estimates for its applicable revenue related reserves. Additionally, our products are sold to wholesalers with a product shelf life that allows sufficient time for its wholesaler customers to sell its products in their inventory through to retailers and, ultimately, to end-user consumers prior to product expiration.

For new product launches where we do not have the ability to reliably estimate returns, revenue is recognized based on end-user demand, which is typically based on dispensed subscription data, or ship-through data as reported by our international distribution partners. When inventories have been reduced to targeted stocking levels at wholesalers or distribution partners, and we have sufficient data to determine product acceptance in the marketplace which allows us to estimate product returns, we recognize revenue upon shipment, net of discounts and allowances. During the fourth quarter of 2007, we recognized \$303,000 of revenues that had previously been deferred related to the ClindaReach launch in March 2007.

**Table of Contents*****SALES RETURNS***

We account for sales returns in accordance with Financial Accounting Standards Board (FASB) No. 48, *Revenue Recognition When Right of Return Exists*, by establishing an accrual in an amount equal to our estimate of sales recorded for which the related products are expected to be returned. We determine the estimate of the sales return accrual primarily based on historical experience regarding sales and related returns and incorporating other factors that could impact sales returns in the future. These other factors include levels of inventory in the distribution channel, estimated shelf life, product recalls, product discontinuances, price changes of competitive products, introductions of generic products and introductions of competitive new products. Our policy is to accept returns when product is within six months of expiration. We consider all of these factors and adjust the accrual periodically to reflect actual experience. In the PDT Drug and Device Products segment, product sales made through distributors, historically, had been recorded as deferred revenue until the product was sold by the distributors to the end users because we did not have sufficient history with our distributors to be able to reliably estimate returns. Beginning in the first quarter of 2006, we began recognizing revenue as product is sold to distributors because we believe we have sufficient history to reliably estimate returns from distributors beginning January 1, 2006. This change in estimate was not material to our revenues or results of operations.

***CHARGEBACKS, REBATES AND DISCOUNTS***

Chargebacks typically occur when suppliers enter into contractual pricing arrangements with end-user customers, including certain federally mandated programs, who then purchase from wholesalers at prices below what the supplier charges the wholesaler. Since we only offer preferred pricing to end-user customers under federally mandated programs, chargebacks have not been significant. Our rebate programs can generally be categorized into the following two types: Medicaid rebates and consumer rebates. Medicaid rebates are amounts owed based on legal requirements with public sector benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Consumer rebates are amounts owed as a result of mail-in coupons that are distributed by health care providers to consumers at the time a prescription is written.

We offer our wholesaler customers a 2% prompt pay discount. We evaluate the amount accrued for prompt pay discounts by analyzing the unpaid invoices in its accounts receivable aging subject to a prompt pay discount. Prompt pay discounts are known within 15 to 30 days of sale, and therefore can be reliably estimated based on actual and expected activity at each reporting date. We record these discounts at the time of sale and they are accounted for as a reduction of revenues.

***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, Intangible Assets and Goodwill***- We review long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If it is determined that the carrying value of long-lived or intangible assets may not be recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis. At December 31, 2007 and 2006, respectively, total property, plant and equipment had a net carrying value of \$2,143,000



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and \$2,567,000, including \$1,476,000 at December 31, 2007 associated with our manufacturing facility. As of December 31, 2007 and 2006, respectively, we had intangible assets totaling \$54,000 and \$102,000 recorded in deferred charges and other assets 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.

During the fourth quarter of 2007, we performed our annual test for goodwill impairment as required by FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). We use December 1st as the date of our annual goodwill impairment test. Based on the review, we have recorded an impairment charge to goodwill of \$6.8 million, which was all associated with the Non-PDT Drug Products reporting unit and represented the entire goodwill balance. As discussed in more detail in Note 4 to the Consolidated Financial Statements, the impairment charge is primarily related to our revised estimate of cash flows associated with the Sirius products and product pipeline. Decisions related to the product pipeline are based on a number of factors, most importantly, our development partner s, Altana, Inc. s, receipt of a non-approvable letter from the FDA in the fourth quarter of 2007 with respect to its ANDA supplement covering one of the potential products we acquired from Sirius. We no longer expect to launch this product or any other potential product from the Sirius acquisition. We paid and/or accrued \$500,000 in milestone payments in the fourth quarter of 2007 as a result of our decision not to pursue any additional potential products from the acquisition.

In 2006, we reviewed the valuation of our intangible assets and goodwill associated with Nicomide® for impairment as a result of a decision by the U.S courts to dissolve a preliminary injunction that had previously enjoined a competitor from manufacturing and selling a generic and recorded a write down of \$15.7 million in 2006, representing the remaining net asset value of the intangible assets as of December 31, 2006.

**Share-Based Compensation** - In December 2004, the FASB issued Statement No. 123R, *Share-Based Payment* (SFAS 123R). We adopted SFAS 123R effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006, we measure all employee share-based compensation awards using a fair value based method and record share-based compensation expense in our financial statements if the requisite service to earn the award is provided. The pro forma results and assumptions used in fiscal year 2005 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. 123R did not affect our net cash flow, but it did have a material negative impact on our results of operations. In accordance with SFAS 123R, we recognize the expense attributable to stock awards that are granted or vest in periods ending subsequent to December 31, 2005 in the accompanying Consolidated Statements of Operations. For more information about our share-based compensation, see Note 11 to the Consolidated Financial Statements.

**Derivative Financial Instruments** - We follow FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities*, or SFAS 133, for the common stock purchase warrants in connection with the October 2007 private placement. The warrants are accounted for as derivative liabilities at fair value in accordance with SFAS 133. The warrants do not meet the criteria in paragraph 11(a) of SFAS 133 that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders' equity. Changes in fair value of derivative liabilities are recorded in the Consolidated Statements of Operations under the caption "Change in fair value of warrant liabilities."

We record the warrant liability at its fair value using the Black-Scholes option-pricing model and revalue it at each reporting date until the warrants are exercised or expire. Changes in the fair value of the warrants are reported in our Statements of Operations as non-operating income or expense. The fair value of the warrants is subject to significant fluctuation based on changes in our stock price, expected volatility, remaining contractual life and the risk-free interest rate. The market price for our common stock has been and may continue to be volatile.

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Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrants.

**Results of Operations****Year Ended December 31, 2007 As Compared to the Year Ended December 31, 2006**

**Revenues** - Total revenues for 2007 were \$27,663,000, as compared to \$25,583,000 in 2006 and were comprised of the following:

	<b>Year ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>INCREASE/ (DECREASE)</b>
<b>PDT PRODUCT REVENUES</b>			
<b>LEVULAN® KERASTICK® PRODUCT REVENUES</b>			
United States	\$ 15,139,000	\$ 12,425,000	\$ 2,714,000
Canada	740,000	1,147,000	(407,000)
Korea	436,000		436,000
Rest of world	92,000		92,000
Subtotal Levulan® Kerastick® product revenues	16,407,000	13,572,000	2,835,000
<b>BLU-U® PRODUCT REVENUES</b>			
United States	1,724,000	2,292,000	(568,000)
Canada	94,000	233,000	(139,000)
Korea	50,000		50,000

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	<b>Year ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>INCREASE/ (DECREASE)</b>
Subtotal BLU-U <sup>®</sup> product revenues	1,868,000	2,525,000	(657,000)
<b>TOTAL PDT PRODUCT REVENUES</b>	<b>18,275,000</b>	<b>16,097,000</b>	<b>2,178,000</b>
<b>TOTAL NON-PDT DRUG PRODUCT REVENUES</b>	<b>9,388,000</b>	<b>9,486,000</b>	<b>(98,000)</b>
<b>TOTAL PRODUCT REVENUES</b>	<b>\$ 27,663,000</b>	<b>\$ 25,583,000</b>	<b>\$ 2,080,000</b>

For the year ended December 31, 2007 total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick<sup>®</sup> and BLU-U<sup>®</sup> products, were \$18,275,000. This represents an increase of \$2,178,000 or 14%, over the comparable 2006 total of \$16,097,000. The incremental revenue was driven primarily by increased Kerastick<sup>®</sup> revenues.

For the year ended December 31, 2007, Kerastick<sup>®</sup> revenues were \$16,407,000, representing an increase of \$2,835,000 or 21%, over the comparable 2006 totals of \$13,572,000. Kerastick<sup>®</sup> unit sales to end-users for the year ended December 31, 2007 were 164,944, including 9,798 sold in Canada and 7,392 sold in Korea. This represents an increase from 140,760 Kerastick<sup>®</sup> units sold in the year ended December 31, 2006, including 15,822 sold in Canada and 0 sold in Korea since the product was not yet approved. Our average net selling price for the Kerastick<sup>®</sup> increased to \$98.99 for the year ended December 31, 2007 from \$96.32 in 2006. Our average net selling price for the Kerastick<sup>®</sup> includes sales made directly to our end-user customers, as well as sales made to our distributors, in the United States, Canada, Korea and the rest of world. The increase in 2007 Kerastick<sup>®</sup> revenues was driven mainly by increased sales volumes in the United States and internationally, through our distribution agreements with Stiefel and Daewoong, and an increase in our average unit selling price. We believe our Kerastick<sup>®</sup> sales were negatively impacted in 2007 by the warning letter we received from the FDA in early 2007 relative to our marketing material. This letter caused us to cease using a significant amount of our marketing materials for several months during 2007 which made the selling effort of Kerastick<sup>®</sup> more difficult.

For the year ended December 31, 2007, BLU-U<sup>®</sup> revenues were \$1,868,000, representing a \$657,000 or a 26% decrease, over the comparable 2006 totals of \$2,525,000. The decrease in 2007 BLU-U<sup>®</sup> revenues was driven by lower overall sales volumes which were partially offset by an increase in our average selling price. In the year ended December 31, 2007, there were 232 units sold, versus 332 units in 2006. The 2007 total consists of 206 units sold in the United States, 16 in Canada by Coherent-AMT and 10 in Korea by Daewoong. The 2006 total consists of 292 sold in the United States and 40 sold in Canada. Our average net selling price for the BLU-U<sup>®</sup> increased to \$7,595 for the year ended December 31, 2007 from \$7,449 for 2006. Our BLU-U<sup>®</sup> evaluation program allows customers to take delivery for a limited number of BLU-U<sup>®</sup> units for a period of up to four months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At December 31, 2007, there were approximately 31 units in the field pursuant to this evaluation program, compared to 40 units in the field at December 31, 2006. 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 three years.

Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our March 10, 2006 acquisition of Sirius. Total revenues for the year ended December 31, 2007 were \$9,388,000, compared to \$9,486,000 for the period from March 10, 2006 (date of acquisition) through December 31, 2006. The substantial majority of the Non-PDT product revenues were from sales of Nicomide<sup>®</sup>. Nicomide<sup>®</sup> sales in 2007 were significantly



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impacted by the introduction into the market of NIC 750, a niacinamide product that was substituted for Nicomide<sup>®</sup>, which was re-launched in March 2007 following the dissolution by the court of a preliminary injunction. We have since reached a settlement agreement with River s Edge, the manufacturer of NIC 750. The settlement agreement is described further in Item 3. Legal Proceedings River s Edge.

The increase in our total revenues results from increased PDT segment revenues in the United States, as well as our PDT product launches in Korea and the rest of world. However, we must increase sales significantly from these levels in order for us to become profitable. We remain confident that sales should continue to increase through increased consumption of our PDT segment products by our existing customers, as well as the addition of new customers. We expect to be able to grow our PDT segment revenues in the United States during 2008, primarily due to the 18% percent increase in reimbursement of our PDT-related procedure fee, which became effective January 1, 2008. We also expect our PDT revenues in Canada to remain flat in 2008 largely due to the level of reimbursement to physicians in that country. In addition, with the settlement of the River s Edge litigation in 2007, we expect moderate growth in our Non-PDT Drug Products revenues in 2008, primarily due to our belief that existing quantities of NIC 750 in the distribution channel should be substantially depleted by the end of March 2008 and we should regain our market share beginning in the second quarter of 2008. Our expectations for growth assume that there are no other products successfully introduced into the marketplace which would be substitutable for Nicomide<sup>®</sup> and that the FDA does not take enforcement action against Nicomide as a marketed unapproved drug. We are pursuing an alternative labeling and distribution strategy that we believe we could deploy if the FDA takes such action. Also see the section entitled Risk Factors Any Failure to Comply with Government Regulations in the United States and Elsewhere Will Limit Our Ability to Market Our Products.

**Cost Of Product Revenues and Royalties** - Cost of product revenues and royalties for the year ended December 31, 2007 were \$7,829,000 as compared to \$26,116,000 for the year ended December 31, 2006 (including an impairment of intangible assets totaling \$15,740,000). A summary of the components of cost of product revenues and royalties is provided below:

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>Increase/ (Decrease)</b>
<b>Levulan<sup>®</sup> Kerastick<sup>®</sup> Cost of Product Revenues and Royalties</b>			
Direct Levulan <sup>®</sup> Kerastick <sup>®</sup> Product costs	\$ 2,384,000	\$ 1,944,000	\$ 440,000
Other Levulan <sup>®</sup> Kerastick <sup>®</sup> production costs including internal costs assigned to support products, net	280,000	837,000	(557,000)
Royalty and supply fees (1)	717,000	659,000	58,000
Subtotal Levulan <sup>®</sup> Kerastick <sup>®</sup> Cost of Product Revenues and Royalties	3,381,000	3,440,000	(59,000)
<b>BLU-U<sup>®</sup> Cost of Product Revenues</b>			
Direct BLU-U <sup>®</sup> Product Costs	733,000	1,131,000	(398,000)

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	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>Increase/ (Decrease)</b>
Other BLU-U <sup>®</sup> Product Costs including internal costs assigned to support products; as well as, costs incurred to ship, install and service the BLU-U <sup>®</sup> in physicians offices	836,000	1,015,000	(179,000)
Subtotal BLU-U <sup>®</sup> Cost of Product Revenues	1,569,000	2,146,000	(577,000)
<b>TOTAL PDT DRUG &amp; DEVICE COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>4,950,000</b>	<b>5,586,000</b>	<b>(636,000)</b>
Impairment of Intangible Assets (2)		15,746,000	(15,746,000)
Non-PDT Drug Cost of Product Revenues and Royalties	2,879,000	4,784,000	(1,905,000)
<b>TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>2,879,000</b>	<b>20,530,000</b>	<b>(17,651,000)</b>
<b>TOTAL COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>\$ 7,829,000</b>	<b>\$ 26,116,000</b>	<b>\$ (18,287,000)</b>

- 1) Royalty and supply fees reflect amounts paid to our licensor, PARTEQ and amortization of an upfront fee and ongoing royalties paid to Draxis Health, Inc., on sales of the Levulan<sup>®</sup> Kerastick<sup>®</sup> in Canada.
- 2) An impairment resulting from our review of the carrying amount of our intangible assets

of \$15,746,000.

**Margins** - Total product margins for 2007 were \$19,833,000, or 72% as compared to \$(533,000), or (2)% for 2006, as shown below:

	Year Ended December 31,				Increase/ (Decrease)
	2007		2006		
Levulan® Kerastick® Gross Margin	\$ 13,025,000	79%	\$ 10,132,000	75%	\$ 2,893,000
BLU-U® Gross Margin	299,000	16%	379,000	15%	(80,000)
Total PDT Drug & Device Gross Margin	\$ 13,324,000	73%	\$ 10,511,000	65%	\$ 2,813,000
Total Non-PDT Drug Gross Margin	6,509,000	69%	(11,044,000)	(116)%	17,553,000
<b>TOTAL GROSS MARGIN</b>	<b>\$ 19,833,000</b>	<b>72%</b>	<b>\$ (533,000)</b>	<b>(2)%</b>	<b>\$ 20,336,000</b>

For the year ended December 31, 2007, total PDT Drug and Device Product Margins were 73% versus 65% for the year ended December 31, 2006. The incremental margin was driven by positive margin gains on both the Kerastick® and BLU-U®.

Kerastick® gross margins for the year ended December 31, 2007 were 79%, versus 75% for the year ended December 31, 2006. The increase in margin is mainly attributable to an increase in our average unit selling price and lower overall manufacturing costs due to increased production volumes. Our long-term goal is to achieve higher gross margins on Kerastick® sales which will be significantly dependent on increased volume. We believe that we can achieve

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improved gross margins on our Kerastick® during 2008 due to the anticipated increased volumes from international, as well as continued domestic growth.

BLU-U® margins for the year ended December 31, 2007 were 16%, versus 15% for the year ended December 31, 2006. The increase in gross margin is a result of an increase in the average selling price per unit as well as the impact of a one-time sales promotion where we sold a limited number of earlier generation devices with zero cost basis. Our short-term strategy is to at a minimum break even on device sales in an effort to drive Kerastick® sales volumes.

Non-PDT Drug Product Margins reflect the gross margin generated by the products acquired as part of our March 10, 2006 merger with Sirius. Total margin for the year ended December 31, 2007 was 69% compared with (116%) for the period March 10, 2006 (date of acquisition) through December 31, 2006. In 2006, Non-PDT Drug Product Margins were negatively impacted by the recording of the inventory acquired in the Sirius merger at its fair value, in accordance with purchase accounting rules, and an impairment charge of \$15.7 million, representing the remaining net book value of the intangible assets. Non-PDT margins in 2007 were negatively impacted by increased rebates primarily associated with our Nicomide® product, increased royalty costs as a result of having a full year of royalties associated with our ClindaReach product, and general product mix. In 2008, we expect Non-PDT Drug Product gross margins to be in the 75-80% range due primarily to the expected growth of Nicomide® revenues with the settlement of the River's Edge litigation.

**Research and Development Costs** - Research and development costs for 2007 were \$5,977,000 as compared to \$7,814,000 in 2006, which for 2006 included \$1,600,000 related to in-process research and development acquired as part of the acquisition of Sirius.

In addition to the non-recurring \$1.6 million in-process research and development charge, the remaining decrease in 2007 compared to 2006 was due primarily to lower compensation costs for personnel attributable to research and development activities in the form of lower bonuses in 2007, a decrease in share-based compensation expense, reduced spending on Barrett's Esophagus, and the elimination of spending on photodamaged skin, all offset by increased spending on our Phase IIb clinical trial on acne, which commenced in March 2007.

Research and development expenses reflect the costs of our Phase IIb clinical trial for acne, which commenced in March 2007. We expect our research and development costs to increase to an even greater extent at such time as we may commence Phase III trials, or potentially a larger Phase II trial. The current Phase II trial is being conducted at 14 sites and will involve approximately 260 patients, when fully enrolled. To date, approximately 251 patients have been enrolled in this study. In November 2004, we signed a clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP are working together to prepare the overall clinical development plan for Levulan® PDT in this indication, starting with Phase I/II trials. A Phase I/II protocol has been finalized. The NCI DCP used its resources to file its own investigational new drug application with the FDA, and approval to initiate the study was received. Our costs related to this study will be limited to providing Levulan®, leasing lasers and the necessary training for the investigators involved. All other costs of this study are the responsibility of the NCI DCP. Although we expect the clinical trial on oral cavity dysplasia to commence in the first quarter of 2008, the actual timing of the initiation is within the total control of NCI so we cannot be certain of the initiation date. We have options on any new intellectual property.



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We have retained the services of a regulatory consultant to assist us with seeking foreign marketing approvals for our products, which will also cause research and development expenses to increase.

We are currently planning to initiate, in 2008, a DUSA-sponsored clinical trial, which we expect will include 30 to 40 patients, for the chemoprevention of squamous cell carcinoma in immunosuppressed solid organ transplant patients who are at risk of developing multiple skin cancers annually. A protocol outline has been prepared and reviewed, and we are expecting to file an Orphan Drug Designation Application during the first quarter of 2008.

We have entered into a series of agreements for our research projects and clinical studies. As of December 31, 2007, future payments to be made pursuant to these agreements, under certain terms and conditions, total approximately \$2,102,000 for 2008.

**Marketing and Sales Costs** Marketing and sales costs for the year ended December 31, 2007 were \$13,311,000 as compared to \$12,645,000 for the year ended December 31, 2006. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$8,386,000 for the year ended December 31, 2007, compared to \$8,672,000 in the year ended December 31, 2006. The decrease in this category was due to lower commissions earned in 2007 in comparison to 2006 due to lower performance against internal corporate goals. The remaining expenses consisted of tradeshow, miscellaneous marketing and outside consultants totaling \$4,685,000 for the year ended December 31, 2007, compared to \$3,603,000 for the year ended December 31, 2006. The increase in this category is due primarily to additional expenses related to the launch of ClindaReach, and increased expenses related to reimbursement improvement initiatives. We also recorded share-based compensation expense of \$240,000 for the year ended December 31, 2007, compared with \$370,000 in 2006. We expect marketing and sales costs to increase in 2008, compared with 2007, but to decrease as a percentage of revenues.

**General and Administrative Costs** General and administrative costs for the twelve months ended December 31, 2007 were \$10,311,000 as compared to \$11,196,000 for the year ended December 31, 2006. The decrease is mainly attributable to lower compensation in the form of bonuses for 2007, decreases in legal and share-based compensation expenses; offset partially by an increase in other professional services fees. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period particularly in light of our litigation strategy to protect our intellectual property. We expect general and administrative costs to decrease in 2008 due to lower expected patent litigation costs in light of the settlement with River's Edge.

**Impairment of Goodwill** During the fourth quarter of 2007, we performed our annual test for goodwill impairment as required by Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). Based on the review, we recorded an impairment charge to goodwill of \$6.8 million. The impairment charge was primarily related to our revised estimate of cash flows associated with the Sirius products and product pipeline.

**Net gain from settlement of litigation** During the fourth quarter of 2007 we entered into a Settlement Agreement and Mutual Release with River's Edge Pharmaceuticals, LLC. Under the terms of the Settlement Agreement, River's Edge made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and will pay to DUSA \$25.00 for every bottle of NIC 750 above 5,000 bottles that are substituted for Nicomide® after September 30, 2007. The net gain from settlement of litigation is comprised of the following:

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Proceeds from Settlement Agreement	\$ 425,000
Less: cost of inventory transferred to River s Edge	(95,000)
Plus: excess prescriptions filled	253,000
Net gain from settlement of litigation	\$ 583,000

**Other Income, Net** Other income for the year ended December 31, 2007, decreased to \$554,000, as compared to \$838,000 in 2006. This decrease reflects a reduction in our average investable cash balances during 2007 as compared to 2006 as we used cash to support our operating activities.

**Gain on change in fair value of warrants** The warrants issued to investors in connection with the October 29, 2007 private placement were recorded initially at fair value. The decrease in value during the period from the transaction date October 29, 2007 to December 31, 2007 of \$687,000, resulted in a non-cash gain. The decrease in fair value was due primarily to a reduction in our stock price from the transaction date to December 31, 2007.

**Income Taxes** There is no provision for income taxes due to ongoing operating losses. As of December 31, 2007, we had net operating loss carryforwards of approximately \$88,000,000 and tax credit carryforwards of approximately \$1,400,000 for Federal reporting purposes. These amounts expire at various times through 2027. We have provided a full valuation allowance against the net deferred tax assets at December 31, 2007 and 2006.

**Net Loss** For 2007, we recognized a net loss of \$14,714,000, or \$0.73 per share, as compared to \$31,350,000, or \$1.65 per share, for 2006. Net losses are expected to continue until our revenues increase to offset the cost of our sales force and marketing initiatives, and the costs for other business support functions. We believe we can achieve profitability and be cash-flow positive on a quarterly basis by the fourth quarter of 2008. Achieving profitability in 2008 is dependent on our ability to continue to grow our PDT segment revenues, both internationally and domestically, our ability to regain the level of Nicomide® revenues we had attained without generic competition beginning in the second quarter of 2008, and our ability to sustain that level of revenues for the remainder of the year.

**Year Ended December 31, 2006 As Compared to the Year Ended December 31, 2005**

**Revenues** - Total revenues for the year ended December 31, 2006 were \$25,583,000, as compared to \$11,337,000 in 2005 and were comprised of the following:

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>INCREASE/ (DECREASE)</b>
<b>PDT PRODUCT REVENUES</b>			
<b>KERASTICK® PRODUCT REVENUES</b>			
United States	\$ 12,425,000	\$ 7,957,000	\$ 4,468,000
Canada	1,147,000	935,000	212,000
Subtotal Kerastick® product revenues	13,572,000	8,892,000	4,680,000
<b>BLU-U® PRODUCT REVENUES</b>			
United States	2,292,000	1,930,000	362,000
Canada	233,000	515,000	(282,000)

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	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>INCREASE/ (DECREASE)</b>
Subtotal BLU-U <sup>®</sup> product revenues	2,525,000	2,445,000	80,000
<b>TOTAL PDT PRODUCT REVENUES</b>	<b>16,097,000</b>	<b>11,337,000</b>	<b>4,760,000</b>
<b>TOTAL NON-PDT DRUG PRODUCT REVENUES</b>	<b>9,486,000</b>		<b>9,486,000</b>
<b>TOTAL PRODUCT REVENUES</b>	<b>\$ 25,583,000</b>	<b>\$ 11,337,000</b>	<b>\$ 14,246,000</b>

For the year ended December 31, 2006, total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick<sup>®</sup> and BLU-U<sup>®</sup> products, were \$16,097,000. This represents an increase of \$4,760,000 or 42%, over the comparable 2005 total of \$11,337,000. The incremental revenue was driven primarily by increased Kerastick<sup>®</sup> revenues.

For the year ended December 31, 2006, Kerastick<sup>®</sup> revenues were \$13,572,000, representing an increase of \$4,680,000 or 53%, over the comparable 2005 totals of \$8,892,000. Kerastick<sup>®</sup> unit sales to end-users for the year ended December 31, 2006 were 140,760 including 15,822 sold in Canada. This represents an increase from 100,668 Kerastick<sup>®</sup> units sold in the year ended December 31, 2005, including 13,458 sold in Canada. Our average net selling price for the Kerastick<sup>®</sup> increased to \$96.32 for the year ended December 31, 2006 from \$88.33 in 2005. Our average net selling price for the Kerastick<sup>®</sup> includes sales made directly to our end-user customers, as well as sales made to our distributors, both in the United States during 2005 and Canada during 2005 and 2006. The increase in 2006 Kerastick<sup>®</sup> revenues was driven mainly by increased sales volumes, an increase in our average unit selling price and increased levels of direct distribution to customers. Effective January 1, 2006, DUSA became the sole United States distributor of the Kerastick<sup>®</sup>.

For the year ended December 31, 2006, BLU-U<sup>®</sup> revenues were \$2,525,000, representing an increase of \$80,000 or 3%, over the comparable 2005 totals of \$2,445,000. The increase in 2006 BLU-U<sup>®</sup> revenues was driven by slightly lower overall sales volumes which were offset by an increase in our average selling price. In the year ended December 31, 2006, there were 332 units sold versus 368 units in 2005. The 2006 total consists of 292 units sold in the United States and 40 sold in Canada by Coherent-AMT. The 2005 total consists of 276 sold in the United States and 92 sold in Canada. Our average net selling price for the BLU-U<sup>®</sup> increased to \$7,449 for the year ended December 31, 2006 from \$6,542 for 2005. The decrease in BLU-U<sup>®</sup> units sold in the year ended December 31, 2006 compared to the year ended December 31, 2005 is due primarily to lower Canadian sales volumes. Our BLU-U<sup>®</sup> evaluation program, which commenced in the fourth quarter of 2006, allows customers to take delivery of a unit for a limited number of BLU-U<sup>®</sup> units 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, 2006, there were approximately 40 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.

Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our March 10, 2006 acquisition of Sirius. Total revenues for the period from March 10, 2006 through December 31, 2006 were \$9,486,000. The substantial majority of the Non-PDT product revenues were from sales of Nicomide<sup>®</sup>. The products acquired from Sirius all belong to the same therapeutic category, non-photodynamic therapy dermatological treatment of acne and rosacea.



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**Cost Of Product Revenues and Royalties** - Cost of product revenues and royalties for the year ended December 31, 2006 were \$26,116,000 (including an impairment of intangible assets totaling \$15,740,000) as compared to \$6,214,000 for the year ended December 31, 2005. A summary of the components of cost of product revenues and royalties is provided below:

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>Increase/ (Decrease)</b>
<b>Kerastick® Cost of Product Revenues and Royalties</b>			
Direct Kerastick® Product costs	\$ 1,944,000	\$ 1,771,000	\$ 173,000
Other Kerastick® Product costs including internal costs assigned to support products	837,000	1,357,000	(520,000)
Royalty and supply fees (1)	659,000	456,000	203,000
Subtotal Kerastick® Cost of Product Revenues and Royalties	3,440,000	3,584,000	(144,000)
<b>BLU-U® Cost of Product Revenues</b>			
Direct BLU-U® Product Costs	1,131,000	1,249,000	(118,000)
Other BLU-U® Product Costs including internal costs assigned to support products; as well as, costs incurred to ship, install and service the BLU-U® in physicians offices	1,015,000	1,381,000	(366,000)
Subtotal BLU-U® Cost of Product Revenues	2,146,000	2,630,000	(484,000)
<b>TOTAL PDT DRUG &amp; DEVICE COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>5,586,000</b>	<b>6,214,000</b>	<b>(628,000)</b>
Impairment of Intangible Assets (2)	15,746,000		15,746,000
Non-PDT Drug Cost of Product Revenues and Royalties (3)	4,784,000		4,784,000
<b>TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>20,530,000</b>		<b>20,530,000</b>
<b>TOTAL COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>\$ 26,116,000</b>	<b>\$ 6,214,000</b>	<b>\$ 19,902,000</b>

- 1) Royalty and supply fees reflect amounts paid to our licensor, PARTEQ and amortization of

an upfront fee and ongoing royalties paid to Draxis Health, Inc., on sales of the Levulan® Kerastick® in Canada.

- 2) An impairment resulting from our review of the carrying amount of our intangible assets of \$15,746,000.
- 3) Non-PDT Drug Cost of Product Revenues and Royalties reflect the costs associated with the products acquired as part of our March 10, 2006 merger with Sirius.

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**Margins** - Total product margins for 2006 were \$(533,000) as compared to \$5,123,000 for 2005, as shown below:

	Year Ended December 31,				Increase/ (Decrease)
	2006		2005		
Kerastick® Gross Margin	\$ 10,132,000	75%	\$ 5,308,000	60%	\$ 4,824,000
BLU-U® Gross Margin	379,000	15%	(185,000)	(7)%	564,000
Total PDT Drug & Device Gross Margin	\$ 10,511,000	65%	\$ 5,123,000	45%	\$ 5,388,000
Total Non-PDT Drug Gross Margin	(11,044,000)	(116)%			(11,044,000)
<b>TOTAL GROSS MARGIN</b>	<b>\$ (533,000)</b>	<b>(2)%</b>	<b>\$ 5,123,000</b>	<b>45%</b>	<b>\$ 5,656,000</b>

For the year ended December 31, 2006, total PDT Drug and Device Product Margins were 65%, versus 45% for the year ended December 31, 2005. The incremental margin was driven by positive margin gains on both the Kerastick® and BLU-U®.

Kerastick® gross margins for the year ended December 31, 2006 were 75%, versus 60% for the year ended December 31, 2005. Similar to the increase in revenues, the increase in margin is mainly attributable to an increase in our average unit selling price, and increased levels of direct distribution to customers eliminating the cost of distributors.

BLU-U® margins for the year ended December 31, 2006 were 15%, versus (7%) for the year ended December 31, 2005. The increase in gross margin is a result of an increase in the average selling price per unit; as well as, lower overall costs incurred to support the product line.

Non-PDT Drug Product Margins reflect the gross margin generated by the products acquired as part of our March 10, 2006 merger with Sirius. Total margin for the period from March 10, 2006 (date of acquisition) through December 31, 2006 was (116%). Non-PDT Drug Product Margins were negatively impacted by the recording of the inventory acquired in the Sirius merger at its fair value, in accordance with purchase accounting rules, and an impairment charge. The full impact of the inventory adjustment was recognized over the six months following the acquisition. We reviewed the valuation of our intangible assets and goodwill associated with our Non-PDT products for impairment and recorded a write down of \$15.7 million in 2006, representing the remaining book value of the intangible assets.

**Research and Development Costs** Research and development costs for the year ended December 31, 2006 were \$6,214,000 as compared to \$5,588,000 in 2005.

Contributing to the increase in spending in 2006 compared with 2005 is the receipt of a refund from the FDA in 2005 for our 2003 and 2004 product and registration fees in the amount of approximately \$530,000.

	2006	2005	Increase (Decrease)
Research & Development costs incurred	\$ 6,214,000	\$ 6,118,000	\$ 96,000
Refund of FDA product and registration fees		(530,000)	530,000
Total Research and Development Expense	\$ 6,214,000	\$ 5,588,000	\$ 626,000

The increase in 2006 compared to 2005 was due primarily to the recording of share-based compensation expense of \$621,000 for the year ended December 31, 2006 resulting from the





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adoption of SFAS 123R. This increase was offset, in part, by reduced spending on clinical programs as we completed both our Phase II acne study and our interim analysis study on photodamaged skin in the first quarter of 2006.

**Marketing and Sales Costs** Marketing and sales costs for the year ended December 31, 2006 were \$12,645,000 as compared to \$9,069,000 for the year ended December 31, 2005. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel and telephone, totaling \$8,672,000 for the year ended December 31, 2006, compared to \$6,934,000 in the year ended December 31, 2005. The increase in this category was due to increased headcount in 2006 in comparison to 2005, primarily as the result of the Sirius acquisition. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling \$3,603,000 for the year ended December 31, 2006, compared to \$2,135,000 for the year ended December 31, 2005. The increased spending in this category was due primarily to additional expenses related to the Sirius acquisition. We also recorded share-based compensation expense of \$370,000 for the year ended December 31, 2006, resulting from the adoption of SFAS 123R.

**General and Administrative Costs** General and administrative costs for the year ended December 31, 2006 were \$11,196,000 as compared to \$6,703,000 for the year ended December 31, 2005. The increase was mainly attributable to incremental legal fees primarily related to the River s Edge litigation, share-based compensation expense of \$1,213,000 for the year ended December 31, 2006 resulting from the adoption of SFAS 123R, and incremental costs associated with the acquisition of Sirius.

**Other Income, Net** Other income for the year ended December 31, 2006 decreased to \$838,000, as compared to \$1,388,000 in 2005. This decrease reflects a reduction in our average investable cash balances during 2006 as we used cash to purchase Sirius, as well as to support our operating activities.

**Income Taxes** There was no provision for income taxes due to ongoing operating losses. We have provided a full valuation allowance against the net deferred tax assets at December 31, 2006 and 2005.

**Net Loss** For the year ended December 31, 2006, we recognized a net loss of \$31,350,000, or \$1.65 per share, as compared to \$14,999,000, or \$0.89 per share, for the year ended 2005.

**QUARTERLY RESULTS OF OPERATIONS**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2007 and 2006, respectively:

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2007			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31(1)
Net revenues	\$ 6,676,840	\$ 6,862,198	\$ 5,784,194	\$ 8,339,366
Gross profit	4,520,688	5,085,707	4,210,297	6,016,622
Net loss	(3,370,928)	(2,477,407)	(1,877,782)	(6,987,390)
Basic and diluted loss per share	\$ (0.17)	\$ (0.13)	\$ (0.10)	\$ (0.31)

  

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2006			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31(2)
Net revenues	\$ 4,750,520	\$ 6,619,109	\$ 6,062,720	\$ 8,150,637
Gross profit	2,959,761	3,623,946	3,213,236	(10,329,946)
Net loss	(4,640,309)	(4,653,954)	(3,786,639)	(18,268,605)
Basic and diluted loss per share	\$ (0.26)	\$ (0.24)	\$ (0.19)	\$ (0.94)

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(1) In the fourth quarter of 2007, we recorded an impairment charge to our goodwill balance of \$6.8 million.

(2) In the fourth quarter of 2006, we recorded an impairment charge to our intangible assets of \$15.7 million.

**Liquidity and Capital Resources**

At December 31, 2007, we had approximately \$23,025,000 of total liquid assets, comprised of \$4,713,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$18,312,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next two years. We have invested our funds in liquid investments, so that we will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis. As of December 31, 2007, these securities had a weighted average yield of 2.34% and maturity dates ranging from January 2008 to October 2011. Our net cash used in operations for the year ended December 31, 2007 was \$4,986,000, versus \$8,727,000 used in the year ended December 31, 2006. The year over year decrease is directly attributable to growth in revenues and gross margins in our PDT operating segment. As of December 31, 2007, working capital (total current assets minus total current liabilities) was \$24,021,000, as compared to \$18,085,000 as of December 31, 2006. Total current assets increased by \$6.0 million during the year ended December 31, 2007, due primarily to increases in cash and cash equivalents and marketable securities. This increase resulted from our private placement of 4,581,043 shares of our common stock in the fourth quarter of 2007 in which we received net proceeds of approximately \$10.3 million, milestone payments received in the aggregate amount of \$2.4 million from our international distribution partners, Daewoong and Stiefel, and proceeds from the settlement agreement reached with River s Edge, offset in part by payments made to the former shareholders of Sirius in the amount of \$500,000 related to the achievement of a product approval and/or launch milestones and \$250,000 in lieu of a product approval milestone, as provided for in the merger agreement. In addition, in January 2008, we made a second payment of \$250,000 to the former Sirius shareholders in lieu of a product approval milestone, which relieved us of all of our obligations with respect to such milestone payments. Total current liabilities increased by \$61,000 during the same period due primarily to increases in accounts payable and deferred revenues, offset in part by decreases in accrued compensation and other accrued expenses.

Since our inception, we have generated significant losses while we have advanced our product candidates into preclinical and clinical trials, development and commercialization. We have funded our operations primarily through public offerings, private placements of equity securities and payments received under our collaboration agreements. We expect to incur significant additional research and development and other costs including costs related to preclinical studies and clinical trials. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our collaborators may exceed revenues in the future, which may result in continued losses from operations.

We have agreed to pay additional consideration to the former shareholders of Sirius in future periods, based upon the attainment of pre-determined total cumulative sales milestones for the Sirius products. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments which may be paid in cash or DUSA shares, as DUSA may determine, are, as follows:

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Cumulative Sales Milestone:	Additional Consideration:
\$25.0 million	\$1.5 million
35.0 million	\$1.0 million
45.0 million	\$1.0 million
Total	\$3.5 million

As of December 31, 2007, none of these milestones had been achieved. However, we expect that the first of these milestones will be achieved in 2008.

We are actively seeking to further expand or enhance our business by using our resources to acquire by license, purchase or other arrangements, additional businesses, new technologies, or products in the field of dermatology. For 2008, we are focusing primarily on increasing the sales of the Levulan<sup>®</sup> Kerastick<sup>®</sup> and the BLU-U<sup>®</sup>, as well as the Non Photodynamic Therapy Drug Products and advancing our Phase II study for use of Levulan<sup>®</sup> PDT in acne.

DUSA has no off-balance sheet financing arrangements.

**Contractual Obligations and Other Commercial Commitments*****ALTANA, INC.***

In September 2005, the former Sirius entered into a development and product license agreement with Altana, Inc. relating to a reformulated dermatology product pursuant to a supplement to an abbreviated new drug application, or ANDA, which was submitted by Altana to the FDA. This agreement was assigned to us by virtue of the Sirius merger. According to the agreement, we were required to pay for all development costs. In January 2008, Altana received a non-approvable letter from the FDA with respect to its ANDA supplement. Based on the FDA action which required Altana to withdraw the ANDA supplement, DUSA will not receive pre-market approval to launch this product as previously anticipated. Furthermore, in light of preliminary market research data which was equivocal as to the potential acceptability of the product due to the changing competitive environment, DUSA has decided not to launch this product and has notified Altana to cease all development activities.

***ACTAVIS TOTOWA, LLC***

Under an agreement dated May 18, 2001, and amended on February 8, 2006, the former Sirius entered into an arrangement for the supply of Nicomide<sup>®</sup> with Amide Pharmaceuticals, Inc., now known as Actavis Totowa, LLC. The agreement was assigned to us as part of the Sirius merger. Currently, Actavis Totowa supplies all of our requirements; however, we have the right to use a second source for a significant portion of our needs if we choose to do so. The agreement expires on February 8, 2009. Actavis Totowa has received several warning letters from the FDA regarding certain regulatory observations. To our knowledge, the primary observations noted in the warning letters were not related to Nicomide. However, with respect to Nicomide<sup>®</sup> and certain other products manufactured by Actavis Totowa that would be covered under FDA's recent compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs", Actavis Totowa has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and that the FDA believes Nicomide<sup>®</sup> could not be marketed as a dietary supplement with its current labeling. The FDA may take further action against Actavis Totowa and DUSA is evaluating its options in order to be prepared in case such actions occur.

**Table of Contents*****L. PERRIGO COMPANY***

On October 25, 2005, the former Sirius entered into a supply agreement with L. Perrigo Company, or Perrigo, for the exclusive manufacture and supply of a proprietary device/drug kit designed by Sirius pursuant to an approved ANDA owned by Perrigo. The agreement was assigned to us as part of the Sirius merger. We were responsible for all development costs and for obtaining all necessary regulatory approvals and have now launched the product, ClindaReach. Perrigo is entitled to royalties on net sales of the product, including certain minimum annual royalties, which commenced May 1, 2006, in the amount of \$250,000. The initial term of the agreement expires in July, 2011 and may be renewed based on certain minimum purchase levels and other terms and conditions.

***MERGER WITH SIRIUS LABORATORIES, INC.***

In March 2006, we closed our merger to acquire all of the common stock of Sirius Laboratories Inc. in exchange for cash and common stock worth up to \$30,000,000. Of the up to \$30,000,000, up to \$5,000,000, (\$1,500,000 of which would be paid in cash, and \$3,500,000 of which would be paid 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. With the launch of ClindaReach, one of the new Sirius products, we were obligated to make a cash payment of \$500,000 to the former shareholders of Sirius. Also, as a consequence of the decision not to launch the product under development with Altana and pursuant to the terms of the merger agreement with Sirius, DUSA paid \$250,000 on a pro rata basis to the former Sirius shareholders. Similarly, with the decision by DUSA in early 2008 not to develop a third product from a list of product candidates acquired as part of the merger, another \$250,000 was paid on a pro rata basis to the former Sirius shareholders. The payments for ClindaReach and the other two product decisions satisfy DUSA's obligations for the \$1,500,000 portion of the purchase price mentioned above.

***PHOTOCURE ASA***

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby we granted a non-exclusive license to PhotoCure for esters of aminolevulinic acid, or ALA, under the patents we license from PARTEQ. ALA is the active ingredient in DUSA's Levula<sup>®</sup> products. Furthermore, we granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any DUSA patents that may issue or be licensed by us in the future. PhotoCure received FDA approval to market Metvixia<sup>®</sup> for treatment of AKs in July 2004 and Metvixia<sup>®</sup> would be directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product should PhotoCure decide to begin marketing this product. While we are entitled to royalties from PhotoCure on its net sales of Metvixia<sup>®</sup>, this product may adversely affect our ability to maintain or increase our market.

***WINSTON LABORATORIES, INC.***

On or about January 30, 2006 Winston Laboratories, Inc., or Winston, and the former Sirius entered into a license agreement relating to a Sirius product, Psoriatec<sup>®</sup> (known by Winston as Micanol) revising a former agreement. The original 2006 Micanol License Agreement granted an exclusive license, with limitation on rights to sublicense, to all property rights, including all intellectual property and improvements, owned or controlled by Winston to manufacture, sell and distribute products containing anthralin, in the United States. On January 29, 2008, our wholly-owned subsidiary, Sirius, entered into the 2006 Micanol Transition License Agreement with Winston. The Transition License Agreement amends the original 2006 Micanol License Agreement which was due to expire pursuant to its terms on January 31, 2008.

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The parties entered into the Transition License Agreement to extend the term of the 2006 Micanol License Agreement to September 30, 2008 in order to allow DUSA to sell its last batch of product, to reduce the period of time that Sirius is required to maintain product liability insurance with respect to its distribution and sale of products containing anthralin after the termination of the Transition License Agreement and to confirm the allocation of certain costs and expenses relating to the product during and after the transition period. We will pay royalties on net sales of Psoriatec<sup>®</sup>, but we are no longer required to pay Winston a minimum royalty to maintain the license.

***PARTEQ AGREEMENT***

We license certain patents underlying our Levulan<sup>®</sup> PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations, or PARTEQ. Under the agreement, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell certain products, including ALA. The agreement covers certain use patent rights. When we sell 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 payments we receive on sales of products by the sublicensee. We are 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.

For the years ended December 31, 2007, 2006 and 2005, actual royalties based on product sales were approximately \$620,000, \$522,000, and \$340,000, respectively. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$102,000 as of December 31, 2007).

***NATIONAL BIOLOGICAL CORPORATION AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT***

On June 21, 2004, we signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation ( NBC ), the manufacturer of our BLU<sup>®</sup>light source. This agreement provides for the elimination of certain exclusivity clauses, permits us to order on a purchase order basis without minimums, and includes 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. We paid \$110,000 to NBC upon execution of the agreement which is being amortized over the remaining term of the agreement, expiring November 5, 2008. We expect to enter into discussions with NBC in the second quarter of 2008 regarding an extension to the agreement.

***SOCHINAZ SA***

Under an agreement dated December 24, 1993, Sochinaz SA manufactures and supplies our requirements of Levulan<sup>®</sup> 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.

**Table of Contents****LEASE AGREEMENTS**

We have 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.

**RESEARCH AGREEMENTS**

We have entered into various agreements for research projects and clinical studies. As of December 31, 2007, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$2,425,000. Included in this future payment is a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years, with annual renewal periods thereafter, to engage Therapeutics to manage the clinical development of our products in the field of dermatology. The agreement was renewed on June 15, 2007 for a one year period. Therapeutics is entitled to receive a bonus valued at \$50,000, in cash or stock at our discretion, upon each anniversary of the effective date. Therapeutics has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000 depending on the regulatory phase of development of products during Therapeutics management.

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, 2007:

	Total	1 Yr or less	2-3 Years	4-5 Years	After 5
Operating lease obligations	\$ 2,186,000	\$ 509,000	\$ 922,000	\$ 755,000	\$ 0
Purchase obligations (1, 2)	3,456,000	3,048,000	408,000		
Minimum royalty obligations (3)	1,270,000	361,000	672,000	172,000	65,000
Total obligations	\$ 6,912,000	\$ 3,918,000	\$ 2,002,000	\$ 927,000	\$ 65,000

- 1) Research and development projects include various commitments including obligations for our Phase II clinical study for 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) Minimum royalty obligations relate to our agreements with PARTEQ, Winston and Perrigo described above. Rent expense incurred under these operating leases was approximately \$476,000, \$477,000, and \$477,000 for the years ended December 31, 2007, 2006, and 2005, respectively.

**Recently Issued Accounting Guidance**

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*. This statement amends SFAS No. 141 and provides revised guidance for recognizing and measuring assets acquired and liabilities assumed in a business combination. This statement also requires that transaction costs in a business combination be expensed as incurred. SFAS No. 141R applies

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prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS No. 141R will impact our accounting for business combinations, if any, completed beginning January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*. SFAS No. 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method will significantly change the accounting for transactions with minority interest holders. The provisions of this standard are effective beginning January 1, 2009. We are evaluating the potential impact of adoption of this standard on our consolidated financial position and results of operations.

In February 2007 the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. This statement is effective for fiscal years beginning after November 15, 2007. We are in the process of evaluating the impact, if any, that SFAS 159 will have on our financial statements.

In September 2006 the FASB issued SFAS No. 157, *Fair Market Measurements*. SFAS No. 157 establishes a framework for measuring fair value and expands disclosures about the use of fair value measurements and liabilities in interim and annual reporting periods subsequent to initial recognition. Prior to SFAS 157, which emphasizes that fair value is a market-based measurement and not an entity-specific measurement, there were different definitions of fair value and limited definitions for applying those definitions in GAAP. SFAS 157 is effective for us on a prospective basis for the reporting period beginning January 1, 2008. In February 2008, the Board issued FASB Staff Position (FSP) FAS 157-2, *Partial Deferral of the Effective Date of Statement 157*. The effect of adoption on the Company's financial position and results of operations have not been determined.

### **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**

### **Interest Rates**

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

As of December 31, 2007, the weighted average rate of return on our investments was 2.34%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of December 31, 2007, the fair market value of the portfolio would decline by \$188,000. Declines in interest rates could, over time, reduce our interest income.

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**Derivative Financial Instruments**

The warrants that we issued on October 29, 2007 in connection with the private placement of our common stock were determined to be derivative financial instruments and accounted for as a liability. These warrants are revalued on a quarterly basis with the change in value reflected in our earnings. We value these warrants using various assumptions, including the Company's stock price as of the end of each reporting period, the historical volatility of the Company's stock price, and risk-free interest rates commensurate with the remaining contractual term of the warrants. Changes in the Company's stock price or in interest rates would result in a change in the value of the warrants.

**Currency Exchange Rates**

The royalties we earn each quarter under our agreement with Stiefel Laboratories are based on a percentage of the net sales to end-users. These royalties are calculated in local currencies and converted to and paid in United States dollars each reporting period.

Under our agreement with Daewoong, revenues we earn under the excess purchase price provision of the agreement, if any, are calculated based on end-user pricing in local currencies and converted to United States dollars before a determination is made whether any payments are due us. These payments, if any, are made in United States dollars each reporting period.

**Forward-Looking Statements Safe Harbor**

This report, including the Management's Discussion and Analysis of Financial Condition and Results of Operations, 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 expectation of becoming profitable during 2008, statements regarding our strategies and core objectives for 2008, the results of our integration of Sirius Laboratories, Inc. with our business and matters relating thereto, our expectations concerning the introduction of generic substitutes for Nicamide<sup>®</sup> and such products' impact on sales of Nicamide<sup>®</sup>, our use of estimates and assumptions in the preparation of our financial statements and policies and impact on us of the adoption of certain accounting standards, the impact of compounding pharmacies, beliefs regarding estimates, beliefs concerning ClindaReach<sup>®</sup> and its impact on other products and revenues, management's beliefs regarding the unique nature of Levulan<sup>®</sup> and its use and potential use, expectations regarding the timing of results of clinical trials, future development of Levulan<sup>®</sup> and our other products 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 beliefs regarding the safety, simplicity, reliability and cost-effectiveness of certain light sources, our expectations regarding other product launches in Brazil and other territories, expectations regarding additional market expansion, expectations for commercialization of Levulan<sup>®</sup> Kerastick<sup>®</sup> in 11 Asian countries and a distribution agreement for Japan, expectations regarding the marketing and distribution of Levulan<sup>®</sup> Kerastick<sup>®</sup> by Daewoong Pharmaceutical Co., Ltd., beliefs regarding the clinical benefit of Levulan<sup>®</sup> PDT for acne and other indications, beliefs regarding the suitability of clinical data, expectations regarding the confidentiality of our proprietary information, statements of our intentions to seek additional U.S. and foreign regulatory approvals, and to 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, intentions to defend our patent estate, the impact of a third-party's regulatory compliance and fulfillment of contractual obligations, and our anticipation that third parties will launch products upon receipt of regulatory approval,



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expectations of increases in cost of product sales, expected use of cash resources, requirements of cash resources for our future liquidity, beliefs regarding investments and economic conditions, expectations regarding outstanding options and warrants and our dividend policy, anticipation of increases or decreases in personnel, beliefs regarding the effect of reimbursement policies on revenues and acceptance of our therapies, expectations for future strategic opportunities and research and development programs and expenses, expectations for continuing operating losses and competition including from Metvixia, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding increased sales and marketing costs and research and development costs, levels of interest income and our capital resource needs, intention to raise additional funds to meet capital requirements and the potential dilution and impact on our business, potential for additional inspection and testing of our manufacturing facilities or additional FDA actions, beliefs regarding the adequacy of our inventory of Kerastick® and BLU-U® units, our manufacturing capabilities and the impact of inventories on revenues, beliefs regarding interest rate risks to our investments and effects of inflation, beliefs regarding the impact of any current or future legal proceedings, dependence on key personnel, and beliefs concerning product liability insurance, the enforceability of our patents, the impact of generic products, our beliefs regarding our sales and marketing efforts, competition with other companies, the adoption of our products, and the outcome of such efforts, our beliefs regarding our sales and marketing efforts, our beliefs regarding the use of our products and technologies by third parties, our beliefs regarding our compliance with applicable laws, rules and regulations, our beliefs regarding available reimbursement for our products, our beliefs regarding the current and future clinical development and testing of our potential products and technologies and the costs thereof, the volatility of our stock price, the impact of our rights plan, and the possibility that the holders of options and warrants will purchase our common stock by exercising these securities. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, 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 us, 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**

The following financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K:

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.

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**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures.* We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

*Changes In Internal Control Over Financial Reporting.* The Chief Executive Officer and Chief Financial Officer have concluded that there have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our 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, 2007.

The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of

DUSA Pharmaceuticals, Inc.

Wilmington, Massachusetts

We have audited the internal control over financial reporting of DUSA Pharmaceuticals, Inc. and subsidiaries (the Company ) as of December 31, 2007, 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, included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 of the Company and our report dated March 10, 2008 expressed an unqualified opinion on those financial statements and included an explanatory paragraph relating to the adoption of Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of Financial Accounting Standards Board Statement No. 109*, effective January 1, 2007.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 10, 2008

**ITEM 9B. OTHER INFORMATION**

None.



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**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by Item 10 is hereby incorporated by reference to the sections entitled Nominees, Executive Officers who are not Directors, Compliance with Section 16(a) of the Exchange Act, Meetings and Committees of the Board, and Code of Ethics Applicable to Senior Officers of the Registrant's 2008 Proxy Statement.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by Item 11 is hereby incorporated by reference to the sections entitled Director Compensation, Executive Compensation, Summary Compensation Table, Grants of Plan-Based Awards, Outstanding Equity Awards at Fiscal Year-End, Option Exercises and Stock Vested, NonQualified Deferred Compensation, Compensation Discussion and Analysis, and Board Compensation Committee Report of Registrant's 2008 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 and Equity Compensation Plan Information of the Registrant's 2008 Proxy Statement.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by Item 13 is hereby incorporated by reference to the section entitled Certain Relationships and Related Transactions and Meetings and Committees of the Board of the Registrant's 2008 Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTING 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 2008 Proxy Statement.

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

***A. List of Financial Statements and Schedules***

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

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***B. Exhibits filed as part of this Report***

- 2(a.1)\* Merger Agreement by and among the Registrant, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005 filed as Exhibit 2(a.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; and
- 2(a.2) First Amendment to Merger Agreement by and among the Registrant, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006 filed as Exhibit 2(a.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference.
- 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 3.1 to the Registrant's current report on Form 8-K, filed on November 2, 2007, 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) Form of D. Geoffrey Shulman's Class B Warrant;
- 4(c) Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K filed October 11, 2002, and is incorporated herein by reference;
- 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 filed October 11, 2002, and is incorporated herein by reference;
- 4(e) Form of Common Stock Purchase Warrant, dated October 29, 2007 filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference; and
- 4(f) Registration Rights Agreement, dated October 29, 2007, by and between the Registrant and each of the respective selling shareholders named therein filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference.
- 10(a) License Agreement between the Registrant, 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 Registrant, 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 Registrant 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 Registrant 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; +

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- 10(d.1) 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(d.2) Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated March 20, 1997, filed as Exhibit 10(d.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
- 10(e) Amended and Restated License Agreement between the Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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

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December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

Supply Agreement between the Registrant 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 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

License and Supply Agreement dated August 7, 2007 among the Registrant, photonamic GmbH & Co. KG and medac, GmbH, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2007, and is incorporated herein by reference;

Securities Purchase Agreement dated as of February 27, 2004, by and among the Registrant 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 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

Registration Rights Agreement dated as of February 27, 2004 by and among the Registrant 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;

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;

License, Promotion, Distribution and Supply Agreement between the Registrant and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;

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; +

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; +

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; +

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; +

Amendment to Employment Agreement of Richard Christopher dated as of October 18, 2006 filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended September 30, 2004, and is incorporated herein by reference;

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; +

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; +

Severance Agreement and General Release between the Registrant 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;

Final Agreement and General Release, between the Registrant and Peter Chakoutis, dated as of April 4, 2005, filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed on April 4, 2005, and is incorporated herein by reference; +

) Compensation Policy Applicable to the Registrant's Non-Employee Directors filed as Exhibit 10(cc) to the

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Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; and +

- 10(bb) Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated May 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(cc) Amendment and Extension of the Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, 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(dd) Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(ee) Amendment and Extension of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, 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, as filed as Exhibit 10.D to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(ff) Second Amendment of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, 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, as filed as Exhibit 10.E to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(gg) Supply Agreement between Sirius Laboratories, Inc. and L. Perrigo Registrant dated October 21, 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, as filed as Exhibit 10.F to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(hh) 2006 Micanol License Agreement between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, 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, as filed as Exhibit 10.G to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference; and
- 10(hh.1) 2006 Micanol Transition License Agreement, dated as of January 29, 2008, by and between Winston Laboratories, Inc. and Sirius Laboratories, Inc. 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, as filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 31, 2008, and is incorporated herein by reference;
- 10(ii) Development, License and Supply Agreement between Sirius Laboratories, Inc. and Altana Inc. dated June 13, 2005, portions of which have been omitted pursuant to a request for confidential treatment

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pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and as filed as Exhibit 10.H to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference.

- 10(jj) Employment Agreement of William O Dell dated as of April 4, 2006 filed as Exhibit 10(ii) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(kk) Patent License Agreement between the Registrant and PhotoCure ASA, dated as of May 30, 2006, 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, filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended June 30, 2006, and is incorporated herein by reference;
- 10(ll) Separation Agreement between the Registrant and Paul Sowyrda, dated as of August 31, 2006 filed as Exhibit 10(kk) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(mm) Employment Agreement of Michael Todisco dated as of September 20, 2006 filed as Exhibit 10(11) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(nn) Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and

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DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 4, 2007, 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, filed as Exhibit 10(mm) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;

- 10(nn.1) First Amendment to Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 10, 2007, 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, filed as Exhibit 10(nn) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(oo) DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, filed as Appendix A to Registrant's Schedule 14A definitive Proxy Statement dated April 24, 2006, and is incorporated herein by reference; +
- 10(pp) DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, as amended October 18, 2006 filed as Exhibit 10(pp) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
- 10(qq) DUSA Pharmaceuticals, Inc. 2006 Deferred Compensation Plan, October 18, 2006 filed as Exhibit 10(qq) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
- 10(rr) Marketing, Distribution and Supply Agreement between the Registrant 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 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(aa) to the Registrant's Form 10-K for the fiscal year ended December 31, 2005, and is incorporated herein by reference;
- 10(rr.1) Amendment to the Marketing, Distribution and Supply Agreement dated September 26, 2007, between the Registrant and Stiefel Laboratories, Inc. portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(a) to the Registrant's Form 10-Q for the fiscal quarter ended September 30, 2007, and is incorporated herein by reference;
- 10(ss) Securities Purchase Agreement, dated October 29, 2007, by and among the Registrant and each of the selling shareholders named therein portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference; and
- 10(tt) Settlement Agreement and Mutual Release, including License Agreement dated October 28, 2007 between Registrant and River's Edge Pharmaceuticals LLC.
- 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. 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.

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



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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of

DUSA Pharmaceuticals, Inc.

Wilmington, Massachusetts

We have audited the accompanying consolidated balance sheets of DUSA Pharmaceuticals, Inc. and subsidiaries (the Company ) as of December 31, 2007 and 2006, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, the Company adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of Financial Accounting Standards Board Statement No. 109*, effective January 1, 2007.

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for share-based payments upon the adoption of Financial Accounting Standards Board Statement No. 123R, *Share-Based Payment*, effective January 1, 2006.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2007, 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, 2008 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 10, 2008

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**Table of Contents****DUSA PHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS**

	<b>DECEMBER 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 4,713,619	\$ 3,267,071
Marketable securities	18,311,650	14,943,196
Accrued interest receivable	97,243	158,374
Accounts receivable, net of allowance for doubtful accounts of \$158,000 and \$256,000 in 2007 and 2006, respectively	2,667,178	2,060,565
Inventory	2,672,105	2,343,472
Prepaid and other current assets	1,843,873	1,535,819
<b>TOTAL CURRENT ASSETS</b>	<b>30,305,668</b>	<b>24,308,497</b>
Restricted cash	170,510	162,805
Property, plant and equipment, net	2,142,658	2,567,286
Goodwill		5,772,505
Deferred charges and other assets	273,404	944,720
<b>TOTAL ASSETS</b>	<b>\$ 32,892,240</b>	<b>\$ 33,755,813</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,213,867	\$ 649,523
Accrued compensation	491,529	1,674,470
Other accrued expenses	3,322,642	3,841,891
Deferred revenue	1,256,494	57,270
<b>TOTAL CURRENT LIABILITIES</b>	<b>6,284,532</b>	<b>6,223,154</b>
Deferred revenues	2,918,850	993,085
Warrant liability	1,262,600	
Other liabilities	319,736	206,001
<b>TOTAL LIABILITIES</b>	<b>10,785,718</b>	<b>7,422,240</b>
<b>COMMITMENTS AND CONTINGENCIES (NOTE 16)</b>		
<b>SHAREHOLDERS EQUITY</b>		
Capital Stock		
Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding:		
24,076,110 and 19,480,067 shares of common stock, no par, at December 31, 2007 and December 31, 2006, respectively	151,648,943	142,959,298

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Additional paid-in capital	5,885,353	4,320,625
Accumulated deficit	(135,600,484)	(120,886,977)
Accumulated other comprehensive income (loss)	172,710	(59,373)
TOTAL SHAREHOLDERS EQUITY	22,106,522	26,333,573
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 32,892,240	\$ 33,755,813

See the accompanying Notes to the Consolidated Financial Statements.

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**Table of Contents****DUSA PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS**

	YEAR ENDED DECEMBER 31,		
	2007	2006	2005
Product revenues	\$ 27,662,598	\$ 25,582,986	\$ 11,337,461
Cost of product revenues			
Cost of product revenues and royalties	7,829,284	10,369,957	6,213,601
Impairment of intangible assets		15,746,032	
Total cost of product revenues	7,829,284	26,115,989	6,213,601
<b>GROSS MARGIN</b>	19,833,314	(533,003)	5,123,860
Operating costs			
Research and development	5,976,728	6,213,851	5,587,599
In-process research and development		1,600,000	
Marketing and sales	13,311,314	12,644,654	9,068,984
General and administrative	10,311,290	11,195,726	6,703,047
Impairment of goodwill	6,772,505		
Net gain from settlement of litigation	(582,866)		
Restructuring			150,917
<b>TOTAL OPERATING COSTS</b>	35,788,971	31,654,231	21,510,547
<b>LOSS FROM OPERATIONS</b>	(15,955,657)	(32,187,234)	(16,386,687)
Gain on change in fair value of warrants	687,300		
Other income, net	554,850	837,727	1,387,978
<b>NET LOSS</b>	\$ (14,713,507)	\$ (31,349,507)	\$ (14,998,709)
<b>BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>	\$ (0.73)	\$ (1.65)	\$ (0.89)
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED</b>	20,292,729	19,006,609	16,932,138

See the accompanying Notes to the Consolidated Financial Statements.

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**Table of Contents****DUSA PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Number of Shares	Amount			(Loss)	
BALANCE, JANUARY 1, 2005	16,876,822	\$ 124,698,059	\$ 2,016,339	\$ (74,538,761)	\$ 331,381	\$ 52,507,018
Comprehensive loss:						
Net loss				(14,998,709)		(14,998,709)
Net unrealized loss on marketable securities available-for-sale					(427,129)	(427,129)
Total comprehensive loss						(15,425,838)
Exercises of options	164,375	928,104				928,104
Share-based compensation for the acceleration of vesting of stock options (see Note 11)			19,444			19,444
BALANCE, DECEMBER 31, 2005	17,041,197	\$ 125,626,163	\$ 2,035,783	\$ (89,537,470)	\$ (95,748)	\$ 38,028,728
Comprehensive loss:						
Net loss				(31,349,507)		(31,349,507)
Net unrealized gain on marketable securities available-for-sale					36,375	36,375
Total comprehensive loss						(31,313,132)
Issuance of common stock upon acquisition of Sirius Laboratories, Inc.	2,396,245	17,203,449				17,203,449
Share-based compensation expense			2,284,842			2,284,842
Exercises of options	42,625	129,686				129,686
	19,480,067	\$ 142,959,298	\$ 4,320,625	\$ (120,886,977)	\$ (59,373)	\$ 26,333,573

BALANCE,  
DECEMBER 31,  
2006

Comprehensive loss:					
Net loss			(14,713,507)		(14,713,507)
Net unrealized gain on marketable securities available-for-sale				232,083	232,083

Total comprehensive loss					(14,481,424)
Adjustment to equity issuance costs for the acquisition of Sirius Laboratories, Inc.		250,590			250,590
Share-based compensation expense			1,564,728		1,564,728
Exercises of options	15,000	40,651			40,651
Issuance of common stock in private placement, net of issuance costs and fair value of warrants at issuance	4,581,043	8,398,404			8,398,404

BALANCE,  
DECEMBER 31,  
2007

24,076,110	\$ 151,648,943	\$ 5,885,353	\$ (135,600,484)	\$ 172,710	\$ 22,106,522
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See the accompanying Notes to the Consolidated Financial Statements.

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**Table of Contents****DUSA PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS**

	YEAR ENDED DECEMBER 31,		
	2007	2006	2005
<b>CASH FLOWS USED IN OPERATING ACTIVITIES</b>			
Net loss	\$(14,713,507)	\$(31,349,507)	\$(14,998,709)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization (accretion) of premiums and discounts on marketable securities, available-for-sale	(199,164)	35,167	416,550
Realized loss (gain) on sale of marketable securities, available-for-sale	14,617	(14,015)	(74,512)
Share-based compensation	1,564,728	2,284,842	19,444
In-process research and development charge		1,600,000	
Depreciation and amortization	671,387	3,908,532	925,185
Gain on change in fair value of warrants	(687,300)		
Deferred revenues recognized	(1,576,091)	(43,913)	
Impairment of intangible assets		15,746,032	
Impairment of goodwill	6,772,505		
Changes in other assets and liabilities impacting cash flows from operations (net of impact of acquisition):			
Accrued interest receivable	61,131	195,076	288,348
Accounts receivable	(606,613)	24,732	337,886
Inventory	(328,633)	(263,857)	(443,632)
Prepaid and other current assets	(308,054)	(802,000)	(729,537)
Deferred charges and other assets	671,316	(781,148)	
Accounts payable	564,344	(888,001)	77,426
Accrued compensation and other accrued expenses	(1,701,599)	620,779	201,907
Deferred revenues	4,701,080	999,985	(136,432)
Other liabilities	113,735	431	15,131
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(4,986,118)</b>	<b>(8,726,865)</b>	<b>(14,100,945)</b>
<b>CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES</b>			
Cash paid for acquisition, net of cash received	(750,000)	(7,767,006)	
Purchases of marketable securities	(23,740,590)	(9,619,879)	(58,850,356)
Proceeds from maturities and sales of marketable securities	20,788,766	25,271,393	73,724,674
Restricted cash	(7,705)	(18,264)	(3,777)
Purchases of property, plant and equipment	(246,760)	(212,669)	(415,168)
	<b>(3,956,289)</b>	<b>7,653,575</b>	<b>14,455,373</b>

NET CASH (USED IN) PROVIDED BY  
INVESTING ACTIVITIESCASH FLOWS PROVIDED BY FINANCING  
ACTIVITIES

Issuance of common stock in private placement, net of costs	10,348,304		
Proceeds from exercise of options	40,651	129,686	928,104

NET CASH PROVIDED BY FINANCING  
ACTIVITIES

	10,388,955	129,686	928,104
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NET INCREASE (DECREASE) IN CASH AND  
CASH EQUIVALENTS

	1,446,548	(943,604)	1,282,532
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CASH AND CASH EQUIVALENTS AT  
BEGINNING OF PERIOD

	\$ 3,267,071	\$ 4,210,675	\$ 2,928,143
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CASH AND CASH EQUIVALENTS AT END OF  
PERIOD

	\$ 4,713,619	\$ 3,267,071	\$ 4,210,675
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See the accompanying Notes to the Consolidated Financial Statements.

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DUSA Pharmaceuticals, Inc. ( DUSA or the Company ) is a vertically-integrated dermatology company that is developing and marketing Levulan® photodynamic therapy (PDT) and other products for common skin conditions. The Company's marketed products include among others Levulan® Kerastick® 20% Topical Solution with PDT, the BLU-U® brand light source, Nicomide®, Nicomide-T®, and ClindaReach®.

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® brand light source were launched in the United States of America ( U.S. ) in September 2000 for the treatment of non-hyperkeratotic actinic keratoses ( 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, the Company received clearance from the U.S. Food and Drug Administration, or FDA, to market the BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

Sirius Laboratories, Inc. ( Sirius ), a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment acne vulgaris and rosacea. Nicomide®, its key product, is an oral prescription vitamin supplement which targets the market for inflammatory skin conditions such as acne. ClindaReach® was in development prior to the merger and the Company successfully launched the product in March 2007.

The Company operates in two segments, Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Drug Products. The Company's Levulan® Kerastick® and BLU-U® products comprise its PDT segment, while Nicomide®, ClindaReach® and the other products acquired in the acquisition of Sirius comprise its Non-PDT segment.

**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 subsidiaries, DUSA Pharmaceuticals New York, Inc. and Sirius Laboratories, Inc. All intercompany balances and transactions have been eliminated in consolidation.

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

*c) Cash and Cash Equivalents* - Cash equivalents include short-term highly liquid money market funds. All other investments are classified as marketable securities. The Company maintained cash of \$171,000 and \$163,000 at December 31, 2007 and 2006, respectively, in a separate bank account in support of a letter of credit of \$162,000 that was issued in lieu of a security deposit on the lease for its manufacturing facility in Wilmington,

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Massachusetts. The cash is presented in restricted cash as a non-current asset in the Consolidated Balance Sheets.

**d) Marketable Securities** - The Company records marketable securities at fair value as available-for-sale with unrealized holding gains (losses) recorded in accumulated other comprehensive income. The Company records other-than-temporary impairment charges for investments that are in an unrealized loss position at the end of the period since the Company's portfolio is managed by a third-party investment advisor that has discretionary authority to sell the investments. The other-than-temporary impairment charge was \$16,000 for the year ended December 31, 2007 and \$0 for the years ended December 31, 2006 and 2005. The Company amortizes or accretes the premiums and discounts from the investment cost of marketable debt securities into interest income over the period to maturity 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.

**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 such inventory is designated for such use. BLU-U® commercial light sources placed in physicians' offices for an initial evaluation period are included in inventory in the accompanying Consolidated Balance Sheets and amortized over a three year period or until sold to the physician's office evidenced by the fact that all revenue recognition criteria have been met. Inventories are continually reviewed for slow moving, obsolete and excess items. Sales projections are used to estimate the appropriate level of inventory reserves, if any, that are necessary at each balance sheet date.

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

**g) 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.

**h) Goodwill and Other Intangible Assets** - Goodwill and intangible assets with indefinite lives are not amortized but are reviewed annually for impairment or more frequently if impairment indicators arise. Separable intangible assets that are not deemed to have indefinite lives will continue to be amortized over their useful lives. The Company has adopted December 1st as the date of the annual impairment test for goodwill.

**i) Revenue Recognition and Provisions for Estimated Reductions to Gross Revenues** - The Company recognizes revenues in accordance with Staff Accounting Bulletin ( SAB ) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*. Accounting for revenue transactions relies on certain estimates that require difficult, subjective and complex judgments on the part of management.

For revenues associated with contractual agreements with multiple deliverables, the Company applies the revenue recognition criteria outlined in Securities and Exchange

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Commission ( SEC ) Staff Accounting Bulletin Topic 13, *Revenue Recognition* ( SAB Topic 13 ) and Emerging Issues Task Force ( EITF ) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, ( EITF 00-21 ). Accordingly, revenues from contractual agreements are recognized based on the performance requirements of those agreements. As prescribed by EITF 00-21, the Company analyzes each contract in order to separate each deliverable into separate units of accounting, if applicable, and then recognizes revenue for those separated units at their fair values as earned in accordance with the SAB Topic 13 or other applicable revenue recognition guidance.

**PHOTODYNAMIC THERAPY (PDT) DRUG AND DEVICE PRODUCTS**

Revenues on the Levulan<sup>®</sup> Kerastick<sup>®</sup> and BLU-U<sup>®</sup> product sales in the U.S. and Canada are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is probable. Product sales made through distributors, historically, have been recorded as deferred revenue until the product was sold by the distributors to the end users because the Company did not have sufficient history with its distributors to be able to reliably estimate returns. Beginning in the first quarter of 2006, the Company began recognizing revenue as product is sold to distributors because it believes it has sufficient history to reliably estimate returns from distributors beginning January 1, 2006. This change in estimate was not material to the Company's revenues or results of operations. We offer programs that allow physicians access to our BLU-U<sup>®</sup> device for a trial period. No revenue is recognized on these units until the physician elects to purchase the equipment and all other revenue recognition criteria are met.

The Company has entered into exclusive marketing, distribution and supply agreements with distributors in Latin America and Korea that contain multiple deliverables. Revenues on Levulan<sup>®</sup> Kerastick<sup>®</sup> product sales made under these agreements are recorded in accordance with EITF 00-21 as described below.

*Stiefel Laboratories Agreement.* In January 2006, as amended in September 2007, the Company entered into an exclusive marketing, distribution and supply agreement (the Stiefel Agreement) with Stiefel Laboratories, Inc. ( Stiefel ) for Levulan<sup>®</sup> PDT in Latin America (see Note 12 to the Consolidated Financial Statements). Under the Stiefel Agreement, Stiefel is required to purchase Levulan<sup>®</sup> Kerastick<sup>®</sup> from the Company and make up front, milestone and royalty payments. Stiefel may cancel the Stiefel Agreement if there is a breach of contract, if either party files for bankruptcy, if its sales during any year are less than its minimum purchase obligations, or, as to Brazil only, if acceptable pricing approval, as defined in the Agreement, is not obtained. No upfront or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications. The Company is obligated under the Stiefel Agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. The Stiefel Agreement establishes a fixed supply price per unit, as well as a royalty based on a percentage of the net sales price to end-users. Under EITF 00-21 the deliverables under the Stiefel Agreement are treated as a single unit of accounting. The Company determines attribution methods for each of the separate payment streams. Revenues from unit sales of Levulan<sup>®</sup> Kerastick<sup>®</sup> are recognized based on end-user demand as the Company does not have sufficient data to determine product acceptance in the marketplace and therefore does not have the ability to estimate product returns. Royalty revenues are recorded each quarter based on Stiefel's reported net sales for that quarter and are included in product revenues. The Stiefel Agreement also establishes minimum purchase quantities over the first five years following regulatory approval.

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The non-refundable up-front payments are being recognized into revenues on a straight-line basis commencing upon the first product shipments in a country over the remaining contractual term of the Stiefel Agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2007, in accordance with the Company's policy of deferring revenues on new product launches, the Company has deferred revenues of \$206,000 related to product shipments of Levulan® Kerastick® into Mexico and Argentina that have not yet been sold through to the end user customers. Deferred revenues at December 31, 2007 associated with milestone payments received from Stiefel are \$345,000.

*Daewoong Agreement.* On January 4, 2007, the Company entered into an exclusive marketing, distribution and supply agreement (the Daewoong Agreement) with Daewoong Pharmaceuticals (Daewoong) for Levulan® Kerastick® in Korea (see Note 13). Under the Daewoong Agreement, Daewoong is required to purchase Levulan® Kerastick® from the Company and make up-front and milestone payments. Daewoong may cancel the Daewoong Agreement only if there is a breach of contract or if either party files for bankruptcy. Under the terms of the agreement, Daewoong will make up to \$3.5 million in milestone payments to DUSA, \$1.0 million of which was paid upon contract execution during the first quarter of 2007 and another \$1.0 million of which was paid during the fourth quarter of 2007 upon achieving regulatory approval in Korea. The milestone payments are non-refundable. Product shipments are subject to return and refund only if the product does not comply with technical specifications. The Company is obligated under the Daewoong Agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. The Daewoong Agreement establishes a fixed supply price per unit, as well as an Excess Purchase Price component if the Average Selling Price to end-users exceeds a certain threshold. Under EITF 00-21 the deliverables under the Agreement are treated as a single unit of accounting. The Company determines attribution methods for each of the separate payment streams. Revenues from unit sales of Levulan® Kerastick® are recognized based on end-user demand as the Company does not have sufficient data to determine product acceptance in the marketplace and therefore does not have the ability to estimate product returns. Excess purchase price revenues are recorded each quarter based on Daewoong's reported net sales for that quarter and are included in product revenues. The Daewoong Agreement also establishes minimum purchase quantities over the first five years following regulatory approval in Korea.

The non-refundable up-front payments are recognized into revenues on a straight-line basis commencing upon the first product shipment in the territory over the remaining contractual term of the Agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2007, in accordance with the Company's policy of deferring revenues on new product launches, the Company has deferred revenues of \$762,000 related to product shipments of Levulan® Kerastick® into Korea that have not yet been sold through to the end user customers. Deferred revenues at December 31, 2007 associated with milestone payments received from Daewoong are \$1,848,000.

*Photocure Agreement.* On May 30, 2006, the Company entered into a patent license agreement under which the Company granted PhotoCure ASA a non-exclusive license under the patents the Company licenses from PARTEQ for ALA esters. In addition, the Company granted a non-exclusive license to PhotoCure for its existing formulations of Hexvix® and Metvix® (known in the U.S. as Metvixia®) for any patent the Company owns now or in the future.

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Photocure is obligated to pay the Company royalties on sales of its ester products to the extent they are covered by its patents in the U.S. and certain other territories. As part of the agreement, PhotoCure paid the Company a prepaid royalty in the amount of \$1 million. Revenues recognized pursuant to the Photocure Agreement have not been material to date. The balance of the prepaid royalty under the Photocure Agreement is included in deferred revenues in the accompanying Consolidated Balance Sheets.

***NON-PDT DRUG PRODUCTS***

The Company recognizes revenue for sales of Non-PDT Drug Products when substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment to wholesale customers, with the exceptions described below. Revenue is recognized net of revenue reserves, which consist of allowances for discounts, returns, rebates, chargebacks and fees paid to wholesalers under distribution service agreements.

In the case of sales made to wholesalers as a result of incentives and that are in excess of the wholesaler's ordinary course of business inventory level, substantially all the risks and rewards of ownership do not transfer upon shipment and, accordingly, such sales are recorded as deferred revenue and the related costs as deferred cost of revenue until the product is sold through to the wholesaler's customers on a first in, first out basis.

The Company evaluates inventory levels at its wholesaler customers, which account for the vast majority of its sales in the Non-PDT Drug Products segment, through an analysis that considers, among other things, wholesaler purchases, wholesaler shipments to retailers, available end-user prescription data obtained from third parties and on-hand inventory data received directly from our three largest wholesaler customers. The Company believes that this evaluation of wholesaler inventory levels, allows it to make reasonable estimates for its applicable revenue related reserves. Additionally, the Company's products are sold to wholesalers with a product shelf life that allows sufficient time for its wholesaler customers to sell its products in their inventory through to retailers and, ultimately, to end-user consumers prior to product expiration.

For new product launches where the Company does not have the ability to reliably estimate returns, revenue is recognized based on end-user demand, which is typically based on dispensed subscription data, or ship-through data as reported by the Company's international distribution partners. When inventories have been reduced to targeted stocking levels at wholesalers or distribution partners, and the Company has sufficient data to determine product acceptance in the marketplace which allows the Company to estimate product returns, the Company recognizes revenue upon shipment, net of discounts and allowances. The Company determined in the fourth quarter of 2007 that it had reached targeted stocking levels of ClindaReach, which enabled the Company to estimate product returns and recognize \$303,000 of revenues that had previously been deferred related to the launch in March 2007.

***SALES RETURNS*** - The Company accounts for sales returns in accordance with Financial Accounting Standards Board (FASB) Statement No. 48, *Revenue Recognition When Right of Return Exists*, by establishing an accrual in an amount equal to its estimate of sales recorded for which the related products are expected to be returned. The Company determines the estimate of the sales return accrual primarily based on historical experience regarding sales and related returns and incorporating other factors that could impact sales returns in the future. These other factors include levels of inventory in the distribution channel, estimated shelf life, product recalls, product discontinuances, price changes of competitive products, introductions of generic products and introductions of competitive new products. The Company's policy is to

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accept returns when product is within six months of expiration. The Company considers all of these factors and adjusts the accrual periodically to reflect actual experience.

**CHARGEBACKS, REBATES AND DISCOUNTS** - Chargebacks typically occur when suppliers enter into contractual pricing arrangements with end-user customers, including certain federally mandated programs, who then purchase from wholesalers at prices below what the supplier charges the wholesaler. Since the Company only offers discounts to end-user customers under federally mandated programs, chargebacks have not been significant to the Company. The Company's rebate programs can generally be categorized into the following two types: Medicaid rebates and consumer rebates. Medicaid rebates are amounts owed based on legal requirements with public sector benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Consumer rebates are amounts owed as a result of mail-in coupons that are distributed by health care providers to consumers at the time a prescription is written.

The Company offers its wholesaler customers a 2% prompt pay discount. The Company evaluates the amount accrued for prompt pay discounts by analyzing the unpaid invoices in its accounts receivable aging subject to a prompt pay discount. Prompt pay discounts are known within 15 to 30 days of sale, and therefore can be reliably estimated based on actual and expected activity at each reporting date. The Company records these discounts at the time of sale and they are accounted for as a reduction of revenues. A summary of activity in the Company's valuation accounts are as follows:

	FOR THE YEAR ENDED DECEMBER 31, 2007:				
	BALANCE AT JANUARY 1, 2007	PROVISION RELATED TO SALES MADE IN THE CURRENT PERIOD	PROVISION FOR SALES MADE IN PRIOR PERIODS	ACTUAL RETURNS OR CREDITS IN THE CURRENT PERIOD	BALANCE AT DECEMBER 31, 2007
Accrued Expenses:					
Returns and allowances	\$ 632,000	\$ 708,000	\$	\$ (794,000)	\$ 546,000
Chargebacks and rebates	\$ 26,000	\$ 675,000	\$	\$ (501,000)	\$ 200,000

	FOR THE YEAR ENDED DECEMBER 31, 2006:					
	BALANCE ACQUIRED AT JANUARY 1, 2006	AS PART OF SIRIUS ACQUISITION	PROVISION RELATED TO SALES MADE IN THE CURRENT PERIOD	ACTUAL RETURNS OR CREDITS IN THE CURRENT PERIOD	BALANCE AT DECEMBER 31, 2006	
Accrued Expenses:						
Returns and allowances	\$	\$ 357,000	\$ 1,235,000	\$	\$ (960,000)	\$ 632,000
Accounts receivable:						
Prompt payment discounts	\$	\$	\$ 223,000	\$	\$ (200,000)	\$ 23,000

**j) Warranty costs** - The Company accrues for estimated future warranty costs on its BLU-U<sup>®</sup> sales at the time of sale. The Company's products are subject to rigorous regulation and quality



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standards. Warranty costs, which are included in cost of product revenues, were \$73,000, \$61,000 and \$53,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

**k) Research and Development Costs** - Costs related to the conceptual formulation and design of products and processes are expensed as research and development costs as incurred. Purchased technology, including the costs of licensed technology for a particular research project that do not have alternative future uses, is expensed as incurred.

**l) Marketing and Sales Costs** - Costs included in marketing and sales 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 costs, miscellaneous marketing and outside consultants. All such costs are expensed as incurred.

**m) 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.

On July 13, 2006, FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109* ( FIN 48 ). FIN 48 prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the amount of tax benefits recognized must be the largest amount of tax benefit that has a greater than 50% likelihood of being sustained upon audit by the relevant taxing authority. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, and accounting for interim periods and requires expanded disclosure with respect to the uncertainty in income taxes.

The Company adopted the provisions of FIN 48 on January 1, 2007. As of the date of adoption, the total amount of unrecognized tax benefits was \$1,803,000, all of which, if recognized, would affect the effective tax rate prior to the adjustment for the Company's valuation allowance. As a result of the implementation of FIN 48, the Company did not recognize an increase in tax liability for the unrecognized tax benefits because the Company has recorded a tax net operating loss carryforward that would offset this liability.

The Company recognizes interest and penalties related to unrecognized tax benefits in operating expenses. Since a full valuation allowance was recorded against the Company's net deferred tax assets and the unrecognized tax benefits determined under FIN 48 would not result in a tax liability, the Company has not accrued for any interest and penalties relating to these unrecognized tax benefits.



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**n) Basic and Diluted Net Loss Per Common Share** - Basic net loss per common share is based upon the weighted average number of common shares outstanding during each period. Stock options and warrants are not included in the computation of the weighted average number of common shares outstanding for dilutive net loss per common share during each of the periods presented in the Consolidated Statements of Operations, as the effect would be antidilutive. For the years ended December 31, 2007, 2006, and 2005, stock options and warrants totaling approximately 4,250,000, 3,031,000, and 3,150,000 shares, respectively, have been excluded from the computation of diluted net loss per share. The 2,396,245 shares issued in the Sirius acquisition, which includes 422,892 shares placed into the liability escrow account, are included in the weighted average number of shares outstanding from the date of issuance, March 10, 2006.

**o) Share-Based Compensation** - In December 2004, the FASB issued Statement No. 123(R), *Share-Based Payment*, ( SFAS 123(R) ). The Company adopted SFAS 123(R) effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006, the Company measures all employee share-based compensation awards using a fair value based method and records share-based compensation expense in its financial statements over the vesting period of the award. The pro forma results and assumptions used in fiscal year 2005 was based solely on historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected life of its stock options. The adoption of SFAS 123(R) did not affect the Company's net cash flow, but it did have a material negative impact on its results of operations. Prior to January 1, 2006, the Company recorded estimated compensation expense for employee stock options based on their intrinsic value on the date of grant pursuant to Accounting Principles Board Opinion 25 (APB 25), *Accounting for Stock Issued to Employees*.

**p) Comprehensive Loss** - The Company has reported comprehensive loss and 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.

**q) Segment Reporting** - Beginning in the first quarter of 2006 with the acquisition of Sirius Laboratories, the Company has two reportable segments, Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Drug Products. Prior to the beginning of the first quarter of 2006, the Company had a single reportable segment. Operating segments are defined as components of the Company for which separate financial information is available to manage resources and evaluate performance regularly by the chief operating decision maker. The Company does not allocate research and development, selling and marketing and general and administrative expenses or long-lived assets to its reportable segments, because these activities are managed at a corporate level.

**r) 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.

**s) Concentrations** - 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 total revenues for 2007, 2006, and 2005, and accounts receivable as of December 31, 2007 and December 31, 2006 were as follows:

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	% of Revenue for year ended			% of Accounts Receivable as of	
	December 31,			December 31,	
	2007	2006	2005	2007	2006
Customer A	4%	5%	13%	5%	14%
Customer B	11%	12%	%	10%	16%
Customer C	15%	18%	%	12%	17%
Customer D	6%	7%	%	7%	10%
Customer E	2%	%	%	26%	%
Customer F	%	%	16%	%	%
Other customers	62%	58%	71%	40%	43%
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 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.

**t) Derivative Financial Instruments** - The Company has issued common stock warrants in connection with the October 2007 private placement (See Note 11). The warrants are accounted for as derivative liabilities at fair value in accordance with FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities*, or SFAS 133. The warrants do not meet the criteria in paragraph 11(a) of SFAS 133 that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders' equity. Changes in fair value of derivative liabilities are recorded in the Consolidated Statements of Operations under the caption "Gain on change in fair value of warrants."

The fair value of the warrant liability is determined using the Black-Scholes option-pricing model. The fair value of the warrants is subject to significant fluctuation based on changes in the Company's stock price, expected volatility, remaining contractual life and the risk-free interest rate.

In connection with the October 2007 private placement, the Company was obligated to file a registration statement with the SEC for the registration of the total number of shares sold to the investors and shares issuable upon exercise of the warrants. The Company is required under the agreement to use commercially reasonable efforts to cause the registration to be declared effective by the SEC and to remain continuously effective until such time when all of the registered shares are sold. In the event the Company fails to meet the requirements in regards to the registration statement, it will be obligated to pay the investors, as partial liquidated damages and not as a penalty, an amount in cash equal to 1% of the aggregate purchase price paid by investors for each monthly period that the registration statement is not effective, up to 12%. The Company follows EITF Issue No. 00-19-2, *Accounting for Registration Payment Arrangements* (EITF 00-19-2), which specifies that registration payment arrangements should play no part in determining the initial classification of, and subsequent accounting for, securities to which the payments relate. Contingent obligations in a registration payment arrangement are separately analyzed under FASB Statement No. 5, *Accounting for Contingencies*. If the Company determines a payment under this registration rights arrangement is probable and can be reasonably estimated, a liability will be recorded. As of December 31, 2007, the Company concluded the likelihood of having to make any payments under the arrangements was remote, and therefore did not record any related contingent liability as of December 31, 2007. The registration statement for the shares of common stock and warrants issued in the private placement was declared effective by the SEC on January 24, 2008.

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**u) Recently Issued Accounting Pronouncements** - In December 2007, the FASB issued Statement No. 141R, *Business Combinations* ( SFAS 141(R) ). SFAS 141(R) amends FASB Statement No. 141 and provides revised guidance for recognizing and measuring assets acquired and liabilities assumed in a business combination. SFAS141(R) also requires that transaction costs in a business combination be expensed as incurred. SFAS141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS141(R) will impact the Company's accounting for business combinations, if any, completed beginning January 1, 2009.

In December 2007, the FASB issued Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* ( SFAS 160 ) SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method will significantly change the accounting for transactions with minority interest holders. The provisions of this standard are effective beginning January 1, 2009. The Company is evaluating the potential impact of adoption of this standard on its consolidated financial position and results of operations.

In February 2007 the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS 159 ). SFAS 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. This statement is effective for fiscal years beginning after November 15, 2007. The Company is in the process of evaluating the impact, if any, that SFAS 159 will have on its financial statements.

In September 2006 the FASB issued Statement No. 157, *Fair Market Measurements* ( SFAS 157 ). SFAS 157 establishes a framework for measuring fair value and expands disclosures about the use of fair value measurements and liabilities in interim and annual reporting periods subsequent to initial recognition. SFAS 157 is effective for the Company on a prospective basis for the reporting period beginning January 1, 2008. In February 2008, the Board issued FASB Staff Position (FSP) FAS 157-2, *Partial Deferral of the Effective Date of Statement 157*. The effect of adoption on the Company's financial position and results of operations have not been determined.

**3) BUSINESS ACQUISITION**

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius in exchange for 2,396,245 shares of unregistered DUSA common stock and \$8 million in cash. Pursuant to the terms of the Merger Agreement, the actual number of shares that were issued in the transaction was derived by dividing \$17 million by the average closing price of the Company's shares over the 20 trading day period prior to the close, or \$7.094 per share. For accounting purposes, these shares are valued at \$7.30 per share, the average market price of the Company's common stock over the five day period beginning two days prior and ending two days subsequent to the public announcement of the signing of the First Amendment to the Merger Agreement. Sirius was a dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. The purchase of Sirius was intended to enable DUSA to expand its product portfolio, capitalize on cross-selling and marketing opportunities, increase its sales force size; as well as, provide a pipeline of new products.

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The aggregate initial purchase price, net of cash received of \$0.5 million, was approximately \$26.8 million, which consisted of \$17.2 million in shares of common stock, net of estimated registration costs of \$0.3 million, \$7.5 million in cash, \$0.3 million outstanding balance on line of credit, and transaction costs of \$1.8 million, which primarily consisted of fees for legal and financial advisory services. Of the 2,396,245 shares issued in the acquisition, 422,892 shares have been placed in an escrow account established to secure the indemnification obligations of the shareholders of Sirius as set forth in the Merger Agreement. The escrow account is established for a period of two years and will be used to satisfy liability claims, if any, made by the Company. No amounts may be distributed from the liability escrow account unless and until any individual claim exceeds \$25,000 and cumulative claims exceed \$100,000.

The Company has agreed to pay additional consideration in future periods, based upon the attainment of defined operating objectives, including new product approvals or launches and the achievement of pre-determined total cumulative sales milestones for the Sirius products over the period ending 50 months, as amended and as described further in Note 16 from the date of close. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments are, as follows:

Cumulative Sales Milestone: (in millions)	Payment Earned (in millions):
\$ 25.0	\$ 1.5
35.0	1.0
45.0	1.0
Total	\$ 3.5

In addition, the merger agreement provides for the payment of three milestones related to new product approvals and/or launches each in the amount of \$500,000 per milestone, or \$1.5 million in the aggregate, if the milestones are achieved. During the first quarter of 2007, the Company paid the first of these milestones in the amount of \$500,000 to the former shareholders of Sirius related to the March 2007 launch of ClindaReach. This payment has increased goodwill in the accompanying Consolidated Balance Sheets. During the fourth quarter of 2007, the Company decided that it would not pursue the second and third potential products related to the merger approvals and/or launches. In such circumstances, the merger agreement obligates DUSA to pay \$250,000 in lieu of the \$500,000 milestone to the former Sirius Shareholders on a pro rata basis. The first of the two payments was made in December 2007 and the second was made in January 2008, which together relieved DUSA of all of its obligations with respect to such milestones. The second payment was accrued in the Consolidated Financial Statements at December 31, 2007 and is included in other accrued expenses in the Consolidated Balance Sheets. These payments increased goodwill by \$500,000 prior to an impairment charge recorded in the fourth quarter of 2007 in the amount of \$6.8 million, which is described in more detail below and in Note 4. The maximum remaining potential future consideration pursuant to the Merger Agreement, to be resolved over the potential milestone period from the date of close, is \$3.5 million. The cumulative sales milestones, if attained, are payable in either common stock or cash, at the Company's sole discretion. The Company will not accrue contingent consideration obligations prior to the attainment of the objectives.

The acquisition was accounted for using the purchase method of accounting and the results of operations of the acquired business since March 10, 2006, the date of acquisition, were included in the results of the Company. The total purchase consideration was allocated to the assets acquired and liabilities assumed at their estimated fair values as of the date of acquisition,

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as determined by management.

The following table summarizes the estimated fair value of the assets acquired and liabilities assumed at the date of acquisition, as adjusted:

	Original	Adjustments	As Adjusted
Total consideration (in thousands):			
Common stock issued	\$17,454	\$	\$17,454
Cash paid to stockholders, including \$250,000 accrued but not paid at December 31, 2007	8,000	1,000	9,000
Balance on line-of-credit	251		251
Transaction costs paid	1,620		1,620
Total purchase consideration	27,325	1,000	28,325
Allocation of the purchase consideration			
Current assets (including cash of \$485), exclusive of inventory	2,198		2,198
Inventory	1,983		1,983
Fixed assets	109		109
Long-term assets	14		14
Identifiable intangible assets	17,160		17,160
In-process research and development	1,600		1,600
Goodwill	5,773	1,000	6,773
Total assets acquired	28,837	1,000	29,837
Fair value of liabilities assumed	(1,512)		(1,512)
Fair value of assets acquired and liabilities assumed	\$27,325	\$1,000	\$28,325

The identifiable intangible assets related to core/developed technology, comprised of the combined value of Sirius product lines, which inherently included the value of related patents, trademarks and trade names. The substantial majority of the initial projected revenues and cash flows from the acquisition were attributable to Nicomide®. The core/developed technologies all belonged to the same therapeutic category, non-photodynamic therapy dermatological treatment of acne and rosacea and are considered a single asset group for purposes of measuring impairment. The values of the intangible assets acquired were determined using projections of revenues and expenses specifically attributed to the intangible assets. The income streams were then discounted to present value using estimated risk adjusted discount rates. The intangible assets were valued using the income approach, specifically the excess earnings method. The key assumptions used in valuing the intangible assets are discount rates of 17% for core/developed technology and 18% for in-process research and development and an assumed tax rate of 40%. See Note 4 for the discussion of the intangible asset impairment charge recorded in 2006.

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The in-process research and development represents the estimated fair value based on risk-adjusted cash flows related to product development projects. At the date of acquisition, the development of these projects had not yet reached technological feasibility and the research and development in progress had no alternative future uses. Accordingly, these costs were expensed as of the acquisition date.

The amount allocated to goodwill and other intangible assets are not deductible for tax purposes. See Note 4 for the discussion of the goodwill impairment charge recorded in 2007.

**4) GOODWILL AND INTANGIBLE ASSETS**

Under FASB Statement No. 142, *Goodwill and Other Intangible Assets* ( SFAS 142 ), goodwill and certain intangible assets are deemed to have indefinite lives and are no longer amortized, but are reviewed at least annually for impairment. Other identifiable intangible assets are amortized over their estimated useful lives. SFAS 142 requires that goodwill be tested for impairment annually, utilizing the fair value methodology. The Company has adopted December 1st as the date of the annual impairment test for goodwill.

Based on the Company's annual review of goodwill in 2007, the Company recorded an impairment charge of \$6.8 million, which was all associated with the Non-PDT Drug Products reporting unit and represented the entire goodwill balance. Prior to the impairment charge being recorded, the goodwill balance had increased by \$1.0 million during 2007 as a result of three milestone payments to the former shareholders of Sirius during the year.

Goodwill impairment is determined using a two-step process. The first step of the goodwill impairment test is used to identify potential impairment by comparing the fair value of a reporting unit with the net book value (of carrying amount), including goodwill. If the fair value of the reporting unit exceeds the carrying amount, goodwill of the reporting unit is considered not impaired and the second step of the impairment test is unnecessary. If the carrying amount of the reporting unit exceeds the fair value, the second step of the goodwill impairment test is performed to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of the reporting unit's goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination. Accordingly, the fair value of the reporting unit is allocated to all of the assets and liabilities of that unit as if the reporting unit had been acquired in a business combination and the fair value of the reporting unit was the purchase price paid to acquire the reporting unit. The fair value of the Company's Non-PDT reporting unit was determined using an income approach. Under the income approach, the fair value of a reporting unit is calculated based on the present value of estimated future cash flows. The present value of future cash flows uses our estimates of revenue for the reporting unit, driven by assumed growth rates and estimated costs as well as appropriate discount rates.

In performing the first step of the fiscal 2007 goodwill impairment test, management determined there was an indicator of impairment in the Non-PDT goodwill because the carrying value of the reporting unit exceeded its estimated fair value. The excess of the carrying value over the estimated fair value of the reporting unit was primarily due to decisions related to the Non-PDT product pipeline, which were based on a number of factors including, most importantly, the receipt by the Company's development partner, Altana, Inc., of a non-approval letter from the FDA in November 2007 with respect to its ANDA supplement covering one of the potential products the Company acquired from Sirius. The Company no longer expects to further develop or launch this product or any other potential product from the Sirius acquisition.

In performing the second step of the goodwill impairment test, the Company allocated the estimated fair values of the Non-PDT reporting unit determined in step one of the impairment test, to the assets and liabilities as if a new acquisition were being accounted for in accordance with SFAS 141.

Determining the fair value of the reporting unit under the first step of the goodwill impairment test and determining the fair value of individual assets and liabilities of a reporting unit under the second step of the goodwill impairment test is judgmental in nature and often involves the use of significant estimates and assumptions. Since the fair value of the Non-PDT reporting unit was derived from projected revenues associated solely with developed technologies, which were identified as intangible assets in the original purchase accounting allocation and subsequently written down to zero in 2006, the fair value of the reporting unit was hypothetically all allocated to developed technologies,

with no remaining value to assign to goodwill. The result was a full write-down of the Company's goodwill balance in 2007.

Shortly after the closing of the merger with Sirius in 2006, the Company became engaged in patent litigation with River's Edge, a company that launched a generic Nicomid® product. Although the court issued a preliminary injunction against sales of River's Edge's product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. As a result, in 2006 the identifiable intangible assets resulting from the Sirius acquisition were determined to be impaired based on an analysis of the carrying value

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and projected future cash flows of the assets. The impairment analysis resulted in a write down of approximately \$15.7 million, which was recorded in cost of product revenues. The River s Edge litigation was settled in 2007 (see Note 16). Under GAAP, once an intangible asset is impaired, the revised value is the carrying value and subsequent increases in fair value are not recognized.

**5) MARKETABLE SECURITIES**

The Company s investment securities consist of securities of the U.S. government and its agencies, and investment grade corporate bonds. The Company has historically classified all investment securities as available-for-sale and recorded such investments at fair market value. Since the Company s investments are managed by a third-party investment advisor pursuant to a discretionary arrangement, for securities with unrealized losses at December 31, 2007, which totaled \$16,000, an other-than-temporary impairment was considered to have occurred and the cost basis of such securities were written down to their fair values with the amount of the write-down included in earnings as realized losses. A similar adjustment was not made for 2006 or 2005. As of December 31, 2007, current yields range from 2.52% to 6.18% and maturity dates range from January 2008 to October, 2011. The estimated fair value and cost of marketable securities at December 31, 2007 and December 31, 2006 are as follows:

		December 31, 2007		
	Amortized	Gross	Gross	Fair
	Cost	Unrealized	Unrealized	Value
		Gains	Losses	
United States government securities	\$ 16,429,249	\$ 162,619	\$	\$ 16,591,868
Corporate securities	1,709,691	10,091		1,719,782
Total marketable securities available-for-sale	\$ 18,138,940	\$ 172,710	\$	\$ 18,311,650

		December 31, 2006		
	Amortized	Gross	Gross	Fair
	Cost	Unrealized	Unrealized	Value
		Gains	Losses	
United States government securities	\$ 11,673,884	\$ 112	\$(51,687)	\$ 11,622,309
Corporate securities	3,328,685	295	(8,093)	3,320,887
Total marketable securities available-for-sale	\$ 15,002,569	\$ 407	\$(59,780)	\$ 14,943,196

The change in net unrealized gains and losses on such securities for the years ended December 31, 2007, 2006 and 2005 was \$232,083, \$36,375, and (\$427,129), respectively, and has been recorded in accumulated other comprehensive income, which is reported as part of shareholders equity in the Consolidated Balance Sheets. Realized (losses) gains on sales of marketable securities were \$(15,000), \$14,000 and \$75,000 in 2007, 2006 and 2005, respectively.

**6) INVENTORY**

Inventory consisted of the following at December 31:

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	2007	2006
Finished goods	\$1,624,502	\$ 861,830
BLU-U® evaluation units	130,985	166,812
Work in process	409,465	257,358
Raw materials	507,153	1,057,472
	\$2,672,105	\$2,343,472

BLU-U® commercial light sources placed in physicians' offices for an initial evaluation period are included in inventory until all revenue recognition criteria are met. The Company amortizes the cost of the evaluation units during the evaluation period of three years to cost of product revenues to approximate its net realizable value.

**7) PROPERTY, PLANT AND EQUIPMENT**

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

	Useful Life (in years)	2007	2006
Computer equipment and software	3	\$ 2,698,076	\$ 2,560,627
Furniture, fixtures and equipment	5	959,296	849,981
Manufacturing facility	Term of lease	2,204,120	2,204,122
Manufacturing equipment	5	2,282,343	2,282,343
Leasehold improvements	Lesser of useful life or term of lease	845,435	845,432
Accumulated depreciation and amortization		8,989,270 (6,846,612)	8,742,505 (6,175,219)
		\$ 2,142,658	\$ 2,567,286

Depreciation and amortization related to property, plant and equipment was \$671,000, \$722,000, and \$925,000 for 2007, 2006, and 2005, respectively.

**8) OTHER ACCRUED EXPENSES**

Other accrued expenses consisted of the following at December 31:

	2007	2006
Research and development costs	\$ 293,136	\$ 458,792
Marketing and sales costs	334,178	314,770
Reserve for sales returns and allowances	545,982	632,299
Reserve for chargebacks and rebates	200,000	25,917
Other product related costs	873,326	1,081,208
Legal and other professional fees	483,867	634,655
Employee benefits	235,642	294,673
Other expenses	356,511	399,577
	\$3,322,642	\$3,841,891

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**Table of Contents****9) INCOME TAXES**

The tax effect of significant temporary differences representing deferred tax assets at December 31 are as follows:

	2007	2006
<b>DEFERRED TAX ASSETS</b>		
Current		
Reserves	\$ 349,000	\$ 358,000
Accrued Charges	219,000	212,000
Total current deferred tax assets	568,000	570,000
Noncurrent		
Operating loss carryforwards	32,023,000	30,922,000
Capitalized research and development	8,138,000	7,275,000
Research and development tax credit carryforwards	1,483,000	3,281,000
Deferred revenue	379,000	372,000
Intangible assets	264,000	402,000
Accrued charges	207,000	182,000
Stock-based compensation	1,202,000	716,000
Fixed assets	617,000	300,000
Total noncurrent deferred tax assets	44,313,000	43,450,000
Net deferred tax assets before allowance	44,881,000	44,020,000
Valuation allowance	(44,881,000)	(44,020,000)
Total	\$	\$

During the years ended December 31, 2007, 2006, and 2005, the valuation allowance was increased by approximately \$861,000, \$4,582,000, and \$6,453,000, respectively, due to the uncertainty of future realization of the net deferred tax assets which were increasing. The current year increase in the valuation allowance of \$861,000 is primarily comprised of an increase due to the current year change in temporary differences of \$1,267,000, a decrease in research and development credit carryforwards as a result of the Company's adoption of FIN 48 of \$1,803,000 and an increase in the net operating loss carryforwards of \$1,397,000.

Included in deferred tax assets at December 31, 2007 and 2006 is \$2,150,000 and \$2,171,000 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, 2007, the Company had Federal net operating loss carryforwards for tax purposes of approximately \$88,759,000 and research and development tax credits of approximately \$1,394,000, both of which, if not utilized, will expire on various dates through 2027 as follows:

Operating Loss Carryforwards	Research and Development Tax Credits
---------------------------------	---

2010	\$2,325,000	\$
2011	6,638,000	
2012	6,841,000	
2013		
2014		
2015		
2016		

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	Operating Loss Carryforwards	Research and Development Tax Credits
2017		
2018	5,738,000	
2019		
2020		110,000
2021	3,143,000	288,000
2022	16,018,000	308,000
2023	12,872,000	147,000
2024	10,498,000	195,000
2025	13,425,000	182,000
2026	5,923,000	164,000
2027	5,338,000	
	\$88,759,000	\$ 1,394,000

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

	2007	%	2006	%	2005	%
Income tax benefit at statutory rate	\$ (5,003,000)	(34.0)	\$ (10,659,000)	(34.0)	\$ (5,100,000)	(34.0)
State taxes	59,000	0.4	(1,632,000)	(5.2)	(939,000)	(6.3)
Tax credit carryforwards			(141,000)	(0.5)	(234,000)	(1.6)
Charges for in process R&D			627,000	2.0		
Goodwill impairment	2,303,000	15.6				
Warrant valuation adjustment	(234,000)	(1.6)				
Change in valuation allowance	2,831,000	19.2	11,747,000	37.5	6,233,000	41.6
Other	44,000	0.4	58,000	0.2	40,000	0.3
Effective tax rate	\$		\$		\$	

***FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes- An Interpretation of FASB No. 109 ( FIN 48 )***

On July 13, 2006, the FASB issued FIN 48. FIN 48 prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the amount of tax benefits recognized must be the largest amount of tax benefit that has a greater than 50% likelihood of being sustained upon audit by the relevant taxing authority. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, and accounting for interim periods and requires expanded disclosure with respect to the uncertainty in income taxes.

The Company adopted the provisions of FIN 48 on January 1, 2007. As of the date of adoption and December 31, 2007, the total amount of unrecognized tax benefits was \$1,803,000 and \$1,739,000, respectively, which, if recognized, would affect the effective tax rate prior to the adjustment for the Company's valuation allowance. As a result of the implementation of FIN 48, the Company did not recognize an increase in tax liability for the unrecognized tax benefits because the Company has recorded a tax net operating loss carryforward that would offset this liability. The change in unrecognized tax benefits for the 12 months ended December 31, 2007 is as follows:

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Balance at January 1, 2007	\$ 1,803,000
Reductions for expiration of statute of limitations	(64,000)
Balance at December 31, 2007	\$ 1,739,000

The Company recognizes interest and penalties related to unrecognized tax benefits in operating expenses. Since a full valuation allowance was recorded against the Company's net deferred tax assets and the unrecognized tax benefits determined under FIN 48 would not result in a tax liability, the Company has not accrued for any interest and penalties relating to these unrecognized tax benefits.

Tax years ended December 31, 2004, 2005, 2006 and 2007 remain subject to examination by major tax jurisdictions, which are Federal and the Commonwealth of Massachusetts. However, since the Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, those years may also be subject to review by relevant taxing authorities if utilized.

The Company has performed an analysis of its changes in ownership under Internal Revenue Code Section 382 and has determined that approximately \$4,100,000 of state net operating loss carryforwards are limited and unavailable to offset future taxable income, resulting in a reduction of the related deferred tax asset and valuation allowance of approximately \$187,000.

**10) SHAREHOLDERS EQUITY**

**Common Stock Issuances** On October 29, 2007, the Company entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement with certain accredited investors for the private placement of 4,581,043 shares of our common stock at a purchase price of \$2.40 per share which resulted in gross proceeds to us of \$11,000,000. The Company also issued warrants to purchase an additional 1,145,259 shares of common stock (see Note 11). The shares that were issued and the shares underlying the warrants were registered with the Securities and Exchange Commission on a Form S-3 registration statement, which became effective on January 24, 2008. We paid the placement agent its fee, including expenses, of \$695,000 for its services in connection with the transaction.

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius in exchange for cash and 2,396,245 shares of DUSA common stock.

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

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stock compensation expense was recorded as part of general and administrative costs in the Consolidated Statements of Operations.

**11) STOCK OPTIONS AND WARRANTS**

On October 29, 2007, the Company sold, through a private placement, 4,581,043 shares of our common stock and warrants to purchase 1,145,259 shares of common stock with an exercise price of \$2.85. The warrants have a 5.5 year term and become exercisable on April 30, 2008. As described in Note 2, the warrants are recorded as a derivative liability at fair value. Upon issuance of the warrants on October 29, 2007, we recorded the warrant liability at its initial fair value of \$2.0 million. Warrants that are classified as a liability are revalued at each reporting date until the warrants are exercised or expire with changes in the fair value reported in our Consolidated Statements of Operations as gain or loss on fair value of warrants. At December 31, 2007, the aggregate fair value of these warrants decreased to \$1.3 million, from their initial fair value, resulting in a non-cash gain of \$0.7 million during the year ended December 31, 2007. Assumptions used for the Black-Scholes option-pricing models as of October 29, 2007 and December 31, 2007 are as follows:

	October 29, 2007	December 31, 2007
Expected volatility	71.0%	67.3%
Remaining contractual term (years)	5.5	5.33
Risk-free interest rate	4.04%	3.45%
Expected dividend yield	0%	0%
Common stock price	\$ 2.71	\$ 2.07

On October 18, 2006 the Company's Board of Directors extended the term of 250,000 Class B warrants, originally issued to the Company's Chairman of the Board of Directors and Chief Executive Officer at the time of DUSA's initial public offering, for an additional four years to January 29, 2011. An additional 50,000 of the 300,000 Class B warrants lapsed on January 29, 2007. The warrants have an exercise price of \$6.00 per share. No other terms of the warrants were amended. There are no other holders of the Class B warrants. The Company recorded a non-cash charge to earnings of approximately \$534,000 during the fourth quarter of 2006 related to the extension of the warrants. The fair value of the warrants was estimated on the date of the amendment using a Black-Scholes valuation model.

Under the Company's 2006 Equity Compensation Plan (the "2006 Plan"), the Company may grant stock-based awards in amounts not to exceed the lesser of: (i) 20% of the total number of shares of the Company's common stock issued and outstanding at any given time less the number of shares issued and outstanding under any other equity compensation plan of the Company at such time; or (ii) 3,888,488 shares less the number of shares issued and outstanding under any other equity compensation plan of the Company from time to time. The maximum number of shares of common stock that may be granted to any individual during any calendar year is 300,000.

The 2006 Plan is administered by the Compensation Committee of the Board of Directors (the "Committee"). The 2006 Plan provides for the grant of incentive stock options ("ISO"), nonqualified stock options ("NSO"), stock awards, and stock appreciation rights to (i) employees, consultants, and advisors; (ii) the employees, consultants, and advisors of the Company's parents, subsidiaries, and affiliates; and (iii) and the Company's non-employee directors.

*Non-Qualified Stock Options* - All the NSOs granted under the 2006 Plan have an expiration period not exceeding seven years and are issued at a price not less than the market



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value of the common stock on the grant date. The Committee may establish such vesting and other conditions with respect to options as it deems appropriate. In addition, the Company initially grants each individual who agrees to become a director 15,000 NSO to purchase common stock of the Company. Thereafter, each director reelected at an Annual Meeting of Shareholders will automatically receive an additional 10,000 NSOs on June 30 of each year. Grants to directors immediately vest on the date of the grant.

*Incentive Stock Options* - ISOs granted under the 2006 Plan have an expiration period not exceeding seven 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. The Committee may establish such vesting and other conditions with respect to options as it deems appropriate.

The 2006 Plan replaced the Company's 1996 Omnibus Plan (the 1996 Plan), which expired on June 6, 2006. A summary of stock option activity in both the 1996 Plan and the 2006 Plan, for 2007 follows:

	Options	Weighted Average Exercise Price
Outstanding, beginning of year	2,730,875	\$ 11.57
Options granted	424,000	\$ 3.27
Options forfeited	(83,499)	\$ 6.13
Options expired	(201,251)	\$ 8.55
Options exercised	(15,000)	\$ 2.71
Outstanding, end of year	2,855,125	\$ 10.76
Exercisable, end of year	2,040,692	\$ 12.44
Options vested and expected to vest, end of year	2,705,435	\$ 11.03

A summary of stock options outstanding at December 31, 2007 follows:

Range of Exercise Prices	Outstanding as of December 31, 2007	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable as of December 31, 2007	Weighted Average Exercise Price
\$ 1.60- \$ 3.37	686,000	5.69	\$ 2.93	346,500	\$ 2.58
\$ 3.87- \$ 7.71	606,125	5.46	\$ 6.27	376,625	\$ 6.05
\$ 8.49- \$ 9.92	571,000	4.66	\$ 9.50	506,939	\$ 9.45
\$ 9.99- \$17.63	575,000	5.33	\$12.24	393,628	\$12.61
\$26.19- \$31.00	417,000	2.24	\$29.86	417,000	\$29.86
	2,855,125	4.86	\$10.76	2,040,692	\$12.44

The weighted average remaining contractual term was approximately 4.86 years for stock options outstanding and approximately 4.03 years for stock options exercisable as of December 31, 2007.

The total intrinsic value (the excess of the market price over the exercise price) was approximately \$44,000 and \$43,000 for stock options outstanding and exercisable, respectively, as of December 31, 2007. The total intrinsic value for stock options exercised in 2007, 2006 and 2005 was approximately \$31,000, \$100,000 and \$557,000, respectively. The total intrinsic value for stock options vested/expected to vest was approximately \$44,000, \$593,000 and \$6,415,000 as of December 31, 2007, 2006 and 2005. At December 31, 2007, total unrecognized estimated compensation cost related to non-vested stock options granted prior to

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that date was \$2,295,000, which was expected to be recognized over a weighted average period of 2.2 years.

The amount of cash received from the exercise of stock options in 2007 and 2006 was approximately \$41,000 and \$130,000, respectively, and the related tax benefit was approximately \$31,000 and \$69,000 in 2007 and 2006, respectively.

**SHARE-BASED COMPENSATION INFORMATION UNDER SFAS 123(R)**

The weighted-average estimated fair value of employee stock options granted during the years ended December 31, 2007 and 2006 was \$1.97 and \$4.61 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Years ended December 31,	
	2007	2006
Volatility	62.2%	63.7%
Risk-free interest rate	4.01%-4.92%	4.31%-5.21%
Expected dividend yield	0%	0%
Expected life-directors and officers	5.9 years	5.9-8.5 years
Expected life-non-officer employees	5.5 years	5.5-6.3 years

The Company used a combination of historical and implied volatility of market-traded options in the Company's stock for the expected volatility assumption input to the Black-Scholes model. The decision to use a combination of historical and implied volatility data to estimate expected volatility was based upon the availability of actively traded options on the Company's stock and the Company's assessment that this is more representative of future stock price trends than historical volatility alone.

The risk-free interest rate assumption is based upon observed interest rates appropriate for the term of the Company's employee stock options. The expected life is based on the Company's historical option cancellation and employee exercise information. The expected life of employee stock options includes the weighted-average period the stock options are expected to remain outstanding post-vesting. In calculating the expected life of the options for 2007 and 2006, the Company classified its grantee population into two groups, directors and officers and non-officer employees. As share-based compensation expense recognized in the Consolidated Statements of Operations for fiscal 2007 and 2006 is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In 2007, forfeiture rates were estimated to be approximately 2.95% for officers and directors and 8.10% for non-officer employees. In 2006, forfeiture rates were estimated to be approximately 3.82% for officers and directors and 9.48% for non-officer employees.

Total share-based compensation expense, related to all of the Company's share-based awards, recognized for the years ended December 31, 2007 and 2006 is included in the following line items:

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	Year ended	
	2007	2006
Cost of product revenues	\$ 99,000	\$ 81,000
Research and development	373,000	621,000
Selling and marketing	241,000	370,000
General and administrative	852,000	1,213,000
Share-based compensation expense	\$1,565,000	\$2,285,000

**PRO FORMA INFORMATION UNDER SFAS 123 FOR 2005**

Prior to adopting the provisions of SFAS 123(R), the Company recorded estimated compensation expense for employee stock options based upon their intrinsic value on the date of grant pursuant to Accounting Principles Board Opinion 25 ( APB 25 ), *Accounting for Stock Issued to Employees* and provided the required pro forma disclosures of SFAS 123. Because the Company established the exercise price based on the fair market value of the Company's stock at the date of grant, the stock options had no intrinsic value upon grant, and therefore no estimated expense was generally recorded prior to adopting SFAS 123(R).

For purposes of pro forma disclosures under FASB Statement No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ) for the year ended December 31, 2005, the estimated fair value of the stock options was amortized to expense over the stock options' vesting periods. The pro forma effects of recognizing estimated compensation expense under the fair value method on net loss and loss per common share for the year ended December 31, 2005 were as follows:

	December 31, 2005
Net loss, as reported	\$ (14,998,709)
Add: stock-based compensation expense included in reported net loss	19,444
Deduct: Share-based employee compensation expense determined under the fair value based method for all awards	(1,738,275)
Pro forma net loss	\$ (16,717,540)
Basic and diluted loss per share-as reported	\$ (0.89)
Basic and diluted loss per share pro forma	\$ (0.99)

The fair value of awards granted in 2005 was estimated at the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	2005
Volatility	72.05%
Risk-free interest rate	3.97%
Dividend yield	0.0%
Expected life (years)	5.0

Using these assumptions, the weighted-average fair value per option granted during the year ended December 31, 2005 was \$6.71.

**Table of Contents****12) STIEFEL AGREEMENT**

In January 2006, as amended in September 2007, DUSA licensed to Stiefel the exclusive Latin American rights to market Levulan® PDT for payments by Stiefel of up to \$2.25 million. The Company also manufactures and supplies finished product for Stiefel, which the Company began shipping in September 2007. In consideration for the transaction Stiefel agreed to pay the Company as follows: (i) \$375,000 upon launch of the product in either Mexico or Argentina; (ii) \$375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of \$375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of \$375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. Stiefel launched the product in October 2007 in Mexico and Argentina. The Company is deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the fourth quarter of 2015, which is the term of the Stiefel Agreement. Stiefel pays a fixed price per unit for the inventory as well as a royalty based on a percentage of the net sales price to end-users. During 2007, the Company's product sales of Levulan® Kerastick® to Stiefel were \$248,000, of which \$206,000 has been deferred at December 31, 2007 in accordance with the Company's policy of deferring revenues during a product's launch phase and recognizing revenues based on end-user demand. Deferred revenues at December 31, 2007 associated with milestone payments received from Stiefel are \$345,000. The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval.

**13) DAEWOONG AGREEMENT**

In January 2007 the Company licensed to Daewoong the exclusive Korean rights to market Levulan® PDT for payments by Daewoong of up to \$3.5 million. The Company also manufactures and supplies finished product for Daewoong, which the Company began shipping in October 2007. In consideration for the transaction Daewoong agreed to pay the Company as follows: (i) \$1.0 million upon contract signing; (ii) \$1.0 million upon achieving regulatory approval in Korea; and (iii) two installments of \$750,000 each for cumulative end-user sales totaling 200,000 units and 500,000 units. Daewoong launched the product in November 2007 in Korea. The Company is deferring and recognizing the up-front and regulatory approval milestones as license revenues on a straight-line basis, beginning with product launch in the Territory through the fourth quarter of 2016, which is the term of the Daewoong Agreement. Daewoong pays a fixed price per unit for the inventory and an Excess Purchase Price, as defined in the Agreement, if the Average Selling Price to end-users during any calendar quarter exceeds a certain threshold. During 2007, DUSA's product sales of Levulan® Kerastick® to Daewoong were \$1.1 million, of which \$762,000 has been deferred at December 31, 2007 in accordance with the Company's policy of deferring revenues during a product's launch phase and recognizing revenues based on end-user demand. Deferred revenues at December 31, 2007 associated with milestone payments received from Daewoong are \$1,848,000. The agreement with Daewoong also establishes minimum purchase quantities over the first five years following regulatory approval.

**14) RETIREMENT AND DEFERRED COMPENSATION PLANS**

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, the Company 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 the Company. The Company's matching contributions in 2007, 2006 and 2005 were \$59,000, \$49,000 and \$42,000, respectively.

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In October 2006, the Company adopted the DUSA Pharmaceuticals, Inc. Non-Qualified Deferred Compensation Plan (the Plan), a non-qualified supplemental retirement plan maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees and members of the Board of Directors of the Company (the Participants). Participants may defer up to 80% of their compensation. A Participant will be 100% vested in all of the amounts he or she defers as well as in the earnings attributable to a Participant's deferred account. A Participant may elect to receive distributions from the deferred account at various times, either in a lump sum or in up to ten annual installments. Included in other liabilities is \$127,000 at December 31, 2007, representing the Company's obligation under the Plan. DUSA's obligation to pay the Participant an amount from his or her deferred account is an unsecured promise and benefits shall be paid out of the general assets of the Company. The Company has purchased corporate owned life insurance to serve as the funding vehicle for the Plan. The cash surrender value of the life insurance policy is recorded in deferred charges and other assets and totaled \$124,000 at December 31, 2007. As of December 31, 2006, amounts deferred under the Plan were not material.

**15) SEGMENT REPORTING**

Beginning in the first quarter of 2006 with the acquisition of Sirius, the Company has two reportable operating segments: Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Drug Products. Prior to the beginning of the first quarter of 2006, the Company was a single reportable segment entity. Operating segments are defined as components of the Company for which separate financial information is available to manage resources and evaluate performance regularly by the chief operating decision maker. The table below presents the revenues, costs of revenues and gross margins attributable to these reportable segments for the periods presented. The Company does not allocate research and development, selling and marketing and general and administrative expenses to its reportable segments, because these activities are managed at a corporate level.

	YEAR ENDED DECEMBER 31,		
	(in thousands)		
	2007	2006	2005
<b>REVENUES</b>			
PDT Drug & Device Product Revenues	\$18,275,000	\$ 16,097,000	\$ 11,337,000
Non-PDT Drug Product Revenues	9,388,000	9,486,000	
<b>Total Revenues</b>	<b>27,663,000</b>	<b>25,583,000</b>	<b>11,337,000</b>
<b>COSTS OF REVENUES</b>			
PDT Drug & Device Cost of Product Revenues and Royalties	4,950,000	5,586,000	6,213,000
Non-PDT Drug Cost of Product Revenues and Royalties	2,880,000	4,784,000	
Impairment of intangible assets		15,746,000	
<b>Total Non-PDT Drug Cost of Product Revenues and Royalties</b>	<b>2,880,000</b>	<b>20,530,000</b>	
<b>Total Costs of Product Revenues and Royalties</b>	<b>7,830,000</b>	<b>26,116,000</b>	<b>6,213,000</b>
<b>GROSS MARGINS</b>			
PDT Drug and Device Product Gross Margin	13,325,000	10,511,000	5,124,000
Non-PDT Drug Product Gross Margin	6,508,000	(11,044,000)	
<b>Total Gross Margins</b>	<b>\$19,833,000</b>	<b>\$ (533,000)</b>	<b>\$ 5,124,000</b>



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During the years ended December 31, 2007 and 2006, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

	Year Ended December 31,	
	2007	2006
United States	95%	96%
Canada	3%	4%
Korea	2%	
Total	100%	100%

Asset information by reportable segment is not reported to or reviewed by the chief operating decision maker and, therefore, the Company has not disclosed asset information for each reportable segment. As discussed in Note 4, the Company recorded a goodwill impairment charge of \$6.8 million in 2007, and an intangible asset impairment charge of \$15.7 million in 2006, which were assets related to the Non-PDT segment.

**16) COMMITMENTS AND CONTINGENCIES****LEGAL MATTERS:****RIVER S EDGE LITIGATION SETTLEMENT**

On March 28, 2006, a lawsuit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division by River s Edge Pharmaceuticals, LLC ( River s Edge ) against us alleging, among other things, that, prior to the merger with DUSA, Sirius agreed to authorize River s Edge to market a generic version of Nicomide<sup>®</sup>, and that the United States patent covering Nicomide<sup>®</sup> issued to Sirius in December 2005 is invalid. Nicomide<sup>®</sup> is the key product DUSA acquired from Sirius in its merger. River s Edge also filed an application with the U.S. Patent and Trademark Office requesting reexamination of the Nicomide<sup>®</sup> patent. On April 20, 2006, the Company filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that the River s Edge niacinamide product infringes U.S. Patent No. 6,979,468.

On October 28, 2007, the Company entered into a Settlement Agreement and Mutual Release (the Settlement Agreement ) to dismiss the lawsuit brought by DUSA against River s Edge asserting a number of claims arising out of River s Edge s alleged infringement of its Nicomide<sup>®</sup> patent under which DUSA has marketed, distributed and sold Nicomide<sup>®</sup>. Under the terms of the Settlement Agreement, River s Edge unconditionally acknowledged the validity and enforceability of the Nicomide<sup>®</sup> patent, made a lump-sum settlement payment to DUSA in the amount of \$425,000 for damages and will pay to DUSA \$25.00 for every bottle of NIC 750 above 5,000 bottles that is substituted for Nicomide<sup>®</sup> after September 30, 2007. River s Edge shall be responsible for all returns of NIC 750 from the distribution chain and/or order its destruction and immediately ceased the manufacture, distribution and sale of NIC 750. River s Edge withdrew from and ceased participating in the re-examination of the Company s Nicomide<sup>®</sup> patent and consented to the return to the Company of the \$750,000 bond, which the Company received from the courts during the fourth quarter of 2007. On March 6, 2008, the United States Patent and Trademark Office vacated the reexamination of the Nicomide<sup>®</sup> patent.

As part of the settlement, DUSA and River s Edge have also entered into a license agreement, dated October 28, 2007 (the License Agreement ) whereby DUSA granted a perpetual, exclusive license to River s Edge to manufacture and sell four of its products from the AVAR<sup>®</sup> line, including AVAR cleanser, AVAR gel, AVAR E-emollient cream and AVAR E- green in exchange for a royalty on net sales of these products, including a guaranteed minimum royalty of \$300,000, payable in equal annual installments of \$100,000 for three years. DUSA



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provided its on-hand inventory of these products to River s Edge for no cost. The Company will participate in returns of split lots based on the two company s respective pro-rata sales of these lots. DUSA acquired the AVAR products from Sirius Laboratories, Inc., the Illinois corporation, as a result of the merger which closed on March 10, 2006. In connection with the License Agreement, DUSA requested and received a waiver to certain obligations to promote the AVAR products being licensed to River s Edge from the Sirius shareholder representatives acting on behalf of all of the former shareholders of Sirius Laboratories, Inc. As consideration for the waiver, the Company and the Sirius shareholder representatives agreed to amend the merger agreement to extend the milestone termination date provided in the merger agreement by 8 additional months and agreed that for the balance of the 50 month period prior to the milestone termination date (as amended), DUSA will credit the cumulative net sales milestone amounts under the merger agreement with a monthly amount equal to the average of the last 12-months of net sales by DUSA of the four products licensed to River Edge.

The net gain from settlement of litigation is comprised of the following:

Proceeds from Settlement Agreement	\$ 425,000
Less: cost of inventory transferred to River s Edge	(95,000)
Plus: excess prescriptions filled	253,000
Net gain from settlement of litigation	\$ 583,000

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The net gain on litigation settlement was recorded as a separate component of operating expenses on the Company's Consolidated Statements of Operations for year ended December 31, 2007.

The Company has not accrued any amounts for potential contingencies as of December 31, 2007.

**17) SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)****Supplementary Information:**

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2007			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31(1)
Net revenues	\$ 6,676,840	\$ 6,862,198	\$ 5,784,194	\$ 8,339,366
Gross profit	4,520,688	5,085,707	4,210,297	6,016,622
Net loss	(3,370,928)	(2,477,407)	(1,877,782)	(6,987,390)
Basic and diluted loss per share	\$ (0.17)	\$ (0.13)	\$ (0.10)	\$ (0.31)

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2006			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31(2)
Net revenues	\$ 4,750,520	\$ 6,619,109	\$ 6,062,720	\$ 8,150,637
Gross profit	2,959,761	3,623,946	3,213,236	(10,329,946)
Net loss	(4,640,309)	(4,653,954)	(3,786,639)	(18,268,605)
Basic and diluted loss per share	\$ (0.26)	\$ (0.24)	\$ (0.19)	\$ (0.94)

(1) In the fourth quarter of 2007, the Company recorded a goodwill impairment charge of \$6.8 million.

(2) In the fourth quarter of 2006, the Company recorded an intangible asset impairment charge of \$15.7 million.

**Table of Contents****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/ Robert F. Doman

President and Chief Executive Officer

Date: March 10, 2008

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/ Robert F. Doman	President and Chief Executive Officer	March 10, 2008
Robert F. Doman	(principal executive officer)	Date
/s/ Richard C. Christopher	Vice President, Finance and Chief Financial Officer (principal financial officer	March 10, 2008
Richard C. Christopher	and principal accounting officer)	Date
/s/ D. Geoffrey Shulman	Director, Chairman of the Board and Chief Strategy Officer	March 10, 2008
D. Geoffrey Shulman, MD, FRCPC		Date
/s/ John H. Abeles	Director	March 10, 2008
John H. Abeles		Date
/s/ David Bartash	Director	March 10, 2008
David Bartash		Date
/s/ Jay M. Haft, Esq.	Vice Chairman of the Board and Lead Director	March 10, 2008
Jay M. Haft, Esq.		Date
/s/ Richard C. Lufkin	Director	March 10, 2008
Richard C. Lufkin		Date

/s/ Magnus Moliteus Director

March 10,  
2008

Magnus Moliteus

Date

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**EXHIBIT INDEX**

- 2(a.1)\* Merger Agreement by and among the Registrant, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005 filed as Exhibit 2(a.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; and
- 2(a.2) First Amendment to Merger Agreement by and among the Registrant, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006 filed as Exhibit 2(a.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference.
- 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 3.1 to the Registrant's current report on Form 8-K, filed on November 2, 2007, 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) Form of D. Geoffrey Shulman's Class B Warrant;
- 4(c) Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K filed October 11, 2002, and is incorporated herein by reference;
- 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 filed October 11, 2002, and is incorporated herein by reference;
- 4(e) Form of Common Stock Purchase Warrant, dated October 29, 2007 filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference; and
- 4(f) Registration Rights Agreement, dated October 29, 2007, by and between the Registrant and each of the respective selling shareholders named therein filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference.
- 10(a) License Agreement between the Registrant, 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 Registrant, 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 Registrant 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 Registrant 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;

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- 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.1) 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(d.2) Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated March 20, 1997, filed as Exhibit 10(d.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
- 10(e) Amended and Restated License Agreement between the Registrant 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 Registrant 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 Registrant 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 Registrant 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;

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- 10(j.1) First Amendment to Supply Agreement between the Registrant 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 Registrant 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 Registrant 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;
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- 10(k) Master Service Agreement between the Registrant 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 Registrant 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 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(m) Supply Agreement between the Registrant 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 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(n) License and Supply Agreement dated August 7, 2007 among the Registrant, photonamic GmbH & Co. KG and medac, GmbH, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2007 and is incorporated herein by reference
- 10(o) Securities Purchase Agreement dated as of February 27, 2004, by and among the Registrant 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 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(p) Registration Rights Agreement dated as of February 27, 2004 by and among the Registrant 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(q) 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(r) License, Promotion, Distribution and Supply Agreement between the Registrant and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;
- 10(s) 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(t) 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(u)

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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(u.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(v) Amendment to Employment Agreement of Richard Christopher dated as of October 18, 2006 filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended September 30, 2004, and is incorporated herein by reference;

10(w) 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;  
+

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- 10(x) 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(y) Severance Agreement and General Release between the Registrant 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(z) Final Agreement and General Release, between the Registrant 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(aa) Compensation Policy Applicable to the Registrant'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(bb) Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated May 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(cc) Amendment and Extension of the Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, 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(dd) Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(ee) Amendment and Extension of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, 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, as filed as Exhibit 10.D to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(ff) Second Amendment of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, 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, as filed as Exhibit 10.E to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(gg) Supply Agreement between Sirius Laboratories, Inc. and L. Perrigo Registrant dated October 21, 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, as filed as Exhibit 10.F to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(hh)

2006 Micanol License Agreement between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, 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, as filed as Exhibit 10.G to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference; and

- 10(hh.1) 2006 Micanol Transition License Agreement, dated as of January 29, 2008, by and between Winston Laboratories, Inc. and Sirius Laboratories, Inc. 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, as filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 31, 2008, and is incorporated herein by reference;
- 10(ii) Development, License and Supply Agreement between Sirius Laboratories, Inc. and Altana Inc. dated June 13, 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 as filed as Exhibit 10.H to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference.
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- 10(jj) Employment Agreement of William O Dell dated as of April 4, 2006 filed as Exhibit 10(ii) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(kk) Patent License Agreement between the Registrant and PhotoCure ASA, dated as of May 30, 2006, 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, filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended June 30, 2006, and is incorporated herein by reference;
- 10(ll) Separation Agreement between the Registrant and Paul Sowyrda, dated as of August 31, 2006 filed as Exhibit 10(kk) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(mm) Employment Agreement of Michael Todisco dated as of September 20, 2006 filed as Exhibit 10(11) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(nn) Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 4, 2007, 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, filed as Exhibit 10(mm) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(nn.1) First Amendment to Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 10, 2007, 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, filed as Exhibit 10(nn) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
- 10(oo) DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, filed as Appendix A to Registrant's Schedule 14A definitive Proxy Statement dated April 24, 2006, and is incorporated herein by reference; +
- 10(pp) DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, as amended October 18, 2006 filed as Exhibit 10(pp) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
- 10(qq) DUSA Pharmaceuticals, Inc. 2006 Deferred Compensation Plan, October 18, 2006 filed as Exhibit 10(qq) to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
- 10(rr) Marketing, Distribution and Supply Agreement between the Registrant 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 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(aa) to the Registrant's Form 10-K for the fiscal year ended December 31, 2005, and is incorporated herein by reference;
- 10(rr.1) Amendment to the Marketing, Distribution and Supply Agreement dated September 26, 2007, between the Registrant and Stiefel Laboratories, Inc. portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as

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Exhibit 10(a) to the Registrant's Form 10-Q for the fiscal quarter ended September 30, 2007, and is incorporated herein by reference;

- 10(ss) Securities Purchase Agreement, dated October 29, 2007, by and among the Registrant and each of the selling shareholders named therein portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference; and
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- 10(tt) Settlement Agreement and Mutual Release, including License Agreement dated October 28, 2007 between Registrant and River s Edge Pharmaceuticals LLC.
- 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. 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 Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Commission upon request.