DUSA PHARMACEUTICALS INC
Form 10-K
March 04, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
Form 10-K

(MARK ONE)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009

o **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	**22-3103129**
(State or other jurisdiction of Incorporation or organization)	*(I.R.S. Employer Identification No.)*
25 Upton Drive, Wilmington, MA	**01887**
(Address of principal executive offices)	*(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 o No þ

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

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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 þ

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 o	Accelerated filer o	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of March 2, 2010, the Registrant had 24,108,908 shares of Common Stock, no par value, outstanding.

Based on the last reported sale price of the Company s common stock on the NASDAQ Global Market on June 30, 2009 ($1.10) (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 $22,741,353.

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, 2009 are incorporated by reference into Part III of this report.	Items 10, 11, 12, 13 and 14

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PART I

PART II

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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 20 through 30, as well as those noted in the documents incorporated herein by reference. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. However, readers should carefully review the statements set forth in other reports or documents we file from time to time with the Securities and Exchange Commission, particularly the Quarterly Reports on Form 10-Q and any Current Reports on Form 8-K.

ITEM 1. BUSINESS

General

DUSA is a vertically integrated dermatology company that is developing and marketing Levulan® photodynamic therapy, or Levulan® PDT, and other products for common skin conditions. Our marketed products include Levulan® Kerastick® 20% Topical Solution with PDT, the BLU-U® brand light source, and ClindaReach®.

We devote most of our resources to advancing the development and marketing of our Levulan® PDT 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. The Kerastick® is our proprietary applicator that delivers Levulan®. The BLU-U® is our patented light device.

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® 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® was its key product, a vitamin-mineral product prescribed by dermatologists. We merged with Sirius in March 2006. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® in June 2008.

On August 12, 2008, we entered into a worldwide non-exclusive patent license agreement with respect to our patent covering Nicomide®, or License Agreement, with River s Edge Pharmaceuticals, LLC, or River s Edge, and an amendment to our settlement agreement with River s Edge regarding earlier litigation. The amendment to the settlement agreement allowed River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changed certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we were paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales. In April 2009, we and River s Edge entered into an Amendment to the License Agreement, or License Amendment. The License Amendment grants River s Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the

trademark associated with the licensed products worldwide. Under the License Amendment, we are required to transfer all of our rights, title and interest in and to DUSA s patent, know-how and trademark relating to the licensed products (but not the copyright registration relating to product labeling) to River s Edge upon our receipt of $5,000,000. Of the $5,000,000, River s Edge is required to make payment to us of $2,600,000, in thirteen monthly installments of $200,000, subject to reduction under certain conditions, and pay additional consideration of

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$2,400,000 payable over time based on a share of River s Edge s net revenues as defined in the License Amendment. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the licensed products. If the License Agreement is terminated prior to the payment of the $5,000,000, all of the rights and licenses granted by us to River s Edge will revert to us. We are recording the revenue under the License Amendment on a cash basis. We received the first $200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations, but have not received any further payments. We are considering our options relative to the collection of amounts due from River s Edge and termination of the License Agreement, which we have the right to do for non-payment. Two other companies have launched substitutable niacinamide products. The validity of the Nicomide® patent is being tested again as a request for *exparte* reexamination of this patent was filed by a third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. An order issued by the USPTO on October 16, 2009 accepted the request for reexamination and we have received the first office action. At this time we are unable to assess the possible outcome of the reexamination.

We manufacture our Levulan® Kerastick®. We are also responsible for the regulatory, sales, marketing, customer service and other related activities for all of our products, including our Levulan® Kerastick®. We are developing Levulan® PDT 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. In January 2009, we filed a request for reexamination with the United States Patent and Trademark Office, or USPTO, of one of the patents licensed from Queens University covering certain methods of using our product, Levulan®, for our FDA-approved indication. The USPTO accepted our request for reexamination during the first quarter of 2009 and we have responded to the first office action. There is no guarantee that the process will be successful since the USPTO reviews the entire prosecution history of a patent during a reexamination and could determine that some or all of the patent claims are invalid. Typically, a reexamination takes approximately 18 months to complete. The patent is due to expire in 2013. If the USPTO finds that the patent is invalid, generic competitors could enter the market earlier than otherwise anticipated and revenues could be adversely affected. This would adversely affect our financial condition and results of operations and possibly prevent us from becoming profitable on an annual basis. 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®, ClindaReach®, Meted®, and Psoriacap® 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, 2009, we had an accumulated deficit of approximately $144,359,000. 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 an annual basis. We must increase sales from current levels in order for us to reach profitability on an annual basis. We cannot provide any assurance that we will be able to increase sales sufficiently from these levels, nor can we provide assurance that an increase in sales will cause us to be profitable on an annual basis.

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 office is 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, 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, 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 .

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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 focused effort to increase sales of our PDT products to both new and existing medical dermatology customers, and internationally through continued support of our partners. Increase the return on our Non-PDT products through establishing and growing the market for ClindaReach®.

Conduct Selected Research Programs. In May 2009, we initiated a Phase II clinical trial at seven clinical trial sites across the United States for the treatment of broad area actinic keratoses and reduction in the incidence of non-melanoma skin cancers in immunosuppressed solid organ transplant recipients, or SOTR, who have demonstrated that they are at risk of developing multiple squamous cell carcinomas. We expect to enroll up to 36 patients, which could take at least one year. We expect that we would receive preliminary results from the study in approximately 15 months and full results in approximately two years.

Enter into 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 product opportunities.

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

Use the Results of Independent Researchers to Identify New Applications. We continue to support research by independent investigators so that we have the benefit of the resulting anecdotal human data for use in evaluating potential Levulan® indications for corporate development.

PDT Overview

In general, photodynamic therapy, or PDT, is a two-step process:

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.

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.

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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 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 effects.

Our Levulan® PDT Platform

Our Levulan® Brand of ALA

We have a unique approach to PDT 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 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, 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 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 refer to it as the Levulan® Kerastick®. It is a single-use, disposable applicator, which allows for uniform application of Levulan® topical solution in standardized doses. The Kerastick® has two separate glass ampoules, one containing Levulan® powder and one containing a liquid vehicle, both enclosed within a single plastic tube and an outer cardboard sleeve. There is a filter and a metered dosing tip at one end. Prior to application, the physician, nurse or other qualified healthcare practitioner 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 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:

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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

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, our therapy uses 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.

Our Products

The following table outlines the development status of our key products and planned product candidate. Our research and development expenses for the last three years were $4,313,000 in 2009, $6,643,000 in 2008 and $5,977,000 in 2007.

Indication/Product	Regulatory status
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)
ClindaReach®	ANDA(2)
Levulan® PDT for SOTR	Phase II Clinical Trial(3)

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

(2) ANDA owned by L. Perrigo Company.

(3)

We initiated this Phase II clinical trial in 2009.

Dermatology Indications

Actinic Keratoses.

AKs are superficial precancerous skin lesions usually appearing in sun-exposed areas as rough, scaly patches of skin with some underlying redness. The traditional methods of treating AKs are cryotherapy, or the 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, can be painful at the site of freezing and can cause blistering and loss of skin pigmentation, leaving temporary or 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

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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® 20% topical solution using the Kerastick® to individual AK lesions, followed 14 to 18 hours later with exposure to our BLU-U® 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.

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®[1] 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® in the skin, and possibly by other anti-inflammatory actions.

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

Solid Organ Transplant Recipients (SOTR).

We have initiated a DUSA-sponsored Phase II clinical trial for the treatment of actinic keratoses and reduction in the incidence of non-melanoma skin cancers in immunosuppressed solid organ transplant recipients, or SOTRs, who have demonstrated that they are at risk of developing multiple squamous cell carcinomas. We expect to enroll up to 36 patients at seven clinical trial sites across the United States which could take at least one year. We expect that we could receive preliminary results from the study in approximately 15 months and full results in approximately two years. To date, the pace of enrollment in the study has been slower than we anticipated at the outset of the trial. In May 2008, we filed an Orphan Drug Designation Application with the FDA for the prevention of cancer occurrence in these patients. We received initial correspondence that the application was not granted on the basis that the agency believed that the prevalence of the target population with the disease state is greater than 200,000, which is the maximum number of patients allowed under the Orphan Drug legislation. We met with the FDA during the third quarter of 2009 to clarify and explain further our application and, based on that meeting, the agency invited us to submit an amendment to our application for further evaluation. We submitted a draft amendment in January 2010 along with a request for a follow-on meeting with the agency. In February 2010, the FDA indicated that a meeting was not necessary and suggested that we formally submit the amended application. We expect to make the formal submission in March 2010.

Other Potential Levulan® Indications

We believe that there may be numerous other potential uses for Levulan® PDT in dermatology, and we intend to 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® in dermatology may 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, warts, and inflammatory acne. There are other potential indications outside of dermatology that we could pursue with sufficient resources, including, but not limited to, treatment of brain cancer.

[1] Accutane ® is a registered trademark of Hoffmann-La Roche, Inc.

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Internal Indications

Oral Cavity Dysplasia.

Since November 2004 we have been supporting a clinical trial under the terms of an agreement with the National Cancer Institute (NCI) Division of Cancer Prevention (DCP) for the treatment of oral cavity dysplasia. The NCI DCP used its resources to file its own investigational new drug application with the FDA. DUSA and the NCI DCP worked together to prepare the overall clinical development plan for Levulan® PDT in this indication, starting with Phase I/II trials. A Phase I clinical trial was launched in April 2008, which continues to accrue patients. Our costs related to this study are limited to providing Levulan®, leasing lasers and providing the necessary training for the investigators involved. All other costs of this study are the responsibility of the NCI DCP. We have options on any new intellectual property which may arise from this study. Depending on the results of the study, NCI may choose to move forward with a Phase II trial.

Supply Partners

National Biological Corporation.

On June 21, 2004, we signed an amended and restated purchase and supply agreement with National Biological Corporation, or NBC, the principal manufacturer of our BLU-U® brand light source. This agreement 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. On June 29, 2009, we extended the term of this agreement with NBC until June 30, 2011. We have an option to further extend the term for an additional two (2) years if we purchase a certain number of units. The parties agreed upon a tiered price schedule based on the volume of purchases and updated certain quality control provisions. All other terms and conditions of the 2004 agreement remain in effect.

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. In 2009, the parties renewed the agreement until December 31, 2015 on substantially the same terms, albeit with a revised pricing schedule to cover the new term. Sochinaz is our sole source for Levulan® and while we can obtain alternative supply sources in certain circumstances, any new supplier would have to be inspected and qualified by the FDA.

L. Perrigo Company.

On October 21, 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 launched the product, ClindaReach®, in March 2007. 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 October 2010 and may be renewed based on certain minimum purchase levels and other terms and conditions.

Medac/photonamic GMBH & Co. KG.

On August 7, 2007, we entered into a license and supply agreement among DUSA, photonamic GmbH & Co, a subsidiary of medac GmbH, a German pharmaceutical company, and medac confirming our rights to use certain pre-clinical data and licensed technology on a non-exclusive basis 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 system 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

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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. In January 2009, we filed a request for reexamination of one of the Queen s patents with the USPTO. The USPTO accepted our request for reexamination during the first quarter of 2009 and we have responded to the first office action. There is no guarantee that the process will be successful since the USPTO reviews the entire prosecution history of a patent during a reexamination and could determine that some or all of the patent claims are invalid. Typically, a reexamination takes approximately 18 months to complete. The patent is due to expire in 2013. If the USPTO finds that the patent is invalid, generic competitors could enter the market earlier than otherwise anticipated and our revenues could be adversely affected. This would adversely affect our financial condition and results of operations and possibly prevent us from becoming profitable on an annual basis. Annual minimum royalties to PARTEQ must total at least CDN $100,000 (U.S. $95,000 as of December 31, 2009) in order to retain the license. For 2009, 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 ended in the second quarter of 2009. 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®. In 2004, we appointed a Canadian distributor who launched our Levulan® Kerastick® and BLU-U® in Canada. See the section entitled Distribution.

Winston Laboratories Arbitration Settlement

In October 2008, we were notified that Winston Laboratories, Inc. had filed a demand for arbitration against us. The demand for arbitration arose out of two agreements known as the 2006 Micanol License Agreement and the 2006 Micanol Transition License Agreement, and claimed that the Company breached the agreements. Winston Laboratories claimed damages in excess of $2.0 million. The matter was settled on April 28, 2009 for cash consideration of $75,000, and a mutual release.

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® and Metvix® (known in the United States as Metvixia®) 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 this product, which is directly competitive with our Levulan® Kerastick® product, is now commercially available. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company, and on January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma will provide marketing support and distribution. PhotoMedex s sales force will promote Metvixia and Galderma s Aktilite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which

could adversely affect our ability to maintain or increase our market share.

River s Edge

On August 12, 2008, we entered into a worldwide non-exclusive patent license agreement to our patent covering Nicomide®, with River s Edge and an amendment to our settlement agreement with River s Edge regarding earlier litigation. The amendment to the settlement agreement allowed River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the license agreement, or License Agreement, and changed

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certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we were paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales. In April 2009, we and River s Edge entered into an amendment to the License Agreement, or License Amendment. The License Amendment grants River s Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the trademark associated with the licensed products worldwide. Under the License Amendment, we are required to transfer all of our rights, title and interest in and to DUSA s patent, know-how and trademark relating to the Licensed Products (but not the copyright registration relating to product labeling) to River s Edge upon our receipt of $5,000,000. Of the $5,000,000, River s Edge is required to make payment to us of $2,600,000, in thirteen monthly installments of $200,000, subject to reduction under certain conditions, and pay additional consideration of $2,400,000 payable over time based on a share of River s Edge s net revenues as defined in the License Amendment. The License Agreement, as amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the licensed products. If the License Agreement is terminated prior to the payment of the $5,000,000, all of the rights and licenses granted by us to River s Edge will revert to us. We are recording the revenue under the License Amendment on a cash basis. We received the first $200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations, but have not received any further payments. We are considering our options relative to the collection of amounts due from River s Edge and termination of the License Agreement, which we have the right to do for non-payment. Two other companies have launched substitutable niacinamide products. The validity of the Nicomide® patent is being tested again as a request for *exparte* reexamination of this patent was filed by a third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. An order issued by the USPTO on October 16, 2009 accepted the request for reexamination and we have received the first office action. It is too early in the reexamination process to assess the possible outcome.

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 cannot assure you that we will defend or successfully defend our patents.

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 to treat conditions such as AKs and acne,
- compositions and apparatus for those methods, and
- unique physical forms of ALA.

The patents relating to methods of using ALA for detecting or treating disease, other than for acne and our approved indication for AKs of the face or scalp, started to expire in July 2009. The patents covering our AK product do not start to expire until 2013. In January, 2009 we filed a request for reexamination with the USPTO of one of the patents covering certain methods of using Levulan® for our FDA-approved indication. While we believe that the reexamination will strengthen the patent, there is no guarantee that the process will be successful since the USPTO reviews the entire prosecution history of a patent during a reexamination and could determine that some or all of the patent claims are invalid. Typically, a reexamination takes approximately 18 months to complete.

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 . The 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® brand 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® and the AVAR® products which we have licensed, 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® patent expires in 2025 and the AVAR® patent expires in 2021. The validity of the Nicomide patent is being tested again as a request for *ex parte* reexamination of this patent was filed by an unknown third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. The USPTO accepted the reexamination on October 16, 2009 and has issued its first office action. Also, other new products have been launched that are competing with Nicomide®.

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 know that our patents, whether owned or licensed, or any future patents that may issue, have not prevented 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® and AVAR® 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.

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 130 trademark registrations, including trademarks for DUSA ®, DUSA Pharmaceuticals, Inc.®, Levulan®, Kerastick®, BLU-U®, Nicomide®, Nicomide-T®, ClindaReach®, Meted®, and Psoriacap®, 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. In 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 source suppliers. We intend to continue to use third-party manufacturers for our Non-PDT Drug Products under agreements we assumed as part of the merger with Sirius. See the section entitled Business Supply Partners.

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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 Clarion Medical Technologies, Inc., or Clarion (formerly known as Coherent-AMT), a leading Canadian medical device and laser distribution company. Clarion 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. Clarion has the right for a period of time following termination of its agreement to return inventory of product.

In January 2006, as amended in September 2007, 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 south of and including Mexico, and all other countries in the Caribbean, excluding United States territories. We 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. In September 2007, 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 is scheduled to make aggregate milestone payments to us of up to $2,250,000, as follows: (i) $375,000 upon launch of the product in either Mexico or Argentina which has been paid; (ii) $375,000 upon receipt of acceptable pricing approval in Brazil which has been paid; (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. The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval. The first contract year for all countries other than Brazil began in October 2007, and for Brazil began in April 2008. For the contract years ended in October 2008 and 2009 and April 2009 Stiefel did not meet its minimum purchase obligations under the agreement. The agreement provides that within 60 days of the year end, Stiefel is required to pay us the difference between its actual purchases and the contractual minimums (a gross-up payment). To date, Stiefel has failed to make the gross-up payments, and accordingly, we are considering our remedies, which include, without limitation, appointing one or more other distributors in the territory or terminating the agreement. Also, since Stiefel s sales to third parties during the contract years ended October 2008 and 2009 and April 2009 were below its minimum purchase obligations, Stiefel has the unilateral right to terminate the contract. Stiefel has not exercised this right.

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong Pharmaceutical Co., Ltd. and Daewoong s wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, together referred to as 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 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 over the first five years following regulatory approval in Korea. We receive a minimum transfer price per unit plus a percentage of Daewoong s end-user price if it exceeds a certain level. In 2007, the product was launched Korea, and we began recognizing revenue under the agreement in the fourth quarter of 2007. In the third quarter of 2008, we amended this agreement to allow

Daewoong to distribute our product in Japan on a named-patient basis only in order to test this market. This amendment has a term of two years.

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

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Marketing and Sales

DUSA markets its products in the United States. We have appointed Clarion as our marketing partner for our PDT products in Canada, Stiefel for our Levulan® Kerastick® in Mexico, Central and South America and Daewoong for our Levulan® Kerastick® in several Asian countries. See the section entitled Business Distribution.

As of December 31, 2009 and 2008, we had 39 and 40, respectively, sales representatives and management deployed nationally.

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: Galderma S.A./PhotoMedex; 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). There are many pharmaceutical companies that compete with us in the field of dermatology, particularly in the acne market.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AK and basal cell carcinoma, called BCC, in the European Union, New Zealand, Australia, and countries in Scandinavia. PhotoCure received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this product, which is directly competitive with our Levulan® Kerastick® product, is now commercially available. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company, and on January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma will provide marketing support and distribution. PhotoMedex s sales force will promote Metvixia and Galderma s Aktilite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia under the patent license to PhotoCure described below, Galderma and PhotoMedex together have considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share.

In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen s University at Kingston, Ontario, alleging that one of the patents covered by our agreement with PARTEQ, Australian Patent No. 624985, relating to ALA, was invalid. As a consequence of this action, Queen s University assigned the Australian patent to us so that we could participate directly in this litigation. In April 2005, the Federal Court of Australia ruled that the Australian patent assigned to DUSA by Queen s University which relates to DUSA s aminolevulinic acid photodynamic therapy is valid and remains in full force and effect. However, the Court also ruled that PhotoCure s product, Metvix, does not infringe the claims in the Australian patent. 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.

There are also non-PDT products for the treatment of AKs, including cryotherapy with liquid nitrogen, 5-fluorouracil (Efudex®)[2], diclofenac sodium (Solaraze®)[3], and imiquimod (ALDARA®)[4]. Other AK therapies are also known to be under development by companies such as Medigene GmbH, Leo Pharmaceuticals (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

[2] Efudex® is a registered trademark of Valeant Pharmaceuticals International.

[3] Solaraze® is a registered trademark of SkyePharma PLC.

[4] ALDARA® is a registered trademark of Graceway Pharmaceuticals, LLC

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therapeutic or cost advantages for competitive products. We believe that with increased reimbursement for our PDT-related procedure fee, including a 6% increase effective January 2009, our treatment is increasingly financially viable for practitioners, and more competitive with alternative AK therapies from a practice management perspective. However, no assurance can be given that developments by other parties will not render our products uncompetitive or obsolete.

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

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

Government Regulation

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

registration and inspection of manufacturing facilities, including adherence to current good manufacturing practice regulations, or cGMPs, quality system regulations, or QSRs, and good laboratory and good clinical practices or GLPs and GCPs;

adequate and well-controlled clinical studies and preclinical testing of products;

the submission of applications for marketing approval containing manufacturing, preclinical and clinical data and information to establish the safety and efficacy of the product for its intended use;

post-approval recordkeeping and reporting, including safety surveillance and reporting of adverse events to regulatory authorities; and

compliance with requirements and restrictions for marketing activities, including advertising and labeling.

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 or medical device can be produced and marketed for human use in the United States include:

preclinical testing;

the filing of an Investigational New Drug application, or IND, for new drugs, and an Investigational Device Exemption application, or IDE, for medical devices;

human clinical trials, including the analysis of data collected from those trials; and

the preparation, submission, and approval of a New Drug Application, or NDA, for new drugs, or a Premarket Approval Application, or PMA, for medical devices.

Preclinical testing is conducted in the laboratory and on animals to obtain preliminary information primarily on the safety of a new drug or device, although preclinical data may provide some information relevant to the potential efficacy of the product. The time required for conducting preclinical testing varies greatly depending on the nature of the product and the nature and design of the testing. The collection and analysis of preclinical data can take many years to complete. Such data are submitted to the FDA as part of the IND or IDE. Human studies can begin if the FDA does not object to the IND application.

The human clinical testing program involves three phases, Phase I, Phase II, and Phase III. 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 potential risks to study subjects, and the possible liability of the institution. A clinical plan, or protocol, must be submitted to the FDA prior to commencement of each clinical trial. All subjects 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 before or after a study begins for a variety of reasons, particularly if safety concerns exist. These clinical studies must be conducted in conformance with the FDA s human subject protection and IND regulations.

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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 two years to complete, but can take longer, depending on the drug and the nature of the study. Phase III involves significant numbers of patients with the targeted disease or condition to provide comparisons against placebo or, in some cases, 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 from preclinical testing and clinical studies, verification and analysis of data, as well as the preparation of summaries of the chemistry, manufacturing, and control processes. Submission of an NDA does not assure FDA approval for marketing. The application review process may take 180 days but more often it takes one to four years to complete, although reviews of treatments for AIDS, cancer and other serious and life-threatening diseases and conditions 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 for the product s intended use with sufficient levels of statistical significance. However, additional information or data may be required. For example, the FDA may also request long-term toxicity studies, one or more additional pivotal or Phase III 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 studies following NDA approval, often referred to as Phase IV clinical trials, to confirm safety and efficacy for the intended use.

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, the addition of new indications any changes to the dosage form, or dosage levels, and certain other labeling changes for the same product may only be made after a supplemental NDA, or sNDA, is submitted to FDA support the safety and efficacy of the proposed changes and approved by the FDA.

The FDA regulations also require extensive recordkeeping and reporting of certain manufacturing deviations and certain safety and other information, often referred to as adverse events that become known to the 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. Usually the preparation and review of a sNDA takes less time than the original NDA because the sNDA may rely upon the data and information from the NDA to support the safety and efficacy of the proposed change.

On December 3, 1999, the FDA approved the NDA we submitted for Levulan® Kerastick® 20% Topical Solution with PDT for treatment of non-hyperkeratotic actinic keratoses, or AKs, of the face or scalp. The commercial version of our BLU-U®, used together with the Kerastick® to provide PDT for the treatment of non-hyperkeratotic AKs of the face or scalp, was approved on September 26, 2000. In September 2003, we received approval from the FDA to market the BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

We may develop other potential PDT products for other uses, including treatment of SOTR, which would require significant development, including approval and completion of preclinical and/or clinical testing and PMA approval prior to commercialization. The process of obtaining PMA approvals can be costly and time consuming and there can be no guarantee that the use of Levulan® with 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-enforced laws and regulations. These products are required to be tested, developed, manufactured and distributed in accordance with FDA regulations, including cGMP, set forth under QSRs, and good laboratory and clinical practices. Under the Food, Drug and Cosmetic Act, all medical devices are classified as Class I, II or III devices. The classification of a device reflects the level of risk to a patient, with Class III devices having the highest risk and subject to the most stringent requirements and FDA review. Class I devices are generally the lowest risk devices and are subject only to general controls (for example, labeling and adherence to QSRs. Class II devices are generally moderate risk devices and are subject to general controls and special controls (for example, performance standards, postmarket surveillance, FDA guidelines specific to the type of product). 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 PMA with extensive data, including preclinical and

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clinical trial data, to demonstrate the safety and effectiveness of the device for its intended use. If human clinical trials of a device are required and the device presents a significant risk, the manufacturer of the device must file an IDE and receive FDA approval prior to commencing human clinical trials.

Following receipt of the PMA, the FDA will determine whether the application is sufficiently complete to permit a substantive review, and if so, the agency will accept the PMA for filing and further review. Once the PMA 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 and respond to the applicant. The review of PMAs more often occurs over a significantly protracted time period, and the FDA may take up to two 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 with a new drug will not be approved unless and until the NDA 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 may be convened to review and evaluate the data in a PMA and provide recommendations to the FDA as to whether the device should be approved for marketing. In addition, the FDA will inspect the manufacturing facility to ensure compliance with QSR requirements prior to approval of the PMA. 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, the Agency may issue a notice of noncompliance in the form of inspectional observations on Form FDA-483, general correspondence, or a Warning Letter. If the noncompliance is not corrected to the satisfaction of the FDA, the agency may take any or all of the following legal actions: detain or seize the products, order a recall, impose operating restrictions, temporarily stop the manufacture of the product, seek injunctive relief to enjoin future violations, assess civil penalties against that company, its officers or its employees, and recommend criminal prosecution to the Department of Justice.

When a drug must be used with a specific medical device to be safe and effective for a specific indication, the drug and the device 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 jurisdictional decisions as well as the timeliness and effectiveness of pre-market review, and the consistency and appropriateness of post-market regulation.

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

The United States Drug Price Competition and Patent Term Restoration Act of 1984 known as the Hatch-Waxman Act establishes a 5-year period of marketing exclusivity from the date of NDA approval for new chemical entities approved after September 24, 1984. Levulan® is a new chemical entity and we received 5 years of market exclusivity, which 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 for each patent that claims the drug and is listed in the FDA s Orange Book for Approved Drug Products with Therapeutic Equivalence Evaluations that: (i) no such patent information has been listed (ii) the patent has expired; (iii) marketing will not commence until the patent has expired; or (iv) the patent is invalid or will not be infringed by the

manufacture, use, or sale of the product that is the subject of the new application.

If any person submits an abbreviated NDA, or ANDA, or an NDA that intends to rely on some or all of the data in our Levulan NDA (also referred to as a 505(b)(2) application), the applicant also must notify us as the NDA holder and the owner of a patent that claims the drug. Such notice will enable us to determine whether to bring a patent infringement lawsuit to protect our patent rights.

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

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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 are subject to laws and regulations regarding customs, import-export business transactions, and other local laws specific to each country. Among other things, laws in certain countries restrict, and in some cases prohibit, United States companies from directly or indirectly selling goods, technology or services to people or entities in those 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, state pharmacy and wholesale drug distribution laws, and the maintenance of personal health information. As a public company, we are subject to securities laws and regulations, including the Sarbanes-Oxley Act of 2002. We may also be subject to other present and possible future local, state, federal and foreign regulations.

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 meets applicable FDA criteria for export. We can provide no assurance that we will be able to get additional approvals for any of our products from any importing nations regulatory authorities or be able to participate in additional foreign pharmaceutical markets.

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 affect 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 event, we could be held liable for any damages that result, and any such liability could exceed our resources.

Product Liability and Insurance

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

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Segment Reporting

We operate in two segments, Photodynamic Therapy, or PDT, Drug and Device Products and Non-Photodynamic Therapy, or Non-PDT, Drug Products. Our Levulan® Kerastick® and BLU-U® products comprise our PDT segment, while Nicomide®, ClindaReach® and the other products acquired in the acquisition of Sirius comprise our Non-PDT segment. For more information about our segments, including financial results of each segment, see Note 11 of the Notes to Consolidated Financial Statements.

Information About Geographic Sources of Revenue

For information about the geographic sources of our revenue, see Management s Discussion and Analysis of Financial Condition and Results of Operations Results of Operations .

Employees

At the end of 2009, we had 86 employees, including 2 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. 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.

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 our investment.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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 business, financial condition and results of operations 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.

Risks Related To DUSA

We Are Not Currently Profitable On An Annual Basis And May Not Be Profitable In The Future Unless We Can Successfully Market And Sell Significantly Higher Quantities Of Our Products.

If We Do Not Become Profitable, We May Need More Capital

We have approximately $16,669,000 in cash, cash equivalents and marketable securities as of December 31, 2009. Our cash, cash equivalents and marketable securities should be sufficient for current operations for at least the next 12 months. If we are unable to become profitable on an ongoing basis in the near term, we may have to reduce our headcount, curtail certain variable expenses, or raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

If A Competitive Product Is Successful Our Revenues Could Decline, and Our Ability To Become Profitable Could Be Delayed

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® and Metvix® (known in the United States as

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Metvixia®) products for any of our 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 this product, which is directly competitive with our Levulan® Kerastick® product, is now commercially available. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company, and on January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma will provide marketing support and distribution. PhotoMedex s sales force will promote Metvixia and Galderma s Aktilite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share and make it more difficult for us to be profitable on an ongoing basis.

If We Are Not Successful With The Reexamination Of Our Levulan® Patent, Our Revenues Could Decline.

In January 2009, we filed a request for reexamination with the United States Patent and Trademark Office, or USPTO, of one of the patents licensed from Queens University covering certain methods of using our product, Levulan®, for our FDA-approved indication. The USPTO accepted our request for reexamination during the first quarter of 2009 and we have responded to the first office action. There is no guarantee that the process will be successful since the USPTO reviews the entire prosecution history of a patent during a reexamination and could determine that some or all of the patent claims are invalid. Typically, a reexamination takes approximately 18 months to complete. The patent is due to expire in 2013. If the USPTO finds that the patent is invalid, generic competitors could enter the market earlier than otherwise anticipated and we could lose revenues. This would adversely affect our financial condition and results of operations and possibly prevent us from becoming profitable on an on-going basis.

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

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,

control of marketing activities, including advertising and labeling, and

state permits for the sale and distribution of products manufactured out-of-state.

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:

send 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.

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We and our manufacturers must continue to comply with current Good Manufacturing Practice regulations, or cGMP, and Quality System Regulation, or QSR, and equivalent foreign regulatory requirements. The cGMP and QSR requirements govern quality control and documentation policies and procedures. In complying with cGMP, QSR 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.

Manufacturing facilities are subject to ongoing periodic inspection by the FDA, including unannounced inspections. We cannot guarantee that our third-party supply sources, including our sole source supplier for the active ingredients in Levulan® and the BLU-U® 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 the BLU-U®, 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 has requested additional information, which was provided to them in June 2008. We are awaiting their response. 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. Any such problems could affect our ability to become profitable on an ongoing basis.

If Product Sales Do Not Continue to Increase, 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 approved.

If we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon our development program for solid organ transplant recipients or other programs we may wish to initiate. 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 and results of operations. 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 our technology.

The Current Global Credit And Financial Market Conditions May Affect Our Business.

Sales of our products are dependent, in large part, on reimbursement from government health and administration authorities, private health insurers, distribution partners and other organizations. As a result of the current global credit and financial market conditions, government authorities and private insurers may not satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenues.

Due to the tightening of global credit, there may be disruption or delay in the performance by our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including the active ingredient in Levulan® and key portion of the BLU-U®, portions of our product manufacturing, royalty revenues, conduct of clinical trials and the supply of raw materials. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

If The Economic Slowdown Adversely Affects Our Customer s Ability To Meet Our Payment Terms, Our Cash Flow Would Be Adversely Affected And Our Ability To Achieve Profitability On An Annual Basis Could Be Delayed.

If any of our large customers were to fail to pay us or fail to pay us on a timely basis for their purchases of our products, our ability to maintain profitability on a sustainable on-going basis could be delayed, and our financial position, results of operations and cash flows could be negatively affected.

We Have Had Significant Losses And May Have Losses In The Future.

We have had a history of operating losses. We may continue to incur losses on an annual basis unless sales of our products increase from present levels. We incurred net losses of $2,508,000, $6,250,000 and $14,714,000 for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, our accumulated deficit was

approximately $144,000,000. 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 an annual basis, and to sustain profitability if it is achieved.

Our Ability To Use Net Operating Loss Carryforwards and Tax Credit Carryforwards To Offset Future Taxable Income May Be Further Limited As A Result Of Past Or Future Transactions Involving Our Common Stock.

Under Internal Revenue Code (IRC) Section 382 the amount of our net operating loss carryforwards and other tax attributes that we may utilize to offset future taxable income, when earned, may be subject to certain limitations, based upon changes in the ownership of our common stock. In general, under IRC Section 382, a corporation that undergoes an

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ownership change is subject to limitations on its ability to utilize its pre-change net operating losses and certain other tax assets to offset future taxable income. An ownership change occurs if the aggregate stock ownership of certain shareholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period, which is generally three years. We currently estimate that our utilization of our net operating loss carryforwards and other tax attributes may be limited due to prior changes in our ownership. We further believe that it is reasonably possible that a future ownership change, which could be the result of transactions involving our common stock that are outside of our control (such as sales by existing stockholders), could occur. Future ownership changes could further restrict the utilization of our net operating losses and tax credits, reducing or eliminating the benefit of such net operating losses and tax credits.

If We Are Unable To Obtain The Necessary Capital To Fund Our Operations, We Will Have To Delay Our Development Program And May Not Be Able To Complete Our Clinical Trials.

We may need substantial additional funds to fully develop, manufacture, market and sell other potential products. We may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. Depending on the extent of available funding, we may delay, reduce in scope or eliminate our solid organ transplant recipient, or SOTR, research and development program. 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 could include restrictive covenants that would adversely affect the operation of our business. Failure to raise capital if needed could materially adversely affect our business, our financial condition, results of operations and cash flows.

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 to treat conditions such as AKs and acne,
- compositions and apparatus for those methods, and
- unique physical forms of ALA.

We also own patents covering our BLU-U® and our Kerastick®. However, other third parties may have blue light devices or drug delivery devices that do not infringe our patents.

The patents relating to methods of using ALA for detecting or treating disease, other than for acne and our approved indication for AKs of the face or scalp, started to expire in July 2009. The patents covering our AK product do not start to expire until 2013. In January 2009, we filed an application with the USPTO for reexamination of one of our patents that cover our approved product. The USPTO accepted our request for reexamination during the first quarter of 2009 and we have responded to the first office action. If the USPTO determines that the patent is invalid, generic competitors could enter the market earlier than otherwise anticipated.

We have limited ALA patent protection outside the United States, which may make it easier for third parties to compete there. Our basic methods 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 us, 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

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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® product even though they are marketed for different uses.

On August 12, 2008, we entered into a worldwide non-exclusive patent license agreement to our patent covering Nicomide® with River s Edge and an amendment to our settlement agreement with River s Edge. The amendment to the settlement agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the license agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In April 2009, we and River s Edge entered into an amendment to the license agreement, or License Amendment. The License Amendment grants River s Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the trademark associated with the licensed products worldwide. Under the License Amendment, DUSA is required to transfer all of its rights, title and interest in and to DUSA s patent know-how and trademark relating to the licensed products (but not the copyright registration relating to product labeling) to River s Edge upon our receipt of $5,000,000. Of the $5,000,000, River s Edge is required to make payment to us of $2,600,000, in thirteen monthly installments of $200,000, subject to reduction under certain conditions, and pay additional consideration of $2,400,000 payable over time based on a share of River s Edge s net revenues as defined in the License Amendment. We received the first $200,000 installment payment under the License Amendment in the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations but have not received any further payments. We are considering our options relative to the collection of amounts due from River s Edge and termination of the license agreement, which we have the right to do for non-payment. The validity of the Nicomide® patent is being tested again as a request for *exparte* reexamination of this patent was filed by an unknown third party with the U.S. Patent and Trademark Office, or USPTO, on August 19, 2009. An order issued by the USPTO on October 16, 2009 accepted the request for reexamination and we have received the first office action. It is too early in the reexamination process to assess the possible outcome. These events could negatively impact our revenues and delay our ability to be profitable.

Furthermore, PhotoCure received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this product, which is directly competitive with our Levulan® Kerastick® product, is now commercially available. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. On January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma will provide marketing support and distribution. PhotoMedex s sales force will promote Metvixia and Galderma s Aktilite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share.

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 all of the following issues could negatively impact our ability to be profitable:

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.

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 or contractual 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 litigation. 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) as has happened with the patent covering Nicomide. We cannot guarantee that a third-party will not claim, with or without merit, that our patents are not valid or that we have infringed their patent(s) or misappropriated their proprietary material. We could

get drawn into or decide to join, litigation as the holder of the patent. 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, 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 USPTO 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, which could involve substantial legal fees and result in a loss or lessening of our patent protection.

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Since We Now Operate The Only FDA Approved Manufacturing Facility For The Kerastick® And Continue To Rely Heavily On Sole Suppliers For The Manufacture Of Levulan®, The BLU-U®, ClindaReach®, And Meted®, Any Supply Or Manufacturing Problems Could Negatively Impact Our Sales.

If we experience problems producing Levulan® Kerastick® 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® and the Levulan® Kerastick® in our Wilmington, Massachusetts facility, at this time, with respect to the BLU-U®, we expect to utilize our own facility only as a back-up to our current third party manufacturer or for repairs.

Manufacturers and their subcontractors often encounter difficulties when commercial quantities of products are manufactured for the first time, or large quantities of 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 manufacture our products. 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 is 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 and could increase costs.

We Have Only Limited Experience Marketing And Selling Pharmaceutical Products Outside of the United States 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 in negotiations with Stiefel, our distributor in Latin America, because they did not purchase the required minimum number of Kerastick® units under our agreement. Both parties have the right to terminate the contract. In July 2009, GlaxoSmithKline, or GSK, completed its acquisition of Stiefel, and we do not know whether GSK wants Stiefel to continue to distribute the Levulan® Kerastick®. If our sales and marketing efforts fail, then sales of the Levulan® Kerastick®, the BLU-U®, and other products will be adversely affected, which would adversely affect our results of operations and financial condition.

The Commercial Success Of Any Product 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 product that we may develop will be highly dependent upon the extent to which the product gains 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 a product does 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 currently marketed products and our SOTR product candidate, if approved for commercial sale, will depend on a number of factors, including:

the effectiveness, or perceived effectiveness, of our product 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 product for sale at competitive prices,

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relative convenience and ease of administration,

the strength of marketing and distribution support, and

sufficient third-party coverage or reimbursement.

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® Kerastick® for AK therapy will be limited. While we continue to support efforts to improve reimbursement levels to physicians and are working with the major private insurance carriers to improve coverage for our therapy, if our efforts are not successful, broader adoption of our therapy and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK were made over the last five years, 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 our products, reduce the amounts of coverage or stop covering our products which are covered, our sales could be dramatically reduced.

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 Additional Commercially Successful Products.

Except for Levulan® PDT for AKs, the BLU-U® for acne, the ClindaReach® pledget and several other products we acquired in our merger with Sirius, all of our 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,

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® drug technology.

We Must Receive Separate Approval For Any Drug or Medical Device Products Before We Can Sell Them Commercially In The United States Or Abroad.

Any potential Levulan® product will require the approval of the FDA before it can be marketed in the United States. 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® 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®. 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 any other regulatory approvals. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan® PDT is safe and effective for any new use we may study. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy. We have been informed by FDA that the agency

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does not believe that our application for Orphan Drug designation of use of Levulan® in immunosuppressed solid organ transplant recipients should be granted. We met with the FDA during the third quarter of 2009 to clarify and explain further our application and, based on that meeting, the agency has invited us to submit an amendment to our application for further evaluation. If we cannot obtain this designation, we may not continue to develop this indication. We submitted a draft amendment in January 2010 along with a request for a follow-on meeting with the agency. In February 2010, the FDA indicated that a meeting was not necessary and suggested that we formally submit the amended application. We expect to make the formal submission in March 2010.

We have been informed by FDA that our 510(k) application for clearance of our BLU-U® to treat severe acne requires additional clinical data. Based on this information and the anticipated costs of additional clinical trials, we have decided that we will not pursue the 510(k) application for an expansion of our BLU-U® claims at this time.

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 86 employees, including 2 part-time employees, as of December 31, 2009. 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 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 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 we believe the cost of coverage is too high, we may 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. 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 financial condition. 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.

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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 Our Products Or Potential Products Noncompetitive Or Obsolete.

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of AKs and acne. 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.

Many companies are also seeking to develop new products and technologies, and receiving approval for treatment of AKs and acne. Our industry is subject to rapid, unpredictable and significant technological change. Competition is intense. Our competitors may succeed in developing products that are safer, more effective or more desirable 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, results of operations and financial condition.

Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technology obsolete or less advantageous.

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® and Metvix® (known in the United States as Metvixia®) products for any of our 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 this product, which is directly competitive with our Levulan® Kerastick® product, is now commercially available and its price is comparable to the price of Levulan®. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. On January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma will provide marketing support and distribution. PhotoMedex s sales force will promote Metvixia and Galderma s Aktilite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which could significantly hamper our ability to maintain or increase our market share.

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: Galderma/PhotoMedex, medac GmbH and photonamic GmbH & Co. KG (Germany); Biofrontera, PhotoTherapeutics, Inc. (U.K.), and PhotoCure ASA (Norway). We also anticipate that we will face increased competition as the scientific development of PDT 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.

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,

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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 market includes 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. The entry of new products from time to time would likely cause us to lose market share.

Risks Related To Our Stock

Our Common Stock May Not Continue To Trade On The Nasdaq Global Market, Which Could Reduce The Value Of Your Investment And Make Your Shares More Difficult To Sell.

In order for our common stock to trade on the Nasdaq Global Market, we must continue to meet the listing standards of that market. Among other things, those standards require that our common stock maintain a minimum closing bid price of at least $1.00 per share. During 2009, our common stock has traded at prices near and below $1.00. If we do not continue to meet Nasdaq s applicable minimum listing standards, Nasdaq could delist us from the Nasdaq Global Market. If our common stock is delisted from the Nasdaq Global Market, we could seek to have our common stock listed on the Nasdaq Capital Market or other Nasdaq markets. However, delisting of our common stock from the Nasdaq Global Market could hinder your ability to sell, or obtain an accurate quotation for the price of, your shares of our common stock. Delisting could also adversely affect the perception among investors of DUSA and its prospects, which could lead to further declines in the market price of our common stock. Delisting may also make it more difficult and expensive for us to raise capital. In addition, delisting might subject us to a Securities and Exchange Commission rule that could adversely affect the ability of broker-dealers to sell or make a market in our common stock, thus hindering your ability to sell your shares.

Our Stock Price Is Highly Volatile And Sudden Changes In The Market Value Of Our Stock Occur Making An Investment Risky.

The price of our common stock has been highly volatile, which may create an increase in the risk of capital losses for our shareholders. From January 1, 2008 to March 2, 2010, the price of our stock has ranged from a low of $0.87 to a high of $2.58. The significant general market volatility in similar stage pharmaceutical and biotechnology companies also made the market price of our stock volatile.

Significant Fluctuations In Orders For Our Products, On A Monthly And Quarterly Basis, Are Common Based On External Factors And Sales Promotion Activities. These Fluctuations Could Increase The Volatility Of Our Stock Price.

The price of our common stock may be affected by the amount of quarterly shipments of our products to end-users. Since our PDT products are still in relatively 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 level of penetration of new markets outside of the United States, 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.

Future Sales Of Securities May Cause Our Stock Price To Decline.

As of March 2, 2010, there were outstanding options and warrants to purchase 4,059,000 shares of common stock, with exercise prices ranging from $1.08 to $31.00 per share for options, and exercise prices ranging from $2.85 to $6.00 per share for warrants. In addition, there are 393,000 shares of unvested common stock. 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. Also, if some or all of such shares are sold into the public market over a short period of time, the value of all publicly traded shares could decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all. The holders may exercise their securities during a time when we would likely be able to raise capital from the public on terms more favorable than those provided in these securities.

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

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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 our 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 certain 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 us 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 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 we are 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 our certificate of incorporation consistent with the terms of the rights plan.

ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

None.

ITEM 2. ***PROPERTIES***

In May 1999 we entered into a five-year lease for 16,000 sq. ft. of office/warehouse space to be used for offices and manufacturing in Wilmington, Massachusetts. In December 2001 we entered into a 15 year lease covering the entire building through November 2016. We have the ability to terminate the Wilmington lease after the 10th year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. Commencing in August 2002, we entered into a five year lease for office space for our Toronto location which had accommodated the Toronto office of our former 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. In the fourth quarter of 2008, we vacated the Toronto, Ontario office and have subleased the space through June 30, 2010. We are presently in discussions with the subtenant regarding extending the sublease beyond June 30, 2010.

ITEM 3. ***LEGAL PROCEEDINGS***

Winston Laboratories Arbitration Settlement

In October 2008, we were notified that Winston Laboratories, Inc. had filed a demand for arbitration against us. The demand for arbitration arose out of two agreements, the 2006 Micanol License Agreement and 2006 Micanol Transition License Agreement, and claimed that we breached the agreements. Winston Laboratories claimed damages in excess of $2.0 million. The matter was settled on April 28, 2009 for cash consideration of $75,000, and a mutual release.

ITEM 4. ***RESERVED***

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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, 2009:

	First	Second	Third	Fourth
NASDAQ				
High	$1.39	$1.49	$1.29	$1.87
Low	$0.88	$0.88	$1.00	$1.05

Price range per common share by quarter, 2008:

	First	Second	Third	Fourth
NASDAQ				
High	$2.58	$2.57	$2.15	$1.69
Low	$1.75	$1.95	$1.13	$0.87

On March 2, 2010, the closing price of our common stock was $1.60 per share on the NASDAQ Global Market. On March 2, 2010, there were 701 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 Hemscott 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, 2004 to December 31, 2009. 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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ASSUMES $100 INVESTED ON DEC. 31, 2004
ASSUMES DIVIDEND REINVESTED
FISCAL YEAR ENDING DEC. 31, 2009

	Cumulative Return Total					
	12/31/04	**12/31/05**	**12/31/06**	**12/31/07**	**12/31/08**	**12/31/09**
DUSA PHARMACEUTICALS, INC.	$100.00	$ 75.31	$ 30.07	$ 14.48	$ 7.34	$ 10.84
HEMSCOTT GROUP INDEX	$100.00	$110.97	$123.94	$140.77	$112.14	$147.15
NASDAQ MARKET INDEX	$100.00	$102.20	$112.68	$124.57	$ 74.71	$108.56

The list of companies in the Hemscott Group Index includes: Access Pharmaceuticals, Inc., Acusphere, Inc., Adolor Corporation, Advanced Viral Research Corporation, Aeolus Pharmaceuticals, Inc., Akesis Pharmaceuticals, Inc., Alexion Pharmaceuticals, Inc., Alexza Pharmaceuticals Inc., Allergan, Inc., Allos Therapeutics, Inc., Altana AG, Amarin Corporation PLC, Angiotech Pharmaceuticals, Inc., Ardea Biosciences, Inc., Arena Pharmaceuticals, Inc., Arqule, Inc., ARYx Therapeutics, Inc., Astralis, Ltd., AVANIR Pharmaceuticals, AVI BioPharma, Inc., Bayer AG, Benda Pharmaceutical, Incorporated, Biodel, Inc., BioTransplant, Inc., Cardiome Pharma Corporation, Cephalon, Inc., China YCT International Group, Inc., Cortex Pharmaceuticals, Inc., Cubist Pharmaceuticals, Inc., Cumberland Pharmaceuticals, Inc., DelSite, Inc., DepoMed, Inc., DOV Pharmaceutical, Inc., Dr Reddy Laboratories, Ltd., Dragon Pharmaceuticals, Inc., Durect Corporation, DUSA Pharmaceuticals Inc., Dynavax Technologies Corporation, Elite Pharmaceuticals, Inc., Endo Pharmaceutical Holdings, Inc., Entropin, Inc., eXegenics, Inc., Forest Laboratories, Inc., Gamma Pharmaceuticals, Incorporated, Genova Biotherapeutics, Inc., Gentium SpA., Geron Corporation, Inspire Pharmaceuticals, Inc., Isis Pharmaceuticals Inc., Ista Pharmaceuticals, Inc., Kendle International, Inc., Kent International Holdings, Inc., King Pharmaceuticals, Inc., Lannett Company, Inc., Lescarden, Inc., MAP Pharmaceuticals, Inc., Marshall Edwards, Inc., Med Gen, Inc., Medicines, MiddleBrook Pharmaceuticals, Inc., Millenia Hope, Inc., Miravant Medical Technologies, Naturade, Inc., Neurogen Corporation, NeurogesX, Inc., Neuro-Hitech, Inc., NexMed, Inc., NovaBay Pharmaceuticals, Inc., Novo Nordisk A/S, Orexigen Therapeutics, Inc., Oxis International, Pain Therapeutics, Inc., Paladin Labs, Inc., Pharmacyclics, Inc., Pharmasset, Inc., Pharmaxis Ltd., POZEN, Inc., Prana Biotechnology Limited, Prescient Neuopharma, Inc., Protalex, Inc., Puramed Bioscience Incorporated, Regenerx Biopharmaceuticals, Inc., Reliv , International, Santarus, Inc., SciClone Pharmaceuticals, Shire PLC, Siga Technologies, Inc., Simcere Pharmaceutical Group, Sinobiopharma, Inc., Somaxon Pharmaceuticals, Inc., Sucampo Pharmaceuticals, Inc., SuperGen, Inc., Synergy Pharmaceuticals,, Incorporated, Synvista Therapeutics, Inc., Tapestry Pharmaceuticals, Inc., Taro Pharmaceutical Industries, Telik, Inc., Teva Pharmaceutical Industries, Ltd., Tian an Pharma Co Ltd, Tianyin Pharmaceutical Co., Inc., Unigene Laboratories, Inc., United Therapeutics Corporation, Valeant Pharmaceuticals International, Vaso Active Pharmaceuticals, Inc., VaxGen., Inc., Vertex Pharmaceuticals Inc., Viral Genetics, Inc., Vital Living, Inc., Warner Chilcott Limited, and YM Biosciences, Inc.

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,				
2009	**2008**	**2007**	**2006(5)**	**2005**

Product revenues	$29,807,829	$29,545,406	$ 27,662,598	$ 25,582,986	$ 11,337,461
Net loss	(2,508,292)	(6,250,441)(1)	(14,713,507)(2)	(31,349,507)(3)	(14,998,709)
Basic and diluted net loss per common share	$ (0.10)	$ (0.26)	$ (0.73)	$ (1.65)	$ (0.89)

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CONSOLIDATED BALANCE SHEET DATA

	Year Ended December 31,				
	2009	**2008**	**2007**	**2006**	**2005**
Total assets	$24,933,377	$28,210,454	$32,892,240	$33,755,813	$42,330,631
Long-term obligations(4)	3,841,941	4,838,436	4,501,186	1,199,086	
Shareholders equity	$15,841,474	$17,712,199	$22,106,522	$26,333,573	$38,028,728

(1) Includes an impairment charge of $1,500,000 resulting from our review of the carrying amount of our goodwill resulting from a contingent payout to the former shareholders of Sirius Laboratories, Inc.

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

(3) Includes an impairment charge of $15,746,000 resulting from our review of the carrying amount of our intangible assets.

(4) 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.

(5) 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 .

We are a vertically integrated dermatology company that is developing and marketing Levulan® PDT and other products for common skin conditions. Our marketed products include Levulan® Kerastick® 20% Topical Solution with PDT, the BLU-U® brand light source, and ClindaReach®.

We devote most of our resources to advancing the development and marketing of our Levulan® PDT 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. The Kerastick® is our proprietary applicator that delivers Levulan®. The BLU-U® is our patented light device.

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® 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® was its key product, a vitamin-mineral product prescribed by dermatologists. We merged with Sirius in March 2006.

We are marketing Levulan® PDT 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. In January, 2009, we filed a request for reexamination with the USPTO of one of the Queen s patents that cover our

approved indication for AK. We responded to the first office action on October 27, 2009. We also own or license certain other patents relating to our BLU-U® device and 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®, ClindaReach®, Meted®, and Psoriacap® 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.

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We are responsible for manufacturing our Levulan® Kerastick® and for the regulatory, sales, marketing, and customer service and other related activities for all of our products, including our Levulan® Kerastick®.

In February 2010, we incurred a loss on the purchase of one of our Non-PDT Drug Products that was in-transit having an approximate cost of $300,000. We have not yet determined the financial statement impact as we are evaluating our insurance coverage.

2009 TRANSACTIONS

The following significant transactions occurred during 2009:

River s Edge Litigation Settlement

In April 2009, we and River s Edge entered into an amendment to a license agreement, or License Amendment. The License Amendment grants River s Edge an exclusive license to U.S. Patent, No. 6,979,468, and a license to use all know-how and the trademark associated with the licensed products worldwide. Under the License Amendment, we are required to transfer all of our rights, title and interest in and to DUSA s patent, know-how and trademark relating to the licensed products (but not the copyright registration relating to product labeling) to River s Edge upon our receipt of $5,000,000. Of the $5,000,000, River s Edge is required to make payment to us of $2,600,000, in thirteen monthly installments of $200,000, subject to reduction under certain conditions, and pay additional consideration of $2,400,000 payable over time based on a share of River s Edge s net revenues as defined in the License Amendment. The original license agreement, entered into in August 2008, or License Agreement, as now amended, has a term of 30 months, subject to a further extension under certain circumstances to 48 months, and may be terminated early by River s Edge on 30 days prior written notice. Under the License Agreement, River s Edge has assumed all regulatory responsibilities for the licensed products. If the License Agreement is terminated prior to the payment of the $5,000,000, all of the rights and licenses granted by us to River s Edge will revert to us. We are recording the revenue under the License Amendment on a cash basis. We received the first $200,000 installment payment under the License Amendment during the second quarter of 2009, which is included in Product Revenues in the accompanying Consolidated Statements of Operations, but have not received any further payments. We are considering our options relative to the collection of amounts due from River s Edge and termination of the License Agreement, which we have the right to do for non-payment.

Winston Laboratories Arbitration Settlement

In October 2008, we were notified that Winston Laboratories, Inc. had filed a demand for arbitration against us. The demand for arbitration arose out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement and claimed that we had breached the agreements. Winston Laboratories claimed damages in excess of $2.0 million. The matter was settled on April 28, 2009 for cash consideration of $75,000, and a mutual release.

Third Amendment to the Sirius Merger Agreement

In April 2009, we and the former shareholders of Sirius entered into a letter agreement providing for the consent of the former Sirius shareholders to the License Amendment with River s Edge mentioned above, a release, and a third amendment to the merger agreement, dated as of December 30, 2005, by and among the DUSA Pharmaceuticals, Inc., Sirius and the shareholders of Sirius. Pursuant to the merger agreement prior to this amendment, we agreed to pay additional consideration after the closing of the merger to the former shareholders of Sirius based upon the attainment of pre-determined total cumulative sales milestones for the products acquired from Sirius over the period ending 50 months from the date of the March 2006 closing of the merger. Pursuant to the agreements entered into in April 2009, we agreed to extend the milestone termination date from 50 months from the date of the closing of the merger until December 31, 2011 and to include in the definition of net sales in the merger agreement payments which we may receive from the divestiture of Sirius products. The third amendment to the merger agreement also removes our obligation to market the Sirius products according to certain previously required standards and allows us to manage all business activities relating to the products acquired from Sirius without further approval from the former Sirius shareholders.

In April 2009, we paid to the former Sirius shareholders, on a pro rata basis, $100,000. In addition, in the event that the $1,000,000 milestone payment that would become due to the former Sirius shareholders under the merger agreement if cumulative net sales of the Sirius products reach $35,000,000 is not, in fact, triggered by the new

milestone termination date, then we have agreed to pay $250,000 to the former Sirius shareholders on a pro rata basis on or before January 6, 2012.

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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, or NBC, the principal manufacturer of our BLU-U® light source. This agreement 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. On June 29, 2009, we extended the term of the agreement with NBC until June 30, 2011. We have an option to further extend the term for an additional two (2) years if we purchase a certain number of units. The parties agreed upon a tiered price schedule based on the volume of purchases and updated certain quality control provisions. All other terms and conditions of the 2004 agreement remain in effect.

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 Accounting for revenue transactions relies on certain estimates that require difficult, subjective and complex judgments on the part of management.

PDT Revenue

Revenues on Kerastick® and BLU-U® 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 reasonably assured. We offer programs that allow physicians access to our BLU-U® 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. Our terms with customers do not provide for the right of return for sales of Kerastick® and BLU-U®, unless the product does not comply with the technical specifications.

For revenues associated with contractual agreements with multiple elements, the Company applies the revenue recognition criteria outlined in Securities and Exchange Commission (SEC) Staff Accounting Bulletin Topic 13, *Revenue Recognition* (SAB Topic 13) and ASC 605-25, *Multiple Element Arrangements.* We analyze each contract in order to separate each deliverable into separate units of accounting, if applicable, and then recognize revenue for those separated units as earned. Significant judgment is required in determining the units of accounting and the attribution method for such arrangements.

We have entered into exclusive marketing, distribution and supply agreements with distributors in Latin America and Korea that contain multiple deliverables. The deliverables are treated as a single unit of accounting. We have determined the attribution method for each of the separate payment streams. Under the terms of these agreements, we receive non-refundable milestone payments, a fixed price per unit sold and royalties based on a percentage of the net sales price to end-users. We defer and recognize the approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through term of the agreement. We record royalty revenue when earned, which is upon sell through to the end user. We record the fixed price per unit sold once the price is fixed and determinable, which is upon sell through to the end user. Additionally, we do not have sufficient data to determine product acceptance in the marketplace. The agreements require the distributors to make minimum purchases. If minimum purchase obligations are not fulfilled, the distributors are required to pay the difference between its actual purchases and the contractual minimums (a gross-up payment). We record revenue for the gross-up payment upon cash receipt. To date, Stiefel, the distributor in Latin America, has failed to meet its contractual obligations and is required to make the gross-up payment; we have not received payment to date. For Daewoong, the distributor in Asia Pacific, the minimum purchase commitment is measured over a five-year period, which has not yet ended.

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Non-PDT Revenue

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. 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.

We evaluate inventory levels at our wholesaler customers 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 our applicable revenue related reserves. Additionally, our products are sold to wholesalers with a product shelf life that allows sufficient time for our wholesaler customers to sell the 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.

We account for sales returns 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. Our reserve for sales returns has declined as revenues from Non-PDT Drug Products have declined.

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.

Inventory Inventories are stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Inventories are continually reviewed for slow-moving, obsolete and excess items. Inventory items identified as slow-moving are evaluated to determine if an adjustment is required. Additionally, our industry is characterized by regular technological developments that could result in obsolete inventory. Although we make every effort to assure the reasonableness of our estimates, any significant unanticipated changes in demand, technological development, or significant changes to our business model could have a significant impact on the value of our inventory and our results of operations. We use sales projections to estimate the appropriate level of inventory reserves, if any, that are necessary at each balance sheet date.

Valuation Of Long-lived and Intangible Assets 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,

2009 and 2008, respectively, total property, plant and equipment had a net carrying value of $1,661,000 and $1,938,000, including $1,150,000 at December 31, 2009 associated with our manufacturing facility.

In 2008 we made a cash payment of $1.5 million to former Sirius shareholders as additional consideration for a cumulative sales milestone. As this payment was deemed additional consideration related to the acquisition, we recorded goodwill in the amount of $1.5 million and immediately recorded an impairment charge to the statement of operations for the same amount. In 2007 we recorded an impairment charge to goodwill of $6.8 million, which represented the entire goodwill

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balance related to the Sirius acquisition and was all associated with the Non-PDT Drug Products reporting unit. While we do not have any goodwill on the balance sheet at December 31, 2009, we may incur future goodwill impairment charges if we are required to make additional payments to former Sirius shareholders. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments which may be paid in cash or shares, as we may determine, are as follows:

Cumulative Sales Milestone:	Additional Consideration:
$35.0 million	$1.0 million
$45.0 million	$1.0 million
Total	$2.0 million

In April 2009, we entered into the Third Amendment to the Merger Agreement, or Third Amendment, as described in Note 13 to the Notes to the Consolidated Financial Statements. As consideration for the Third Amendment and related documents, we paid the former Sirius shareholders $100,000 on a pro rata basis and have guaranteed a payment of $250,000 in January 2012 if the $35,000,000 sales milestone is not triggered.

Share-Based Compensation 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. We recognize the expense attributable to stock awards as the awards vest in the Consolidated Statements of Operations. We issue stock options and unvested shares. The fair value of stock options is determined using the Black-Scholes option valuation model, which incorporates assumptions as to stock volatility, the expected life of the options, a risk-free interest rate and dividend yield. The fair value of unvested shares is normally the price per share of our common stock on the date of grant. Share-based compensation expense is not recorded if the awards do not vest. Accordingly we estimate the forfeitures in determining the share-based compensation expense to record for the period. If our actual forfeiture experience differs from our estimate, share-based compensation expense will be adjusted.

Financial Instruments Financial instruments recorded at fair value on the consolidated balance sheets include cash equivalents, marketable securities and the common stock purchase warrant liability.

Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We follow the fair value disclosure hierarchy, that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted market prices in active markets for identical assets or liabilities. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data. Level 2 includes financial instruments that are valued using models or other valuation methodologies.

Level 3: Unobservable inputs that are not corroborated by market data. Level 3 is comprised of financial instruments whose fair value is estimated based on internally developed models or methodologies utilizing significant inputs that are generally less readily observable.

Our cash equivalents are Level 1 instruments. The fair value is based on transacted prices in an active market. In determining the fair value of our marketable securities, we consider the level of market activity and the availability of prices for the specific securities that we hold. For our Level 2 financial instruments, comprising our corporate debt and United States government-backed securities, we use quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency in the determination of value. We also access publicly available market activity from third party databases and credit ratings of the issuers of the securities we hold to corroborate the data used in the fair value calculations obtained from our primary source. We take into account credit rating changes, if any, of the securities or recent marketplace activity. We do not have any Level 3 marketable

securities.

The warrant liability is a Level 3 instrument. We initially recorded 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 under the caption (Loss) gain on change in fair value of warrants . 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. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrants.

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Results of Operations

Year Ended December 31, 2009 As Compared to the Year Ended December 31, 2008

Revenues Total revenues for 2009 were $29,808,000, as compared to $29,545,000 in 2008 and were comprised of the following:

	Year Ended December 31,		
	2009	2008	Increase/ (Decrease)
PDT PRODUCT REVENUES			
LEVULAN® KERASTICK® PRODUCT REVENUES			
United States	$ 24,756,000	$ 20,206,000	$ 4,550,000
Canada	543,000	699,000	(156,000)
Korea	646,000	820,000	(174,000)
Rest of world	434,000	345,000	89,000
Subtotal Levulan® Kerastick® product revenues	26,379,000	22,070,000	4,309,000
BLU-U® PRODUCT REVENUES			
United States	1,943,000	1,810,000	133,000
Canada	16,000		16,000
Korea		50,000	(50,000)
Subtotal BLU-U® product revenues	1,959,000	1,860,000	99,000
TOTAL PDT PRODUCT REVENUES	28,338,000	23,930,000	4,408,000
TOTAL NON-PDT DRUG PRODUCT REVENUES	1,470,000	5,615,000	(4,145,000)
TOTAL PRODUCT REVENUES	$ 29,808,000	$ 29,545,000	$ 263,000

For the year ended December 31, 2009, total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were $28,338,000. This represents an increase of $4,408,000 or 18%, over the comparable 2008 total of $23,930,000. The incremental revenue was driven primarily by increased Kerastick® revenues and BLU-U® revenues in the United States.

For the year ended December 31, 2009, Kerastick® revenues were $26,379,000, representing an increase of $4,309,000 or 20%, over the comparable 2008 totals of $22,070,000. Kerastick® unit sales to end-users for the year ended December 31, 2009 were 220,288, including 6,000 sold in Canada and 8,472 sold in Korea. This represents an increase from 207,516 Kerastick® units sold in the year ended December 31, 2008, including 8,700 sold in Canada and 11,826 sold in Korea. Our average net selling price for the Kerastick® increased to $117.73 for the year ended December 31, 2009 from $104.80 in 2008. Our average net selling price for the Kerastick® includes sales made directly to our end-user customers, as well as sales made to our distributors, in Canada, Korea and the rest of the world. The increase in 2009 Kerastick® revenues was driven mainly by increased sales volumes in the United States along with an increase in our overall average unit selling price.

For the year ended December 31, 2009, BLU-U® revenues were $1,959,000, an increase of 99,000, or 5%, over 2008 BLU-U® revenues of $1,860,000. The slight increase in 2009 BLU-U® revenues was driven by increased sales volumes which were offset by a decrease in our average selling price. In the year ended December 31, 2009, there were 252 units sold, as compared to 229 units in 2008. The 2009 total consists of 251 sold in the United States and one sold in Canada. The 2008 total consists of 224 units sold in the United States and 5 in Korea by Daewoong. Our

average net selling price for the BLU-U® decreased to $7,418 for the year ended December 31, 2009 from $7,861 for 2008. Our BLU-U® evaluation program allows customers to take delivery for a limited number of BLU-U® units for a period of up to four months for private practitioners and up to one year for hospital clinics, before we require a purchase decision. At December 31, 2009, there were approximately 12 units in the field pursuant to this evaluation program, compared to 58 units in the field at December 31, 2008. 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.

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. We are aware that physicians are 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.

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Non-PDT Drug Product revenues reflect the revenues generated by the products acquired as part of our acquisition of Sirius. Total Non-PDT drug product revenues for the year ended December 31, 2009 were $1,470,000, compared to $5,615,000 for the year ended December 31, 2008. The substantial majority of the Non-PDT Drug Product revenues were from Nicomide® related royalties from River s Edge, and sales of ClindaReach®. During 2010, royalties from our license of the AVAR® product line will cease under the terms of our license agreement with River s Edge relating to these products. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® in June 2008.

The increase in our total revenues in 2009 compared with 2008 results primarily from increased PDT segment revenues in the United States, partially offset by decreases in international PDT revenues and Non-PDT revenues. We must continue to increase sales from these levels in order for us to become profitable on an annual basis. We cannot provide any assurance that we will be able to increase sales sufficiently to become profitable on an annual basis, and we cannot provide assurance that a material increase in sales will necessarily cause us to be profitable on an annual basis. PhotoCure received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this PDT product, which is directly competitive with our Levulan® Kerastick® product, is now commercially available. On October 1, 2009, PhotoCure announced that it had sold Metvix/Metvixia to Galderma, S.A., a large dermatology company. On January 11, 2010, Galderma announced a co-promotion agreement with PhotoMedex for Metvixia under which Galderma will provide marketing support and distribution. PhotoMedex s sales force will promote Metvixia and Galderma s Aktilite lamp to healthcare professionals throughout the United States. While we are entitled to royalties on net sales of Metvixia, Galderma and PhotoMedex together have considerably more resources than we have, which could adversely affect our ability to maintain or increase our market share. During 2009, our PDT segment revenues in the United States grew, due in part to the 6% increase in Medicare reimbursement of our PDT-related procedure fee, which became effective January 1, 2009, as well as our pricing strategies. Although we expect growth in our PDT segment revenues, we are susceptible to the uncertain economic conditions, particularly with our customer base in the U.S. and internationally where our product lacks reimbursement, and to increased competition particularly from Metvixia. Reduced sales on non-reimbursed procedures and softness in the international markets could be expected until the economy recovers. We expect our Non-PDT revenues for 2010 to be reduced from 2009 levels since we are experiencing difficulty collecting payments due under the License Agreement with River s Edge. 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 And Become Profitable.

Cost Of Product Revenues and Royalties Cost of product revenues and royalties for the year ended December 31, 2009 were $6,675,000 as compared to $7,125,000 for the year ended December 31, 2008. A summary of the components of cost of product revenues and royalties is provided below:

	Year Ended December 31,		
	2009	2008	Increase/ (Decrease)
Levulan® Kerastick® Cost of Product Revenues and Royalties			
Direct Levulan® Kerastick® Product costs	$ 2,437,000	$ 2,541,000	$ (104,000)
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	630,000	229,000	401,000
Royalty and supply fees(1)	1,042,000	966,000	76,000
Subtotal Levulan® Kerastick® Cost of Product Revenues and Royalties	4,109,000	3,736,000	373,000
BLU-U® Cost of Product Revenues			

Direct BLU-U® Product Costs	907,000	822,000	85,000
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	719,000	794,000	(75,000)
Subtotal BLU-U® Cost of Product Revenues	1,626,000	1,616,000	10,000
TOTAL PDT DRUG & DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	5,735,000	5,352,000	383,000
Non-PDT Drug Cost of Product Revenues and Royalties	940,000	1,773,000	(833,000)
TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES AND ROYALTIES	940,000	1,773,000	(833,000)
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	$ 6,675,000	$ 7,125,000	$ (450,000)

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1) Royalty and supply fees reflect amounts paid to our licensor, PARTEQ, and amortization of an upfront fee and royalties paid to Draxis Health, Inc. on sales of the Levulan® Kerastick® in Canada .

Margins Total product margins for 2009 were $23,133,000, or 78%, as compared to $22,420,000, or 76% for 2008, as shown below:

	Year Ended December 31,				
	2009		2008		Increase/ (Decrease)
Levulan® Kerastick® Gross Margin	$ 22,270,000	84%	$ 18,334,000	83%	$ 3,936,000
BLU-U® Gross Margin	333,000	17%	244,000	13%	89,000
Total PDT Drug & Device Gross Margin	$ 22,603,000	80%	$ 18,578,000	78%	$ 4,025,000
Total Non-PDT Gross Margin	530,000	36%	3,842,000	68%	(3,312,000)
TOTAL GROSS MARGIN	$ 23,133,000	78%	$ 22,420,000	76%	$ 713,000

Kerastick® gross margins for the year ended December 31, 2009 were 84%, as compared to 83% for the year ended December 31, 2008. The margin improvement for 2009 is attributable to increased U.S. sales volumes and an increased overall average selling price. 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 could achieve improved gross margins on our Kerastick® from further volume growth and price increases in the U.S.

BLU-U® margins for the year ended December 31, 2009 were 17%, as compared to 13% for the year ended December 31, 2008. The increase in gross margin is a result of increased sales volumes, partially offset by a decrease in our average selling price. It is important for us to sell BLU-U® units in an effort to drive Kerastick® sales volumes and accordingly, we may sell BLU-U s at low profit margins.

Non-PDT gross margins reflect the gross margin generated by the products acquired as part of our merger with Sirius. Total Non-PDT gross margin for the year ended December 31, 2009 was 36% compared to 68% for the year ended December 31, 2008. Non-PDT margins in 2009 were negatively impacted by our discontinuance of sales of Nicomide®.

Research and Development Costs Research and development costs for 2009 were $4,313,000 as compared to $6,643,000 in 2008. The decrease in 2009 compared to 2008 was due was due primarily to the absence of spending related to our Phase IIb clinical trial on acne, which concluded in October 2008, and a one-time $600,000 Prescription

Drug User Fee Act, or PDUFA charge, which occurred in the first quarter of 2008, related to our approved AK indication.

Based on the results of the Phase IIb clinical trial, which were previously announced, we will not pursue further clinical development of Levulan® PDT with BLU-U® for moderate to severe acne. However, we do expect to continue to support investigator initiated studies in moderate to severe acne with Levulan® and various light sources. In May 2009, we filed a 510(k) application with the FDA for an expansion of our BLU-U® label to include severe acne. We previously had filed a patent application to cover an invention arising from the study. We received a response to our 510(k) application from the FDA in June 2009. The agency requested additional information in order to complete its review of our application, which included supplementary clinical data in support of our claims. Based on the FDA s requests and the anticipated costs of additional clinical trials, we have decided that we will not pursue the 510(k) application for an expansion of our BLU-U® claims at this time.

We have initiated a DUSA-sponsored Phase II clinical trial, for the treatment of actinic keratoses and reduction in the incidence of non-melanoma skin cancers in immunosuppressed solid organ transplant recipients, or SOTRs, who have demonstrated that they are at risk of developing multiple squamous cell carcinomas. We expect to enroll up to 36 patients at seven clinical trial sites across the United States. We expect enrollment of these patients to take at least one year, to receive preliminary results from the study in approximately 15 months and full results in approximately two years. To date, the pace of enrollment in the study has been slower than we anticipated at the outset of the trial. In May 2008, we filed an Orphan Drug Designation Application with the FDA for the prevention of cancer occurrence in these patients. We received initial correspondence that the application was not granted on the basis that the agency believed that the prevalence of the target population with the disease state is greater than 200,000, which is the maximum number of patients allowed under the Orphan Drug legislation. We met with the FDA during the third quarter of 2009 to clarify and explain further our application and, based on that meeting, the agency invited us to submit an amendment to our application for further evaluation. We submitted a draft amendment in January 2010 along with a request for a follow-on meeting with the agency. In February 2010, the FDA

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indicated that a meeting was not necessary and suggested that we formally submit the amended application. We expect to make the formal submission in March 2010. We expect that our overall research and development costs for 2010 will be slightly increased from 2009 levels due to increased spending on the SOTR clinical study and potential other initiatives not yet determined.

Marketing and sales costs Marketing and sales costs for the year ended December 31, 2009 were $12,897,000 as compared to $13,112,000 for the year ended December 31, 2008. 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 $9,389,000 in 2009, compared to $9,458,000 in 2008. The decrease in spending in 2009 in this category is due primarily to lower commissions and fringe benefit costs, offset in part by additional salaries expense resulting from increased headcount. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling $3,508,000 in 2009, compared to $3,654,000 in 2008. The decrease in this category is due primarily to a decrease in tradeshow and other promotional spending in 2009. We expect marketing and sales costs for 2010 to increase compared to 2009 levels, but to decrease as a percentage of revenues.

General and administrative costs General and administrative costs for the year ended December 31, 2009 were $8,270,000 as compared to $9,188,000 for the year ended December 31, 2008. The decrease is mainly attributable to a decrease in compensation-related costs, which in 2008 included severance and stock-compensation costs related to the departure of an officer, offset in part by the payment of $100,000 and accrual of $214,000 related to the Third Amendment to the Merger Agreement and related documents between us and the former Sirius shareholders entered into in April 2009. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period. We expect general and administrative costs to remain relatively flat in 2010 compared with 2009, but to decrease as a percentage of revenues.

Impairment of goodwill In the third quarter of 2008 we made a contingent payment to the former shareholders of Sirius Laboratories in the amount of $1.5 million and in the same period deemed the resulting goodwill to be impaired. During the fourth quarter of 2007, we performed our annual test for goodwill impairment, and based on that review, we recorded an impairment charge to goodwill of $6.8 million. The impairment charges were primarily related to our revised estimates of cash flows associated with Nicomide® and the other Sirius products, including the lack of a product pipeline.

Settlements, net During the second quarter of 2009, we settled the arbitration proceeding initiated by Winston Laboratories, Inc., for a payment of $75,000, and a mutual release and other customary terms. Winston alleged, in October 2008, that we breached the 2006 Micanol License Agreement and 2006 Micanol Transition License Agreement.

During the fourth quarter of 2007, we entered into a settlement agreement and mutual release relating to litigation with River s Edge. Under the terms of the settlement agreement, River s Edge made a lump-sum payment to us in the amount of $425,000 for damages and paid to us $25.00 for every prescription of its product, NIC 750 above 5,000 prescriptions that were substituted for Nicomide® from September 30, 2007 through June 30, 2008. During the years ended December 31, 2008 and 2007 the net gain from settlement of the litigation was $283,000 and $583,000, respectively. The payments under the settlement agreement ceased in 2008 when the parties entered into an amendment to the settlement, which the parties entered into effective as of July 3, 2008.

(Loss) 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 and are marked to market each reporting period. The (increase) decrease in the liability during 2009 and 2008 was $(376,000) and $826,000, respectively, which resulted in non-cash (losses) gains in the respective periods. The increases or decreases in fair value of the warrants are primarily due to changes in our stock price and the length of time remaining prior to expiration.

Other Income, Net Other income for the year ended December 31, 2009 decreased to $291,000, as compared to $663,000 in 2008. This decrease reflects a decrease in our average investable cash balances during 2009 as compared to 2008 along with a general decrease in interest rates over the same timeframe.

Income Taxes There is no provision for income taxes due to ongoing operating losses. As of December 31, 2009, we had net operating loss carryforwards of approximately $94,465,000 and tax credit carryforwards of approximately $1,556,000 for Federal tax purposes. These amounts expire at various times through 2029. We have provided a full

valuation allowance against the net deferred tax assets at December 31, 2009 and 2008.

The amount of the net operating loss carryforwards and other tax attributes that we may utilize to offset our future taxable income, when earned, may be subject to certain limitations, based upon changes in the ownership of our common stock under IRC Section 382. We currently believe that prior ownership changes have occurred as defined under IRC Section 382. We currently estimate that our utilization of our net operating loss carryforwards and other tax attributes may be limited to an annual limitation between approximately $1.5 million and $2.4 million per year. The final determination of the annual limitation is dependent upon certain technical rules that potentially could reduce the pre-change value utilized to calculate the annual limitation. Further, additional rules could result in an enhancement of the aforementioned annual

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limitation for the first five years after the ownership change. Based on these additional factors, we estimate that we will be able to utilize approximately $37.0 million to $57.0 million of our current net operating losses, provided that sufficient income is generated and no further ownership changes were to occur. The analysis has not been finalized. As we finalize the analysis, these amounts may change.

Net Loss For 2009, we incurred a net loss of $2,508,000, or $0.10 per share, as compared to $6,250,000, or $0.26 per share, for 2008. The decrease in net loss is attributable to the reasons discussed above.

Year Ended December 31, 2008 As Compared to the Year Ended December 31, 2007

Revenues Total revenues for 2008 were $29,545,000, as compared to $27,663,000 in 2007 and were comprised of the following:

	Year Ended December 31,		
	2008	**2007**	**Increase/ (Decrease)**
PDT PRODUCT REVENUES			
LEVULAN® KERASTICK® PRODUCT REVENUES			
United States	$ 20,206,000	$ 15,139,000	$ 5,067,000
Canada	699,000	740,000	(41,000)
Korea	820,000	436,000	384,000
Rest of world	345,000	92,000	253,000
Subtotal Levulan ® Kerastick® product revenues	22,070,000	16,407,000	5,663,000
BLU-U® PRODUCT REVENUES			
United States	1,810,000	1,724,000	86,000
Canada		94,000	(94,000)
Korea	50,000	50,000	
Subtotal BLU-U® product revenues	1,860,000	1,868,000	(8,000)
TOTAL PDT PRODUCT REVENUES	23,930,000	18,275,000	5,655,000
TOTAL NON-PDT DRUG PRODUCT REVENUES	5,615,000	9,388,000	(3,773,000)
TOTAL PRODUCT REVENUES	$ 29,545,000	$ 27,663,000	$ 1,882,000

For the year ended December 31, 2008, total PDT Drug and Device Products revenues, comprised of revenues from our Kerastick® and BLU-U® products, were $23,930,000. This represented an increase of $5,655,000 or 31%, over the comparable 2007 total of $18,275,000. The incremental revenue was driven primarily by increased Kerastick® revenues.

For the year ended December 31, 2008, Kerastick® revenues were $22,070,000, representing an increase of $5,663,000 or 35%, over the comparable 2007 totals of $16,407,000. Kerastick® unit sales to end-users for the year ended December 31, 2008 were 207,516, including 8,700 sold in Canada and 11,826 sold in Korea. This represented an increase from 164,944 Kerastick® units sold in the year ended December 31, 2007, including 9,798 sold in Canada and 7,392 sold in Korea. Our average net selling price for the Kerastick® increased to $104.80 for the year ended December 31, 2008 from $98.99 in 2007. Our average net selling price for the Kerastick® included sales made directly to our end-user customers, as well as sales made to our distributors, in Canada, Korea and the rest of the world. The increase in 2008 Kerastick® revenues was driven mainly by increased sales volumes in the United States, due in part to our continued focus on the medical dermatology market, and internationally, through our distribution agreements with

Stiefel and Daewoong, and an increase in our average unit selling price.

For the year ended December 31, 2008, BLU-U® revenues were $1,860,000, essentially flat in comparison with 2007 BLU-U® revenues of $1,868,000. The slight decrease in 2008 BLU-U® revenues were driven by slightly lower sales volumes which were offset by an increase in our average selling price. In the year ended December 31, 2008, there were 229 units sold, as compared to 232 units in 2007. The 2008 total consisted of 224 units sold in the United States and 5 in Korea by Daewoong. The 2007 total consisted of 206 sold in the United States, 16 sold in Canada and 10 in Korea. Our average net selling price for the BLU-U® increased to $7,861 for the year ended December 31, 2008 from $7,595 for 2007. At December 31, 2008, there were approximately 58 units in the field pursuant to the BLU-U® evaluation program, compared to 31 units in the field at December 31, 2007. 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.

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Total Non-PDT Drug Product revenues for the year ended December 31, 2008 were $5,615,000, compared to $9,388,000 for the year ended December 31, 2007. The substantial majority of the Non-PDT Drug Product revenues were from sales of Nicomide® and Nicomide® related royalties. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we had previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008.

On August 12, 2008, we entered into a worldwide non-exclusive patent license agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to our settlement agreement with River s Edge. The amendment to the settlement agreement allowed River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changed certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we were paid a share of the net revenues, as defined in the license agreement, of River s Edge s licensed product sales under the license agreement. Nicomide® sales in 2008 were negatively impacted by residual levels of NIC 750, that were substituted for Nicomide®, remaining in the distribution channel subsequent to the settlement with River s Edge.

The increase in our total revenues in 2008 resulted from increased PDT segment revenues in the United States, as well as our PDT product launches in Korea and the rest of the world.

Cost Of Product Revenues and Royalties Cost of product revenues and royalties for the year ended December 31, 2008 were $7,125,000 as compared to $7,829,000 for the year ended December 31, 2007. A summary of the components of cost of product revenues and royalties is provided below:

	Year Ended December 31,		
	2008	**2007**	**Increase/ (Decrease)**
Levulan ® Kerastick ® Cost of Product Revenues and Royalties			
Direct Levulan® Kerastick® Product costs	$ 2,541,000	$ 2,384,000	$ 157,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	229,000	280,000	(51,000)
Royalty and supply fees(1)	966,000		