

DUSA PHARMACEUTICALS INC

Form 10-K

March 16, 2007

**Table of Contents**

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

(MARK ONE)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934  
FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_  
COMMISSION FILE NUMBER 001-31533  
DUSA PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)**

NEW JERSEY  
(State or other jurisdiction of  
Incorporation or organization)

22-3103129  
(I.R.S. Employer  
Identification No.)

25 Upton Drive, Wilmington, MA  
(Address of principal executive offices)

01887  
(Zip Code)

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

**Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer**

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes  No

As of March 15, 2007, the registrant had 19,480,067 shares of Common Stock, no par value, outstanding.

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Based on the last reported sale price of the Company's common stock on the NASDAQ National Market on June 30, 2006 (\$5.65) (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 \$98,630,762.

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, 2006 are incorporated by reference into Part III of this report.

Items 10, 11, 12, 13 and 14

---

**TABLE OF CONTENTS TO FORM 10-K**

	PAGE NUMBER
<b><u>PART I</u></b>	
<u>Item 1. Business</u>	4
<u>Item 1A. Risk Factors</u>	28
<u>Item 1B. Unresolved Staff Comments</u>	41
<u>Item 2. Properties</u>	41
<u>Item 3. Legal Proceedings</u>	42
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	43
<b><u>PART II.</u></b>	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	43
<u>Item 6. Selected Financial Data</u>	45
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	45
<u>Item 7a. Quantitative and Qualitative Disclosures About Market Risk</u>	69
<u>Item 8. Financial Statements and Supplementary Data</u>	71
<u>Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure</u>	71
<u>Item 9a. Controls and Procedures</u>	71
<u>Item 9b. Other Information</u>	74
<b><u>PART III</u></b>	
<u>Item 10. Directors and Executive Officers of the Registrant</u>	74
<u>Item 11. Executive Compensation</u>	74
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	74
<u>Item 13. Certain Relationships and Related Transactions</u>	74
<u>Item 14. Principal Accountant Fees and Services</u>	74
<u>Item 15. Exhibits and Financial Statement Schedules</u>	74
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets</u>	F-2
<u>Consolidated Statements of Operations</u>	F-3
<u>Consolidated Statements of Shareholders' Equity</u>	F-4
<u>Consolidated Statements of Cash Flows</u>	F-5
<u>Notes To The Consolidated Financial Statements For the Years Ended December 31, 2006, 2005, and 2004</u>	F-7
<b><u>Signatures</u></b>	108
<b><u>Exhibit Index</u></b>	109
<u>EX-4.B: FORM OF CLASS B WARRANT</u>	
<u>EX-10.D.2: EMPLOYMENT AGREEMENT</u>	
<u>EX-10.II: EMPLOYMENT AGREEMENT</u>	
<u>EX-10.KK: SEPARATION AGREEMENT</u>	
<u>EX-10.LL: EMPLOYMENT AGREEMENT</u>	
<u>EX-10.MM: MARKETING DISTRIBUTION AND SUPPLY AGREEMENT</u>	
<u>EX-10.NN: FIRST AMENDMENT TO MARKETING DISTRIBUTION AND SUPPLY AGREEMENT</u>	
<u>EX-10.PP: 2006 EQUITY COMPENSATION PLAN</u>	
<u>EX-10.QQ: 2006 DEFERRED COMPENSATION PLAN</u>	
<u>EX-21.A: SUBSIDIARIES OF THE REGISTRANT</u>	
<u>EX-23.A: CONSENT OF DELOITTE &amp; TOUCHE LLP</u>	
<u>EX-31.A: CERTIFICATION</u>	
<u>EX-31.B: CERTIFICATION</u>	

EX-32.A: CERTIFICATION

EX-32.B: CERTIFICATION

EX-99: PRESS RELEASE

**Table of Contents**

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

**Table of Contents**

**ITEM 1. BUSINESS**

**General**

DUSA Pharmaceuticals, Inc. is a vertically integrated dermatology company that is developing and marketing Levulan<sup>®</sup> photodynamic therapy and other products for common skin conditions. Our marketed products include among others Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT, the BLU-U<sup>®</sup> brand light source, Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup> and the AVAR<sup>®</sup> line of products.

Historically, we devoted most of our resources to fund research and development efforts in order to advance the Levulan<sup>®</sup> PDT/PD technology platform. Our drug, Levulan<sup>®</sup> brand of aminolevulinic acid HCl, or ALA, is being used with light, investigational, in a broad range of medical conditions. When Levulan<sup>®</sup> is used and followed with exposure to light to treat a medical condition, it is known as Levulan<sup>®</sup> photodynamic therapy, or Levulan<sup>®</sup> PDT. When Levulan<sup>®</sup> is used and followed with exposure to light to detect medical conditions, it is known as Levulan<sup>®</sup> photodetection, or Levulan<sup>®</sup> PD.

We launched Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT and the BLU-U<sup>®</sup> brand light source in the United States in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003, we received clearance from the U.S. Food and Drug Administration, or FDA, to market the BLU-U<sup>®</sup> without Levulan<sup>®</sup> PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions. We are devoting significant resources to developing Levulan PDT for the treatment of moderate to severe acne.

We are developing Levulan<sup>®</sup> PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain Levulan<sup>®</sup> and related processes and improvements. We have entered into several distribution and license agreements in order to exploit our Levulan<sup>®</sup> technology platform internationally.

In March 2006, we acquired Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup>, the AVAR<sup>®</sup> line of products, among others, called Non-PDT Drug Products and certain product candidates in early stages of development, which target the treatment of acne vulgaris and acne rosacea, as well as psoriasis, in connection with our merger with Sirius Laboratories, Inc. Sirius was a dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. We believe that the purchase of Sirius has enabled us to expand our product portfolio, capitalize on cross-selling and marketing opportunities, increase our sales force size; as well as, develop a pipeline of new products.

Shortly after the closing of the merger, we became engaged in patent litigation with River's Edge, a company that launched a generic Nicomide<sup>®</sup> product. River's Edge also requested that the United States Patent and Trademark Office, or USPTO, reexamine the Nicomide<sup>®</sup> patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. Although the court issued a preliminary injunction against sales of River's Edge's product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. We expect that River's Edge will reenter the market with its product in competition with Nicomide<sup>®</sup>. We expect that Nicomide<sup>®</sup> sales will be adversely impacted throughout the litigation process. In the interim, we are considering alternative strategies aimed at mitigating market share loss. If we do not ultimately prevail in our lawsuit, or if the Nicomide<sup>®</sup> patent is found to be invalid by the court or the USPTO, our revenues from sales of Nicomide<sup>®</sup> will decrease permanently. We expect to eliminate some expenses planned for 2007 and reallocate others to provide more support to Levulan<sup>®</sup> and our new product, ClindaReach. We have reviewed the valuation of our intangible assets and goodwill associated with Nicomide<sup>®</sup> for impairment have recorded an impairment charge of \$15.7 million to write down

**Table of Contents**

the remaining net book value of the intangible assets. See sections entitled, Risk Factors Risks Related to DUSA and Management s Discussion and Analysis of Financial Condition and Results of Operations .

Nicomide<sup>®</sup>, one of the key products we purchased from Sirius, is an oral prescription vitamin supplement, and Nicomide-T<sup>®</sup> is a topical cosmetic product. Both products target the acne and acne rosacea markets. Acne is a common skin condition caused, in part, by the blockage and/or inflammation of sebaceous (oil) glands. Acne rosacea is a condition that primarily affects the skin of the face and typically first appears between the ages of 30 and 60 as a transient flushing or blushing on the nose, cheeks, chin or forehead, progressing in many patients to a papulopustular form clinically similar to acne vulgaris (inflammatory acne). The AVAR line of products includes a number of leave-on and cleanser formulations of sodium sulfacetamide and sulphur, a drug combination long known to have anti-acne, anti-inflammatory properties. In addition, we launched one of the product candidates, ClindaReach, a medicated pad with a proprietary wand applicator for use in the treatment of acne of the back.

We are continuing to evaluate and develop several other potential products that we acquired in our merger with Sirius which target patients with acne and rosacea. We are also continuing to seek to acquire and/or license additional dermatology products that complement our current product portfolio that would provide our sales force with additional complementary products to sell in the near to medium term.

In the United States, AVAR<sup>®</sup>, AVAR Green<sup>®</sup>, AVAR-e<sup>®</sup>, AVAR-e Green<sup>®</sup>, AVAR Cleanser<sup>®</sup>, BLU-U<sup>®</sup>, DUSA<sup>®</sup>, DUSA Pharmaceuticals, Inc.<sup>®</sup>, Kerastick<sup>®</sup>, Levulan<sup>®</sup>, METED<sup>®</sup>, Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup>, Psoriacap<sup>®</sup>, Psoriatec<sup>®</sup> and Sirius Laboratories, Inc.<sup>®</sup> are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

As of December 31, 2006, we had an accumulated deficit of approximately \$120,887,000. We expect to continue to incur operating losses through 2007. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our PDT therapy by the medical and consumer constituencies, and increasing sales of the products we acquired from Sirius, particularly ClindaReach , and other factors contained in this report, including prevailing in the Nicomide<sup>®</sup> patent litigation, and in the filings we make with the Securities and Exchange Commission.

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

We were incorporated on February 21, 1991, under the laws of the State of New Jersey. Our principal executive offices are located at 25 Upton Drive, Wilmington, Massachusetts 01887 (telephone: (978) 657-7500) (webaddress: www.dusapharma.com). On March 3, 1994, we formed DUSA Pharmaceuticals New York, Inc., a wholly owned subsidiary located in Valhalla, New York, to coordinate our research and development efforts. 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 a private placement under Regulation D of the Act which was consummated on February 27, 2004, and from payments received as part of the agreement with a former marketing collaborator. See sections entitled Management s Discussion and Analysis of Financial Condition Overview; Results of Operations; and Liquidity and Capital Resources .



## **Table of Contents**

### **Business Strategy**

The key elements of our strategy include the following:

*Expand the Marketing and Sales of our Products.* With completion of the Sirius merger in March, 2006, we expanded our direct sales force to 37 representatives by year-end which increased revenues of all of our products.

*Leveraging our Levulan® PDT/PD Platform to Develop Additional Products.* During 2006, we completed Phase II multi-center clinical trials in the United States using Levulan® PDT in the treatment of moderate to severe inflammatory acne and facial photodamage. If we are able to obtain FDA approval, there may be significant additional market opportunities for Levulan® and the BLU-U®. We are also actively marketing the BLU-U® without Levulan®, to treat moderate inflammatory acne vulgaris, which supports a multi-use capability of our BLU-U®, in addition to its use in our approved AK therapy. Outside of dermatology, we developed a proprietary endoscopic device for use with Levulan® PDT to develop products for Barrett's Esophagus dysplasia and oral cavity dysplasia.

*Enter into Additional Strategic Alliances.* If we determine that the development program for a given indication may be beyond our own resources or may be advanced to market more rapidly by collaborating with a corporate partner, we may seek opportunities to license, market or co-promote our products. We are exploring opportunities to develop, market, and distribute our Levulan® PDT platform in Europe following our completed distribution agreements with Stiefel Laboratories, Inc. for Latin America, and Daewoong Pharmaceutical Co., Ltd. for certain Asian countries. We are also continuing to seek to acquire and/or license additional dermatology products that complement our current products, and that would provide our sales force with additional synergistic products to sell in the near term.

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

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

*Use the Results of Independent Researchers to Identify New Applications.* We continue to work closely with and support research by independent investigators so that we have the benefit of the resulting anecdotal human data for use in evaluating potential Levulan® indications for corporate development. We also continue to monitor independent research in order to identify other potential new indications.

### **PDT/PD Overview**

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

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

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

## **Table of Contents**

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

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

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

the efficiency of the light in activating the photosensitizer.

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

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

PDT can be a highly selective treatment that targets specific tissues while minimizing damage to normal surrounding tissues. It also can allow for multiple courses of therapy. The most common side effect of photosensitizers that are applied topically or taken systemically is temporary skin sensitivity to bright light. Patients undergoing PDT and PD treatments are usually advised to avoid direct sunlight and/or to wear protective clothing during this period. Patients' indoor activities are generally unrestricted except that they are told to avoid bright lights. The degree of selectivity and period of skin photosensitivity varies among different photosensitizers and is also related to the drug dose given. Unless activated by light, photosensitizers have no direct PDT/PD effects.

### **Our Levulan® PDT/PD Platform**

#### **Our Levulan® Brand of ALA**

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

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

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

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

## **Table of Contents**

*Highly Selective.* Levulan<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Brand Applicator**

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

### **Our Light Sources**

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

are compact and tailored to fit specific medical needs,

are pre-programmed and easy to use, and

provide cost-effective therapy.

Our proprietary BLU-U<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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

**Table of Contents**

far less expensive.

For treatment of AKs, our BLU-U<sup>®</sup> uses blue light which is a potent activator of PpIX and does not penetrate deeply into the skin. Longer red wavelengths penetrate more deeply into tissue but are not as potent activators of PpIX. Therefore, for treatment of superficial lesions of the skin, such as AKs, we are using our relatively low intensity, non-laser, non-pulsed BLU-U, which is designed to treat areas such as the face or scalp. For treatment of diseases that may extend several millimeters into the skin or other tissues, including many forms of cancer; high-powered red light is usually preferable. We have also received clearance from the FDA to market the BLU-U<sup>®</sup> without Levulan<sup>®</sup> for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions and we intend to use the BLU-U in our upcoming Phase IIb Levulan PDT study of moderate to severe acne. We are also evaluating whether to develop and/or license additional light devices for use with Levulan<sup>®</sup>.

**Our Products**

The following table outlines the development status of our products and planned product candidates. Our product sales for the last three years were \$25,583,000 in 2006, \$11,337,000 in 2005, and \$7,988,000 in 2004. Our research and development expenses for the last three years were \$6,214,000 in 2006, \$5,588,000 in 2005, and \$6,490,000 in 2004.

<b>Indication/Product</b>	<b>Regulatory status</b>
<b>Dermatology</b>	
Levulan <sup>®</sup> Kerastick <sup>®</sup> and BLU-U <sup>®</sup> for PDT of AKs	Approved
BLU-U <sup>®</sup> Treatment of Moderate Inflammatory Acne Vulgaris and general dermatological conditions Without Levulan <sup>®</sup>	Market Clearance <sup>1</sup>
Levulan <sup>®</sup> PDT for Photodamaged Skin	Phase II <sup>2</sup>
Levulan <sup>®</sup> PDT for Moderate to Severe Acne Vulgaris	Phase II <sup>3</sup>
Nicomide <sup>®</sup> , Nicomide-T <sup>®</sup> , AVAR <sup>®</sup> products, and Psoriatec <sup>®</sup>	Marketed Unapproved
ClindaReach	Drug
Meted <sup>®</sup> Shampoo	sANDA <sup>4</sup>
Nicomide-T <sup>®</sup>	OTC
Psoriacap <sup>®</sup>	Cosmetic
	Dietary Supplement
<b>Other Indications</b>	
Levulan <sup>®</sup> PDT for Barrett's Esophagus Dysplasia using DUSA <sup>®</sup> Endoscopic Light Delivery System	Phase I/II <sup>5</sup>
Levulan <sup>®</sup> Oral Cavity Dysplasia	Phase I/II <sup>6</sup>

1 In September 2003, the FDA provided market clearance

2 Phase II clinical trial interim results were released in the first quarter of 2006. Due to strategic and

financial considerations, we are not continuing to advance development of the photodamage indication at this time.

- 3 Phase II clinical trial results were released in the first quarter of 2006. New Phase II studies was initiated in the first quarter of 2007.
- 4 sANDA owned by L. Perrigo Company.
- 5 Phase II single-center clinical trial was initiated in second quarter 2004 using DUSA's new endoscopic light delivery device. All patients have been accrued and treated and follow-up is continuing. The NCI DCP has recently determined that it will not initiate a previously planned Phase II protocol during 2007, but may do so in the future.
- 6 Phase I/II clinical trial planned to be initiated with

the NCI DCP in  
2007.

**Table of Contents****Dermatology Indications**

Our current Levulan<sup>®</sup> research and development efforts focus on supporting our approved AK product and a Phase II clinical program examining the safety and efficacy of Levulan<sup>®</sup> PDT for the treatment of moderate to severe acne vulgaris which, if successfully developed through FDA approval, could lead to an additional dermatological indication and significant market opportunities. The results of our initial Phase II trials examining acne and facial photodamage were announced in early 2006 and indicated that more work was required before advancing to Phase III trials. Initiation of the Phase II trials on acne started in February 2007. Due to strategic and financial considerations, we have decided not to continue to advance development of the photodamage indication at this time. DUSA also continues to support a wide range of independent investigator studies using the Levulan<sup>®</sup> Kerastick<sup>®</sup> to explore the potential for additional new indications for future development. With the completion of the Sirius merger, we continue several development efforts for products aimed at the acne and rosacea markets. The first of these pipeline products, ClindaReach, was launched in March, 2007.

*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, is usually painful at the site of freezing and can cause blistering and loss of skin pigmentation, leaving permanent white spots. In addition, because there is no standardized treatment protocol, results are not uniform. 5-FU can be highly irritating and requires twice-a-day application by the patient for approximately 2 to 4 weeks, resulting in inflammation, redness and erosion or rawness of the skin. Following the treatment, an additional 1 to 2 weeks of healing is required. Surgery is generally most useful for one or a few individual lesions, but not large numbers of lesions, and leaves permanent scars. Imiquimod or diclofenac require extended applications of cream, lasting up to 3 or 4 months, during which the skin is often very red and inflamed. Our approved treatment method involves applying Levulan<sup>®</sup> 20% topical solution using the Kerastick<sup>®</sup> to individual AK lesions, followed 14 to 18 hours later with exposure to our BLU-U<sup>®</sup> for approximately 17 minutes. In our Phase III trials, using this overnight drug application, our treatment produced varying degrees of pain during light treatment, but the therapy was generally well tolerated. The resulting redness and/or inflammation generally resolved within days without any change in pigmentation.

*Acne.*

Acne is a common skin condition caused in part by the blockage and/or inflammation of sebaceous (oil) glands. Traditional treatments for mild to moderate facial inflammatory acne include over-the-counter topical medications for mild cases, and prescription topical medications or oral antibiotics for mild to moderate cases. For nodulo-cystic acne, an oral retinoid drug called Accutane<sup>®</sup> <sup>1</sup> is the most commonly prescribed treatment. It is also commonly used for moderate to severe inflammatory acne.

Over-the-counter treatments are not effective for many patients and can result in side effects including drying, flaking and redness of the skin. Prescription antibiotics lead to improvement in many cases, but patients must often take them on a long-term basis, with the associated risks of increased antibiotic resistance. Blue light alone has been shown to improve mild to moderate inflammatory acne, in part by targeting the bacterium *Propionibacterium acnes* (*P. acnes*), which accumulates its own photosensitizer much like that produced by Levulan<sup>®</sup> in the skin, and possibly by other anti-inflammatory actions. With Levulan<sup>®</sup> PDT therapy for moderate to severe acne vulgaris an independent investigator study using Levulan<sup>®</sup> Kerastick<sup>®</sup> under occlusion for 3 hours followed by red light (Hongcharu et al , 2000) reported that Levulan<sup>®</sup> can be taken up by the sebaceous glands and decrease their activity and result in long-term clearance of acne.

<sup>1</sup> Accutane<sup>®</sup> is a registered trademark of Hoffmann-La

Roche, Inc.



**Table of Contents**

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

During the fourth quarter of 2004, we initiated a DUSA-sponsored Phase II study which we completed in early 2006. This 72 patient, investigator blinded study was designed to examine various safety and efficacy parameters as a function of varying Levulan/vehicle incubation times, namely 15, 60 and 120 minutes. Patients were randomized within each incubation group so that 18 subjects received `Levulan BLU-U` and six received vehicle plus `BLU-U alone`. There were no formal placebo arms in this study, as all patients were pre-treated with acetone scrub and all received blue light which has been shown by itself to improve moderate acne. Up to four PDT treatments were given at 2-week intervals. The primary efficacy parameters were the percent change in total acne lesion count for inflammatory, non-inflammatory, and total lesions at 4 and 8 weeks after the final PDT session. Acne severity scores (grades 0-4) were also assessed. Safety and tolerability were also followed throughout the study. The results of the study indicate that both `Levulan BLU-U` and `BLU-U alone` appear to effectively reduce the number of both inflammatory and non-inflammatory acne lesions. Given the higher than anticipated `BLU-U alone` response rate using this protocol, the study was not powered (sized) to discern differences between these arms. Treatment was well tolerated in both arms of the study with no unanticipated adverse events being reported, suggesting that future development is warranted. We have recently initiated another Phase II, multi-site study with over two hundred patients to investigate whether Levulan<sup>®</sup> PDT, with our BLU-U<sup>®</sup>, is safe and effective to treat moderate to severe acne.

Several of our products acquired in the Sirius merger target acne and acne rosacea. These include Nicamide<sup>®</sup>, Nicamide-T<sup>®</sup>, and the AVAR line of products. Acne rosacea is a condition that primarily affects the skin of the face and typically first appears between the ages of 30 and 60 as a transient flushing or blushing on the nose, cheeks, chin or forehead, progressing in many patients to a papulopustular form clinically similar to acne vulgaris (inflammatory acne). Given its resemblance to inflammatory acne, and the general public's limited knowledge of rosacea, the condition is frequently mistaken by patients as adult acne. If untreated, rosacea has the tendency to worsen over time, although it can also wax and wane. The AVAR line of products includes a number of leave-on and cleanser formulations of sodium sulfacetamide and sulphur, a drug combination long known to have anti-acne, anti-inflammatory properties.

*Facial Photodamaged Skin.*

Photodamaged skin, which is skin damaged by the sun, occurs primarily in fair-skinned individuals after many years of sun exposure. Signs of photodamaged skin include roughness, wrinkles and brown spots. AKs also occur frequently in areas of photodamaged skin. There are numerous consumer cosmetic and herbal products which claim to lessen or relieve the symptoms of photodamaged skin. In most cases, there is little scientific data to support these claims. The FDA has approved only one prescription drug, Renova<sup>®2</sup>, to treat this common skin condition. Patients generally use the product for between six and 24 weeks before improvement may be observed. There are also a number of FDA approved laser and light-based treatments being used in the treatment of photodamaged skin.

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

<sup>2</sup> Renova<sup>®</sup> is a registered trademark of Johnson & Johnson.



**Table of Contents**

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

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

Due to strategic and financial considerations, we have decided not to continue to advance the development of the photodamage indication at this time.

**Other Potential Levulan® Dermatology Indications**

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

**Internal Indications***Barrett's Esophagus Dysplasia.*

Barrett's Esophagus is an acquired condition in which the normal tissue lining of the esophagus is replaced by abnormal tissue in response to chronic exposure to stomach acid. Over time, the area of the esophagus affected can develop dysplastic (precancerous) cells. As the dysplasia progresses from low-grade to high-grade, the risk of esophageal cancer increases significantly, such that patients with confirmed high-grade dysplasia often undergo major surgery to remove the affected portion of the esophagus. The condition is often undetected until the disease reaches later stages.

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

Independent European studies have reported that in late-stage Barrett's Esophagus the high-grade dysplasia, or HGD, can be destroyed by ALA PDT. In a randomized, controlled European investigator study supported by DUSA, the investigators reported that Levulan® PDT allowed the conversion of early-stage Barrett's Esophagus with low-grade dysplasia and portions of non-dysplastic Barrett's back to a normal esophageal lining.

We have conducted several small pilot Phase I/II studies for the treatment of early and late-stage Barrett's Esophagus, respectively, with encouraging results. We continue to follow the patients that were treated. Currently, for the treatment of HGD in Barrett's Esophagus, insertion of a fiber optic is done by placement of a balloon catheter system, which requires approximately three insertions into the patient's esophagus, with blind light treatment by the physician (the endoscope is removed before light treatment and then replaced afterwards). DUSA's proprietary endoscopic light delivery allows fiber optic placement

## **Table of Contents**

and light treatment to the esophagus to be performed under direct visualization, utilizing a single insertion. The goal of this device is to allow the endoscopic light treatment to be performed more rapidly, under direct visualization, and with greater comfort for the patient. In the second quarter of 2004 we initiated a small single-center pilot Phase II clinical trial for enrollment of up to six patients at a single site using DUSA's proprietary endoscopic light delivery device for the treatment of HGD. The protocol was amended to lower the light dosage and to allow in-hospital observation for the remaining 3 patients commencing in March 2005. As of the end of 2006, six patients received at least one Levulan® PDT treatment in this single-center study, and 5 are evaluable for acute efficacy. Four out of five (4/5, 80%) remained free of HGD.

While we were cooperating with the National Cancer Institute Division of Cancer Prevention (NCI DCP), for the clinical development of Levulan® PDT for the treatment of HGD within Barrett's Esophagus, the NCI DCP has recently decided not to initiate the previously planned protocol during 2007, but may do so in the future.

### *Oral Cavity Dysplasia.*

We have entered into a clinical trial agreement with the NCI DCP for the clinical development of Levulan® PDT for the treatment of oral cavity dysplasia. During 2005, DUSA and the NCI DCP collaborated to develop the protocol for a Phase I study in subjects with oral leukoplakia (a premalignant lesion) using NCI's Phase I/II Cancer Prevention Clinical Trials Consortia to perform the studies. The NCI DCP finalized a clinical protocol and submitted its IND to the FDA before the end of 2006. An application for orphan drug status has also been submitted to the FDA for this indication.

### *Brain Cancer.*

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

In December 2002, we entered into a License and Development Agreement with photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company, in order to gain access to certain pre-clinical data for multiple uses and a license to us of photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. photonamic completed its European Phase III clinical trial in which ALA-induced fluorescence was used to guide surgical tumor resection in patients suffering from glioblastoma multiforme, but as we do not intend to carry out additional studies in this indication which we believe would be necessary for FDA approval, we are currently renegotiating our relationship with photonamic and medac. See section entitled "Business Licenses".

## **Third-Party Reimbursement**

We have continued to support efforts to improve reimbursement levels to physicians. Such efforts included working with the Centers for Medicare and Medicaid Services, or CMS, and the American Academy of Dermatology Association, or AADA, on matters related to the PDT procedure fee and the separate drug reimbursement fee. Doctors can also bill for any applicable visit fees. We are aware that some physicians believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices. We believe that the issues related to reimbursement have negatively impacted the economic competitiveness of our therapy with other AK therapies and have hindered its adoption in the past. DUSA continues to support ongoing efforts that might lead to further increases in reimbursement in the future; and intends to continue supporting efforts to seek reimbursement for our

**Table of Contents**

FDA-cleared use of the BLU-U<sup>®</sup> alone in the treatment of mild to moderate inflammatory acne of the face.

Most major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, plus future improvements, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time.

**Supply Partners**

*National Biological Corporation.*

In November 1998, we entered into a purchase and supply agreement with National Biological Corporation, or NBC, for the manufacture of some of our light sources, including the BLU-U<sup>®</sup>. We agreed to order from NBC all of our supply needs of these light sources for the United States and Canada, and NBC agreed to supply us with the quantities we order. If an opportunity arises, the parties have agreed to negotiate the terms under which NBC would supply us with light sources for sale in countries other than the current territories. On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with NBC, which provides for the elimination of certain exclusivity clauses, permits DUSA to order on a purchase order basis without minimums, grants DUSA an exclusive irrevocable worldwide and fully-paid up license to manufacture, or have the BLU-U<sup>®</sup> manufactured by any third party subcontractor, and other modifications which provide both parties greater flexibility related to the development and manufacture of light sources, and the associated technology within the field of PDT. The agreement maintains the original term, which will expire in November 2008, subject to earlier termination for breach or insolvency or for convenience. However, a termination for convenience requires 12 months prior written notice.

*Sochinaz SA.*

Under an agreement dated December 24, 1993, Sochinaz SA manufactures and supplies our requirements of Levulan<sup>®</sup> from its FDA approved facility in Switzerland. The agreement expires on December 31, 2009. While we can obtain alternative supply sources in certain circumstances, any new supplier would have to be inspected and qualified by the FDA.

*Actavis Totowa, LLC*

Under an agreement dated May 18, 2001, and amended on February 8, 2006, Sirius entered into an arrangement for the supply of Nicomide<sup>®</sup> with Amide Pharmaceuticals, Inc., now Actavis Totowa, LLC. Currently, Actavis Totowa supplies all of our requirements; however, we have the right to use a second source for a significant portion of our needs if we choose to do so. The agreement expires on February 8, 2009. The agreement was assigned to us as part of the Sirius merger. Actavis Totowa has received several warning letters from the FDA regarding certain regulatory observations. To our knowledge, the primary observations noted in the warning letters were not related to Nicomide<sup>®</sup>. However, with respect to Nicomide<sup>®</sup> and certain other products manufactured by this supplier, the FDA requested that the manufacturer provide a copy of the labeling and information providing the basis for an exemption from the drug approval requirements. The FDA regulates such products under the compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. The FDA may take further action against Actavis Totowa and DUSA in evaluation its options in order to maintain supply of Nicomide<sup>®</sup>.

*Harmony Labs, Inc.*

Under an agreement dated September 18, 2001, and amended on February 16, 2006 and March 10, 2006, Sirius entered into an arrangement for the manufacturing and supply of the AVAR<sup>®</sup> line of products and Nicomide-T<sup>®</sup> with Harmony Labs, Inc. The agreement was assigned to us as part of the Sirius merger. Currently, Harmony supplies all of our requirements; however, we have the right to use a

**Table of Contents**

second source for a significant portion of its needs if we choose to do so. The agreement expires on February 16, 2009.

*L. Perrigo Company*

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

*medac*

medac GmbH. In December 2002, we entered into a supply agreement with medac GmbH in connection with the photonic license agreement mentioned above. We have a license to market and sell the formulation exclusively in the United States and in several other countries and non-exclusively in the rest of the world subject to certain field limitations including Barrett's Esophagus, as well as for other mutually agreed upon indications. The agreement which is being renegotiated provides for minimum purchase requirements following our first commercial sale and has a term of 10 years from the date of our first commercial sale, subject to earlier termination rights, as well as successive one-year renewal terms.

**Licenses**

*PARTEQ*

PARTEQ Research and Development Innovations. We license (or, in the case of the patents in Australia, were assigned) the patents underlying our Levulan® PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations, or PARTEQ, the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, which became effective August 27, 1991, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ's patent rights, to make, have made, use and sell products which are precursors of PpIX, including ALA. The agreement also covers any improvements discovered, developed or acquired by or for PARTEQ, or Queen's University, to which PARTEQ has the right to grant a license. A non-exclusive right is reserved to Queen's University to use the subject matter of the agreement for non-commercial educational and research purposes. A right is reserved to the Department of National Defense Canada to use the licensed rights for defense purposes including defense procurement but excluding sales to third-parties.

When we are selling our products directly, we have agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where we have a sublicensee, we will pay 6% and 4% when patent rights do and do not exist, respectively, on our net selling price less the cost of goods for products sold to the sublicensee, and 6% of royalty payments we receive on sales of products by the sublicensee. We are also obligated to pay 5% of any lump sum sublicense fees paid to us, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts. The agreement is effective for the life of the latest United States patents and becomes perpetual and royalty-free when no United States patent subsists. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$86,000 as of December 31, 2006) in order to retain the license. For 2006, 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

**Table of Contents**

upfront fee and a 10% royalty on sales of the Levulan® Kerastick® in Canada over a five-year term following the first commercial sale in Canada. We are now responsible for any royalties which would be due to PARTEQ for Canadian sales. Draxis also agreed to assign to us the Canadian regulatory approvals for the Levulan® Kerastick® with PDT for AKs. We also hold Canadian regulatory approval for the BLU-U®. During 2004, we appointed a Canadian distributor who launched our Levulan® Kerastick® and BLU-U® in Canada. See sections entitled Distribution.

*Altana, Inc.*

In June 2005, Sirius entered into a development and product license agreement with Altana, Inc. relating to a reformulated dermatology product. According to the agreement, Sirius pays for all development costs. The agreement was assigned to us by virtue of the Sirius merger. Should development efforts be successful, Altana will manufacture the product for us and we will be obligated to pay royalties, including certain minimum royalties on net sales of the product. The agreement expires six years after the first commercial sale of the product.

*photonamic GmbH & Co. KG.*

In December 2002, we entered into a license and development agreement with photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company. This agreement which is being renegotiated by the parties provides for the licensing to us of photonamic's proprietary technology related to aminolevulinic acid (ALA), the compound we use in our Levulan® PDT and photodetection (PD) for certain fields of use.

Under the terms of the agreement, we received a license for the United States and several other countries, to use photonamic's technology, including pre-clinical and clinical data, related to ALA for systemic dosing in the field of brain cancer, and for indications which the parties may jointly develop during the term of their collaboration. Additionally, we are entitled to use the pre-clinical data for indications which we may develop on our own. Since we do not believe that the results from medac's European Phase III clinical study will be acceptable to the FDA and we do not intend to conduct additional clinical trials in the brain cancer field, we are renegotiating this agreement.

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

*Winston Laboratories, Inc.*

On or about January 30, 2006 Winston Laboratories, Inc. and Sirius entered into a license agreement relating to a Sirius product, Psoriatec® (known by Winston as Micanol) revising a former agreement. Winston Laboratories, Inc. is controlled by Dr. Joel Bernstein, a principal shareholder of Sirius. The 2006 agreement grants to Sirius an exclusive license, with limitation on rights to sublicense, to all property rights, including all intellectual property and improvements, owned or controlled by Winston to manufacture, sell and distribute products containing anthralin, in the United States. Royalties are paid on net sales of the product by Sirius, and certain minimum royalties are due each year to maintain the license. Sirius has an option to purchase the product from Winston at certain times during the two-year term of the agreement. The agreement is due to expire on January 31, 2008, subject to rights to extend or terminate the agreement earlier. This agreement was assigned to us as part of the Sirius Merger. Minimum royalties to Winston are \$300,000 per year ending January 31, 2008.

*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, the licensing

## **Table of Contents**

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

### **Patents and Trademarks**

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

Our ability to compete successfully depends, in part, on our ability to defend our patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. Even where we have patent protection, there is no guarantee that we will be able to enforce our patents. Patent litigation is expensive, and we may not be able to afford the costs.

We have no product patent protection for the compound ALA itself, as our basic patents are for methods of detecting and treating various diseased tissues using ALA or related compounds called precursors, in combination with light. We own or exclusively license patents and patent applications related to the following:

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

compositions and apparatus for those methods, and

unique physical forms of ALA.

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

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

We also own patents covering Nicomide<sup>®</sup> and the AVAR<sup>®</sup> products, and have patent applications pending that will cover other products, if those applications issue as patents, including an application on the design of the applicator wand for ClindaReach pledgets. The Nicomide<sup>®</sup> patent expires in 2025 (though it is being reexamined by the United States Patent and Trademark Office, and is being challenged by River's Edge in our patent litigation). See section entitled Legal Proceedings . The AVAR patent expires in 2021.

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



**Table of Contents**

in only six foreign countries and under the European Patent Convention. See section entitled **Risk Factors** **Risks Related to DUSA** .

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

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

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

Even in the absence of composition of matter patent protection for ALA, we may receive financial benefits from: (i) patents relating to the use of such products (like PARTEQ's patents); (ii) patents relating to special compositions and formulations (like the Nicomide 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 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 50 trademark registrations, and other applications are pending.

**Manufacturing**

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

**Table of Contents**

**Distribution**

We have been a direct distributor of the BLU-U<sup>®</sup> since its launch. Effective January 1, 2006, we have increased our own distribution capacity and have become the sole distributor for our Levulan<sup>®</sup> Kerastick<sup>®</sup> in the United States. In March 2004, we signed an exclusive Canadian marketing and distribution agreement for the Levulan<sup>®</sup> Kerastick<sup>®</sup> and BLU-U<sup>®</sup> with Coherent-AMT Inc., or Coherent, a leading Canadian medical device and laser distribution company. Coherent began marketing the BLU-U<sup>®</sup> in April 2004 and the Kerastick<sup>®</sup> in June 2004, following receipt of the applicable regulatory approval from Health Canada. The agreement has a three-year term, which can be automatically renewed for additional one-year terms, unless either party notifies the other party prior to a term expiration that it does not intend to renew the agreement. Coherent has the right for a period of time following termination of its agreement to return inventory of product.

On January 12, 2006, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc. The agreement covers current and future uses of our Levulan<sup>®</sup> Kerastick<sup>®</sup> PDT in dermatology. The agreement, which has an initial term of ten years, grants Stiefel the right to market and distribute our product in Mexico, Central and South America. The Mexican and Brazilian health regulatory authorities have granted their respective approvals to market the product, however, the launch of the product in Brazil is dependent upon receipt of acceptable final pricing approval from Brazilian government regulators at CMED. We expect that the launches in both countries will occur pending resolution of the final pricing by CMED in Brazil. All regulatory filings and registrations for approval will be owned by DUSA, unless otherwise agreed by DUSA. Stiefel will make up to \$3,000,000 in milestone payments, based upon receipt of acceptable final pricing approval of the product from Brazilian regulatory authorities and achievement of certain minimum purchase levels in the territory, subject to certain terms and conditions. We will manufacture the Kerastick<sup>®</sup> for Stiefel in our manufacturing facility in Wilmington, Massachusetts. Stiefel will pay to DUSA a percentage of Stiefel's final selling price to third-parties subject to a certain minimum purchase price per unit and to other terms and conditions. Stiefel has certain minimum purchase obligations. The parties have certain rights to terminate the Agreement prior to the end of the initial term, and Stiefel has an option to extend the term for an additional ten years on mutually agreeable terms and conditions.

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong Pharmaceutical Co., Ltd., or Daewoong, and Daewoong's wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, or DNC, and collectively with Daewoong referred to as D&D, covering current and future uses of the Levulan<sup>®</sup> Kerastick<sup>®</sup> for PDT in dermatology. The agreement grants D&D exclusive rights to distribute, promote and sell the Levulan<sup>®</sup> Kerastick<sup>®</sup> in Korea, Taiwan, China, including without limitation Hong Kong, India, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. We will manufacture and supply the product to D&D on certain terms and conditions.

The agreement has an initial term of ten years (subject to earlier termination and extension provisions). D&D 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, D&D will make up to \$3,500,000 in milestone payments to us, based upon contract execution, certain regulatory approval of the product from regulatory authorities, and achievement of pre-determined cumulative sales targets in the territory subject to certain terms and conditions. In order to maintain its exclusive rights, D&D is obligated to purchase a certain number of units of the product and meet certain regulatory timelines. We will manufacture the product in our manufacturing facility in Wilmington, Massachusetts. We will also receive a minimum transfer price per unit plus a percentage of D&D's end-user price above a certain level. The Non-PDT products are distributed through several major wholesalers in the United States pursuant to customary industry arrangements.

## **Table of Contents**

### **Marketing and Sales**

DUSA markets its products in the United States. We have appointed Coherent-AMT as our marketing partner for our products in Canada, Stiefel for our Levulan® Kerastick® in Mexico, Central and South America and Daewoong for our Levulan® Kerastick® in several Asian countries.

As a result of reacquiring our product rights in late 2002 from a former marketing partner, we commenced marketing and sales activities for our products in 2003, including the launch of our sales force in October 2003. Initially the sales force was comprised of six direct representatives, various independent representatives, and an independent sales distributor, designed to focus on most of our key geographic markets in the United States. During 2006, we continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. As of December 31, 2006, with the addition of sales personnel from our Sirius merger, we have further increased the size of our sales force to 37 sales representatives deployed nationally.

Following the receipt of marketing approval from the Health Protection Branch – Canada in June 2004, we started to market and sell the Levulan® Kerastick® with PDT using the BLU-U® for AKs of the face or scalp in Canada through Coherent-AMT. We anticipate that Stiefel will launch the Levulan® Kerastick® promptly after receipt of acceptable final pricing approval from the Brazilian regulators. See section entitled Business - Distribution .

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received a request from the FDA for labeling information and justification for the belief that the product is exempt from drug approval requirements, has received a warning letter to cease manufacturing a different marketed unapproved drug, and has been cited for GMP violations. We believe that the GMP issues do not directly involve our products. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to make certain labeling changes and market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues, particularly if the action were taken with respect to Nicomide®.

### **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.

**Table of Contents**

Commercial development of PDT agents other than Levulan® is being pursued by a number of companies. These include: QLT Inc. (Canada); Axcan Pharma Inc. (United States); Miravant, Inc. (United States); Pharmacyclics, Inc. (United States); PhotoTherapeutics, Inc. (U.K.); medac GmbH and photonamic GmbH & Co. KG (Germany); and PhotoCure ASA (Norway) who entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications. Several of these companies are also commercializing and/or conducting research with ALA or ALA-related compounds.

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AK and basal cell carcinoma, called BCC, in the European Union, New Zealand, Australia, and countries in Scandinavia. In July 2004, PhotoCure received FDA approval in the United States for its AK therapy. If PhotoCure enters into the marketplace with its AK therapy, its product will directly compete with our products. In April 2002, we received a copy of a notice issued by PhotoCure ASA to Queen's University at Kingston, Ontario, alleging that one of the patents covered by our agreement with PARTEQ, Australian Patent No. 624985, relating to ALA, was invalid. As a consequence of this action, Queen's University assigned the Australian patent to us so that we could participate directly in this litigation. In April 2005, the Federal Court of Australia ruled that the Australian patent assigned to DUSA by Queen's University which relates to DUSA's aminolevulinic acid photodynamic therapy is valid and remains in full force and effect. However, the Court also ruled that PhotoCure's product, Metvix, does not infringe the claims in the Australian patent. 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 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. See section entitled "Legal Proceedings".

In August 2003, Axcan Pharma Inc. received FDA approval for the use of its product, PHOTOFRIN®<sup>3</sup>, for photodynamic therapy in the treatment of high grade dysplasia associated with Barrett's esophagus. This approval enabled Axcan to be the first company to market a PDT therapy for this indication in which we also have an interest.

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

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

We believe that comparisons of the properties of various photosensitizing PDT drugs will also highlight important competitive issues. We expect that our principal methods of competition with other PDT companies will be based upon such factors as the ease of administration of our photodynamic

<sup>3</sup> PHOTOFRIN® is a registered trademark of Axcan Pharma Inc.

<sup>4</sup> Efudex® is a registered trademark of

Valeant  
Pharmaceuticals  
International.

5 Solaraze<sup>®</sup> is a  
registered  
trademark of  
SkyePharma  
PLC.

6 ALDARA is a  
trademark of 3M  
Company.

## **Table of Contents**

therapy; the degree of generalized skin sensitivity to light; the number of required doses; the selectivity of our drug for the target lesion or tissue of interest; and the type and cost of our light systems. New drugs or future developments in PDT, laser products or in other drug technologies may provide therapeutic or cost advantages for competitive products. No assurance can be given that developments by other parties will not render our products uncompetitive or obsolete.

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

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

Our Non-PDT Drug Products compete in the field of acne and rosacea with well-established therapies, such as over-the-counter topical medications for mild cases, and prescription topical medications or oral antibiotics for mild to moderate cases, as well as various laser and non-laser light sources. In addition, we expect that River s Edge s generic Nicamide® product will enter the market quickly. Other generic companies may also decide to enter the market while our patent litigation and reexamination process are proceeding, or thereafter if we do not ultimately prevail in our litigation with River s Edge, or in the patent reexamination process. The entry of new products from time to time would likely cause us to lose market share and cause fluctuations in our product revenues in this market.

### **Government Regulation**

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

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

- controlled research and testing of products,

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

- control of marketing activities, including advertising and labeling.

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

- preclinical studies

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

- human clinical trials, and

**Table of Contents**

the approval of a New Drug Application, or NDA.

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

The human clinical testing program involves three phases. Each clinical study is typically conducted under the auspices of an Institutional Review Board, or IRB, at the institution where the study will be conducted. An IRB will consider among other things, ethical factors, the safety of human subjects, and the possible liability of the institution. A clinical plan, or protocol, must be submitted to the FDA prior to commencement of each clinical trial. All patients involved in the clinical trial must provide informed consent prior to their participation. The FDA may order the temporary or permanent discontinuance of a clinical trial at any time for a variety of reasons, particularly if safety concerns exist. These clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations.

In Phase I, studies are usually conducted on a small number of healthy human volunteers to determine the maximum tolerated dose and any product-related side effects of a product. Phase I studies generally require several months to complete, but can take longer, depending on the drug and the nature of the study. Phase II studies are conducted on a small number of patients having a specific disease to determine the most effective doses and schedules of administration. Phase II studies generally require from several months to 2 years to complete, but can take longer, depending on the drug and the nature of the study. Phase III involves wide scale studies on patients with the same disease in order to provide comparisons with currently available therapies. Phase III studies generally require from six months to four years to complete, but can take longer, depending on the drug and the nature of the study.

Data from Phase I, II and III trials are submitted to the FDA with the NDA. The NDA involves considerable data collection, verification and analysis, as well as the preparation of summaries of the manufacturing and testing processes and preclinical and clinical trials. Submission of an NDA does not assure FDA approval for marketing. The application review process generally takes 1 to 4 years to complete, although reviews of treatments for AIDS, cancer and other life-threatening diseases may be accelerated, expedited or subject to fast track treatment. The process may take substantially longer if, among other things, the FDA has questions or concerns about the safety and/or efficacy of a product. In general, the FDA requires properly conducted, adequate and well-controlled clinical studies demonstrating safety and efficacy with sufficient levels of statistical assurance. However, additional information may be required. For example, the FDA may also request long-term toxicity studies or other studies relating to product safety or efficacy. Even with the submission of such data, the FDA may decide that the application does not satisfy its regulatory criteria for approval and may disapprove the NDA. Finally, the FDA may require additional clinical tests following NDA approval to confirm safety and efficacy, often referred to as Phase IV clinical trials.

Upon approval, a prescription drug may only be marketed for the approved indications in the approved dosage forms and at the approved dosage with the approved labeling. Adverse experiences with the product must be reported to the FDA. In addition, the FDA may impose restrictions on the use of the drug that may be difficult and expensive to administer. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems occur or are discovered after the product reaches the market. After a product is approved for a given indication, subsequent new indications, dosage forms, or dosage levels for the same product must be reviewed by the FDA after the filing and upon approval of a supplemental NDA. The supplement deals primarily with safety and effectiveness data related to the new indication or dosage. Finally, the FDA requires reporting of certain safety and other information, often referred to as adverse events that become known to a manufacturer of an approved drug. Safety information collected through this process can result in changes to a product's labeling or withdrawal of a product from the market. If an active ingredient of a drug product has been previously approved, drug applications can be filed that may be less time-consuming and costly.

**Table of Contents**

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

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

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

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

The PMA process can be expensive, uncertain and lengthy. A number of other companies have sought premarket approval for devices that have never been approved for marketing. The review time is often significantly extended by the FDA, which may require more information or clarification of information already provided in the submission. During the review period, an advisory committee likely will be convened to review and evaluate the PMA application and provide recommendations to the FDA as to whether the device should be approved for marketing. In addition, the FDA will inspect the manufacturing facility to ensure compliance with cGMP requirements for medical devices prior to approval of the PMA application. If granted, the premarket approval may include significant limitations on the indicated uses for which the product may be marketed, and the agency may require post-marketing





**Table of Contents**

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

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

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

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

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

Generally, we try to design our protocols for clinical studies so that the results can be used in all the countries where we hope to market the product. However, countries sometimes require additional studies to be conducted on patients located in their country. Prior to marketing a product in other countries, approval by that nation's regulatory authorities must be obtained. We have received such approval in Canada, and together with Stiefel under our agreement for Latin America are in the process of securing acceptable pricing approval in Brazil, having received regulatory approval in Brazil and Mexico. Also, together with Daewoong, we are applying for approval in Korea, and expect to apply for approvals in additional territories with Stiefel and Daewoong.

Medical device regulations also are in effect in many of the countries outside the United States in which we do business. These laws range from comprehensive device approval and quality system requirements for some or all of our medical device products to simpler requests for product data or certifications. The number and scope of these requirements are increasing. Under the European Union Medical Device Directive, all medical devices must meet the Medical Device Directive standards and receive CE Mark certification. CE Mark certification requires a comprehensive Quality System program

**Table of Contents**

and submission of data on a product to a Notified Body in Europe. The Medical Device Directive, ISO 9000 series and ISO 13485 are recognized international quality standards that are designed to ensure that we develop and manufacture quality medical devices. A recognized Notified Body (an organization designated by the national governments of the European Union member states to make independent judgments about whether or not a product complies with the protection requirements established by each CE marking directive) audits our facilities annually to verify our compliance with these standards. We will be required to meet these standards should we decide to sell our devices outside of the United States.

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

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

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

In addition to the above regulations, we are and may be subject to regulation under federal and state laws, including, but not limited to, requirements regarding occupational health and safety, laboratory practices and the maintenance of personal health information. As a public company, we are subject to the securities laws and regulations, including the Sarbanes-Oxley Act of 2002. We may also be subject to other present and possible future local, state, federal and foreign regulations.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received a request from the FDA for labeling information and justification for the belief that the product is exempt from drug approval requirements, has received a warning letter to cease manufacturing a different marketed unapproved drug, and has been cited for GMP violations. We believe that the GMP issues do not directly involve our products. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to make certain labeling changes and market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the

## **Table of Contents**

market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues, particularly if the action were taken with respect to Nicomide®.

With the enactment of the Drug Export Amendments Act of the United States in 1986, products not yet approved by the FDA may be exported to certain foreign markets if the product is approved by the importing nation and approved for export by the United States government. We can provide no assurance that we will be able to get approval for any of our potential products from any importing nations regulatory authorities or be able to participate in the foreign pharmaceutical market.

Our research and development activities have involved the controlled use of certain hazardous materials, such as mercury in fluorescent tubes. We are subject to various laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products. During the design, construction and validation phases of our Kerastick® facility, we have taken steps to ensure that appropriate environmental controls associated with the facility comply with environmental laws and standards. We can provide no assurance that we will not have to make significant additional expenditures in order to comply with environmental laws and regulations in the future. Furthermore, we cannot assure that current or future environmental laws or regulations will not materially adversely effect our operations, business or assets. Although we believe that our safety procedures for the handling and disposal of such hazardous materials comply with the standards prescribed by current environmental laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could exceed our resources.

### **Product Liability and Insurance**

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

### **Employees**

At the end of 2006, we had 85 employees including two part-time employees, which was an increase over the 2005 levels. We also retain numerous independent consultants and temporary employees to support our business needs.

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

### **Internet Information**

Our internet site is located at [www.dusapharma.com](http://www.dusapharma.com). Copies of our reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, may be accessed from our website, free of charge, as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission. Please note that our internet address is being provided for reference only and no information contained therein is incorporated by reference into our Exchange Act filings.

**Table of Contents**

**ITEM 1A. RISK FACTORS**

*Investing in our common stock is very speculative and involves a high degree of risk. You should carefully consider and evaluate all of the information in, or incorporated by reference in, this report. The following are among the risks we face related to our business, assets and operations. They are not the only ones we face. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of our common stock and you might lose all or part of your investment.*

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

**Risks Related To DUSA**

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

***Nicomide® Will Likely Lose Significant Market Share With The Anticipated Entry Of A Generic Product And Our Ability To Become Profitable Will Be More Difficult***

In March 2006, we acquired Nicomide®, in connection with our merger with Sirius Laboratories, Inc. Shortly after the closing of the merger, we became engaged in patent litigation with River's Edge, a company that launched a generic Nicomide® product. River's Edge has also requested that the United States Patent and Trademark Office reexamine the Nicomide® patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. Although the court issued a preliminary injunction against sales of River's Edge's product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. We expect that River's Edge will reenter the market with its product in competition with Nicomide®. We expect that Nicomide® sales will be adversely impacted throughout the litigation process and have a material negative impact on our revenues, results of operations and liquidity. If we do not ultimately prevail in our lawsuit, or if the Nicomide® patent is found to be invalid, our revenues from sales of Nicomide® will decrease permanently, and our ability to become profitable will be more difficult. We have reviewed the valuation of our intangible assets and goodwill associated with Nicomide® for impairment and have recorded an impairment charge of \$15.7 million to write down the remaining net book value of the intangible assets.

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

The manufacture and marketing of our products are subject to continuing FDA review as well as comprehensive regulation by the FDA and by state and local regulatory authorities. These laws require, among other things: approval of manufacturing facilities, including adherence to good manufacturing and laboratory practices during production and storage,

**Table of Contents**

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

control of marketing activities, including advertising and labeling.

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

send us warning letters,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products

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

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

require us to recall products,

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

impose restrictions on our operations, and/or

criminally prosecute us.

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

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

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

**Table of Contents**

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, *Marketed New Drugs without Approved NDAs or ANDAs*. Under this policy, FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received a request from the FDA for labeling information and justification for the belief that the product is exempt from drug approval requirements, has received a warning letter to cease manufacturing a different marketed unapproved drug, and has been cited for GMP violations. We believe that the GMP issues do not directly involve our products. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to make certain labeling changes and market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues, particularly if the action were taken with respect to Nicomide®. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market these products and could therefore, negatively affect our revenues and profits.

***Patent Litigation Is Expensive, And We May Not Be Able To Afford The Costs.***

The costs of litigation or any proceeding relating to our intellectual property rights could be substantial even if resolved in our favor. Some of our competitors have far greater resources than we do and may be better able to afford the costs of complex patent litigation. For example, third-parties may infringe one or more of our patents, and we are spending significant resources to enforce our patent rights. Also, in a lawsuit against a third-party for infringement of our patents in the United States, that third-party may challenge the validity of our patent(s). We cannot guarantee that a third-party will not claim, with or without merit, that our patents are not valid, as in the case described below, or that we have infringed their patent(s) or misappropriated their proprietary material. Defending these types of legal actions involve considerable expense and could negatively affect our financial results.

Additionally, if a third-party were to file a United States patent application in the United States, or be issued a patent claiming technology also claimed by us in a pending United States application(s), we may be required to participate in interference proceedings in the United States Patent and Trademark Office to determine the priority of the invention. A third-party could also request the declaration of a patent interference between one of our issued United States patents and one of its patent applications. Any interference proceedings likely would require participation by us and/or PARTEQ, could involve substantial legal fees and result in a loss or lessening of our patent protection.

On March 28, 2006, a lawsuit was filed by River's Edge Pharmaceuticals, LLC, or River's Edge, against us alleging, among other things, that, prior to the merger, Sirius Laboratories, Inc. agreed to authorize River's Edge to market a generic version of Nicomide®, and that the United States patent covering Nicomide® issued to Sirius in December, 2005 is invalid. The declaratory judgment suit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division and has been dismissed. Nicomide is one of the key products DUSA acquired from Sirius in its merger. On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River's Edge niacinamide product infringes United States Patent No. 6,979,468, the patent that covers Nicomide®. Although a preliminary injunction against sales of River's Edge's product had been in place since May, 2006, the injunction was lifted on March 7, 2007, so we expect that

**Table of Contents**

River s Edge will sell its product in competition with Nicomide®. We expect that Nicomide® sales will decrease significantly during the litigation process and make it more difficult to afford the cost of the litigation. If we do not ultimately prevail in our lawsuit, or if the Nicomide® patent is found to be invalid, our revenues from sales of Nicomide® will decrease permanently. We expect to eliminate some expenses planned for 2007 and reallocate others to provide more support to Levulan® and our new product, ClindaReach. We have reviewed the valuation of our intangible assets and goodwill associated with Nicomide® for impairment and have recorded an impairment charge of \$15.7 million to write down the remaining net book value of the intangible assets.

During 2005 and 2006, we filed several lawsuits against chemical suppliers, compounding pharmacies, a light device company, its distributor and a sales representative, and physicians alleging violations of patent law. While we have been successful in obtaining a default judgment against one compounding pharmacy, settled other suits favorably, and obtained consent judgments from several physicians, we do not know whether these lawsuits will prevent others from infringing our patents or whether we will be successful in stopping these activities which we believe are negatively affecting our revenues.

***If Product Sales Do Not Increase Significantly We May Not Be Able To Advance Development Of Our Other Potential Products As Quickly As We Would Like To, Which Would Delay The Approval Process And Marketing Of New Potential Products.***

If we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon some or all of our product development programs as we are doing with Levulan® PDT for photodamage. The pharmaceutical development and commercialization process is time consuming and costly, and any delays might result in higher costs which could adversely affect our financial condition. Without sufficient product sales, we might be required to seek additional funding. There is no guarantee that adequate funding sources could be found to continue the development of all our potential products. We might be required to commit substantially greater capital than we have available to research and development of such products and we may not have sufficient funds to complete all or any of our development programs.

***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®, Nicomide®, Nicomide-T®, the AVAR® line of products, METED®, Psoriacap® and Psoriatec®, Any Supply Or Manufacturing Problems Could Negatively Impact Our Sales.***

If we experience problems producing 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 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.

The sole supplier of Nicomide® has received warning letters from the FDA regarding certain regulatory observations. The primary observations noted in the warning letters were not related to Nicomide®. However, with respect to Nicomide® and certain other products manufactured by this supplier, the FDA has requested that the manufacturer provide a copy of the labeling and information providing the basis for an exemption from the drug approval requirements. The FDA regulates such products under the compliance policy guide described above entitled, Marketed New Drugs without Approved NDAs or ANDAs.

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



**Table of Contents**

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

- product yields,

- quality control,

- component and service availability,

- compliance with FDA regulations, and

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

We cannot guarantee that problems will not arise with production yields, costs or quality as we and our suppliers seek to increase production. Any manufacturing problems could delay or limit our supplies which would hinder our marketing and sales efforts.

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

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

If we are unable to successfully market and sell sufficient quantities of our products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. We are responsible for marketing our products in the United States and the rest of the world, except Canada, Latin America and parts of Asia, where we have distributors. We are doing so without the experience of having marketed pharmaceutical products prior to 2000. In October 2003, DUSA began hiring a small direct sales force and we increased the size of our sales force to market our products in the United States. In addition, our sales personnel have only recently begun to sell and market the products we acquired in our merger with Sirius. If our sales and marketing efforts fail, then sales of the Kerastick®, the BLU-U®, Nicomide® and other products will be adversely affected.

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

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan® 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, a broader adoption of our therapy and sales of our products could be negatively impacted. Although some reimbursement changes related to AK were made in 2005 and 2006, some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

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

**Table of Contents**

***The Commercial Success Of Any Products That We May Develop Will Depend Upon The Degree Of Market Acceptance Of Our Products Among Physicians, Patients, Health Care Payors, Private Health Insurers And The Medical Community.***

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

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

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

potential advantages over alternative treatments;

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

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

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

We have a history of operating losses. We expect to have continued losses until sales of our products increase substantially. We incurred a net loss of \$18,269,000 for the quarter ended December 31, 2006. We incurred net losses of \$31,350,000 and \$14,999,000 for the years ended December 31, 2006 and 2005, respectively. As of December 31, 2006, our accumulated deficit was approximately \$120,887,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis.

***If We Are Unable To Protect Our Proprietary Technology, Trade Secrets Or Know-How, We May Not Be Able To Operate Our Business Profitably.***

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

Our ability to compete successfully depends, in part, on our ability to defend patents that have issued, obtain new patents, protect trade secrets and operate without infringing the proprietary rights of others. We have no compound patent protection for our Levulan<sup>®</sup> brand of the compound ALA. Our basic ALA patents are for methods of detecting and treating various diseased tissues using ALA (or related compounds called precursors), in combination with light. We own or exclusively license ALA patents and patent applications related to the following:

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

compositions and apparatus for those methods, and

unique physical forms of ALA.

**Table of Contents**

We have limited ALA patent protection outside the United States, which may make it easier for third-parties to compete there. Our basic method of treatment patents and applications have counterparts in only six foreign countries, and certain countries under the European Patent Convention. Even where we have patent protection, there is no guarantee that we will be able to enforce our patents. Additionally, enforcement of a given patent may not be practicable or an economically viable alternative.

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

Nicomide® is covered by a United States patent which issued in December 2005. River s Edge Pharmaceuticals, LLC has filed an application with the U.S. Patent and Trademark Office, or USPTO, for the reexamination of the patent. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. If the USPTO finds that the patent is invalid, generic products will be able to lawfully compete with Nicomide®. Although the court, in the patent infringement litigation described above, issued a preliminary injunction against sales of River s Edge s product in May 2006, the injunction was lifted on March 7, 2007, due, in part, to the court s determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. We expect that River s Edge will reenter the market with its product in competition with Nicomide®. Also, recently two new products have been launched that could compete with Nicomide®. These events could cause us to lose significant revenues and put our ability to be profitable at risk. If we have to change the Nicomide® formulation to meet regulatory requirements, we may not have patent protection.

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

these persons or entities might breach the agreements,

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

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

**Table of Contents**

**We Have Only 2 Levulan® Therapies That Have Received Regulatory Approval Or Clearance And We Cannot Predict Whether We Will Ever Develop Or Commercialize Any Other Levulan® Products.**

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

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

delays in product development, clinical testing or manufacturing,

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 Each Of Our Potential Products Before We Can Sell Them Commercially In The United States Or Abroad.***

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

We cannot predict whether we will obtain approval for any of our potential products. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan® PDT or photodetection, known as PD, is safe and effective for any new use we are studying. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy. During September 2005, the FDA issued guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. We are developing Levulan® PDT for acne. The FDA may issue additional guidance in the future, which may result on additional costs and delays. We must also obtain foreign regulatory clearances before we can market any potential products in foreign markets. The foreign regulatory

**Table of Contents**

approval process includes all of the risks associated with obtaining FDA marketing approval and may impose substantial additional costs.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received a request from the FDA for labeling information and justification for the belief that the product is exempt from drug approval requirements, has received a warning letter to cease manufacturing a different marketed unapproved drug, and has been cited for GMP violations. We believe that the GMP issues do not directly involve our products. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to make certain labeling changes and market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market, unless and until we submit a marketing application and obtain FDA marketing approval.

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

We may need substantial additional funds to fully develop, manufacture, market and sell our other potential products. We may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. We cannot predict whether any financing will be available at all or on acceptable terms.

Depending on the extent of available funding, we may delay, reduce in scope or eliminate some of our research and development programs. We have, in fact, delayed additional studies relating to the use of Levulan® PDT to treat facial photodamage due, in part, to funding considerations and strategic prioritization. We may also choose to license rights to third parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own which could reduce our potential revenues.

***Because Of The Nature Of Our Business, The Loss Of Key Members Of Our Management Team Could Delay Achievement Of Our Goals.***

We are a small company with only 85 employees, including 2 part-time employees as of December 31, 2006. 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.

**Table of Contents**

***Our Collaborations With Outside Scientists May Be Subject To Restriction And Change.***

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

**Risks Related To Our Industry**

**Product Liability And Other Claims Against Us May Reduce Demand For Our Products Or Result In Damages.**

***We Are Subject To Risk From Potential Product Liability Lawsuits Which Could Negatively Affect Our Business.***

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

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

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

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

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

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of many of the same conditions that we are seeking to treat, including AKs, acne, rosacea, and Barrett's Esophagus. Doctors may prefer to use familiar methods, rather than trying our products. Reimbursement issues affect the economic competitiveness of our products as compared to other more traditional therapies.

## **Table of Contents**

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

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

price reductions,

lower levels of third-party reimbursements,

failure to achieve market acceptance, and

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

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

### **Our Products May Lose Market Share If New Manufacturers Begin Producing Competing Products That Are Able To Penetrate Our Market.**

#### ***We Have Learned That Compounding Pharmacies Are Producing A Form Of Aminolevulinic Acid HCl And Are Marketing It To The Medical Community.***

We are aware that there are compounding pharmacies that market compounded versions of aminolevulinic acid HCl as an alternative to our Levulan<sup>®</sup> product. Since December 2004, we filed lawsuits against two compounding pharmacies and physicians in several states alleging violations of the Lanham Act for false advertising and trademark infringement, and of United States patent law. All of these lawsuits have been settled favorably to us. More recently, we have sued chemical suppliers, and a light device company, its distributor and a sales representative, alleging that they induce physicians to infringe patents licensed to us, among other things. While we believe that certain actions of compounding pharmacies and others go beyond the activities which are permitted under the Food, Drug and Cosmetic Act and have advised the FDA and local health authorities of our concerns, we cannot be certain that our lawsuits will be successful in curbing the practices of these companies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

If generic manufacturers, like River's Edge, launch products to compete with Nicomide<sup>®</sup> in spite of our patent position, or if a court or the United States Patent and Trademark Office determine

**Table of Contents**

that our patent is invalid, these manufacturers may erode our market and negatively impact our sales revenues, liquidity and operations.

***Our Competitors In The Biotechnology And Pharmaceutical Industries May Have Better Products, Manufacturing Capabilities Or Marketing Expertise.***

We anticipate that we will face increased competition as the scientific development of PDT and PD advances and new companies enter our markets. Several companies are developing PDT agents other than Levulan<sup>®</sup>. These include: QLT Inc. (Canada); Axcan Pharma Inc. (U.S.); Miravant, Inc. (U.S.); and Pharmacyclics, Inc. (U.S.). We are also aware of several companies commercializing and/or conducting research with ALA or ALA-related compounds, including: medac GmbH and photonamic GmbH & Co. KG (Germany); PhotoTherapeutics, Inc. (U.K.) and PhotoCure ASA (Norway) which entered into a marketing agreement with Galderma S.A. for countries outside of Nordic countries for certain dermatology indications. There are many pharmaceutical companies that compete with us in the field of dermatology, particularly in the acne and rosacea markets.

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

Axcan Pharma Inc. has received FDA approval for the use of its product, PHOTOFRIN<sup>®</sup>, for PDT in the treatment of high grade dysplasia associated with Barrett's Esophagus. Axcan is the first company to market a PDT therapy for this indication, which we are also pursuing.

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

- the ease of administration of our method of PDT,
- the degree of generalized skin sensitivity to light,
- the number of required doses,
- the selectivity of our drug for the target lesion or tissue of interest, and
- the type and cost of our light systems.

Our primary competition in the acne and rosacea markets include oral and topical antibiotics, other topical prescription and over-the-counter products, as well as various laser and non-laser light treatments. The market is highly competitive and other large and small companies have more experience than we do which could make it difficult for us to penetrate the market. We are also aware of new products that were launched recently which will compete with Nicamide<sup>®</sup> and the AVAR<sup>®</sup> line of products which could negatively impact our market share. In addition, we expect that River's Edge's generic Nicamide<sup>®</sup> product will enter the market quickly, and other generic companies may also decide to enter the market while our patent litigation and reexamination process are proceeding, or thereafter if the court or if the USPTO finds that our Nicamide patent is invalid. The entry of new products from time to time would likely cause us to lose market share.



**Table of Contents**

**Risks Related To Our Stock**

***If the Shares of Common Stock held by former Sirius Shareholders are Sold, the price of the Shares Could Become Depressed***

All of the shares of DUSA's common stock which were issued to the former Sirius shareholders have been subject to a lock-up provision under the terms of the merger agreement. On March 10, 2007, the lock-up provision on 1,380,151 shares was lifted. These shares have been registered and are freely tradable. If these shareholders decide to sell their shares, the price of the shares on NASDAQ could be depressed.

***If Outstanding Options, Warrants And Rights Are Converted, The Value Of Those Shares Of Common Stock Outstanding Just Prior To The Conversion Will Be Diluted.***

As of December 31, 2006 there were outstanding options and warrants to purchase 3,031,000 shares of common stock, with exercise prices ranging from U.S. \$1.60 to \$31.00 per share, and of CDN \$6.79 per share, respectively. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. The holders are likely to exercise their securities when we would probably be able to raise capital from the public on terms more favorable than those provided in these securities.

***Results Of Our Operations And General Market Conditions For Specialty Pharmaceutical And Biotechnology Stocks Could Result In Sudden Changes In The Market Value Of Our Stock.***

The price of our common stock has been highly volatile. These fluctuations create a greater risk of capital losses for our shareholders as compared to less volatile stocks. From January 1, 2005 to December 31, 2006, the price of our stock has ranged from a low of \$3.52 to a high of \$16.30. Factors that contributed to the volatility of our stock during this period included:

quarterly levels of product sales;

clinical trial results;

general market conditions;

patent litigation;

increased marketing activities; and

changes in third-party payor reimbursement for our therapy.

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

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

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

**Table of Contents**

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

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

On September 27, 2002, we adopted a shareholder rights plan at a special meeting of DUSA's board of directors. The rights plan could discourage, delay or prevent a person or group from acquiring 15% or more (or 20% or more in the case of certain parties) of our common stock, thereby limiting, perhaps, the ability of our shareholders to benefit from such a transaction.

The rights plan provides for the distribution of one right as a dividend for each outstanding share of our common stock to holders of record as of October 10, 2002. Each right entitles the registered holder to purchase one one-thousandths of a share of preferred stock at an exercise price of \$37.00 per right. The rights will be exercisable subsequent to the date that a person or group either has acquired, obtained the right to acquire, or commences or discloses an intention to commence a tender offer to acquire, 15% or more of our outstanding common stock (or 20% of the outstanding common stock in the case of a shareholder or group who beneficially held in excess of 15% at the record date), or if a person or group is declared an Adverse Person, as such term is defined in the rights plan. The rights may be redeemed by DUSA at a redemption price of one one-hundredth of a cent per right until ten days following the date the person or group acquires, or discloses an intention to acquire, 15% or 20% or more, as the case may be, of DUSA, or until such later date as may be determined by the our board of directors.

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

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

In May 1999, we entered into a five year lease for 16,000 sq. ft. of office/warehouse space to be used for offices and manufacturing in Wilmington, Massachusetts. In December 2001 we entered into a 15 year lease covering the entire building through November 2016. We have the ability to terminate the Wilmington lease after the 10th year (2011) of the lease by providing the landlord with notice at least 7 and one-half months prior to the date on which the termination would be effective. In October 2002, we entered into a five-year lease commitment for approximately 2,000 sq. ft., for our wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., replacing the space DUSA previously occupied. Commencing in August 2002, we entered into a five year lease for office space for our Toronto location which accommodates the Toronto office of our Chief Executive Officer and shareholder services representative. In December 2006, we extended the Toronto lease for an additional 5 year term through August 2012.

**Table of Contents**

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

**ITEM 3. LEGAL PROCEEDINGS**

***PHOTOCURE ASA***

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby in settlement of patent disputes we granted a non-exclusive license to PhotoCure under the patents we license from PARTEQ, the licensing arm of Queens University, Kingston, Ontario Canada for esters of aminolevulinic acid ( ALA ). Furthermore, we granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix<sup>®</sup> and Metvix<sup>®</sup> (known in the United States as Metvixia<sup>®</sup>) products for any patents that may issue to DUSA or that we may license in the future. We received a \$1.0 million prepaid royalty during the quarter ended June 30, 2006. PhotoCure received FDA approval to market Metvixia for treatment of actinic keratosis in July 2004 and it would be directly competitive with our Levulan<sup>®</sup> Kerastick<sup>®</sup> product should PhotoCure with its marketing partner, Galderma S.A., decide to begin marketing this product. While we are entitled to royalties from PhotoCure on its net sales of Metvixia, this product may adversely affect our ability to maintain or increase our market.

***LEVULAN<sup>®</sup> SUITS***

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

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

More recently, we sued chemical suppliers in United States District Court for the District of Arizona and the District of Utah, and a light device manufacturer, a distributor, and a sales representative in United States District Court for the Southern District of Ohio, Eastern Division, alleging that these defendants induce physicians to infringe patents licensed to us, among other things. One of the cases, the lawsuit against one of the chemical suppliers, has been resolved in DUSA's favor, with DUSA having the right to review its books and records to verify ongoing compliance. The other cases are still at an early stage. While we believe that certain actions of compounding pharmacies and others go beyond the activities which are permitted under the Food, Drug and Cosmetic Act and have advised the FDA and local health authorities of our concerns, we cannot be certain that our lawsuits will be successful in curbing the practices of these companies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

***RIVER S EDGE***

On March 28, 2006, a lawsuit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division by River's Edge Pharmaceuticals, LLC against us alleging,

**Table of Contents**

among other things, that, prior to our merger with the former Sirius Laboratories, Inc., Sirius agreed to authorize River s Edge to market a generic version of Nicomide®, and that the United States patent covering Nicomide® issued to Sirius in December, 2005 is invalid. Nicomide® is one of the key products DUSA acquired from Sirius in our merger. On June 19, 2006, the Georgia court dismissed River s Edge complaint.

River s Edge also filed an application with the United States Patent and Trademark Office requesting an inter partes reexamination of the Nicomide® patent. The USPTO has accepted the application and the parties have submitted their responses to the USPTO s first office action.

On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River s Edge niacinamide product infringes our United States patent 6,979,468. We have posted \$750,000 with the Court that is being held in an interest bearing account. The parties are in the discovery stage of the New Jersey litigation. Although the court issued a preliminary injunction against sales of River s Edge s product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court s determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. We expect that River s Edge will reenter the market with its product in competition with Nicomide®. We expect that Nicomide® sales will be adversely impacted throughout the litigation process. In the interim, we are considering alternative strategies aimed at mitigating market share loss. We have reviewed the valuation of our intangible assets and goodwill associated with Nicomide® for impairment and have recorded an impairment charge of \$15.7 million to write down the remaining net book value of the intangible assets. An unfavorable ruling in the USPTO or in the New Jersey litigation with respect to the validity of the Nicomide® patent, would allow generic manufacturers, including River s Edge, to lawfully compete directly with us and would have a material negative impact on our revenues, results of operations and liquidity.

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

None.

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

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

Price range per common share by quarter, 2006:

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

Price range per common share by quarter, 2005:

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

**Table of Contents**

On March 15, 2007, the closing price of our common stock was \$3.60 per share on the NASDAQ Global Market. On March 15, 2007, there were 849 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.

Company securities authorized for issuance under equity compensation plans as of December 31, 2006:

**Equity Compensation Plan Information**

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c)</b>
Equity compensation plans approved by security holders	2,605,875	\$ 11.67	994,641
Equity compensation plans not approved by security holders	425,000	\$ 6.99	
Total	3,030,875	\$ 11.01	994,641

**COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN  
AMONG DUSA PHARMACEUTICALS, INC.,  
NASDAQ MARKET INDEX AND HEMSCOTT GROUP INDEX  
ASSUMES \$100 INVESTED ON JAN. 1, 2002  
ASSUMES DIVIDEND REINVESTED  
FISCAL YEAR ENDING DEC. 31, 2006**

	12/31/01	12/31/02	Cumulative Return Total			
			12/31/03	12/31/04	12/31/05	12/31/06
DUSA PHARMACEUTICALS, INC. HEMSCOTT GROUP INDEX	\$ 100.00	\$ 20.26	\$ 62.73	\$ 177.64	\$ 133.79	\$ 53.41
NASDAQ MARKET INDEX	\$ 100.00	\$ 100.19	\$ 185.17	\$ 204.06	\$ 162.93	\$ 225.23
	\$ 100.00	\$ 69.75	\$ 104.88	\$ 113.70	\$ 116.19	\$ 128.12

**Table of Contents****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,				
	2006(1)	2005	2004	2003	2002(2)
Revenues (2)	\$ 25,582,986	\$ 11,337,461	\$ 7,987,656	\$ 970,109	\$ 25,483,238
Net income (loss) (1)	(31,349,507)	(14,998,709)	(15,628,980)	(14,826,854)	5,762,518
Basic and diluted net income(loss) per common share	\$ (1.65)	\$ (0.89)	\$ (0.96)	\$ (1.06)	\$ 0.42

**CONSOLIDATED BALANCE SHEETS DATA**

	AS OF DECEMBER 31,				
	2006	2005	2004	2003	2002
Total assets	\$33,755,813	\$42,330,631	\$56,650,888	\$44,697,488	\$60,949,973
Long-term obligations (3)	1,199,086			1,247,500	1,517,500
Shareholders' equity	26,333,573	38,028,728	52,507,018	40,232,049	56,057,730

- (1) An impairment resulting from our review of our intangible assets of \$15,740,000.
- (2) 2002 includes the recognition of approximately \$20,990,000 in revenues, \$2,638,000 in cost of product sales and \$639,000 in research and development costs as a result of the termination of our former dermatology collaboration arrangement. These amounts were previously

deferred and were being amortized into operations over periods ranging from 1 to 12.5 years.

- (3) Long-term obligations are primarily comprised of deferred revenues related to a milestone payment received under a royalty agreement.

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

When you read this section of this report, it is important that you also read the financial statements and related notes included elsewhere in this report. This section contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those we anticipate in these forward-looking statements for many reasons, including the factors described below and in Risk Factors .

### **Overview**

DUSA is a vertically integrated dermatology company that is developing and marketing Levulan<sup>®</sup> PDT and other products for common skin conditions. Our currently marketed products include among others Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT, the BLU-U<sup>®</sup> brand light source, and the

**Table of Contents**

products acquired in the March 10, 2006 merger with Sirius Laboratories, Inc, including, Nicomide<sup>®</sup>, Nicomide-T<sup>®</sup> and the AVAR<sup>®</sup> line of products.

In connection with our merger of Sirius Laboratories, Inc. of Vernon Hills, Illinois, or Sirius, we acquired all of Sirius' common stock in exchange for cash and common stock of DUSA worth up to \$30,000,000. Of the up to \$30,000,000, \$8,000,000 less certain expenses was paid in cash upon closing, \$17,000,000 was paid in shares of DUSA's common stock also upon closing, and up to \$5,000,000, (\$1,500,000 of which would be paid in cash, and \$3,500,000 of which would be paid in cash or common stock) may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. The products acquired in this transaction, called the Sirius merger, focus primarily on the treatment of acne vulgaris and acne rosacea. 2,396,245 DUSA shares were issued pursuant to Regulation D and subsequently registered on a Form S-3 registration statement. The number of shares was determined by dividing \$17,000,000 by the lesser of \$10.10 or the average closing price of DUSA's shares on the NASDAQ Stock Market for the twenty (20) trading days prior to closing date which was \$7.094. All of the shares have been subject to a lock-up provision since the closing, however, approximately 1,300,000 were released from this restriction on March 10, 2007 and are freely tradable.

On March 28, 2006, a lawsuit was filed by River's Edge Pharmaceuticals, LLC against us alleging, among other things, that, prior to our merger with the former Sirius Laboratories, Inc., Sirius agreed to authorize River's Edge to market a generic version of Nicomide<sup>®</sup>, and that the United States patent covering Nicomide<sup>®</sup> issued to Sirius in December, 2005 is invalid. Nicomide<sup>®</sup> is one of the key products DUSA acquired from Sirius in our merger. On June 19, 2006, the Georgia court dismissed River's Edge complaint.

River's Edge also filed an application with the United States Patent and Trademark Office requesting an inter partes reexamination of the Nicomide<sup>®</sup> patent. The USPTO has accepted the application and the parties have submitted their responses to the USPTO's first office action.

On April 20, 2006, we filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River's Edge niacinamide product infringes our United States patent 6,979,468. We have posted \$750,000 with the Court that is being held in an interest bearing account. The parties are in the discovery stage of the New Jersey litigation. Although the court issued a preliminary injunction against sales of River's Edge's product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. We expect that River's Edge will reenter the market with its product in competition with Nicomide<sup>®</sup>. We expect that Nicomide<sup>®</sup> sales will be adversely impacted throughout the litigation process. In the interim, we are considering alternative strategies aimed at mitigating market share loss. We have reviewed the valuation of our intangible assets and goodwill associated with Nicomide<sup>®</sup> for impairment and have recorded an impairment charge of \$15.7 million to write down the remaining net book value of the intangible assets. An unfavorable ruling in the USPTO or in the New Jersey litigation with respect to the validity of the Nicomide<sup>®</sup> patent, would allow generic manufacturers, including River's Edge, to lawfully compete directly with us and would have a material negative impact on our revenues, results of operations and liquidity.

Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. This acquisition has allowed us to expand our product portfolio, capitalize on cross-selling and marketing opportunities, increase our sales force size, as well as provide a pipeline of potential new products, including ClindaReach<sup>®</sup> which was launched in March, 2007.

Nicomide<sup>®</sup> is an oral prescription vitamin supplement, while Nicomide-T<sup>®</sup> is a topical cosmetic product. Both products target the acne and acne rosacea markets. Acne is a common skin condition caused, in part, by the blockage and/or inflammation of sebaceous (oil) glands. Acne rosacea is a condition that primarily affects the skin of the face and typically first appears between the ages of 30 and 60 as a transient flushing or blushing on the nose, cheeks, chin or forehead, progressing in many patients to a papulopustular form clinically similar to acne vulgaris (inflammatory acne). Given its resemblance to inflammatory acne, and the general public's limited knowledge of rosacea, the condition is frequently



**Table of Contents**

mistaken by patients as adult acne. If untreated, rosacea has the tendency to worsen over time, although it can also wax and wane. The AVAR line of products includes a number of leave-on and cleanser formulations of sodium sulfacetamide and sulphur, a drug combination long known to have anti-acne, anti-inflammatory properties.

Historically, we devoted most of our resources to fund efforts in order to advance the Levulan<sup>®</sup> PDT/PD technology platform. Our drug, Levulan<sup>®</sup> brand of aminolevulinic acid HCl, or ALA, is being used with light, investigational, in a broad range of medical conditions. When Levulan<sup>®</sup> is used and followed with exposure to light to treat a medical condition, it is known as Levulan<sup>®</sup> photodynamic therapy, or Levulan<sup>®</sup> PDT. When Levulan<sup>®</sup> is used and followed with exposure to light to detect medical conditions, it is known as Levulan<sup>®</sup> photodetection, or Levulan<sup>®</sup> PD.

The Levulan<sup>®</sup> Kerastick<sup>®</sup> 20% Topical Solution with PDT and the BLU-U<sup>®</sup> brand light source were launched in the United States, or U.S., in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp under a former dermatology collaboration. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003 we received clearance from the United States Food and Drug Administration, or FDA, to market the BLU-U<sup>®</sup> without Levulan<sup>®</sup> PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

We are responsible for regulatory, sales, marketing, customer service, manufacturing of our Levulan<sup>®</sup> Kerastick<sup>®</sup>, and other related product activities. Our objectives include increasing the sales of our products in the United States and Canada, continuing our efforts of exploring partnership opportunities for Levulan<sup>®</sup> PDT for dermatology in Europe, launching Levulan<sup>®</sup> with our distributors in Latin America and Asia, continuing our Levulan<sup>®</sup> PDT clinical development programs for our moderate to severe acne indication as well as our pipeline product programs. To further these objectives, we entered into a marketing and distribution agreement with Stiefel Laboratories, Inc. in January 2006 granting Stiefel an exclusive right to distribute the Levulan<sup>®</sup> Kerastick<sup>®</sup> in Mexico, Central and South America. We expect launch of the product in Brazil following receipt of acceptable pricing approval by government regulators. The Mexican regulatory authorities have approved the product for sale and we expect that the launch in Mexico will also occur pending resolution of the final pricing by CMED in Brazil. Similarly, we entered into a marketing and distribution agreement with Daewoong Pharmaceutical Co., Ltd. granting Daewoong exclusive rights to distribute the Levulan<sup>®</sup> Kerastick<sup>®</sup> in certain Asian countries. Regulatory submissions for Korea are being prepared.

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

As of December 31, 2006, we had an accumulated deficit of approximately \$120,887,000. We expect to continue to incur operating losses through 2007 until sales of our products increase. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our therapy by the medical and consumer constituencies, and our ability to develop and/or acquire new profitable products. Although we have experienced significant operating losses, our net cash used in operating activities declined in each successive quarter of 2006.

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

**Table of Contents**

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

Marketing and sales activities since the launch of our sales force have resulted in significant additional revenues as well as expenses. Kerastick<sup>®</sup> unit sales to end-users were 140,760 and 100,668 for twelve months ended December 31, 2006 and 2005, respectively, including 15,822 and 13,458, respectively, sold in Canada.

The net number of BLU-U<sup>®</sup> units placed in doctors' offices during the twelve months ended December 31, 2006 was 300 including 40 placed in Canada. As of December 31, 2006 and December 31, 2005, respectively, there were 1,637 and 1,337 units in doctors' offices, consisting of 1,402 and 1,142 in the U.S. and 235 and 195 in Canada. During 2005 we began a BLU-U<sup>®</sup> marketing effort to allow prospective customers to evaluate a BLU-U for a short period of time prior to making a purchase decision. BLU-U<sup>®</sup> commercial light sources placed in physicians' offices pursuant to the Company's BLU-U<sup>®</sup> evaluation program are classified as inventory in the accompanying Consolidated Balance Sheets. The Company amortizes the cost of the evaluation units during the evaluation period to cost of product revenues to approximate its net realizable value.

Net revenues generated by the products acquired as part of our acquisition of Sirius totaled \$9,486,000 for the period March 10, 2006 (date of acquisition) through December 31, 2006. The substantial majority of these revenues were from sales of Nicomide<sup>®</sup>. With the dissolution of the preliminary injunction which had previously enjoined River's Edge from selling its generic substitute for Nocomide<sup>®</sup>, we believe that our Non-PDT Drug Products revenues will be materially adversely impacted for 2007. We have continued our efforts to penetrate the market by expanding our sales coverage in key geographic locations. See section entitled Management's Discussion and Analysis - Results of Operations, Marketing and Sales Costs. We are encouraged with the year-over-year increase in PDT sales, as well as the positive feedback we continue to receive from physicians across the country that believe Levulan PDT should become a routine part of standard dermatological practice. We are continuing to explore opportunities to develop, market, and distribute our Levulan<sup>®</sup> PDT platform in Europe and expect that our distribution partners, Stiefel Laboratories, Inc. for Latin America and Daewoong Pharmaceutical Co., Ltd. for Asia will advance our international strategy. We are also continuing to seek to acquire and/or license additional dermatology products that complement our current product portfolio that would provide our sales force with additional complementary products to sell in the near term.

We believe that the issues related to reimbursement have negatively impacted the economic competitiveness of our therapy with other AK therapies and have hindered its adoption in the past. We have continued to support efforts to improve reimbursement levels to physicians. Such efforts included working with the Centers for Medicare and Medicaid Services, or CMS, and the American Academy of Dermatology Association, or AADA, on matters related to the PDT procedure fee and the separate drug reimbursement fee. Doctors can also bill for any applicable visit fees. Effective January 1, 2006, the CMS average national reimbursement for the use of Levulan<sup>®</sup> PDT for AK's Ambulatory Patient Classifications code (APC code) was increased. The APC code is used by many hospitals. The CMS Current Procedural Terminology code (CPT code), which is used by private physician clinics using Levulan PDT for treating AKs was not increased for 2006. However, an increase was implemented as of January 1, 2007. We are aware that some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices. Therefore, we continue to support ongoing efforts that might lead to further increases in reimbursement in the future; and intend to continue supporting efforts to seek reimbursement for our FDA-cleared use of the BLU-U<sup>®</sup> alone in the treatment of mild to moderate inflammatory acne of the face.

Most major private insurers have approved coverage for our AK therapy. We believe that due to these efforts, plus future improvements, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time.

We have been encouraged by the positive response from many physicians and patients who have used our Levulan<sup>®</sup> PDT therapy, but we recognize that we have to continue to demonstrate the clinical

**Table of Contents**

value of our unique therapy, and the related product benefits as compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. While we cannot predict when product sales may offset the costs associated with these efforts, we expect that we will continue to generate operating losses through 2007. We are aware that physicians have been using Levulan<sup>®</sup> with the BLU-U<sup>®</sup> using short incubation, 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.

We believe that some compounding pharmacies exceed the legal limits for their activities, including manufacturing and/or selling quantities of ALA in circumstances which may be inducing purchasers to infringe our intellectual property. We believe that these activities are negatively impacting our Levulan<sup>®</sup> sales growth. Therefore, during the last two years we have filed lawsuits against compounding pharmacies, chemical companies, a distributor and sales representative as well as against several physicians, many of which have already settled favorably to us. See section entitled `Legal Proceedings`.

As of December 31, 2006, we had a staff of 85 employees, including 2 part-time employees, as compared to 64 full-time employees and 2 part-time employees at the end of 2005, including marketing and sales, production, maintenance, customer support, and financial operations personnel, as well as those who support research and development programs for dermatology and internal indications. During 2006, with the addition of the sales force from Sirius we increased the size of our sales force to 37 from 26 at the end of 2005. During 2005 we eliminated 14 positions through a restructuring action, representing 16% of our workforce, to align headcount more closely with our assessment of our resource requirements at this time. These workforce reductions were made across all functions of the Company. We may add and/or replace employees during 2007 as business circumstances deem necessary.

**2006 TRANSACTIONS**

During 2006 and early 2007, DUSA entered into a number of transactions, all designed to foster future growth of DUSA and its Levulan<sup>®</sup> PDT.

*Stiefel Laboratories, Inc.*

In January, 2006, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc., or Stiefel, covering current and future uses of DUSA's proprietary Levulan<sup>®</sup> Kerastick<sup>®</sup> for PDT in dermatology. The agreement, grants Stiefel an exclusive right to distribute, promote and sell the Levulan<sup>®</sup> Kerastick<sup>®</sup> in the western hemisphere from and including Mexico south, and all other countries in the Caribbean, excluding United States territories. DUSA will manufacture and supply to Stiefel on an exclusive basis in the territory all of Stiefel's reasonable requirements for the product. The agreement has an initial term of ten years. The Mexican and Brazilian health regulatory authorities have granted their respective approvals to market the product, however, the launch of the product in Brazil is dependent upon receipt of acceptable final pricing approval from Brazilian government regulators at CMED. We expect that the launch in Mexico will also occur pending resolution of the final pricing by CMED in Brazil. Stiefel will make up to \$3,000,000 in milestone payments, a portion of which will be due upon receipt of acceptable final pricing approval of the product from Brazilian regulatory authorities and the balance upon achievement of pre-determined minimum purchase levels in the territory. The parties are working with CMED to achieve this goal, however if acceptable pricing is not granted, the agreement may be terminated. Stiefel will prepare and file the regulatory applications in other countries in the territory subject to the terms of the agreement. The parties have certain rights to terminate the agreement prior to the end of the initial term, and Stiefel has an option to extend the term for an additional ten years on mutually agreeable terms and conditions.

**Table of Contents***Merger With Sirius Laboratories, Inc.*

In March, 2006, we closed our merger to acquire all of the common stock of Sirius Laboratories Inc. of Vernon Hills, Illinois in exchange for cash and common stock worth up to \$30,000,000. Sirius was a privately held dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Of the up to \$30,000,000, \$8,000,000 less certain expenses was paid in cash upon closing, \$17,000,000 was paid in shares of DUSA's common stock also upon closing in a private placement, and up to \$5,000,000, (\$1,500,000 of which would be paid in cash, and \$3,500,000 of which would be paid in cash or common stock) may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. With the launch of ClindaReach, one of the new Sirius products, we will be obligated to make a cash payment of \$500,000. to the former shareholders. Also, of the 2,396,245 shares of DUSA common stock issued in connection with the merger, approximately 1,300,000 of such shares were released from a lock-up provision of the merger agreement on March 10, 2007. The shares are freely tradable by their respective holders.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received a request from the FDA for labeling information and justification for the belief that the product is exempt from drug approval requirements, has received a warning letter to cease manufacturing a different marketed unapproved drug, and has been cited for GMP violations. We believe that the GMP issues do not directly involve our products. There can be no assurance that the FDA will continue this policy or not take a contrary position with any individual products. If the FDA were to do so, we may be required to make certain labeling changes and market these products as over-the-counter products or as dietary supplements under applicable legislation, or withdraw such products from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues, particularly if the action were taken with respect to Nicomide®.

Shortly after the closing of the merger, we became engaged in patent litigation with River's Edge, a company that launched a generic Nicomide® product. River's Edge also requested that the United States Patent and Trademark Office, or USPTO, reexamine the Nicomide® patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. Although the court issued a preliminary injunction against sales of River's Edge's product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. We expect that River's Edge will reenter the market with its product in competition with Nicomide®. We expect that Nicomide® sales will be adversely impacted throughout the litigation process. In the interim, we are considering alternative strategies aimed at mitigating market share loss. If we do not ultimately prevail in our lawsuit, or if the Nicomide® patent is found to be invalid by the court or the USPTO, our revenues from sales of Nicomide® will decrease permanently. We expect to eliminate some expenses planned for 2007 and reallocate others to provide more support to Levulan® and our new product, ClindaReach. We have reviewed the valuation of our intangible assets and goodwill associated with Nicomide® for impairment and have recorded an impairment charge of \$15.7 million to write down the remaining net book value of the intangible assets.

**Table of Contents***Daewoong Pharmaceutical Co., Ltd.*

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong Pharmaceutical Co., Ltd., or Daewoong, and Daewoong's wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, and collectively with Daewoong referred to as D&D, covering current and future uses of the Levulan® Kerastick® for PDT in dermatology. The agreement grants D&D exclusive rights to distribute, promote and sell the Levulan® Kerastick® in Korea, Taiwan, China, including without limitation Hong Kong, India, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. We will manufacture and supply the product to D&D on certain terms and conditions.

The agreement has an initial term of ten years (subject to earlier termination and extension provisions). D&D 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, D&D will make up to \$3,500,000 in milestone payments to us, \$1,000,000 of which was paid on signing. The remaining milestones are based upon contract execution, certain regulatory approval of the product from regulatory authorities, and achievement of pre-determined cumulative sales targets in the territory subject to certain terms and conditions. In order to maintain its exclusive rights, D&D is obligated to purchase a certain number of units of the product and meet certain regulatory timelines. We will manufacture the product in our facility in Wilmington, Massachusetts. We will also receive a minimum transfer price per unit plus a percentage of D&D's end-user price above a certain level.

*Photocure ASA*

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby we granted a non-exclusive license to PhotoCure for esters of aminolevulinic acid, or ALA under the patents we license from PARTEQ, the licensing arm of Queens University, Kingston, Ontario Canada. ALA is the active ingredient in DUSA's Levulan® products. 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 it would be directly competitive with our Levulan® Kerastick® product should PhotoCure decide to begin marketing this product. While we are entitled to royalties from PhotoCure on its net sales of Metvixia, this product may adversely affect our ability to maintain or increase our market.

*Levulan® Lawsuits Filed*

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

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

**Table of Contents**

More recently, we sued chemical suppliers in United States District Court for the District of Arizona and the District of Utah, and a light device manufacturer, a distributor, and a sales representative in United States District Court for the Southern District of Ohio, Eastern Division, alleging that these defendants induce physicians to infringe patents licensed to us, among other things. One of the cases, the lawsuit against one of the chemical suppliers, has been resolved in DUSA's favor, with DUSA having the right to review its books and records to verify ongoing compliance. The other cases are still at an early stage. While we believe that certain actions of compounding pharmacies and others go beyond the activities which are permitted under the Food, Drug and Cosmetic Act and have advised the FDA and local health authorities of our concerns, we cannot be certain that our lawsuits will be successful in curbing the practices of these companies or that regulatory authorities will intervene to stop their activities. In addition, there may be other compounding pharmacies which are following FDA guidelines, or others conducting illegal activities of which we are not aware, which may be negatively impacting our sales revenues.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Critical accounting policies are those that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods and that can significantly affect our financial position and results of operations. Our accounting policies are disclosed in Note 2 to the Consolidated Financial Statements. We have discussed these policies and the underlying estimates used in applying these accounting policies with our Audit Committee. Since not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We consider the following policies and estimates to be critical to our financial statements.

**REVENUE RECOGNITION AND PROVISIONS FOR ESTIMATED REDUCTIONS TO GROSS REVENUES***Photodynamic Therapy (PDT) Drug and Device Products.*

Revenues on the Kerastick<sup>®</sup> and BLU-U<sup>®</sup> product sales are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is probable. Product sales made through distributors, historically, have been recorded as deferred revenue until the product was sold by the distributors to the end users because we did not have sufficient history with our distributor to be able to reliably estimate returns. Beginning in 2006, we began recognizing revenue as product is sold to distributors because we now believe we have sufficient history to reliably estimate returns from distributors as of January 1, 2006. This change in estimate was not material to our revenues or results of operations. Certain device units are held by physicians 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.

*Non-PDT Drug Products.*

We recognize revenue for these products in accordance with SAB No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104, Revenue Recognition. Our accounting policy for revenue recognition has a substantial impact on our reported results and relies on certain estimates that require difficult, subjective and complex judgments on the part of management. We recognize revenue for sales when substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment to wholesale customers, with the exceptions described below. Revenue is recognized net of revenue reserves, which consists of allowances for discounts, returns, rebates chargebacks and fees paid to wholesalers under distribution service agreements.

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

**Table of Contents**

We evaluate inventory levels at our wholesale customers, which account for the vast majority of our sales in the Non-PDT Drug Products segment, through an analysis that considers, among other things, wholesaler purchases, wholesaler shipments to retailers, available end-user prescription data purchased from third parties and on-hand inventory data received directly from our two largest wholesale customers. We believe that our evaluation of wholesaler inventory levels, as described in the preceding sentence, 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 our products in their inventory through to the retailers and, ultimately, to the end-user consumer prior to product expiration.

A summary of activity in the Company's valuation accounts are as follows:

FOR THE YEAR ENDED DECEMBER 31, 2006:					
BALANCE	BALANCE ACQUIRED AS PART OF SIRIUS ACQUISITION	PROVISION RELATED TO SALES MADE IN THE CURRENT PERIOD	PROVISION FOR SALES MADE IN PRIOR PERIODS	ACTUAL RETURNS OR CREDITS IN THE CURRENT PERIOD	BALANCE AT DECEMBER 31, 2006
AT JANUARY 1, 2006					

## Accrued Expenses:

Returns and allowances	\$	\$357,000	\$1,235,000	\$	\$ (960,000)	\$632,000
------------------------	----	-----------	-------------	----	--------------	-----------

## Accounts receivable:

## Prompt payment

discounts	\$	\$	\$ 223,000	\$	\$(\$200,000)	\$ 23,000
-----------	----	----	------------	----	---------------	-----------

Our provision for returns and allowances consists of our estimates of future sales returns, rebates and chargebacks.

**Sales Returns-** We account for sales returns in accordance with SFAS No. 48 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 returns, but also by considering other factors that could impact sales returns. These 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. It is our policy to accept returns of Non-PDT Drug products when product is within nine months of expiration. We consider all of these factors and adjust the accrual periodically to reflect actual experience.

**Chargebacks and Rebates** - 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 to the Company. 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. Since only a small percentage of our prescriptions are reimbursed under Medicaid and the quantity of consumer coupon redemptions have not been substantial, rebates have not been significant to the Company. Chargebacks and rebates in the aggregate were \$214,000, for the year ended December 31, 2006.

We offer many of our customers a 2% prompt payment discount. We evaluate the amounts accrued for prompt payment discounts by analyzing the unpaid invoices in our accounts receivable aging subject to a prompt payment

discount. Prompt payment discounts are known within 15 to 30 days of sale, and therefore can be reliably estimated based on actual and expected activity at each reporting date. The



**Table of Contents**

Company records these discounts at the time of sale and they are accounted for as a reduction of revenues.

Historically, our adjustments to actual have not been material. The sensitivity of our estimates can vary by type of revenue reserve. Our estimate associated with returns and allowances is evaluated based primarily on historical returns experience relative to sales volumes, but also considers the length of time from the sale to the lapse of the return right. There have been no material adjustments to our accruals based on actual returns.

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

**Valuation Of Long-lived and Intangible Assets** - We review long-lived 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, 2006 and 2005, respectively, total property, plant and equipment had a net carrying value of \$2,567,000 and \$2,972,000 including \$1,639,000 at December 31, 2006 associated with our manufacturing facility. As of December 31, 2006 and 2005, respectively, we had intangible assets totaling \$102,000 and \$150,000 recorded in deferred charges and other assets relating to the unamortized balance of payments made in 2004 to a light source supplier related to an amendment to our agreement and to a licensor related to the reacquisition of our product rights in Canada. We have reviewed the valuation of our intangible assets and goodwill associated with Nicomide<sup>®</sup> for impairment as a result of a decision by the U.S courts to dissolve a preliminary injunction that had previously enjoined a competitor from manufacturing and selling a generic and have recorded a write down of \$15.7 million in 2006, representing the remaining net asset value of the intangible assets as of December 31, 2006.

**Share-Based Compensation** - In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123R, Share-Based Payment, a revision of SFAS Statement No. 123. We adopted SFAS 123R effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006, we measure all employee share-based compensation awards using a fair value based method and record share-based compensation expense in our financial statements if the requisite service to earn the award is provided. The pro forma results and assumptions used in fiscal years 2005 and 2004 were based solely on historical volatility of our common stock over the most recent period commensurate with the estimated expected life of our stock options. The adoption of SFAS No. 123R did not affect our net cash flow, but it did have a material negative impact on our results of operations. In accordance with SFAS 123R, we recognize the expense attributable to stock awards that are granted or vest in periods ending subsequent to December 31, 2005 in the accompanying condensed consolidated statements of operations.

**Table of Contents****Results of Operations****Year Ended December 31, 2006 As Compared to 2005**

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

	2006	2005	INCREASE/ (DECREASE)
PDT PRODUCT REVENUES			
KERASTICK® PRODUCT REVENUES			
United States	\$12,425,000	\$ 7,957,000	\$ 4,468,000
Canada	1,147,000	935,000	212,000
Subtotal Kerastick® product revenues	13,572,000	8,892,000	4,680,000
BLU-U® PRODUCT REVENUES			
United States	2,292,000	1,930,000	362,000
Canada	233,000	515,000	(282,000)
Subtotal BLU-U® product revenues	2,525,000	2,445,000	80,000
TOTAL PDT PRODUCT REVENUES	16,097,000	11,337,000	4,760,000
TOTAL NON-PDT DRUG PRODUCT REVENUES	9,486,000		9,486,000
TOTAL PRODUCT REVENUES	\$25,583,000	\$11,337,000	\$14,246,000

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

For the year ended December 31, 2006, Kerastick® revenues were \$13,572,000, representing an increase of \$4,680,000 or 53%, over the comparable 2005 totals of \$8,892,000. Kerastick® unit sales to end-users for the year ended December 31, 2006 were 140,760 including 15,822 sold in Canada. This represents an increase from 100,668 Kerastick® units sold in the year ended December 31, 2005, including 13,458 sold in Canada. Our average net selling price for the Kerastick® increased to \$96.32 for

**Table of Contents**

the year ended December 31, 2006 from \$88.33 in 2005. 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, both in the United States during 2005 and Canada during 2005 and 2006. The increase in 2006 Kerastick® revenues was driven mainly by increased sales volumes, an increase in our average unit selling price and increased levels of direct distribution to customers. Effective January 1, 2006, DUSA became the sole United States distributor of the Kerastick®.

For the year ended December 31, 2006, BLU-U® revenues were \$2,525,000, representing a \$80,000 or 3% increase, over the comparable 2005 totals of \$2,445,000. The increase in 2006 BLU-U® revenues was driven by slightly lower overall sales volumes which were offset by an increase in our average selling price. In the year ended December 31, 2006, there were 332 units sold versus 368 units in 2005. The 2006 total consists of 292 units sold in the United States and 40 sold in Canada by Coherent-AMT. The 2005 total consists of 276 sold in the United States and 92 sold in Canada. Our average net selling price for the BLU-U® increased to \$7,449 for the year ended December 31, 2006 from \$6,542 for 2005. The decrease in BLU-U® units sold in the year ended December 31, 2006 compared to the year ended December 31, 2005 is due primarily to lower Canadian sales volumes. During the fourth quarter of 2005, we introduced a BLU-U® evaluation program, which, for a limited number of BLU-U® units, allows customers to take delivery of a unit for a period of up to 4 months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At December 31, 2006, there were approximately 40 units in the field pursuant to this evaluation program. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of 3 years.

Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our March 10, 2006 acquisition of Sirius. Total revenues for the period March 10, 2006 through December 31, 2006 were \$9,486,000. The substantial majority of the Non-PDT product revenues were from sales of Nicomide®. The products acquired from Sirius all belong to the same therapeutic category, non-photodynamic therapy dermatological treatment of acne and rosacea. With the dissolution of a preliminary injunction which had previously enjoined a competitor from selling its generic substitute for Nicomide®, we believe that our Non-PDT Drug Products revenues will be materially adversely impacted for 2007.

The increase in our total revenues results from the Sirius acquisition, as well as from the efforts of our sales force and related marketing and sales activities. With respect to United States sales, we increased our average selling prices, increased our direct selling efforts, became the sole US distributor of the Kerastick®, and reduced our overall sales volume discount programs, all of which have had a positive impact on our average selling prices during 2006. However, we must increase sales significantly from these levels in order for us to become profitable. We remain confident that sales should continue to increase through increased consumption of our PDT segment products by our existing customers, as well as the addition of new customers. However, with the dissolution of the preliminary injunction which had previously enjoined River's Edge from selling its generic product, we believe that our Non-PDT Drug Products revenues will be materially adversely impacted for 2007, which would make it more difficult to achieve profitability. Also see 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.

**Table of Contents**

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

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

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

Development  
Innovations, the  
licensing arm of  
Queen's  
University,  
Kingston,  
Ontario, and  
amortization of  
an upfront fee  
and ongoing  
royalties paid to  
Draxis Health,  
Inc., on sales of  
the Levulan<sup>®</sup>  
Kerastick<sup>®</sup> in  
Canada.

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

**Table of Contents**

**Margins** Total product margins for the year ended December 31, 2006 were \$(533,000) as compared to \$5,123,000 for year ended December 31, 2005, as shown below:

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

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

Kerastick<sup>®</sup> gross margins for the year ended December 31, 2006 were 75%, versus 60% for the year ended December 31, 2005. Similar to the increase in revenues, the increase in margin is mainly attributable to an increase in our average unit selling price, and increased levels of direct distribution to customers eliminating the cost of distributors. Our long-term goal is to achieve higher gross margins on Kerastick<sup>®</sup> sales which will be significantly dependent on increased volume.

BLU-U<sup>®</sup> margins for the year ended December 31, 2006 were 15%, versus (7%) for the year ended December 31, 2005. The increase in gross margin is a result of an increase in the average selling price per unit; as well as, lower overall costs incurred to support the product line. Our short-term strategy is to at a minimum break even on device sales in an effort to drive Kerastick<sup>®</sup> sales volumes.

Non-PDT Drug Product Margins reflect the gross margin generated by the products acquired as part of our March 10, 2006 merger with Sirius. Total margin for the period March 10, 2006 (date of acquisition) through December 31, 2006 was (116%). Non-PDT Drug Product Margins were negatively impacted by the recording of the inventory acquired in the Sirius merger at its fair value, in accordance with purchase accounting rules, and an impairment charge. The full impact of the inventory adjustment was recognized over the six months following the acquisition which ended in September 2006. We have reviewed the valuation of our intangible assets and goodwill associated with our Non-PDT products for impairment and have recorded a write down of \$15.7 million in 2006, representing the remaining net asset value of the intangible assets. In 2007, we expect Non-PDT Drug Product gross margins to be in the 80-85% range, due to the elimination of future non-cash amortization charges related to the fully written down intangible assets.

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

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

**Table of Contents**

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

The increase in 2006 compared to 2005 was due primarily to the recording of share-based compensation expense of \$621,000 for the year ended December 31, 2006 resulting from the adoption of FAS 123R. This increase was offset, in part, by reduced spending on clinical programs as we completed both our Phase II acne study and our interim analysis study on photodamaged skin in the first quarter of 2006.

Research and development expenses are expected to increase now that our Phase IIIb clinical trial for acne has commenced, and to an even greater extent at such time as we may commence Phase III trials. We had entered into a clinical trial agreement in September 2004 with the National Cancer Institute, Division of Cancer Prevention, or NCI DCP, to study the use of ALA to treat high grade dysplasia within Barrett's Esophagus. However, the NCI DCP has recently notified us that it will not be pursuing this study. Therefore, we will not be incurring expenses for the laser devices, fiber optics and units of our proprietary sheath device that we were obligated to provide under the agreement. In November 2004, we also signed a clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP are working together to prepare the overall clinical development plan for Levulan® PDT in this indication, starting with Phase I/II trials, and continuing through Phase III studies, if appropriate. The NCI DCP used its resources to file its own Investigational New Drug application with the FDA, as well as an application for orphan drug status. Our costs related to this study will be limited to providing Levulan® and the necessary training for the investigators involved. All other costs of this study will be the responsibility of the NCI DCP. We have options on any new intellectual property.

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

We have entered into a series of agreements for our research projects and clinical studies. As of December 31, 2006, future payments to be made pursuant to these agreements, under certain terms and conditions, total approximately \$1,674,000 for 2007.

**Marketing and Sales Costs** Marketing and sales costs for the year ended December 31, 2006 were \$12,645,000 as compared to \$9,069,000 for the year ended December 31, 2005. These costs consist primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$8,672,000 for the year ended December 31, 2006, compared to \$6,934,000 in the year ended December 31, 2005. The increase in this category is due to increased headcount in 2006 in comparison to 2005, primarily as the result of the Sirius acquisition. The remaining expenses consist of tradeshow, miscellaneous marketing and outside consultants totaling \$3,603,000 for the year ended December 31, 2006, compared to \$2,135,000 for the year ended December 31, 2005. The increased spending in this category is due primarily to additional expenses related to the Sirius acquisition. We also recorded share-based compensation expense of \$370,000 for the year ended December 31, 2006, resulting from the adoption of FAS 123R. We expect marketing and sales costs to increase in 2007, compared with 2006, reflecting a full year of the expanded sales force, as well as expenses associated with the launch of our new product, but to decrease as a percentage of revenues.

**General and Administrative Costs** General and administrative costs for the twelve months ended December 31, 2006 were \$11,196,000 as compared to \$6,703,000 for the year ended December 31, 2005. The increase is mainly attributable to incremental legal fees primarily related to the River's Edge

**Table of Contents**

litigation, share-based compensation expense of \$1,213,000 for the twelve months ended December 31, 2006 resulting from the adoption of FAS 123R, and incremental costs associated with the acquisition of Sirius. General and administrative expenses are highly dependent on our legal and other professional fees, which can vary significantly from period to period particularly in light of our litigation strategy to protect our intellectual property.

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

**Income Taxes** There is no provision for income taxes due to ongoing operating losses. As of December 31, 2006, we had net operating loss carryforwards of approximately \$83,300,000 and tax credit carryforwards of approximately \$2,800,000 for Federal reporting purposes. These amounts expire at various times through 2026. See Note 10 to the Notes to the Consolidated Financial Statements. We have provided a full valuation allowance against the net deferred tax assets at December 31, 2006 and 2005.

**Net Loss** For the year ended December 31, 2005, we recognized a net loss of \$31,350,000, or \$1.65 per share, as compared to \$14,999,000, or \$0.89 per share, for the year ended 2005. Net losses are expected to continue until our revenues increase to offset the cost of our sales force and marketing initiatives, and the costs for other business support functions.

**YEAR ENDED DECEMBER 31, 2005 AS COMPARED TO 2004**

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

	2005	2004	Increase
<b>KERASTICK® REVENUES</b>			
United States	\$ 7,957,000	\$5,450,000	\$2,507,000
Canada	935,000	401,000	534,000
Total	\$ 8,892,000	\$5,851,000	\$3,041,000
<b>BLU-U® REVENUES</b>			
United States	\$ 1,930,000	\$1,795,000	\$ 135,000
Canada	515,000	342,000	173,000
Total	\$ 2,445,000	\$2,137,000	\$ 308,000
Total product sales	\$11,337,000	\$7,988,000	\$3,349,000

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



**Table of Contents**

The increase in 2005 BLU-U® revenue was driven by an increase in our average selling price, which increased to \$6,542 in 2005 from \$4,368 in 2004. During 2005, there were 368 units sold versus 489 units in 2004. The 2005 total consists of 276 units sold in the United States and 92 units sold in Canada by Coherent-AMT. The 2004 total consists of 398 sold in the United States and 91 sold in Canada. The decrease in BLU-U® units sold in 2005 compared to 2004 is due primarily to the implementation of a more focused sales strategy aimed at increasing Kerastick® sales volumes in existing accounts, as well as a decrease in BLU-U® discounting programs. During the fourth quarter of 2005, we introduced the BLU-U® evaluation program mentioned above. At December 31, 2005, there were 80 units in the field pursuant to this evaluation program. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of 3 years. Revenues pursuant to the evaluation program were not significant in 2005.

The increase of both Kerastick® and BLU-U® revenues during 2005 is a result of the increased efforts of our sales force and related marketing and sales activities. With respect to United States sales, we increased our average selling prices, increased our direct selling and distribution efforts, while still maintaining the services of one external distributor, and reduced our overall sales volume discount programs, all of which had a positive impact on our average selling prices during 2005.

**Cost Of Product Sales and Royalties** - Cost of product sales and royalties for the year ended December 31, 2005 were \$6,214,000, as compared to \$3,875,000 in 2004. The components of cost of product sales and royalties for the years ended December 31, 2005 and 2004, including direct and indirect costs to support our product are provided below:

	2005	2004	INCREASE (DECREASE)
<b>KERASTICK® COST OF PRODUCT REVENUES AND ROYALTIES</b>			
Direct Kerastick Product Costs	\$ 1,771,000	\$ 1,478,000	\$ 293,000
Other Kerastick® Product costs including internal costs assigned to support products	1,357,000	261,000	1,096,000
Royalty and Supply fees (1)	456,000	285,000	171,000
Total Kerastick® cost of product revenues and royalties	\$ 3,584,000	\$ 2,024,000	\$ 1,560,000
	2005	2004	INCREASE/ (DECREASE)
<b>BLU-U® COST OF PRODUCT REVENUES</b>			
Direct BLU-U® Product costs (2)	\$ 1,249,000	\$	\$ 1,249,000
Other BLU-U® Product costs including internal costs assigned to support products; as well as costs incurred to ship, install and service the BLU-U® in physicians offices	1,381,000	1,851,000	(470,000)
Total BLU-U® cost of product revenues	\$ 2,630,000	\$ 1,851,000	\$ 779,000
<b>TOTAL COST OF PRODUCT REVENUES AND ROYALTIES</b>	<b>\$ 6,214,000</b>	<b>\$ 3,875,000</b>	<b>\$ 2,339,000</b>

**Table of Contents**

- 1) Royalty and supply fees are paid to our licensor, PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, and starting in 2004, amortization of an upfront fee and a royalty are paid to Draxis, DUSA's former parent, on sales of the Levulan® Kerastick® in Canada.
- 2) Although there were direct BLU-U® product revenues in 2004, there were no related direct BLU-U® product costs as these units had a zero book value due to inventory impairment charges recorded during 2002.

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

	2005		2004		INCREASE/ (DECREASE)
Kerastick®	\$ 5,308,000	60%	\$ 3,827,000	65%	\$ 1,481,000
BLU-U®	(185,000)	(7)%	286,000	13%	(471,000)

Total Margin	\$ 5,123,000	45%	\$ 4,113,000	51%	\$ 1,010,000
--------------	--------------	-----	--------------	-----	--------------

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

BLU-U® margins for the year ended December 31, 2005, were (7)% compared with 13% for the year ended December 31, 2004. The erosion on margin is directly attributable to the fact that in 2005 we sold newly purchased units with an associated production cost, whereas during the 2004 period, we sold units which had a zero net book value due to inventory impairment charges recorded during 2002 following termination of an agreement with a marketing partner. The margin erosion is somewhat offset by an increase in the overall selling price per unit and a decrease in Other BLU-U® Product costs. Our short-term strategy was to break-even on device sales in an effort to drive Kerastick® sales volumes. However, our longer term goal is to move towards a reasonable profit margin on all device sales.

**Research and Development Costs** - Research and development costs for the year ended December 31, 2005 and 2004 were \$5,588,000 as compared to \$6,490,000 in 2004.

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

	2005	2004	INCREASE/ (DECREASE)
Research & Development costs incurred	\$ 6,118,000	\$ 6,490,000	\$ (372,000)
Refund of FDA product and registration fees	(530,000)		(530,000)
Total Research and Development Expense	\$ 5,588,000	\$ 6,490,000	\$ (902,000)

**Table of Contents**

During the fourth quarter of 2004, we initiated a DUSA-sponsored Phase II acne study, the results of which were reported in early 2006.

We also incurred research and development expenses in 2005 relating to our 80 patient, multi-center Phase II split-face clinical study of PDT in the treatment of photodamaged skin using the Levulan® (aminolevulinic acid HCl, ALA) Kerastick® in combination with either the Company's BLU-®<sup>®</sup>, an Intense Pulsed Light, or IPL. In February 2006, we reported the interim analysis results.

On September 27, 2004, DUSA signed a clinical trial agreement with the National Cancer Institute, Division of Cancer Prevention, or NCI DCP, for the clinical development of Levulan® PDT for the treatment of high-grade dysplasia within Barrett's Esophagus. In addition, to further our objectives concerning treatment of internal indications using Levulan® photodynamic therapy (PDT), on November 4, 2004, we signed an additional clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP worked together to prepare overall clinical development plans for Levulan® PDT in these indications, starting with Phase I/II trials. DUSA and the NCI DCP prepared outlines of clinical studies in both indications and worked with DUSA and investigators on clinical trial designs. The NCI DCP used its resources to prepare its own Investigational New Drug applications with the FDA. Our costs related to these studies will be limited to providing Levulan®, device(s) and the necessary training for the investigators involved. All other costs of these studies are the responsibility of the NCI DCP.

**Marketing and Sales Costs** Marketing and sales costs for the year ended December 31, 2005 were \$9,069,000 as compared to \$7,622,000 for 2004. These costs consist of overhead expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling \$6,934,000 in 2005 and \$5,268,000 in 2004. These increases were mainly attributable to the expansion of our sales force during 2005 and related marketing activities. The remaining expenses consist of trade shows, miscellaneous marketing expenses and outside consultants totaling \$2,135,000 in 2005 and \$2,354,000 in 2004.

**General and Administrative Costs** General and administrative expenses for the year ended December 31, 2005, decreased to \$6,703,000 as compared to \$7,210,000 for 2004. The decrease is mainly attributable to lower legal expenses of \$1,902,000 as compared to \$3,144,000 in the comparable period in 2004, due to the absence of patent litigation costs in Australia as the final hearing in the PhotoCure litigation was held in 2004. The savings related to the Australian litigation was partially offset by patent litigation costs against compounding pharmacies and physicians. Additionally, general corporate expenses, including increased personnel related costs, increased as our business has expanded.

**Other Income, Net** Other income for the year ended December 31, 2005, decreased to \$1,388,000, as compared to \$1,580,000 in 2004. This decrease reflects a reduction in our average investable cash balances during 2005 as we used cash to support our operating activities.

**Income Taxes** There is no provision for income taxes due to ongoing operating losses. We have provided a full valuation allowance against the net deferred tax assets at December 31, 2005 and 2004.

**Net Loss** For the year ended December 31, 2005, we recognized a net loss of \$14,999,000, or \$0.89 per share, as compared to \$15,629,000, or \$0.96 per share, for the year ended 2004. Net losses are expected to continue until product sales to physicians offset the cost of our sales force and marketing initiatives, and the costs for other business support functions.

**Table of Contents****QUARTERLY RESULTS OF OPERATIONS**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2006 and 2005, respectively:

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2006			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31(1)
Net revenues	\$ 4,750,520	\$ 6,619,109	\$ 6,062,720	\$ 8,150,637
Gross profit	2,959,761	3,623,946	3,213,236	(10,329,946)
Net loss	(4,640,309)	(4,653,954)	(3,786,639)	(18,268,605)
Basic and diluted loss per share	\$ (0.26)	\$ (0.24)	\$ (0.19)	\$ (0.94)

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2005			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
Net revenues	\$ 3,368,614	\$ 2,228,116	\$ 2,392,244	\$ 3,348,487
Gross profit	1,364,986	757,588	1,084,812	1,916,474
Net loss	(4,331,614)	(4,826,118)	(3,608,281)	(2,232,696)
Basic and diluted loss per share	\$ (0.26)	\$ (0.29)	\$ (0.21)	\$ (0.13)

(1) In the fourth quarter of 2006 the Company recorded an impairment charge to its intangible assets of \$15.7 million

**Liquidity and Capital Resources**

We believe that we have sufficient cash to continue to fund our sales and marketing expenses at current levels, planned research and development activities for our Levulan<sup>®</sup> PDT/PD platform, and to fund operations and capital expenditures for the next two years. We have invested our funds in liquid investments, so that we will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis. At December 31, 2006, we had approximately \$18,210,000 of total liquid assets, comprised of \$3,267,000 of cash and cash equivalents and marketable securities available-for-sale totaling \$14,943,000. As of December 31, 2006, these securities had yields ranging from 2.59% to 5.74% and maturity dates ranging from January 2007 to September 2010. Our net cash used in operations for the year ended December 31, 2006 was \$8,727,000, versus \$14,101,000 used in the year ended December 31, 2005. The year over year decrease is directly attributable to the growth in our PDT segment products, as well as the addition of the Non-PDT Drug Products acquired in the Sirius merger. With the lifting of the preliminary injunction in the River s Edge case, we expect that Nicomide<sup>®</sup> sales will decrease significantly during the litigation process. If we do not ultimately prevail in our lawsuit, or if the Nicomide<sup>®</sup> patent is found to be invalid, revenues from sales of Nicomide<sup>®</sup> will decrease permanently. We expect to eliminate some expenses planned for 2007 and reallocate others to provide more support to Levulan<sup>®</sup> and our new product, ClindaReach. With the launch of ClindaReach, we will incur increased marketing expenses and make a milestone payment in the amount of \$500,000 to the former Sirius shareholders. If our cash flows from operations do not continue to improve, we may need to consider either reducing our operating expenses or raising additional capital to fund our operations.

As of December 31, 2006, working capital (total current assets minus total current liabilities) was \$18,085,000, as compared to \$34,889,000 as of December 31, 2005. Total current assets decreased by \$14.7 million during the year

ended December 31, 2006, due primarily to \$9.3 million spent on the

**Table of Contents**

acquisition of Sirius, including \$1.8 million of acquisition costs, as well as the continued funding of our operating loss. Total current liabilities increased by \$2.1 million during the same period due primarily to an increase in accrued expenses and accrued compensation, offset in part by decreases in accounts payable and deferred revenue.

As stated above, we acquired all of the outstanding common stock of Sirius in March 2006 in exchange for 2,396,245 shares of DUSA common stock and cash. At closing, we paid \$8.0 million less certain expenses, in cash, and 1,973,353 shares of DUSA's common stock, no par value per share to the shareholders of Sirius and issued an additional 422,892 shares to an escrow agent to be held for up to two years subject to certain indemnification provisions of the Merger Agreement. See Note 3 to the Notes to the Condensed Consolidated Financial Statements for the effect of purchase method accounting on the value of the acquisition. We have agreed to pay additional consideration in future periods, based upon the attainment of defined operating objectives, including new product approvals or launches and the achievement of pre-determined total cumulative sales milestones for the Sirius products. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments which may be paid in cash or DUSA shares, as DUSA may determine, are, as follows:

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

In addition, there are three milestones related to new product approvals and/or launches each in the amount of \$500,000 per milestone, or \$1.5 million in the aggregate, that will be paid in cash if the milestones are achieved.

We expect that any such payments will result in increases in goodwill at the time of the payment. As of December 31, 2006 none of these milestones had been achieved. However, we expect that one of the new product milestones will be paid in 2007 with the launch of ClindaReach.

We are actively seeking to further expand or enhance our business by using our resources to acquire by license, purchase or other arrangements, additional businesses, new technologies, or products in the field of dermatology. For 2007, we are focusing primarily on increasing the sales of the Levulan<sup>®</sup> Kerastick<sup>®</sup> and the BLU-U<sup>®</sup>, as well as the Non Photodynamic Therapy Drug Products, advancing our Phase II study for use of Levulan<sup>®</sup> PDT in acne, and continuing to pursue our product development pipeline.

DUSA has no off-balance sheet financing arrangements.

**Table of Contents**

**Contractual Obligations and Other Commercial Commitments**

***ALTANA, INC.***

In September 2005, the former Sirius entered into a development and product license agreement with Altana, Inc. relating to a reformulated dermatology product. The agreement was assigned to us by virtue of the Sirius merger. According to the agreement, we will pay for all development costs. Should development efforts be successful, Altana will manufacture the product for us and we will be obligated to pay royalties, including certain minimum royalties on net sales of the product. The agreement expires six years after the first commercial sale of the product.

***ACTAVIS TOTOWA, LLC***

Under an agreement dated May 18, 2001, and amended on February 8, 2006, the former Sirius entered into an arrangement for the supply of Nicomide<sup>®</sup> with Amide Pharmaceuticals, Inc., now known as Actavis Totowa, LLC. The agreement was assigned to us as part of the Sirius merger. Currently, Actavis Totowa supplies all of our requirements; however, we have the right to use a second source for a significant portion of our needs if we choose to do so. The agreement expires on February 8, 2009. Actavis Totowa has received several warning letters from the FDA regarding certain regulatory observations. To our knowledge, the primary observations noted in the warning letters were not related to Nicomide. However, with respect to Nicomide<sup>®</sup> and certain other products manufactured by Actavis Totowa that would be covered under FDA's recent compliance policy guide entitled, "Marketed New Drugs without Approved NDAs or ANDAs", the FDA requested that the manufacturer provide a copy of the labeling and information providing the basis for an exemption from the drug approval requirements. The FDA may take further action against Actavis Totowa and DUSA is evaluating its options in order to maintain supply of Nicomide<sup>®</sup>.

***HARMONY LABS, INC.***

Under an agreement dated September 18, 2001, and amended on February 16, 2006 and March 10, 2006, the former Sirius entered into an arrangement for the manufacturing and supply of the AVAR<sup>®</sup> line of products and Nicomide-T<sup>®</sup> with Harmony Labs, Inc. The agreement was assigned to us as part of the Sirius merger. Currently, Harmony supplies all of our requirements, however, we have the right to use a second source for a significant portion of our needs if we choose to do so. The agreement expires on February 16, 2009.

***L. PERRIGO COMPANY***

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

***WINSTON LABORATORIES, INC.***

On or about January 30, 2006 Winston Laboratories, Inc., or Winston, and the former Sirius entered into a license agreement relating to a Sirius product, Psoriatec<sup>®</sup> (known by Winston as Micanol) revising a former agreement. Winston Laboratories, Inc. is controlled by Dr. Joel Bernstein, a principal shareholder of the former Sirius. This agreement was assigned to us as part of the Sirius merger. The 2006



**Table of Contents**

agreement grants an exclusive license, with limitation on rights to sublicense, to all property rights, including all intellectual property and improvements, owned or controlled by Winston to manufacture, sell and distribute products containing anthralin, in the United States. We will pay royalties on net sales of the product, and certain minimum royalties are due each year to maintain the license. We have an option to purchase the product from Winston at certain times during the two-year term of the agreement. The agreement is due to expire on January 31, 2008, subject to rights to extend or terminate the agreement earlier. Minimum royalties to Winston are \$300,000 per year ending January 31, 2008.

***PARTEQ AGREEMENT***

The Company licenses certain patents underlying its Levulan® PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations, or PARTEQ, the licensing arm of Queen's University, Kingston, Ontario. Under the agreement, the Company has been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell certain products, including ALA. The agreement covers certain use patent rights. When the Company is selling its products directly, it has agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where the Company has a sublicensee, it will pay 6% and 4% when patent rights do and do not exist, respectively, on its net selling price less the cost of goods for products sold to the sublicensee, and 6% of payments the Company receives on sales of products by the sublicensee.

For the years ended December 31, 2006, 2005 and 2004, actual royalties based on product sales were approximately \$522,000, \$340,000, and \$229,000, respectively. Annual minimum royalties to PARTEQ must total at least CDN \$100,000 (U.S. \$86,000 as of December 31, 2006).

The Company is also obligated to pay to PARTEQ 5% of any lump sum sublicense fees received, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts. While no amounts were due in 2006 to PARTEQ as a result of sublicense fees received, we will pay PARTEQ its share of fees received in March, 2007.

***LICENSE AND SUPPLY AGREEMENTS***

In December 2002, DUSA entered into a License and Development Agreement with photonamic GmbH & Co. KG, a subsidiary of medac GmbH, a German pharmaceutical company, and a supply agreement with medac. These agreements provide for the licensing to DUSA of photonamic's proprietary technology related to ALA for systemic dosing in the field of brain cancer. Since we do not believe that the results from medac's European Phase III clinical study will be acceptable to the FDA and we do not intend to conduct additional clinical trials in the brain cancer field, we are renegotiating this agreement.

***AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT***

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

**Table of Contents****DRAXIS TERMINATION AND TRANSFER AGREEMENT**

On February 24, 2004, the Company reacquired the rights to the aminolevulinic acid (Levulan®) technology for Canada held by Draxis Health Inc. ( Draxis ). These rights were initially assigned to Draxis in 1991. The Company and Draxis terminated the assignment and DUSA agreed to pay to Draxis an upfront fee of \$150,000 CDN (\$114,000 USD at February 24, 2004) and a 10% royalty on sales of the Levulan® Kerastick® in Canada over a five year term commencing in June 2004 based on the first Kerastick® sale in Canada by Coherent, our Canadian marketing and distribution partner. The Company incurred total royalty expense of \$ 138,000, 116,000 and \$56,000 in 2006, 2005 and 2004, respectively, which has been recorded in cost of product sales and royalties.

**LEASE AGREEMENTS**

The Company has entered into lease commitments for office space in Wilmington, Massachusetts, Valhalla, New York, and Toronto, Ontario. These leases generally have five or ten year terms. The minimum lease payments disclosed below include the non-cancelable terms of the leases.

**RESEARCH AGREEMENTS**

The Company has entered into various agreements for research projects and clinical studies. As of December 31, 2006, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately \$1,674,000. Included in this future payment is a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years, with annual renewal periods thereafter, to engage Therapeutics to manage the clinical development of the Company's products in the field of dermatology. The agreement was renewed on June 15, 2006 for a one year period. Therapeutics is entitled to receive a bonus valued at \$50,000, in cash or stock at the Company's discretion, upon each anniversary of the effective date. Therapeutics has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000 depending on the regulatory phase of development of products during Therapeutics' management.

Our contractual obligations and other commercial commitments to make future payments under contracts, including lease agreements, research and development contracts, manufacturing contracts, or other related agreements, are as follows at December 31, 2006:

	Total	1 Yr or less	2-3 Years	4-5 Years	After 5
Operating lease obligations	\$2,722,000	\$ 654,000	\$ 871,000	\$ 932,000	\$265,000
Purchase obligations (1,2)	3,974,000	3,406,000	568,000		
Minimum royalty obligations	1,906,000	636,000	697,000	422,000	151,000
Total obligations	\$8,602,000	\$4,696,000	\$2,136,000	\$1,354,000	\$416,000

- 1) Research and development projects include various commitments including obligations for our Phase II clinical study for moderate to severe acne.
- 2) In addition to the obligations disclosed above,

we have contracted with Therapeutics, Inc., a clinical research organization, to manage the clinical development of our products in the field of dermatology.

This organization has the opportunity for additional stock grants, bonuses, and other incentives for each product indication ranging from \$250,000 to \$1,250,000, depending on the regulatory phase of development of products under Therapeutics management.

- 3) Minimum royalty obligations relate to our agreements with PARTEQ, Winston and Perrigo described above.

**Table of Contents**

Rent expense incurred under these operating leases was approximately \$477,000, \$477,000, and \$472,000 for the years ended December 31, 2006, 2005, and 2004, respectively.

**Recently Issued Accounting Guidance**

In June 2006, the FASB issued Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes. The interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken, in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties accounting in interim periods, disclosure and transition. The interpretation is effective for fiscal years beginning after December 15, 2006. The Company is in the process of determining the effects that adoption of FIN 48 will have on the Company's financial position, cash flows, results of operations and financial statement disclosures.

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

In September 2006, the SEC staff published SAB 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SAB is effective for fiscal years ending after November 15, 2006. Application of this SAB has not altered previous conclusions and has not impacted the Company's financial position, results of operations or cash flows.

In February 2007 the FASB issued Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS No. 159). SFAS No. 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. This Statement is effective for fiscal years beginning after November 15, 2007. We have not decided if we will early adopt SFAS 159 or if we will choose to measure any eligible financial assets and liabilities at fair value.

**Inflation**

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

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our investments consist of United States government

**Table of Contents**

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

As of December 31, 2006, the weighted average rate of return on our investments was 2.91%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of December 31, 2006, the fair market value of the portfolio would decline by \$63,000. Declines in interest rates could, over time, reduce our interest income.

**Forward-Looking Statements Safe Harbor**

This report, including the Management's Discussion and Analysis, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 21E of the Securities Exchange Act of 1934 which represent our expectations or beliefs concerning future events, including, but not limited to management's goal of becoming profitable, statements regarding our strategies and core objectives for 2007, our expectations regarding our proposed merger with Sirius Laboratories, Inc. and matters relating thereto, our expectations concerning the introduction of generic substitutes for Nicamide<sup>®</sup> and such products' impact on sales of Nicamide<sup>®</sup>, our expectations with respect to the River's Edge litigation and the patent reexamination process, management's beliefs regarding the unique nature of Levulan<sup>®</sup> and its use and potential use, expectations regarding the timing of results of clinical trials, future development of Levulan<sup>®</sup> and our other products for cancer, warts, onychomycosis, psoriasis, molluscum contagiosum, oily skin and acne rosacea, facial photodamaged skin, cystic acne, acne vulgaris, Barrett's esophagus, high-grade dysplasia, infected sweat glands (hidradenitis suppurativa) and other potential indications, intention to pursue licensing, marketing, co-promotion, collaboration or acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy and marketing, our intention to develop combination drug and light device systems, our expectations regarding new proprietary endoscopic light delivery systems and the potential use of other light devices, our beliefs regarding the safety, simplicity, reliability and cost-effectiveness of certain light sources, our expectations surrounding the launch of ClindaReach<sup>®</sup> and regarding other product launches in Brazil, Mexico, Korea and other territories, hope that our products will be an AK therapy of choice and barriers to achieving that status, our beliefs regarding revenues and market opportunities from approved and potential products and Levulan<sup>®</sup>'s competitive properties, our intention to postpone or commence clinical trials and investigator studies in 2007, our plans to eliminate certain expenses for the coming year and reallocate others, beliefs regarding the clinical benefit of Levulan<sup>®</sup> PDT for acne and other indications, beliefs regarding the suitability of clinical data, expectations of exclusivity under the Hatch-Waxman Act and other patent laws and the potential benefits thereof, expectations regarding the confidentiality of our proprietary information, intentions to seek additional U.S. and foreign regulatory approvals, trademarks, and to market and increase sales outside the U.S., beliefs regarding regulatory classifications, filings, timelines, off-label use and environmental compliance, beliefs concerning patent disputes and litigation, the impact of a third-party's regulatory compliance and fulfillment of contractual obligations, and our anticipation that third parties will launch products upon receipt of regulatory approval, expectations of increases in cost of product sales, expectations regarding margins on Kerastick<sup>®</sup> and other products, estimations as to the time it takes for a sales representative to break even in comparison to DUSA's investment, expected use of cash resources in 2007, requirements of cash resources for our future liquidity, beliefs regarding investments and economic conditions, beliefs regarding accounting policies and practices, expectations regarding outstanding options and warrants and our dividend policy, anticipation of increases or decreases in personnel, effect of reimbursement policies on revenues and acceptance of our therapies, expectations for future strategic opportunities and research and development programs, expectations for continuing operating losses and competition, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding the status of research and development costs and our efforts with respect thereto, expectations regarding increased sales and marketing costs, levels of

**Table of Contents**

interest income and our capital resource needs, intention to sell securities to meet capital requirements, potential for additional inspection and testing of our manufacturing facilities, beliefs regarding the adequacy of our inventory of Kerastick® and BLU-U® units, our manufacturing capabilities and the impact of inventories on revenues, belief regarding interest rate risks to our investments and effects of inflation and new and existing accounting standards and policies, beliefs regarding the impact of any current or future legal proceedings, dependence on key personnel, beliefs concerning product liability insurance, intention to continue to develop an integrated drug and light device system, our principal methods of competition, competition in general and competitive developments. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the reimbursement by third-parties for our treatments, the impact of competitive products and pricing, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, environmental risks relating to our products, reliance on third-parties for the production, manufacture, sales and marketing of our products, the availability of products for acquisition and/or license on terms agreeable to DUSA, sufficient sources of funds, the securities regulatory process, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statements of Shareholders' Equity	F-4
Consolidated Statements of Cash Flows	F-5
Notes to the Consolidated Financial Statements	F-7

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures.* We carried out an evaluation, under the direction of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2006.

*Changes In Internal Control Over Financial Reporting.* Except for the integration of Sirius, whose financial statements constitute (1.4) percent and 9.7 percent of net assets and total assets, respectively, and 37% of total 2006 revenues, into the Company's internal control structure, the Chief Executive Officer and Chief Financial Officer have concluded that there have been no changes in the Company's internal control over financial reporting as of December 31, 2006 and during the year ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The Company considers the acquisition of Sirius to be material to its results of operations, financial position and cash flows.

**Table of Contents**

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control – Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2006.

Management excluded from its assessment the internal control over financial reporting at Sirius which was acquired on March 10, 2006 and whose financial statements constitute 1.4 percent and 9.7 percent of net assets and total assets, respectively, and 37% of revenues of the consolidated financial statement amounts as of and for the year ended December 31, 2006.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
DUSA Pharmaceuticals, Inc.  
Wilmington, Massachusetts

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that DUSA Pharmaceuticals, Inc. and its subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management's Report on Internal Control Over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Sirius Laboratories, Inc. (Sirius), which was acquired on March 10, 2006 and whose financial statements constitute 1.4 percent and 9.7 percent of net assets and total assets, respectively, and 37 percent of revenues of the consolidated financial statement amounts as of and for the year ended December 31, 2006. Accordingly, our audit did not include the internal control over financial reporting at Sirius. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating

**Table of Contents**

effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2006 of the Company and our report dated March 16, 2007 expressed an unqualified opinion on those financial statements and includes an explanatory paragraph relating to the change in method of accounting for share-based payments upon the adoption of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, effective January 1, 2006.

/s/ DELOITTE & TOUCHE LLP  
Boston, Massachusetts  
March 16, 2007



**Table of Contents**

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

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

The information required by Item 10 is hereby incorporated by reference to the sections entitled Nominees, Executive Officers who are not Directors, Compliance with Section 16(a) of the Exchange Act of the Registrant's 2007 Proxy Statement, Meetings and Committees of the Board, and Code of Ethics Applicable to Senior Officers.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by Item 11 is hereby incorporated by reference to the sections entitled Director Compensation, Executive Compensation, Summary Compensation Table, Grants of Plan-Based Awards, Outstanding Equity Awards at Fiscal Year-End, Option Exercises and Stock Vested, NonQualified Deferred Compensation, Compensation Discussion and Analysis, Board Compensation Committee Report, of Registrant's 2007 Proxy Statement.

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

The information required by Item 12 is hereby incorporated by reference to the section entitled Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters and Equity Compensation Plan Information of the Registrant's 2007 Proxy Statement.

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

The information required by Item 13 is hereby incorporated by reference to the section entitled Certain Relationships and Related Transactions and Meetings and Committees of the Board of the Registrant's 2007 Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by Item 14 is hereby incorporated by reference to the section entitled Ratification and Selection of Auditors of the Registrant's 2007 Proxy Statement.

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

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

Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statements of Shareholders' Equity	F-4
Consolidated Statements of Cash Flows	F-5
Notes to the Consolidated Financial Statements	F-7

**Table of Contents**

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

- 2(a.1)\* Merger Agreement by and among the Company, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005; and
- 2(a.2) First Amendment to Merger Agreement by and among the Company, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006.
- 3(a.1) Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference;
- 3(a.2) Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002 and is incorporated herein by reference; and
- 3(b) By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on March 27, 2006, and is incorporated herein by reference.
- 4(a) Common Stock specimen, filed as Exhibit 4(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2002, and is incorporated herein by reference;
- 4(b) Form of D. Geoffrey Shulman's Class B Warrant;
- 4(c) Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K dated September 27, 2002, filed October 11, 2002, and is incorporated herein by reference; and
- 4(d) Rights Certificate relating to the rights granted to holders of common stock under the Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K, dated September 27, 2002, filed October 11, 2002, and is incorporated herein by reference;
- 10(a) License Agreement between the Company, PARTEQ and Draxis Health Inc. dated August 27, 1991, filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
- 10(b) ALA Assignment Agreement between the Company, PARTEQ, and Draxis Health Inc. dated October 7, 1991, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
- 10(b.1) Amended and Restated Assignment Agreement between the Company and Draxis Health, Inc. dated April 16, 1999, filed as Exhibit 10(b.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
- 10(b.2) Termination and Transfer Agreement between the Company and Draxis Health Inc. dated as of February 24, 2004, filed as Exhibit 10(b.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2003, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(c)

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

**Table of Contents**

- 10(d,1) Amendment to Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated April 14, 1994, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-2, No. 33-98030, and is incorporated herein by reference; +
- 10(d.2) Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated March 20, 1997 +
- 10(e) Amended and Restated License Agreement between the Company and PARTEQ dated March 11, 1998, filed as Exhibit 10(e) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of Exhibit A have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(f) Incentive Stock Option Plan, filed as Exhibit 10.11 of Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference; +
- 10(g) 1994 Restricted Stock Option Plan, filed as Exhibit 1 to Registrant's Schedule 14A definitive Proxy Statement dated April 26, 1995, and is incorporated herein by reference; +
- 10(h) 1996 Omnibus Plan, as amended, filed as Appendix A to Registrant's Schedule 14A Definitive Proxy Statement dated April 26, 2001, and is incorporated herein by reference; +
- 10(h.1) 1996 Omnibus Plan, as amended on May 1, 2003, filed as Exhibit 10(h.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference; +
- 10(h.2) 1996 Omnibus Plan, as amended April 23, 2004, filed as Appendix A to Registrant's Schedule 14A definitive Proxy Statement dated April 28, 2004, and is incorporated herein by reference; +
- 10(i) Purchase and Supply Agreement between the Company and National Biological Corporation dated November 5, 1998, filed as Exhibit 10(i) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(i.1) Amended and Restated Purchase and Supply Agreement between the Company and National Biological Corporation dated as of June 21, 2004 filed as Exhibit 10(a) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed August 11, 2004, and is incorporated herein by reference;
- 10(j) Supply Agreement between the Company and Sochinaz SA dated December 24, 1993, filed as Exhibit 10(q) to Registrant's Form 10-K/A filed on March 21, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(j.1) First Amendment to Supply Agreement between the Company and Sochinaz SA dated July 7, 1994, filed as Exhibit 10(q.1) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;

**Table of Contents**

- 10(j.2) Second Amendment to Supply Agreement between the Company and Sochinaz SA dated as of June 20, 2000, filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K dated June 28, 2000, and is incorporated herein by reference;
- 10(j.3) Third Amendment to Supply Agreement between the Company and Sochinaz SA dated July 29, 2005, filed as Exhibit 10.1 to the Registrant's Form 10-Q filed on August 3, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(k) Master Service Agreement between the Company and Therapeutics, Inc. dated as of October 4, 2001, filed as Exhibit 10(b) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference;
- 10(l) License and Development Agreement between the Company and photonamic GmbH & Co. KG dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference;
- 10(m) Supply Agreement between the Company and medac GmbH dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference;
- 10(n) Securities Purchase Agreement dated as of February 27, 2004, by and among the Company and certain investors, filed as Exhibit 10.1 to the Registrant's current report on Form 8-K, filed on March 2, 2004, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(o) Registration Rights Agreement dated as of February 27, 2004 by and among the Company and certain investors, filed as Exhibit 10.2 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
- 10(p) Form of Additional Investment Right dated as of February 27, 2004, filed as Exhibit 10.3 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
- 10(q) License, Promotion, Distribution and Supply Agreement between the Company and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;
- 10(r) Employment Agreement of Scott L. Lundahl dated as of June 23, 1999 filed as Exhibit 10(u) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +

**Table of Contents**

- 10(s) Amended Employment Agreement of Stuart L. Marcus, MD, PhD dated December 9, 1999 filed as Exhibit 10(v) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(t) Employment Agreement of Mark C. Carota dated as of February 14, 2000 filed as Exhibit 10(w.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(t.1) First Amendment to Employment Agreement of Mark C. Carota dated October 31, 2001 filed as Exhibit 10(w.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(u) Amendment to Employment Agreement of Richard Christopher dated as of October 18, 2006 filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended September 30, 2004, and is incorporated herein by reference;
- 10(v) Employment Agreement of Richard Christopher dated as of January 1, 2004 filed as Exhibit 10(y) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(w) Employment Agreement of Robert F. Doman dated as of March 15, 2005 filed as Exhibit 10(z) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(x) Employment Agreement of Gary F. Talarico dated as of February 15, 2005 filed as Exhibit 10(aa) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y) Severance Agreement and General Release between the Company and Peter Chakoutis dated as of February 25, 2005 filed as Exhibit 10(bb) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y.1) Final Agreement and General Release, between the Company and Peter Chakoutis, dated as of April 4, 2005, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 4, 2005, and is incorporated herein by reference; +
- 10(z) Compensation Policy Applicable to the Company's Non-Employee Directors filed as Exhibit 10(cc) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; and +
- 10(aa) Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated May 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and is incorporated herein by reference;
- 10(bb) Amendment and Extension of the Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and is incorporated herein by reference;



**Table of Contents**

- 10(cc) Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, and is incorporated herein by reference;
- 10(dd) Amendment and Extension of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.D to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(ee) Second Amendment of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.E to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(ff) Supply Agreement between Sirius Laboratories, Inc. and L. Perrigo Company dated October 21, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.F to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(gg) 2006 Micanol License Agreement between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.G to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference; and
- 10(hh) Development, License and Supply Agreement between Sirius Laboratories, Inc. and Altana Inc. dated June 13, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, and as filed as Exhibit 10.H to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference.
- 10(ii) Employment Agreement of William O Dell dated as of April 4, 2006;
- 10(jj) Patent License Agreement between the Company and PhotoCure ASA, dated as of May 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended and filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended June 30, 2006, and is incorporated herein by reference;
- 10(kk) Separation Agreement between the Company and Paul Sowyrda, dated as of August 31, 2006;
- 10(ll) Employment Agreement of Michael Todisco dated as of September 20, 2006; and
- 10(mm) Marketing, Distribution and Supply Agreement between the Company, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Company dated January 4, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the





**Table of Contents**

10(nn)	First Amendment to Marketing, Distribution and Supply Agreement between the Company, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Company dated January 10, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended.
10(oo)	DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, filed as Appendix A to Registrant's Schedule 14A definitive Proxy Statement dated April 24, 2006, and is incorporated herein by reference; +
10(pp)	DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, as amended October 18, 2006; +
10(qq)	DUSA Pharmaceuticals, Inc. 2006 Deferred Compensation Plan, October 18, 2006; +
14(a)	Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers, filed as Exhibit 14(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference.
21(a)	Subsidiaries of the Registrant.
23(a)	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
31(a)	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer; and
31(b)	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
32(a)	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
32(b)	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99	Press Release dated March 16, 2007
+ Management contract or compensatory plan or arrangement.	
* Schedules and exhibits omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a	

copy of any  
omitted schedule  
or exhibit to the  
Commission  
upon request.

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of  
DUSA Pharmaceuticals, Inc.  
Wilmington, Massachusetts

We have audited the accompanying consolidated balance sheets of DUSA Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2006 and 2005, and the related consolidated statements of income, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of DUSA Pharmaceuticals, Inc. and subsidiaries as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

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

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ *DELOITTE & TOUCHE LLP*

Boston, Massachusetts

March 16, 2007

F-1

---

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

	DECEMBER 31,	
	2006	2005
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 3,267,071	\$ 4,210,675
Marketable securities	14,943,196	30,579,486
Accrued interest receivable	158,374	353,449
Accounts receivable, net	2,060,565	373,130
Inventory	2,343,472	1,860,793
Deferred acquisition costs		831,875
Prepaid and other current assets	1,535,819	776,293
<b>TOTAL CURRENT ASSETS</b>	<b>24,308,497</b>	<b>38,985,701</b>
Restricted cash	162,805	144,541
Property, plant and equipment, net	2,567,286	2,971,869
Goodwill	5,772,505	
Deferred charges and other assets	944,720	228,520
<b>TOTAL ASSETS</b>	<b>\$ 33,755,813</b>	<b>\$ 42,330,631</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 649,523	\$ 934,694
Accrued compensation	1,674,470	1,071,677
Other accrued expenses	3,841,891	1,995,679
Deferred revenue	57,270	94,283
<b>TOTAL CURRENT LIABILITIES</b>	<b>6,223,154</b>	<b>4,096,333</b>
Other liabilities	1,199,086	205,570
<b>TOTAL LIABILITIES</b>	<b>7,422,240</b>	<b>4,301,903</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
(NOTE 15)		
<b>SHAREHOLDERS EQUITY</b>		
Capital Stock		
Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 19,480,067 and 17,041,197 shares of common stock, no par, at December 31, 2006 and December 31, 2005, respectively		
	142,959,298	125,626,163

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Additional paid-in capital	4,320,625	2,035,783
Accumulated deficit	(120,886,977)	(89,537,470)
Accumulated other comprehensive loss	(59,373)	(95,748)
<b>TOTAL SHAREHOLDERS EQUITY</b>	<b>26,333,573</b>	<b>38,028,728</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS EQUITY</b>	<b>\$ 33,755,813</b>	<b>\$ 42,330,631</b>

See the accompanying Notes to the Consolidated Financial Statements.

F-2

---

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

	YEAR ENDED DECEMBER 31,		
	2006	2005	2004
Product Revenues	\$ 25,582,986	\$ 11,337,461	\$ 7,987,656
Cost of Product Revenues			
Cost of Product Revenues and Royalties	10,369,957	6,213,601	3,875,018
Impairment of Intangible Assets	15,746,032		
Total Cost of Product Revenues	26,115,989	6,213,601	3,875,018
GROSS MARGIN	(533,003)	5,123,860	4,112,638
Operating Costs			
Research and Development	6,213,851	5,587,599	6,489,723
In-process Research and Development	1,600,000		
Marketing and Sales	12,644,654	9,068,984	7,622,106
General and Administrative	11,195,726	6,703,047	7,209,536
Restructuring		150,917	
TOTAL OPERATING COSTS	31,654,231	21,510,547	21,321,365
LOSS FROM OPERATIONS	(32,187,234)	(16,386,687)	(17,208,727)
Other income	837,727	1,387,978	1,579,747
NET LOSS	\$(31,349,507)	\$(14,998,709)	\$(15,628,980)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (1.65)	\$ (0.89)	\$ (0.96)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	19,006,609	16,932,138	16,317,078

See the accompanying Notes to the Consolidated Financial Statements.

F-3

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

	Common Stock		Additional	Accumulated	Accumulated	
	Number of	Amount	Paid-in	Deficit	Other	Total
	Shares		Capital		Comprehensive	
					Income	
					(Loss)	
Balance, JANUARY 1, 2004	13,966,247	\$ 95,670,554	\$ 2,015,586	\$ (58,909,781)	\$ 1,455,690	\$ 40,322,056
Comprehensive loss:						
Realized loss on marketable securities available-for-sale				(15,628,980)	(1,124,309)	(16,753,289)
Comprehensive loss						(16,753,289)
Issuance of common stock for cash through a private offering, net of total offering costs of \$1,907,952 including shares issued to placement agent	2,742,750	28,262,298				28,262,298
Issuance of options	167,825	765,207				765,207
Issuance of options to consultants			240,753			240,753
Reversal of options issued to consultants			(240,000)			(240,000)
Balance, DECEMBER 31, 2004	16,876,822	\$ 124,698,059	\$ 2,016,339	\$ (74,538,761)	\$ 331,381	\$ 52,266,758
Comprehensive loss:						
Realized loss on marketable securities available-for-sale				(14,998,709)	(427,129)	(15,425,838)
Comprehensive loss						(15,425,838)
Issuance of options	164,375	928,104				928,104
Acceleration of vesting of stock options (see Note 11)			19,444			19,444
Balance, DECEMBER 31, 2005	17,041,197	125,626,163	2,035,783	(89,537,470)	(95,748)	38,018,728
Comprehensive loss:						
Realized gain on marketable securities available-for-sale				(31,349,507)	36,375	(31,313,132)
Comprehensive loss						(31,313,132)
Issuance of common stock upon acquisition of Sirius Pharmaceuticals, Inc.	2,396,245	17,203,449				17,203,449
Issuance of restricted compensation expense			2,284,842			2,284,842
Issuance of options	42,625	129,686				129,686
Balance, DECEMBER 31, 2006	19,480,067	\$ 142,959,298	\$ 4,320,625	\$ (120,886,977)	\$ (59,373)	\$ 26,133,623

See the accompanying Notes to the Consolidated Financial Statements.





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

	YEAR ENDED DECEMBER 31,		
	2006	2005	2004
<b>CASH FLOWS USED IN OPERATING ACTIVITIES</b>			
Net loss	\$(31,349,507)	\$(14,998,709)	\$(15,628,980)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of premiums and accretion of discounts on marketable securities available-for-sale	35,167	416,550	225,614
Realized gain on sale of marketable securities, available-for-sale	(14,015)	(74,512)	
Stock-based compensation	2,284,842	19,444	240,753
In-process research and development charge	1,600,000		
Depreciation and amortization	3,908,532	925,185	1,299,308
Impairment of intangible assets	15,746,032		
Changes in other assets and liabilities impacting cash flows from operations (net of impact of acquisition):			
Accrued interest receivable	195,076	288,348	(108,001)
Accounts receivable	24,732	337,886	(481,533)
Inventory	(263,857)	(443,632)	(704,329)
Prepaid and other current assets	(802,000)	(729,537)	169,518
Deferred charges and other assets	(781,148)		(276,256)
Accounts payable	(888,001)	77,426	(2,014)
Accrued compensation and other accrued expenses	620,779	201,907	906,691
Deferred royalty payments received	999,985	(136,432)	100,815
Deferred royalty revenues recognized	(43,913)		
Other liabilities	431	15,131	190,439
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(8,726,865)</b>	<b>(14,100,945)</b>	<b>(14,067,975)</b>
<b>CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>			
Cash paid for acquisition, net of cash received	(7,767,006)		
Purchases of marketable securities	(9,619,879)	(58,850,356)	(58,858,323)
Proceeds from maturities and sales of marketable securities	25,271,393	73,724,674	44,821,212
Restricted cash	(18,264)	(3,777)	(1,551)
Purchases of property, plant and equipment	(212,669)	(415,168)	(529,707)
Repurchase of options issued to consultants			(240,000)
<b>NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>	<b>7,653,575</b>	<b>14,455,373</b>	<b>(14,808,369)</b>

CASH FLOWS PROVIDED BY FINANCING  
ACTIVITIES

Issuance of common stock (net of stock offering costs of \$200,202)			28,262,298
Payment of long-term debt			(1,517,500)
Proceeds from exercise of options	129,686	928,104	765,207

NET CASH PROVIDED BY FINANCING  
ACTIVITIES

129,686	928,104	27,510,005
---------	---------	------------

F-5

---

**Table of Contents**

	YEAR ENDED DECEMBER 31,		
	2006	2005	2004
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(943,604)	1,282,532	(1,366,339)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	\$4,210,675	\$2,928,143	\$ 4,294,482

See the accompanying Notes to the Consolidated Financial Statements.

F-6

---

**Table of Contents****DUSA PHARMACEUTICALS, INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2006, 2005, AND 2004****1) NATURE OF BUSINESS**

DUSA Pharmaceuticals, Inc. ( DUSA or the Company ) is a dermatology company that is developing and marketing Levulan photodynamic therapy and other products for common skin conditions. The Company's marketed products include Levulan® Kerastick® 20% Topical Solution with PDT, the BLU-U® brand light source, Nicamide®, Nicamide-T® and the AVAR® line of products. The Company acquired Nicamide®, Nicamide-T®, the AVAR® line of products, among others, and certain product candidates in early stages of development, which target the treatment of acne vulgaris and acne rosacea, as well as psoriasis, in connection with its recent merger with Sirius Laboratories, Inc., or Sirius, which was completed on March 10, 2006. The Company is also continuing to seek to acquire and/or license additional dermatology products that complement its current product portfolio that would provide its sales force with additional complementary products to sell in the near to medium term.

The Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® brand light source were launched in the United States of America, or U.S., in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003 we received clearance from the U.S. Food and Drug Administration, or FDA, to market the BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

Nicamide® is an oral prescription vitamin supplement, and Nicamide-T® is a topical cosmetic product. Both products target the acne and acne rosacea markets. Acne is a common skin condition caused, in part, by the blockage and/or inflammation of sebaceous (oil) glands. Acne rosacea is a condition that primarily affects the skin of the face and typically first appears between the ages of 30 and 60 as a transient flushing or blushing on the nose, cheeks, chin or forehead, progressing in many patients to a papulopustular form clinically similar to acne vulgaris (inflammatory acne). Given its resemblance to inflammatory acne, and the general public's limited knowledge of rosacea, the condition is frequently mistaken by patients as adult acne. If untreated, rosacea has the tendency to worsen over time, although it can also wax and wane. The AVAR line of products includes a number of leave-on and cleanser formulations of sodium sulfacetamide and sulphur, a drug combination long known to have anti-acne, anti-inflammatory properties.

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

On March 7, 2007, a preliminary injunction, which had been in place since May 12, 2006 and which had previously enjoined a competitor from marketing a generic substitute for Nicamide®, was dissolved by the United States District Court of New Jersey. As a result of this dissolution, and its expected adverse impact on the Company's projected revenues, results of operations and cash flows, the Company has recorded an impairment charge in 2006 of approximately \$15.7 million. With the lifting of the preliminary injunction, the Company expects sales of Nicamide to decrease significantly during the litigation process. If the Company does not ultimately prevail in its lawsuit, or if the Nicamide® patent is found to be invalid, the Company's revenues from the sales of Nicamide® will decrease permanently. In response to the lifting of the preliminary injunction we expect to eliminate some costs planned for 2007 and reallocate other costs to provide more support for the PDT business segment and for our new product, ClindaReach . The Company believes it has sufficient liquidity to

continue to fund its planned activities for the next twelve months.

F-7

---

**Table of Contents**

**2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**a) Principles of Consolidation** - The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, DUSA Pharmaceuticals New York, Inc. and Sirius Laboratories, Inc. All intercompany balances and transactions have been eliminated in consolidation.

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

**c) Cash and Cash Equivalents** - Cash equivalents include short-term highly liquid money market funds. All other investments are classified as marketable securities. In December 2001, the Company executed a short-term, renewable, irrevocable and unconditional letter of credit in lieu of a security deposit for the Company's Kerastick® manufacturing facility at its Wilmington, Massachusetts location. The cash in support of the letter of credit is held in a separate bank account and is recorded as restricted cash in the Consolidated Balance Sheets. At December 31, 2006, the amount of the letter of credit was \$158,000, and the restricted cash balance was \$163,000.

**d) Marketable Securities** - The Company classifies all investment securities as available-for-sale and records such investments at fair market value. Unrealized gains and losses on available-for-sale securities are recorded as accumulated other comprehensive income (loss) as a separate component of shareholders' equity. The premiums and discounts recorded on the purchase of securities are amortized into interest income over the life of the securities. As the Company's marketable securities are available to fund operations and as management expects to sell a portion of its marketable securities in the next fiscal year in order to meet its working capital requirements, all marketable securities are classified as current assets.

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

**f) Deferred Acquisition Costs** - Deferred acquisition costs are direct costs incurred by the Company through December 31, 2005, related to the Sirius acquisition (see Note 3). Upon the closing of the Sirius acquisition, such amounts were included in the acquisition.

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

**h) Valuation of Long-Lived Assets** - The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable or that the useful lives of these assets are no longer appropriate. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. When it is determined that the carrying value of a long-lived asset is not recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis.

**i) Goodwill and Other Intangible Assets** - Goodwill and intangible assets with indefinite lives are not amortized but are reviewed annually for impairment or more frequently if impairment indicators arise. Separable intangible assets that are

**Table of Contents**

not deemed to have indefinite lives will continue to be amortized over their useful lives. The Company has adopted December 1st as the date of the annual impairment test for goodwill.

**j) Revenue Recognition and Provisions for Estimated Reductions to Gross Revenues** - The Company recognizes revenues in accordance with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104, Revenue Recognition. This accounting policy for revenue recognition has a substantial impact on our reported results and relies on certain estimates that require difficult, subjective and complex judgments on the part of management.

**Photodynamic Therapy (PDT) Drug and Device Products.** Revenues on the Kerastick® and BLU-U® product sales are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is probable. Product sales made through distributors, historically, have been recorded as deferred revenue until the product was sold by the distributors to the end users because the Company did not have sufficient history with its distributors to be able to reliably estimate returns. Beginning in the first quarter of 2006, the Company began recognizing revenue as product is sold to distributors because it believes it has sufficient history to reliably estimate returns from distributors as of January 1, 2006. This change in estimate was not material to the Company's revenues or results of operations. Certain device units are held by physicians 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.

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

In the case of sales made to wholesalers as a result of incentives and that are in excess of the wholesaler's ordinary course of business inventory level, substantially all the risks and rewards of ownership do not transfer upon shipment and, accordingly, such sales are recorded as deferred revenue and the related costs as deferred cost of revenue until the product is sold through to the wholesalers' customers on a FIFO basis. In the case of product launches, where the Company does not have the ability to reliably estimate returns, it does not recognize revenue until the product is sold through to the wholesalers' customers.

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

**Returns and allowances** - The Company's provision for returns and allowances consists of its estimates of future sales returns, rebates and chargebacks.

**Sales Returns** - The Company accounts for sales returns in accordance with Statements of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists*, by establishing an accrual in an amount equal to its estimate of sales recorded for which the related products are expected to be returned. The Company determines the estimate of the sales return accrual primarily based on historical experience regarding sales returns, but also by considering other factors that could impact sales returns. These 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. It is the Company's policy to accept



**Table of Contents**

returns of Non-PDT Drug products when product is within six months of expiration. The Company considers all of these factors and adjust the accrual periodically to reflect actual experience.

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

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

A summary of activity in the Company's valuation accounts are as follows:

FOR THE YEAR ENDED DECEMBER 31, 2006:						
	BALANCE	ACQUIRED	PROVISION RELATED	PROVISION	ACTUAL	
	AS	PART OF	TO	FOR	RETURNS	BALANCE
BALANCE	AT	SIRIUS	SALES	SALES	OR	AT
	JANUARY	ACQUISITION	MADE	MADE	CREDITS	DECEMBER
	1,		IN THE	IN	IN THE	31,
	2006		CURRENT	PRIOR	CURRENT	2006
			PERIOD	PERIODS	PERIOD	

Accrued Expenses:

Returns and allowances	\$	\$357,000	\$1,235,000	\$	\$(960,000)	\$632,000
------------------------	----	-----------	-------------	----	-------------	-----------

Accounts receivable:

Prompt payment discounts	\$	\$	\$223,000	\$	\$(200,000)	\$23,000
--------------------------	----	----	-----------	----	-------------	----------

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

**l) Marketing and Sales Costs** - Costs included in marketing and sales expense consist mainly of overhead expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, as well as costs related to trade shows, miscellaneous marketing and outside consultants. All such costs are expensed as incurred.

**m) Income Taxes** - The Company recognizes deferred income tax assets and liabilities for the expected future tax consequences for events that have been included in the Company's financial statements or tax returns. Deferred tax assets and liabilities are based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which these differences are expected to reverse. A valuation

allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

**n) Basic and Diluted Net Loss Per Common Share** - Basic net loss per common share is based upon the weighted average number of shares outstanding during each period. Stock options and warrants are not included in the computation of the weighted average number of shares outstanding for dilutive net loss per common share during each of the periods presented in the Statement of Operations, as the effect would be antidilutive. For the years ended December 31, 2006, 2005, and 2004, stock options and warrants totaling approximately 3,031,000, 3,150,000, and 3,009,000 shares, respectively, have been excluded from the computation of diluted net loss per share. The 2,396,245 shares issued in the Sirius acquisition, which includes 422,892 shares placed into the liability escrow account, are included in the weighted average number of shares outstanding from the date of issuance, March 10, 2006.

**o) Share-Based Compensation** - In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123(R), *Share-Based Payment*, a revision of SFAS Statement No. 123. The Company adopted SFAS 123(R) effective January 1, 2006, using the modified prospective application method, and beginning with the first quarter of 2006, the Company measures all employee share-based compensation awards using a fair value based method and record share-based compensation expense in its financial statements if the requisite service to earn the award is provided. The pro forma results and assumptions used in fiscal years 2005, 2004 and 2003 were based solely on historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected life of its stock options.

F-10

---

**Table of Contents**

The adoption of SFAS No. 123R did not affect the Company's net cash flow, but it did have a material negative impact on its results of operations. In accordance with SFAS 123R, the Company recognizes the expense attributable to stock awards that are granted or vest in periods ending subsequent to December 31, 2005 in the accompanying condensed consolidated statements of operations.

**p) Comprehensive Loss** - The Company has reported comprehensive loss and its components as part of its Consolidated Statements of Shareholders' Equity. Comprehensive loss, apart from net loss, relates to net unrealized gains and losses on marketable securities.

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

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

**s) Concentration of Credit Risk** - The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company manages the credit risk associated with its investments in marketable securities by investing in U.S. government securities and investment grade corporate bonds. The Company is also exposed to concentration of credit risk related to accounts receivable that are generated from its distributors and customers. To manage credit risk, the Company performs regular credit evaluations of its customers and provides allowances for potential credit losses, when applicable. Concentrations in the Company's accounts receivable as of December 31, 2006 and 2005 and in the Company's revenues for the years ended December 31, 2006, 2005, and 2004, were as follows:

	% of Revenue for year ended			% of Accounts Receivable as of	
	2006	2005	2004	2006	2005
Customer A		16%	31%		
Customer B	5%	13%	5%	14%	6%
Customer C			17%		
Customer D	12%			16%	
Customer E	18%			17%	
Customer F	7%			10%	
Other customers	58%	71%	47%	43%	94%
Total	100%	100%	100%	100%	100%

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

**t) Recently Issued Accounting Pronouncements** - In September 2006, the FASB issued Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*.



**Table of Contents**

The interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken, in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties accounting in interim periods, disclosure and transition. The interpretation is effective for fiscal years beginning after December 15, 2006. The Company is in the process of determining the effects that adoption of FIN 48 will have on the Company's financial position, cash flows and results of operations.

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

In September 2006, the SEC staff published SAB 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ( SAB 108 ). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SAB is effective for fiscal years ending after November 15, 2006. Application of this SAB has not altered previous conclusions and has not impacted the Company's financial position, results of operations or cash flows.

In February 2007 the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS No. 159 ). SFAS No. 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. This Statement is effective for fiscal years beginning after November 15, 2007. The Company has not decided if it will early adopt SFAS 159 or if it will choose to measure any eligible financial assets and liabilities at fair value.

**3) BUSINESS ACQUISITION**

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius Laboratories, Inc. (Sirius) in exchange for 2,396,245 shares of unregistered DUSA common stock and \$8 million in cash. Pursuant to the terms of the Merger Agreement, the actual number of shares that were issued in the transaction was derived by dividing \$17 million by the average closing price of the Company's shares over the 20 trading day period prior to the close, or \$7.094 per share. For accounting purposes, these shares are valued at \$7.30 per share, the average market price of the Company's common stock over the five day period beginning two days prior and ending two days subsequent to the public announcement of the signing of the First Amendment to the Merger Agreement. Sirius was a dermatology specialty pharmaceuticals company founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. The purchase of Sirius was intended to enable DUSA to expand its product portfolio, capitalize on cross-selling and marketing opportunities, increase its sales force size; as well as, provide a pipeline of new products. The aggregate purchase price, net of cash received of \$0.5 million, was approximately \$26.8 million, which consisted of \$17.2 million in shares of common stock, net of estimated registration costs of \$0.3 million, \$7.5 million in cash, \$0.3 million outstanding balance on line of credit, and transaction costs of \$1.8 million, which primarily consisted of fees for legal and financial advisory services. Of the 2,396,245 shares issued in the acquisition, 422,892 shares have been placed in an escrow account established to secure the indemnification obligations of the shareholders of Sirius as set forth in the Merger Agreement. The escrow account is established for a period of two years and will be used to satisfy liability claims, if any, made by the Company. No amounts may be distributed from the liability escrow account unless and until any individual claim exceeds \$25,000 and cumulative claims exceed \$100,000.

The Company has agreed to pay additional consideration in future periods, based upon the attainment of defined operating objectives, including new product approvals or launches and the achievement of pre-determined total cumulative sales

**Table of Contents**

milestones for the Sirius products over the period ending 42 months from the date of close. The pre-determined cumulative sales milestones for the Sirius products and the related milestone payments are, as follows:

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

In addition, there are three milestones related to new product approvals and/or launches each in the amount of \$500,000 per milestone, or \$1.5 million in the aggregate, that will be paid if the milestones are achieved. As of December 31, 2006 none of the milestones had been achieved. The Company will not accrue contingent consideration obligations prior to the attainment of the objectives. At December 31, 2006, the maximum potential future consideration pursuant to such arrangements, to be resolved over the period ending 42 months from the date of close, is \$5.0 million. If attained, a portion of the contingent consideration is payable in cash and a portion is payable in either common stock or cash, at the Company's sole discretion. Any payments made pursuant to these milestones will result in increases in goodwill. The Company expects that one of the milestones will be paid related to the March 2007 launch of a new product.

The acquisition was accounted for using the purchase method of accounting and the results of operations of the acquired business since March 10, 2006, the date of acquisition, were included in the results of the Company. Goodwill may change as a result of final allocations. The total purchase consideration was allocated to the assets acquired and liabilities assumed at their estimated fair values as of the date of acquisition, as determined by management and, with respect to identified intangible assets, by management with the assistance of an appraisal provided by a third-party valuation firm. The excess of the purchase price over the amounts allocated to assets acquired and liabilities assumed has been recorded as goodwill. The value of the goodwill from this acquisition can be attributed to a number of business factors including, but not limited to, expanded product portfolio, cross selling and marketing opportunities, increased sales force and a pipeline of new products.

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

Total consideration (in thousands):

Common stock issued, net of estimated registration costs of \$295	\$17,203
Cash paid to stockholders	8,000
Balance on line-of-credit	251
Transaction costs accrued	304
Transaction costs paid	1,567
Total purchase consideration	27,325
Allocation of the purchase consideration	
Current assets (including cash of \$485), exclusive of inventory	2,198
Inventory	1,983

Fixed assets	109
Long-term assets	14
Identifiable intangible assets	17,160

F-13

---

**Table of Contents**

In-process research and development	1,600
Goodwill	5,773
Total assets acquired	28,837
Fair value of liabilities assumed	(1,512)
Fair value of assets acquired and liabilities assumed	\$27,325

The identifiable intangible assets relate to core/developed technology, comprised of the combined value of Sirius product lines, which inherently includes the value of related patents, trademarks and trade names., The substantial majority of the projected revenues and cash flow the acquisition were attributable to Nicomide®. The core/developed technologies all belong to the same therapeutic category, non-photodynamic therapy dermatological treatment of acne and rosacea and are considered a single asset group for purposes of measuring impairment. The values of the intangible assets acquired were determined using projections of revenues and expenses specifically attributed to the intangible assets. The income streams were then discounted to present value using estimated risk adjusted discount rates. The intangible assets were valued using the income approach, specifically the excess earnings method. The key assumptions used in valuing the intangible assets are discount rates of 17% for core/developed technology and 18% for in-process research and development and an assumed tax rate of 40%. On March 7, 2007, a preliminary injunction, which had been in place since May 12, 2006, and which had previously enjoined a competitor from marketing a generic substitute for Nicomide®, was dissolved, and as a result of its expected adverse impact on the Company's projected revenues, results of operations and cash flows, the Company has recorded an impairment charge of \$15.7 million in 2006, representing the remaining net asset value of the intangible assets. The in-process research and development represents the estimated fair value based on risk-adjusted cash flows related to product development projects. At the date of acquisition, the development of these projects had not yet reached technological feasibility and the research and development in progress had no alternative future uses. Accordingly, these costs were expensed as of the acquisition date.

The amount allocated to goodwill and other intangible assets are not deductible for tax purposes.

The results of operations of Sirius have been included in the financial statements of the Company since March 10, 2006, the date of acquisition. The following table reflects unaudited pro forma results of operations of the Company for the years ended December 31, 2006 and 2005 assuming that the Sirius acquisition had occurred on January 1, 2005 (in thousands, expect per share data):

	Year ended December 31,	
	2006	2005
Revenues	\$ 28,500	\$ 21,493
Net loss	(27,454)	(16,165)
Net loss per share	\$ (1.41)	\$ (0.84)

The pro-forma net loss and net loss per share for the years ended December 31, 2006 and 2005 excludes the impact of increased cost of goods sold resulting from the purchase accounting fair value adjustment to inventory due to its non-recurring nature, and a \$1.6 million charge related to purchased in-process research and development.

**4) GOODWILL AND INTANGIBLE ASSETS**



Under Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets ( SFAS No 142 ), goodwill and certain intangible assets are deemed to have indefinite lives and are no longer amortized, but are reviewed at least annually for impairment. Other identifiable intangible assets are amortized over their estimated useful lives. SFAS

F-14

---

**Table of Contents**

No. 142 requires that goodwill be tested for impairment annually, utilizing the fair value methodology. The Company has adopted December 1st as the date of the annual impairment test for goodwill. At December 31, 2006, goodwill is \$5.8 million and is all associated with the Non-PDT Drug Products operating segment. Amortization expense related to intangible assets was \$1,414,000 for the year ended December 31, 2006 and is included in cost of product revenues and royalties in the accompanying Consolidated Statements of Operations. Shortly after the closing of the merger, the Company became engaged in patent litigation with River's Edge, a company that launched a generic Nicomide® product. River's Edge also requested that the United States Patent and Trademark Office, or USPTO, reexamine the Nicomide® patent claiming that it is invalid. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. Although the court issued a preliminary injunction against sales of River's Edge's product in May, 2006, the injunction was lifted on March 7, 2007, due, in part, to the court's determination that the reexamination process presented sufficient changed circumstances to warrant the dissolution of the injunction. The Company expects that River's Edge will reenter the market with its product in competition with Nicomide®. As a result, in 2006 the identifiable intangible assets resulting from the Sirius acquisition were determined to be impaired based on an analysis of the carrying value and projected future cash flows of the assets. The impairment analysis resulted in a write down of approximately \$15.7 million, which is recorded in cost of product revenues.

**5) RESTRUCTURING CHARGE**

During the quarter ended September 30, 2005, the Company eliminated 14 staff positions, representing 16% of the workforce, to align headcount more closely with management's assessment of its resource requirements at that time. These workforce reductions were made across all functions of the Company. As a result of these actions the Company recorded a restructuring charge of approximately \$151,000. As of December 31, 2006, the Company had paid all of its obligations under the restructuring plan.

**6) MARKETABLE SECURITIES**

The Company's investment securities consist of securities of the U.S. government and its agencies, and investment grade corporate bonds, all classified as available for sale. As of December 31, 2006, current yields range from 2.59% to 5.74% and maturity dates range from January 15, 2007 to September 15, 2010. The estimated fair value and cost of marketable securities at December 31, 2006 and December 31, 2005 are as follows:

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

F-15

**Table of Contents**

		December 31, 2005		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government debt securities	\$19,857,171	\$ 3,732	\$ (72,243)	\$19,788,660
Investment grade corporate debt securities	10,818,063	15,136	(42,373)	10,790,826
Total marketable securities available-for-sale	\$30,675,234	\$18,868	\$(114,616)	\$30,579,486

The change in net unrealized gains and losses on such securities for the years ended December 31, 2006, 2005 and 2004 was \$36,375, (\$427,129), and (\$1,124,309), respectively, and has been recorded in accumulated other comprehensive income, which is reported as part of shareholders' equity in the Consolidated Balance Sheets. Realized gains on sales of marketable securities were \$14,000 and \$75,000 in 2006 and 2005, respectively. There were no realized gains or losses in 2004.

Because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be at maturity, the Company does not consider these investments to be other-than-temporarily impaired at December 31, 2006.

**7) INVENTORY**

Inventory consisted of the following at December 31:

	December 31,	
	2006	2005
Finished goods	\$ 861,830	\$1,004,772
BLU-U <sup>®</sup> evaluation units	166,812	292,129
Work in process	257,358	60,805
Raw materials	1,057,472	503,087
	\$2,343,472	\$1,860,793

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

**Table of Contents****8) PROPERTY, PLANT AND EQUIPMENT**

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

	Useful Life (in years)	2006	2005
Computer equipment and software	3	\$ 2,560,627	\$ 2,389,562
Furniture, fixtures and equipment	5	849,981	810,488
Manufacturing facility	Term of lease	2,204,122	2,204,122
Manufacturing equipment	5	2,282,343	2,187,244
Leasehold improvements	Lesser of useful life or term of lease	845,432	833,967
		8,742,505	8,425,383
Accumulated depreciation and amortization		(6,175,219)	(5,453,514)
		\$ 2,567,286	\$ 2,971,869

Depreciation and amortization related to property, plant and equipment was \$722,000, \$925,000, and \$1,299,000 for 2006, 2005, and 2004, respectively.

**9) OTHER ACCRUED EXPENSES**

Other accrued expenses consisted of the following at December 31:

	2006	2005
Research and development costs	\$ 458,792	\$ 347,220
Marketing and sales costs	314,770	173,092
Product related costs	1,739,424	667,388
Legal and other professional fees	634,655	488,401
Employee benefits	294,673	225,628
Other expenses	399,577	93,950
	\$3,841,891	\$1,995,679

**10) INCOME TAXES**

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

	2006	2005
DEFERRED TAX ASSETS		
Current		

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

Reserves	\$ 358,000	\$ 102,000
Accrued Charges	212,000	60,000
Total current deferred tax assets	570,000	162,000
Noncurrent		
Operating loss carryforwards	\$30,922,000	\$31,916,000
Capitalized R&D	7,275,000	3,571,000
Research and development tax credit carryforwards	3,281,000	2,720,000
Deferred revenue	372,000	19,000

F-17

---

**Table of Contents**

	2006	2005
Intangible assets	402,000	917,000
Accrued charges	182,000	
Stock-based compensation	716,000	
License fee		141,000
Fixed assets	300,000	(8,000)
Total noncurrent deferred tax assets	43,450,000	39,276,000
Net deferred tax assets before allowance	44,020,000	39,438,000
Valuation allowance	(44,020,000)	(39,438,000)
Total	\$	\$

During the years ended December 31, 2006, 2005, and 2004, the valuation allowance was increased by approximately \$4,582,000, \$6,453,000, and \$5,503,000, respectively, due to the uncertainty of future realization of the net deferred tax assets which were increasing. The current year increase in the valuation allowance of \$4,582,000 is primarily comprised of an increase due to the current year change in temporary differences of \$9,277,000, a decrease from acquired intangibles and carryover tax attributes relative to the acquisition of Sirius Laboratories of (\$5,096,000) and a decrease due to the cumulative adjustment of tax attributes of \$401,000.

Included in deferred tax assets at December 31, 2006 and 2005 is \$2,171,000 and \$2,011,000 of future benefits attributable to the exercise of stock options which, if realized, will be credited to additional paid-in capital rather than results of operations.

As of December 31, 2006, the Company has Federal net operating loss carryforwards for tax purposes of approximately \$83,309,000 and research and development tax credits of approximately \$2,821,000, both of which, if not utilized, will expire on various dates through 2026 as follows:

	Operating Loss Carryforwards	Research and Development Tax Credits
2010	\$ 2,325,000	\$
2011	6,638,000	7,000
2012	6,841,000	57,000
2013		66,000
2014		84,000
2015		44,000
2016		102,000
2017		235,000
2018	5,738,000	145,000
2019		81,000
2020		160,000
2021	3,100,000	357,000
2022	16,018,000	490,000
2023	12,872,000	250,000

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 10-K

2024	10,498,000	292,000
2025	13,425,000	237,000
2026	5,854,000	214,000
	\$83,309,000	\$ 2,821,000

The tax loss carryforwards of the Company and its subsidiaries that may be utilized in future periods may be subject to limitation by Section 382 of the Internal Revenue Code if substantial changes in historical ownership have occurred or should occur. The amount of the limitation, if any, has not been quantified by the Company.

F-18

---

**Table of Contents**

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

	<b>2006</b>	<b>%</b>	<b>2005</b>	<b>%</b>	<b>2004</b>	<b>%</b>
Income tax benefit at statutory rate	\$ (10,659,000)	(34.0)	\$ (5,100,000)	(34.0)	\$ (5,314,000)	(34.0)
State taxes	(1,632,000)	(5.2)	(939,000)	(6.3)	(979,000)	(6.3)
Tax credit carryforwards	(141,000)	(0.5)	(234,000)	(1.6)	(435,000)	(2.8)
Charges for In Process						
R&D	627,000	2.0	0	0	0	0
Change in valuation allowance	11,747,000	37.5	6,233,000	41.6	6,676,000	42.7
Other	78,000	.2	40,000	0.3	52,000	0.4
Effective tax rate	\$ 20,000		\$		\$	

**11) SHAREHOLDERS EQUITY***Common Stock Issuances*

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

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

On February 27, 2004, the Company completed a private placement of 2,250,000 shares of its common stock at a purchase price of \$11.00 per share, resulting in gross proceeds of \$24,750,000. The closing date of the private placement was March 2, 2004. The Company also granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at \$11.00 per share. These additional investment rights were exercised on April 14, 2004, resulting in additional gross proceeds of \$3,712,500. Offering costs incurred in connection with the placement were \$1,907,952, of which \$1,707,750 consisted of the placement agent's commission and non-refundable retainer paid in the form of 155,250 shares of common stock calculated at the offering price.

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

**12) STOCK OPTIONS AND WARRANTS**

Under the Company's 2006 Equity Compensation Plan (the 2006 Plan), the Company may grant stock-based awards in amounts not to exceed the lesser of: (i) 20% of the total number of shares of the Company's common stock issued and outstanding at any given time less the number





**Table of Contents**

of shares issued and outstanding under any other equity compensation plan of the Company at such time; or (ii) 3,888,488 shares less the number of shares issued and outstanding under any other equity compensation plan of the Company from time to time. The maximum number of shares of common stock that may be granted to any individual during any calendar year is 300,000.

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

**Non-Qualified Stock Options** All the NSOs granted under the 2006 Plan have an expiration period not exceeding seven years and are issued at a price not less than the market value of the common stock on the grant date. The Committee may establish such vesting and other conditions with respect to options as it deems appropriate. In addition, the Company initially grants each individual who agrees to become a director 15,000 NSO to purchase common stock of the Company. Thereafter, each director reelected at an Annual Meeting of Shareholders will automatically receive an additional 10,000 NSO on June 30 of each year. Grants to directors immediately vest on the date of the grant.

**Incentive Stock Options** ISOs granted under the 2006 Plan have an expiration period not exceeding seven years (five years for ISOs granted to employees who are also ten percent shareholders) and are issued at a price not less than the market value of the common stock on the grant date. The Committee may establish such vesting and other conditions with respect to options as it deems appropriate.

On October 18, 2006 the Company's Board of Directors extended the term of Two Hundred Fifty Thousand (250,000) Class B warrants, originally issued to the Company's Chairman of the Board of Directors and Chief Executive Officer at the time of DUSA's initial public offering, for an additional four years to January 29, 2011. An additional Fifty Thousand (50,000) of the Three Hundred Thousand (300,000) Class B warrants lapsed on January 29, 2007. The warrants have an exercise price of CDN \$6.79 per share. No other terms of the warrants were amended. There are no other holders of the Class B warrants. The Company recorded a non-cash charge to earnings of approximately \$534,000 during the fourth quarter of 2006 related to the extension of the warrants. The fair value of the warrants was estimated on the date of the amendment using a Black-Scholes valuation model.

**Table of Contents**

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

	Shares 2006	Weighted Average Exercise Price
Outstanding, beginning of year	2,850,250	\$ 11.85
Options granted	440,500	\$ 6.56
Options-forfeited	(98,999)	\$ 8.85
Options expired	(418,251)	\$ 9.70
Options exercised	(42,625)	\$ 3.04
Outstanding, end of year	2,730,875	\$ 11.57
Exercisable, end of year	1,907,130	\$ 12.88
Options expected to vest	2,633,792	\$ 11.69

A summary of stock options outstanding at December 31, 2006 follows:

Range of Exercise	Outstanding as of December 31, 2006	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable as of December 31, 2006	Weighted Average Exercise Price
Prices					
\$1.60-\$6.25	554,625	5.35	\$ 3.59	475,375	\$ 3.67
\$6.75-\$8.49	568,000	6.25	\$ 7.14	247,500	\$ 7.60
\$9.04-\$10.00	755,500	6.86	\$ 9.75	439,255	\$ 9.63
\$10.02-\$27.31	548,750	4.36	\$15.98	441,000	\$16.52
\$31.00-\$31.00	304,000	3.19	\$31.00	304,000	\$31.00
	2,730,875	5.52	\$11.57	1,907,130	\$12.88

The weighted average remaining contractual term was approximately 5.52 years for stock options outstanding and approximately 4.32 years for stock options exercisable as of December 31, 2006.

The total intrinsic value (the excess of the market price over the exercise price) was approximately \$602,000 and \$491,000 for stock options outstanding and exercisable, respectively, as of December 31, 2006. The total intrinsic value for stock options exercised in 2006 was approximately \$100,000. At December 31, 2006, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$3,284,000, which was expected to be recognized over a weighted average period of 2.1 years.

**Table of Contents**

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

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

The fair value of stock options granted was estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions in the following table. The Company's employee stock options have various restrictions that reduce option value, including vesting provisions and restrictions on transfer and hedging, among others, and are often exercised prior to their contractual maturity.

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

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

The Company used a combination of historical and implied volatility of market-traded options in the Company's stock for the expected volatility assumption input to the Black-Scholes model. Prior to the first quarter of fiscal 2006, the Company had used its historical stock price for purposes of its pro forma information. The decision to use a combination of historical and implied volatility data to estimate expected volatility was based upon the availability of actively traded options on the Company's stock and the Company's assessment that this is more representative of future stock price trends than historical volatility alone.

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

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

	Year ended December 31, 2006
Cost of product revenues	\$ 81,000
Research and development	621,000
Selling and marketing	370,000
General & administrative	1,213,000
Share-based compensation expense	2,285,000

Share-based compensation expense per common share  
Basic and diluted

\$ 0.12

F-22

---

**Table of Contents**

## PRO FORMA INFORMATION UNDER SFAS 123 FOR PERIODS PRIOR TO FISCAL 2006

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

For purposes of pro forma disclosures under SFAS 123 for the years ended December 31, 2005 and December 31, 2004, the estimated fair value of the stock options was amortized to expense over the stock options vesting periods. The pro forma effects of recognizing estimated compensation expense under the fair value method on net loss and loss per common share for the year ended December 31, 2005 and 2004 were as follows:

	Year Ended December 31,	
	2005	2004
Net loss, as reported	\$ (14,998,709)	\$ (15,628,980)
Add: stock-based compensation expense included in reported net loss	19,444	
Deduct: Share-based employee compensation expense determined under the fair value based method for all awards	(1,738,275)	(2,275,678)
Pro forma net loss	\$ (16,717,540)	\$ (17,904,658)
Basic and diluted loss per share as reported	\$ (0.89)	\$ (0.96)
Basic and diluted loss per share pro forma	\$ (0.99)	\$ (1.10)

The pro forma effects of estimated share-based compensation expense on net loss and loss per common share for the years ended December 31, 2005 and 2004 were estimated at the date of grant using the Black-Scholes option-pricing model based on the following assumptions (annualized percentages):

	2005	2004
Volatility	72.05%	76.40%
Risk-free interest rate	3.97%	3.02%
Dividend yield	0.0%	0.0%
Expected life (years)	5.0	5.0

**Table of Contents**

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

**13) RETIREMENT PLAN**

Effective January 1, 1996, the Company adopted a tax-qualified employee savings and retirement 401(k) Profit Sharing Plan (the 401(k) Plan ), covering all qualified employees. Participants may elect a salary deferral of at least 1% as a contribution to the 401(k) Plan, up to the statutorily prescribed annual limit for tax-deferred contributions. Effective February 1, 2003, DUSA matches a participant's contribution up to 1.25% of a participant's salary (the Match ), subject to certain limitations of the 401(k) Plan. Participants will vest in the Match at a rate of 25% for each year of service to DUSA. The Company's matching contributions in 2006, 2005 and 2004 were \$49,000, \$42,000 and \$39,000, respectively.

In October 2006, the Company adopted the DUSA Pharmaceuticals, Inc. Deferred Compensation Plan (the Plan ), a non-qualified supplemental retirement plan maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees and members of the board of directors of DUSA (the Participants ). Participants may defer up to 80% of their compensation. A Participant will be 100% vested in all of the amounts he or she defers as well as in the earnings attributable to a Participant's deferred account. A Participant may elect to receive distributions from the deferred account at various times, either in a lump sum or in up to ten annual installments. DUSA's obligation to pay the Participant an amount from his or her deferred account is an unsecured promise and benefits shall be paid out of the general assets of the company. As of December 31, 2006, amounts deferred under the Plan were not material.

**14) SEGMENT REPORTING**

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

**Table of Contents**

YEAR ENDED  
DECEMBER 31,

During the years ended December 31, 2006 and 2005, the Company derived revenues from the following geographies (as a percentage of product revenues):

	Year Ended December 31,	
	2006	2005
United States	96%	87%
Canada	4%	13%
Total	100%	100%

Asset information by reportable segment is not reported to or reviewed by the chief operating decision maker and, therefore, the Company has not disclosed asset information for each reportable segment.

*Write down of assets due to impairment*

During 2006, the identifiable intangible assets acquired in the Sirius acquisition were determined to be impaired based on a competitor being able to manufacture and market a generic substitute for one of the Company's Non-PDT products. The impairment charge was \$15.7 million.

**15) COMMITMENTS AND CONTINGENCIES***Legal Matters*

On March 28, 2006, a lawsuit was filed by River's Edge Pharmaceuticals, LLC against the Company alleging, among other things, that, prior to the merger with the former Sirius Laboratories, Inc. Sirius agreed to authorize River's Edge to market a generic version of Nicomide<sup>®</sup>, and that the United States patent covering Nicomide<sup>®</sup> issued to Sirius in December, 2005 is invalid. Nicomide<sup>®</sup> is one of the key products DUSA acquired from Sirius in the merger. The declaratory judgment suit was filed in the United States District Court for the Northern District of Georgia, Gainesville Division. On June 19, 2006, the Georgia court dismissed River's Edge complaint.

F-25

---



**Table of Contents**

River s Edge also filed an application with the U.S. Patent and Trademark Office requesting reexamination of the Nicomide patent. The Patent Office has accepted the application and the parties have submitted their responses to the Patent Office s first office action. On April 20, 2006, the Company filed a patent infringement suit in the United States District Court in Trenton, New Jersey alleging that a River s Edge niacinamide product infringes its U.S. patent 6,979,468. Although a preliminary injunction against sales of River s Edge s product had been in place since May, 2006, the injunction was lifted on March 7, 2007, so the Company expects that River s Edge will sell its product in competition with Nicomide®. The Company has posted \$750,000 in lieu of a performance bond with the Court which bears interest, which would not likely be recoverable by the Company if it does not prevail in litigation, or if its patent is found to be invalid.

The parties are in the discovery stage of the New Jersey litigation. The Company expects to eliminate some expenses planned for 2007 and reallocate others to provide more support to Levulan® and its new product, ClindaReach. The Company has also reviewed the valuation of its intangible assets and goodwill associated with Nicomide® for impairment as a result of the court s decision and has recorded an impairment charge of \$15.7 million to write down the remaining net book value of the intangible assets. See sections entitled, Risk Factors Risks Related to DUSA and Management s Discussion and Analysis of Financial Condition and Results of Operations .

The Company will continue to vigorously defend the validity of its Nicomide® patent and pursue its claim of infringement by River s Edge.

The Company has not accrued any amounts for potential contingencies as of December 31, 2006, as these amounts are neither probable nor estimable.

F-26

---

**Table of Contents****16) QUARTERLY RESULTS OF OPERATIONS****Supplementary Information:**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2006 and 2005, respectively:

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2006			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31(1)
Net revenues	\$ 4,750,520	\$ 6,619,109	\$ 6,062,720	\$ 8,150,637
Gross profit	2,959,761	3,623,946	3,213,236	(10,329,946)
Net loss	(4,640,309)	(4,653,954)	(3,786,639)	(18,268,605)
Basic and diluted loss per share	\$ (0.26)	\$ (0.24)	\$ (0.19)	\$ (0.94)

	QUARTERLY RESULTS FOR YEAR ENDED DECEMBER 31, 2005			
	MARCH 31	JUNE 30	SEPTEMBER 30	DECEMBER 31
Net revenues	\$ 3,368,614	\$ 2,228,116	\$ 2,392,244	\$ 3,348,487
Gross profit	1,364,986	757,588	1,084,812	1,916,474
Net loss	(4,331,614)	(4,826,118)	(3,608,281)	(2,232,696)
Basic and diluted loss per share	\$ (0.26)	\$ (0.29)	\$ (0.21)	\$ (0.13)

(1) In the fourth quarter of 2006 the Company recorded an impairment charge to its intangible assets of \$15.7 million.

F-27

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

(Registrant) DUSA Pharmaceuticals, Inc.

By (Signature and Title) /s/ D. Geoffrey Shulman

Chairman of the Board and Chief Executive Officer

Date: March 16, 2007

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

/s/ D. Geoffrey Shulman

D. Geoffrey Shulman, MD,  
FRCPC

Director, Chairman of the Board and  
Chief Executive Officer (principal  
executive officer)

March 16, 2007  
Date

/s/ Robert F. Doman

Robert F. Doman

President, Chief Operating Officer

March 16, 2007  
Date

/s/ Richard C. Christopher

Richard C. Christopher

Vice President, Finance and Chief  
Financial Officer (principal financial  
officer and  
principal accounting officer)

March 16, 2007  
Date

/s/ John H. Abeles

John H. Abeles

Director

March 16, 2007  
Date

/s/ David Bartash

David Bartash

Director

March 16, 2007  
Date

/s/ Jay M. Haft, Esq.

Jay M. Haft, Esq.

Vice Chairman of the Board and Lead  
Director

March 16, 2007  
Date

/s/ Richard C. Lufkin

Richard C. Lufkin

Director

March 16, 2007  
Date

/s/ Magnus Moliteus

Magnus Moliteus

Director

March 16, 2007  
Date

/s/ Neal S. Penneys

Neal S. Penneys

Director

March 16, 2007  
Date



**Table of Contents**

**EXHIBIT INDEX**

- 2(a.1)\* Merger Agreement by and among the Company, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005; and
- 2(a.2) First Amendment to Merger Agreement by and among the Company, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006.
- 3(a.1) Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference;
- 3(a.2) Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002 and is incorporated herein by reference; and
- 3(b) By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant's current report on Form 8-K, filed on March 27, 2006, and is incorporated herein by reference.
- 4(a) Common Stock specimen, filed as Exhibit 4(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2002, and is incorporated herein by reference;
- 4(b) Form of Class B Warrant;
- 4(c) Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K dated September 27, 2002, filed October 11, 2002, and is incorporated herein by reference; and
- 4(d) Rights Certificate relating to the rights granted to holders of common stock under the Rights Agreement filed as Exhibit 4.0 to Registrant's Current Report on Form 8-K, dated September 27, 2002, filed October 11, 2002, and is incorporated herein by reference;
- 10(a) License Agreement between the Company, PARTEQ and Draxis Health Inc. dated August 27, 1991, filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
- 10(b) ALA Assignment Agreement between the Company, PARTEQ, and Draxis Health Inc. dated October 7, 1991, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
- 10(b.1) Amended and Restated Assignment Agreement between the Company and Draxis Health, Inc. dated April 16, 1999, filed as Exhibit 10(b.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
- 10(b.2) Termination and Transfer Agreement between the Company and Draxis Health Inc. dated as of February 24, 2004, filed as Exhibit 10(b.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2003, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(c) Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated October 1, 1991, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference; +

**Table of Contents**

- 10(d.1) Amendment to Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated April 14, 1994, filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-2, No. 33-98030, and is incorporated herein by reference; +
- 10(d.2) Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated March 20, 1997 +
- 10(e) Amended and Restated License Agreement between the Company and PARTEQ dated March 11, 1998, filed as Exhibit 10(e) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of Exhibit A have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(f) Incentive Stock Option Plan, filed as Exhibit 10.11 of Registrant's Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference; +
- 10(g) 1994 Restricted Stock Option Plan, filed as Exhibit 1 to Registrant's Schedule 14A definitive Proxy Statement dated April 26, 1995, and is incorporated herein by reference; +
- 10(h) 1996 Omnibus Plan, as amended, filed as Appendix A to Registrant's Schedule 14A Definitive Proxy Statement dated April 26, 2001, and is incorporated herein by reference; +
- 10(h.1) 1996 Omnibus Plan, as amended on May 1, 2003, filed as Exhibit 10(h.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference; +
- 10(h.2) 1996 Omnibus Plan, as amended April 23, 2004, filed as Appendix A to Registrant's Schedule 14A definitive Proxy Statement dated April 28, 2004, and is incorporated herein by reference; +
- 10(i) Purchase and Supply Agreement between the Company and National Biological Corporation dated November 5, 1998, filed as Exhibit 10(i) to the Registrant's Form 10-K/A filed on June 18, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(i.1) Amended and Restated Purchase and Supply Agreement between the Company and National Biological Corporation dated as of June 21, 2004 filed as Exhibit 10(a) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed August 11, 2004, and is incorporated herein by reference;
- 10(j) Supply Agreement between the Company and Sochinaz SA dated December 24, 1993, filed as Exhibit 10(q) to Registrant's Form 10-K/A filed on March 21, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(j.1) First Amendment to Supply Agreement between the Company and Sochinaz SA dated July 7, 1994, filed as Exhibit 10(q.1) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;

**Table of Contents**

- 10(j.2) Second Amendment to Supply Agreement between the Company and Sochinaz SA dated as of June 20, 2000, filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K dated June 28, 2000, and is incorporated herein by reference;
- 10(j.3) Third Amendment to Supply Agreement between the Company and Sochinaz SA dated July 29, 2005, filed as Exhibit 10.1 to the Registrant's Form 10-Q filed on August 3, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(k) Master Service Agreement between the Company and Therapeutics, Inc. dated as of October 4, 2001, filed as Exhibit 10(b) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference;
- 10(l) License and Development Agreement between the Company and photonamic GmbH & Co. KG dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference;
- 10(m) Supply Agreement between the Company and medac GmbH dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended and is incorporated herein by reference;
- 10(n) Securities Purchase Agreement dated as of February 27, 2004, by and among the Company and certain investors, filed as Exhibit 10.1 to the Registrant's current report on Form 8-K, filed on March 2, 2004, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
- 10(o) Registration Rights Agreement dated as of February 27, 2004 by and among the Company and certain investors, filed as Exhibit 10.2 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
- 10(p) Form of Additional Investment Right dated as of February 27, 2004, filed as Exhibit 10.3 to the Registrant's current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
- 10(q) License, Promotion, Distribution and Supply Agreement between the Company and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;
- 10(r) Employment Agreement of Scott L. Lundahl dated as of June 23, 1999 filed as Exhibit 10(u) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +

**Table of Contents**

- 10(s) Amended Employment Agreement of Stuart L. Marcus, MD, PhD dated December 9, 1999 filed as Exhibit 10(v) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(t) Employment Agreement of Mark C. Carota dated as of February 14, 2000 filed as Exhibit 10(w.1) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(t.1) First Amendment to Employment Agreement of Mark C. Carota dated October 31, 2001 filed as Exhibit 10(w.2) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(u) Amendment to Employment Agreement of Richard Christopher dated as of October 18, 2006 filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended September 30, 2004, and is incorporated herein by reference;
- 10(v) Employment Agreement of Richard Christopher dated as of January 1, 2004 filed as Exhibit 10(y) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(w) Employment Agreement of Robert F. Doman dated as of March 15, 2005 filed as Exhibit 10(z) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(x) Employment Agreement of Gary F. Talarico dated as of February 15, 2005 filed as Exhibit 10(aa) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y) Severance Agreement and General Release between the Company and Peter Chakoutis dated as of February 25, 2005 filed as Exhibit 10(bb) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
- 10(y.1) Final Agreement and General Release, between the Company and Peter Chakoutis, dated as of April 4, 2005, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 4, 2005, and is incorporated herein by reference; +
- 10(z) Compensation Policy Applicable to the Company's Non-Employee Directors filed as Exhibit 10(cc) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; and +
- 10(aa) Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated May 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and is incorporated herein by reference;
- 10(bb) Amendment and Extension of the Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and is incorporated herein by reference;



**Table of Contents**

- 10(cc) Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, and is incorporated herein by reference;
- 10(dd) Amendment and Extension of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.D to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(ee) Second Amendment of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.E to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(ff) Supply Agreement between Sirius Laboratories, Inc. and L. Perrigo Company dated October 21, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.F to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
- 10(gg) 2006 Micanol License Agreement between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as filed as Exhibit 10.G to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference; and
- 10(hh) Development, License and Supply Agreement between Sirius Laboratories, Inc. and Altana Inc. dated June 13, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, and as filed as Exhibit 10.H to the Registrant's Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference.
- 10(ii) Employment Agreement of William O Dell dated as of April 4, 2006;
- 10(jj) Patent License Agreement between the Company and PhotoCure ASA, dated as of May 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended and filed as Exhibit 10.A to the Registrant's Form 10-Q for the fiscal quarter ended June 30, 2006, and is incorporated herein by reference;
- 10(kk) Separation Agreement between the Company and Paul Sowyrda, dated as of August 31, 2006;
- 10(ll) Employment Agreement of Michael Todisco dated as of September 20, 2006; and
- 10(mm) Marketing, Distribution and Supply Agreement between the Company, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Company dated January 4, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended.

**Table of Contents**

- 10(nn) First Amendment to Marketing, Distribution and Supply Agreement between the Company, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Company dated January 10, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended.
- 10(oo) DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, filed as Appendix A to Registrant's Schedule 14A definitive Proxy Statement dated April 24, 2006, and is incorporated herein by reference; +
- 10(pp) DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, as amended October 18, 2006; +
- 10(qq) DUSA Pharmaceuticals, Inc. 2006 Deferred Compensation Plan, October 18, 2006; +
- 14(a) Form of DUSA Pharmaceuticals, Inc. Code of Ethics Applicable to Senior Officers, filed as Exhibit 14(a) to the Registrant's Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference.
- 21(a) Subsidiaries of the Registrant.
- 23(a) Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
- 31(a) Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer; and
- 31(b) Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer.
- 32(a) Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002; and
- 32(b) Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99 Press Release dated March 16, 2007
  
- + Management contract or compensatory plan or arrangement.
  
- \* Schedules and exhibits omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Commission upon request.