FACET BIOTECH CORP
Form 10-K
March 31, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008

OR

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

For the transition period from to
Commission File Number: 001-34154

Facet Biotech Corporation

(Exact name of registrant as specified in its charter)

Delaware	**26-2940575**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1400 Seaport Boulevard
Redwood City, CA 94063
(Address of principal executive offices)

Registrant's telephone number, including area code
(650) 454-1000

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

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

Common Stock, par value $0.01 per share
(Title of Class)

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

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

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

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

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 and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

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

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

On June 30, 2008, the registrant's stock was not publicly traded. As of March 20, 2009, the registrant had outstanding 24,578,158 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be delivered to stockholders with respect to the registrant's 2009 Annual Meeting of Stockholders to be filed by the registrant with the U.S. Securities and Exchange Commission (hereinafter referred to as the "Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K. The registrant intends to file its proxy statement within 120 days after its fiscal year end.

PART I

Forward-looking Statements

This Annual Report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, including any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth in Item 1A below, and for the reasons described elsewhere in this Annual Report. All forward-looking statements and reasons why results may differ included in this Annual Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

As used in this Annual Report, the terms "we," "us," "our," the "Company" and "Facet Biotech" mean Facet Biotech Corporation and its subsidiaries (unless the context indicates a different meaning). In addition, these terms refer to the former Biotechnology Business that was integrated and operated by PDL Biopharma, Inc. (PDL) prior to December 2008, which is now operated by Facet Biotech.

We own or have rights to numerous trademarks, trade names, copyrights and other intellectual property used in our business, including Facet Biotech, the Facet Biotech logo and HuZAF , each of which is considered a trademark, and *Nuvion*®. All other company names, tradenames and trademarks included in this Annual Report are trademarks, registered trademarks or trade names of their respective owners.

ITEM 1. BUSINESS

OVERVIEW

We are a biotechnology company that takes a disciplined, biology-driven approach to identify and develop oncology therapeutics. We have core competencies in tumor biology and antibody engineering, as evidenced by our pipeline of four clinical-stage candidates, all of which are products of our research efforts, and a proprietary protein engineering technology platform that we believe has the potential to yield near-term value.

Facet Biotech was organized by PDL in July 2008 as a Delaware corporation. At the beginning of 2008, PDL operated three businesses: (1) the biotechnology business (Biotechnology Business), (2) antibody humanization royalty patents and related business (Royalty Business) and (3) the development, sale and marketing of non-antibody commercial products (Commercial and Cardiovascular Business). In 2008, as a result of an ongoing strategic review which the PDL Board commenced in 2007, PDL announced that its Board had authorized in principle the distribution of our common stock to PDL's stockholders in a spin-off of the Biotechnology Business from PDL in order to maximize stockholder value. This resulted in the formation of Facet Biotech.

The spin-off of Facet Biotech from PDL was effected on December 18, 2008, and was accomplished through a series of transactions pursuant to the terms and conditions of the Separation

and Distribution Agreement between Facet Biotech and PDL whereby PDL contributed to us its Biotechnology Business, including certain intellectual property, but not PDL's antibody humanization patents, and distributed to its stockholders of record all of the outstanding shares of Facet Biotech's common stock.

Following the spin-off, we became an independent, publicly traded company owning and operating what previously had been PDL's Biotechnology Business. In connection with the spin-off, PDL contributed to us, from its cash reserves on hand, funding of $405 million in cash. We expect that this initial cash contribution, future payments from Biogen Idec Inc. and Bristol-Myers Squibb Company (BMS) related to our collaboration agreements with these entities, and royalty and milestone revenues from certain other agreements, each of which was assigned to us in the spin-off, will be sufficient to fund our operations and working capital requirements through approximately the end of 2012, based on current operating plans.

Our business strategy focuses primarily on the following areas:

Focusing our efforts in oncology: We recently decided to focus our research and development efforts solely in the oncology therapeutic area. By taking a more focused approach in oncology, we intend to enhance our expertise in this area by both building upon and augmenting our existing internal capabilities and leveraging external expertise to become a leading oncology-focused organization. Three of our four products currently in clinical development are targeted at oncology indications, and we are focused on expanding our pipeline with additional oncology candidates.

Advancing our existing pipeline: We are focused on advancing our existing clinical programs to further stages of development. We currently have four antibodies in the clinic for oncology and immunologic disease indications, of which two are in phase 2 and two in phase 1. We have two strategic development collaborations in place, which we believe will help us increase the likelihood of success of our programs by (1) enhancing our development capabilities, (2) providing therapeutic area knowledge and expertise with bringing products to market and (3) sharing in the cost and risks associated with the development of product candidates.

Expanding our pipeline: We are focused on expanding our pipeline with additional oncology-focused programs. We are seeking to augment our pipeline through primarily business development efforts, including through strategic collaborations and in-licensing opportunities, specifically in the oncology area. Generally, we expect to focus our business development efforts on the pursuit of products that are in phase 1 clinical trials or preclinical development.

Refining our protein engineering platform technologies: Building on our years of experience in the humanization of antibodies, we are leveraging our strength in antibody engineering to improve upon the overall characteristics of antibody therapeutics. We are applying these capabilities toward our own antibodies and to explore the development of improved next-generation antibodies, which we believe may provide strategic advantages to pharmaceutical and biotechnology companies involved in the development of antibody therapeutics. We are currently evaluating opportunities to realize value from these technologies.

We believe we can successfully implement our strategy through our key strengths, including: (1) engineering and optimizing antibody therapeutics, (2) using our process science capabilities to develop highly efficient manufacturing processes and appropriate pharmaceutical dosage forms for our products from clinical through to commercial scale, (3) applying our preclinical expertise to gain detailed biological, pharmacological and toxicological understanding of product candidates, (4) advancing the development of validated preclinical therapeutics from the preclinical stage through phase 1 clinical studies and (5) utilizing our cash position to support our business strategy.

OUR PRODUCTS IN DEVELOPMENT

We currently have several investigational compounds in various stages of development for the treatment of cancer and immunologic diseases, three of which we are developing with our collaboration partners; two with Biogen Idec and one with BMS. The table below lists the antibodies for which we are pursuing development activities either on our own or in collaboration with other companies. These product candidates are at early stages of development, and none of our product candidates have been approved by the United States Food and Drug Administration (FDA) or commercialized in the indication in which our trials are focused. Not all clinical trials for each product candidate are listed below. The development and commercialization of our product candidates are subject to numerous risks and uncertainties, as noted in Item 1A under the heading "Risk Factors."

Product Candidate	Indication/Description	Program Status	Collaborator
Daclizumab	Multiple sclerosis	Phase 2	Biogen Idec
Volociximab (M200)	Solid tumors	Phase 1/2	Biogen Idec
Elotuzumab (HuLuc63)	Multiple myeloma	Phase 1	BMS
PDL192	Solid tumors	Phase 1	
PDL241	Immunologic diseases	Preclinical	*
Other preclinical research candidates	Oncology	Multiple candidates under evaluation	

*

BMS has an option to expand our collaboration to include the PDL241 antibody upon completion of certain pre-agreed preclinical studies, which we expect to complete in the second half of 2009.

Daclizumab. Daclizumab is a humanized monoclonal antibody that binds to the alpha chain (CD25) of the interleukin-2 (IL-2) receptor on activated T cells, which are white blood cells that play a role in inflammatory and immune- mediated processes in the body. Daclizumab has been approved for acute transplant rejection and commercialized by Hoffmann La-Roche (Roche) under the trademark *Zenapax*.

Beyond transplant induction therapy, we believe this antibody has potential in multiple sclerosis as well as other indications. We have created a high-yield manufacturing process for daclizumab and a stable, higher concentration subcutaneous formulation required to move daclizumab into larger areas of immunological disease. Currently, we have a worldwide strategic development collaboration for daclizumab with Biogen Idec in multiple sclerosis and other immunologic disease areas in which we share development costs and commercial rights. Outside of the Biogen Idec collaboration, Facet Biotech wholly owns the rights for daclizumab in respiratory and transplant maintenance indications.

See Our Business Strategic Collaborations and Licensing Agreements section for more details on the collaboration agreement.

Daclizumab in Multiple Sclerosis: We and our collaboration partner, Biogen Idec, are currently testing daclizumab as a monotherapy for relapsing multiple sclerosis in a phase 2 study. In 2007, we and Biogen Idec announced that the CHOICE trial, a phase 2, randomized, double-blind, placebo-controlled trial of daclizumab conducted in 270 patients, met its primary endpoint in relapsing MS patients being treated with interferon beta. These data showed daclizumab administered at 2 mg/kg every two weeks as a subcutaneous injection added to interferon beta therapy significantly reduced new or enlarged gadolinium-enhancing lesions at week 24 compared to interferon beta therapy alone. We and Biogen Idec continue to evaluate the results of the CHOICE study to help further inform the development of daclizumab for multiple sclerosis.

In the first quarter of 2008, we and Biogen Idec initiated a phase 2 monotherapy trial of daclizumab, the SELECT trial, to advance the overall clinical development program in relapsing MS,

which trial is currently ongoing. In the first quarter for 2009, we and Biogen Idec announced that the FDA and European regulatory agencies have agreed to consider an expanded SELECT study as one pivotal trial, thus requiring us to conduct only one additional registration-enabling study. This proposal was endorsed; therefore, we are preparing to amend the SELECT trial to increase the sample size from 300 to 600 subjects and change the primary endpoint to annualized relapse rate. Results of this study or an interim futility analysis will further guide decisions around the second registration-enabling study in which Biogen Idec would play a lead role, leveraging their experience in the commercialization of treatments for multiple sclerosis.

Volociximab (M200). Volociximab is a chimeric monoclonal antibody that inhibits the functional activity of α5ß1 integrin, a protein found on activated endothelial cells. Blocking the activity of α5ß1 integrin has been found to prevent angiogenesis, which is the formation of new blood vessels that feed tumors and allow them to grow and metastasize.

We believe that volociximab may have potential in treating solid tumors and that its role in angiogenesis may also aid in the treatment of age-related macular degeneration (AMD).

Volociximab in Solid Tumors: Currently, we have a worldwide, development collaboration with Biogen Idec for volociximab in oncology under which we are currently investigating volociximab in clinical trials in patients with advanced solid tumors. These include phase 1-2 and phase 1 clinical trials in ovarian cancer and non-small cell lung cancer (NSCLC), respectively. Prior to these trials, we conducted studies of volociximab in third-line ovarian cancer, pancreatic cancer, renal cell carcinoma and melanoma. The data from these trials and associated analyses have contributed to our understanding of the mechanism and safety profile of volociximab, and we are applying this knowledge to our ongoing programs. We plan to continue to evaluate the data from our ongoing studies and collaborate with Biogen Idec on the future development plans for this antibody.

Volociximab in Eye Disorders: We and Biogen Idec have licensed volociximab for ophthalmic indications to Ophthotech for various milestones and eventual royalties on potential product sales. See Our Business Strategic Collaborations and Licensing Agreements section for more details on this out-licensing agreement.

Elotuzumab (HuLuc63). Elotuzumab is a humanized monoclonal antibody that binds to CS1, a cell surface glycoprotein that is highly expressed on myeloma cells but minimally expressed on normal human cells. We believe elotuzumab may induce anti-tumor effects primarily through antibody-dependent cellular cytotoxicity (ADCC) activity on myeloma cells. We believe elotuzumab has significant potential as a targeted therapy for multiple myeloma.

Preclinical data from our elotuzumab program are suggestive of the antibody's biologic activity. Our scientific rationale supporting the development of this antibody includes reduction of human multiple myeloma tumors in animal models, destruction of multiple myeloma cells obtained directly from patients, and an extensive analysis of the target for elotuzumab, CS1, which is highly expressed in almost all cases of multiple myeloma independent of stage or prior therapy.

We are evaluating elotuzumab three phase 1 trials in patients with multiple myeloma: one as a monotherapy in relapsed refractory patients, one in combination with *Velcade*® (bortezomib) as a second line treatment and another in combination with *Revlimid*® (lenalidomide) as a second line treatment. We have published early dose escalation results from the ongoing monotherapy study and combination studies reflecting pharmacokinetic (PK) and tolerance data and some early response data. We also published preclinical data supporting the use of elotuzumab in combination with other agents.

In August 2008, we entered into a collaboration agreement with BMS for the joint development, manufacture and commercialization of elotuzumab in multiple myeloma and other potential oncology

indications. See Our Business Strategic Collaborations and Licensing Agreements section for more details on the collaboration agreement.

PDL192. PDL192 is a humanized monoclonal antibody that binds to the TWEAK (tumor necrosis factor-like weak inducer of apoptosis) receptor (TweakR), also known as Fn14 or TNFRSF12A, a cell surface glycoprotein with homology to the family of tumor necrosis factor (TNF) receptors. PDL192 appears to have dual mechanisms of action, where binding to the target results in a biological signal detrimental to the cancer cell. In addition, PDL192 may be able to recruit the immune system to also mediate ADCC activity to help destroy the tumor. Our scientists have demonstrated that TweakR is over-expressed in a number of solid tumor indications including pancreatic, colon, lung, renal, breast and head and neck cancers, and ongoing scientific work will help prioritize those tumors for therapeutic testing. In preclinical studies, PDL192 also has been shown to inhibit tumor growth of various models of human cancer in mice. We filed the IND for PDL192 in the second quarter of 2008 and have initiated a phase 1 dose escalation program in solid tumors.

In December 2005, we entered into a worldwide licensing agreement with Human Genome Sciences, Inc. (HGS) under which HGS licensed to us certain patent rights which supports our development of PDL192. We would be obligated to pay HGS development milestone payments of up to $30 million should PDL192 be developed to commercialization and, should PDL192 ever receive marketing approval, we would be obligated to pay HGS royalties on potential future sales of covered antibody therapeutics.

PDL241. PDL241 is a novel humanized monoclonal antibody that we believe may have potential in immunologic diseases. We are currently conducting preclinical toxicology and mechanistic studies for this preclinical candidate, which we hope to advance into the clinic. Under the terms of our collaboration agreement with BMS to develop elotuzumab, BMS has an option to expand the collaboration to include the PDL241 antibody upon completion of certain pre-agreed preclinical studies. We expect to complete the pre-agreed preclinical studies in the second half of 2009.

Preclinical research candidates. We are currently evaluating discovery-stage antibodies and target combinations for their suitability to progress into the clinic. To augment our current pipeline, we are evaluating a variety of different business development opportunities, including potential collaborative or in-licensing agreements, for oncology candidates in phase 1 studies or preclinical development.

Our Research and Development Capabilities

Our main research and development organizations include (1) Research, (2) Product Operations and Quality and (3) Preclinical Sciences and Clinical Development. We have a broad range of capabilities, with departments that specialize in the major areas of the drug development process.

Research

Our research activities are focused in three areas: (1) progressing candidates with validated targets and biological pathways from the preclinical stage to the clinic, (2) utilizing translational research to influence and enhance the course of clinical investigation of our therapeutics and (3) refining our protein engineering technology platform.

New therapeutic candidates are advanced through clinical studies following the demonstration of activity in *in vitro* cellular systems along with *in vivo* models of both oncologic and immunological diseases. Appropriate safety testing is performed prior to the submission of documents for regulatory approval for first-in-man studies. To enhance the probability of success for new therapeutic candidates, we intend to focus on the targeting of biological pathways that have a high level of validation.

In addition to the biological models and systems we use to prove the required potency in testing therapeutics candidates, we also use those systems to better understand the utility of our therapeutics during clinical development. An example of this translational research is the testing of our therapeutics in *in vivo* models of human tumor reduction with current standards of care. Translational research suggests a direction for the clinical testing of our products and is an ongoing process from lab bench to patient care. Recent successes of our translational research efforts are elotuzumab (for multiple myeloma) and PDL192 (for solid tumors), both of which are humanized antibodies to novel targets and have demonstrated efficacy in the corresponding *in vivo* tumor models. Continued translational research on these therapeutics will provide information to help us determine the efficacy of each product for the treatment of these types of cancer.

Building on our history with humanizing antibodies, our focus has evolved and we have been developing new proprietary antibody engineering technologies to optimize antibody therapeutics. These technologies are applicable regardless of the underlying platform chimeric, humanized or fully human and enable us to alter specific antibody traits and features. These technologies include novel comprehensive methods to modulate binding affinity, increase half-life, decrease immunogenicity, and customize amino acid sequences within the antibody structure.

Product Operations and Quality

Our product operations organization includes process development, pharmaceutical and analytical development and supply chain functions, and our integrated quality organization is comprised of clinical, non-clinical and product quality functions. Product Operations serves as an integrated unit for advancing antibody molecules by developing robust and efficient processes, stable and user-friendly pharmaceutical dosage forms and comprehensive analytical packages, and by ensuring adequate supplies of antibody product for preclinical and clinical testing. Our technology platform for the production of antibodies is well characterized and established to reliably support the movement of antibody molecules through various stages of clinical development. The quality function ensures that our products for clinical and non-clinical studies are produced and that out non-clinical and clinical studies are conducted in compliance with applicable quality standards and regulations.

Antibodies for use as human therapeutics are generally manufactured using mammalian cell lines. We produce and characterize such cell lines in our facilities, and engage in development activities intended to improve the productivity and ability of these cell lines to produce monoclonal antibodies with desirable physicochemical and biological characteristics. The productivity of our cell lines for antibodies is competitive with that of other biotechnology companies. Our process scientists work closely with research and preclinical scientists to expedite the movement of lead antibody candidates into first in human clinical studies. Our ability to develop robust and consistent bioprocesses, scale-up and transfer processes to manufacturing plants and establish comparability between materials produced at various scales and production sites is key for ensuring a consistent supply of study drug for clinical studies. We believe our knowledge and capabilities in cell line generation, bioprocess, pharmaceutical and analytical development provide a competitive advantage over those companies that currently lack such comprehensive process development operations.

The manufacture of pharmaceutical products is an expensive, multi-step, complex process. We produce antibodies for non-clinical studies in our Redwood City facilities. Products used in clinical trials must be manufactured in facilities that meet all applicable regulations including current Good Manufacturing Practices as outlined by the FDA, the European Medicines Agency (EMEA) and other regulatory authorities. Steps in the manufacturing process, including the manufacture of the active pharmaceutical ingredient, filling, finishing, labeling and packaging of finished drug products, may be performed by multiple third-parties and require extensive coordination and oversight by us.

In March 2008, we sold our manufacturing and related administrative facilities in Brooklyn Park, Minnesota, and related assets therein (together, the Manufacturing Assets) to an affiliate of Genmab A/S (Genmab). In order to fulfill our clinical manufacturing needs in the near-term, we entered into a clinical supply agreement with Genmab that became effective upon the close of the transaction. Under the terms of the clinical supply agreement, Genmab agreed to produce clinical trial material for certain of our pipeline products until March 2010. As of December 31, 2008, we have minimum purchase commitments of approximately $9.6 million under the terms of the clinical supply agreement.

Our collaboration partner Biogen Idec has responsibility for manufacturing volociximab, while we currently retain the manufacturing responsibility for daclizumab under our joint collaboration with them. We currently have responsibility for manufacturing elotuzumab, and BMS will assume responsibility for the manufacture of elotuzumab as we move into phase 2 trials under our collaboration agreement with them. Currently, we believe there is adequate capacity available in the contract manufacturing industry for production and fill-finish of antibodies. We anticipate continuing to rely on collaboration partners and contract manufacturing organizations for production of clinical trial supply materials for the foreseeable future.

Preclinical and Clinical Developmental Sciences and Clinical Development

Our preclinical and clinical developmental sciences activities focus on further characterizing our pipeline products, with the goal of maximizing our biological and pharmacological knowledge of molecules before they enter human testing. We conduct extensive *in vivo* pharmacology studies in animal models to assess dosing, toxicology pharmacokinetics, and pharmacodynamics to support regulatory filings and provide information for the design of subsequent clinical trials. These researchers also support our ongoing clinical trials by conducting immunogenicity and biomarker assays, both of which are critical to understanding how our drug candidates function in humans.

Our clinical development organization relies on a strategic outsourcing approach. We have expertise in the traditional clinical development functions, including clinical operations with therapeutic area expertise, regulatory affairs, drug safety, biometry, quality and compliance, all of which are supported by our program management group. We outsource the majority of the tactical work to contract research organizations, and our in-house personnel provide strategic and operational oversight of the programs to ensure that our clinical trials are appropriately conducted and managed.

Together, our preclinical and clinical capabilities focus on supporting our current pipeline programs and demonstrating their advantages in medical care. These capabilities enable us to conduct clinical research activities for our earlier stage programs and, in cases where the program is part of a strategic collaboration, provide strategic input and scientific knowledge consistent with the joint development activities. Our clinical experts also provide input to our research and discovery operations to inform their activities to generate new therapeutics and identify the promising ones for further research and development activity.

For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see our Risk Factors in Item 1A of this Annual Report.

STRATEGIC COLLABORATIONS AND LICENSING AGREEMENTS

A major component of our business is the pursuit and maintenance of strategic collaborations and licensing activities, which we believe can help us execute our strategy and increase the potential success of the Company.

Strategic Development Collaborations

Strategic development collaborations generally represent relationships in which we and a collaborator share in the effort, costs and success of a development program. The terms of such agreements generally provide for license fees, research and development funding, the opportunity to receive milestone payments related to research results and subsequent product development activities and, if successful, milestones, royalties and/or a share of the profits related to the sales of the product. Strategic collaborations can help to increase the potential value of our drug development programs and our Company in a number of ways, including: (1) allowing us to retain economic participation in programs while providing financial resources to the development effort, (2) supporting the development of additional pipeline products, (3) bringing new capabilities and therapeutic area knowledge that can enhance or complement our own research and development capabilities, (4) helping to accelerate our development timelines and (5) mitigating the overall risk of our strategy.

Our collaboration agreement with Biogen Idec provides for the joint development, manufacture and commercialization of daclizumab in MS and indications other than transplant and respiratory diseases, and for shared development and commercialization of volociximab (M200) in all indications. This agreement requires each party to undertake extensive efforts in support of the collaboration and requires the performance of both parties to be successful. Under the collaboration agreement, in the U.S. and Europe, we and Biogen Idec equally share the costs of all development activities and, if any of the products are commercialized, all operating profits. Each party will have co-promotion rights in the U.S. and Europe, based upon sales capabilities of each party at the time. Outside the U.S. and Europe, Biogen Idec will fund all incremental development and commercialization costs and pay a royalty to us, which would be based on percentages of net sales of collaboration products ranging from the low-teens to approximately the high-teens. We are eligible to receive development, regulatory and sales based milestones based on the further successful development of these antibodies. If the products under our collaboration with Biogen Idec are successfully developed in multiple indications and all milestones are achieved, the agreement with Biogen Idec provides for development, regulatory and sales-based milestone payments totaling up to $660 million. Of this amount, the agreement provides for $260 million in development and regulatory milestone payments related to daclizumab and $300 million in development and regulatory milestone payments and $100 million in sales-based milestone payments related to volociximab. We have previously received $10 million of these milestone payments under the collaboration with Biogen Idec. At certain pre-determined points in the development plans, Biogen Idec and we each have the right to terminate our collaboration agreement, on an indication-by-indication basis, with respect to any products we are jointly developing, except that we may not elect to terminate the development of the daclizumab product in any indication. The term of the Biogen Idec agreement shall, unless earlier terminated, expire on the date on which neither party has nor will have any additional payment obligations to the other party under the terms of the agreement.

Our collaboration agreement with BMS provides for the joint development, manufacture and commercialization of elotuzumab in multiple myeloma and other potential oncology indications. Under the terms of the agreement, BMS has an option to expand the collaboration to include the PDL241 antibody upon completion of certain pre-agreed preclinical studies. Under the terms of the agreement, we share worldwide development costs with BMS funding 80 percent of the costs. The companies would share profits on any U.S. sales under the collaboration agreement with BMS, with us receiving a higher portion of the profit share than represented by our 20 percent share of development funding, and outside the United States, we would receive royalties, which would be based on percentages of net sales of collaboration products ranging from the low- to mid-teens. In addition, we are eligible to receive development and commercialization milestones based on the further successful development of elotuzumab and, PDL241, if it is included in the collaboration. Under the terms of the collaboration, BMS made an upfront cash payment of $30 million for the development and marketing rights to

elotuzumab and for an option to expand the collaboration to include PDL241, another anti-CS1 antibody, upon completion of pre-agreed preclinical studies. We could receive additional payments of up to $480 million based on pre-defined development and regulatory milestones and up to $200 million based on pre-defined sales-based milestones for elotuzumab in multiple myeloma and other potential oncology indications. If BMS exercises its option to expand the collaboration to include PDL241, we would receive an additional cash payment of $15 million and could receive additional payments of up to $230 million based on pre-defined development and regulatory milestones and up to $200 million based on pre-defined sales-based milestones. The same division of development costs and profit sharing that apply to elotuzumab would apply to PDL241, and the royalty rate for products sold outside the United States would be based on percentages of net sales in the low-teens. With four months notice, BMS may terminate our collaboration agreement with respect to any product that is jointly developed under the collaboration on a region by region basis. The BMS agreement shall remain in effect until earlier terminated pursuant to the terms of the agreement, or by mutual written agreement, or until the expiration of all payment obligations under the agreement.

In connection with our efforts to expand our pipeline, we also may enter in to strategic development collaborations under which we would obtain certain development and commercialization rights to programs and would be obligated to make payments related to license fees, research and development funding, milestone payments and, if successful, royalties and/or a share of the profits, related to sales of the product.

Out-Licensing Agreements

In addition to development collaborations, we have a number of agreements under which we have out-licensed rights to our antibody engineering capabilities or technology expertise, as well as certain research and preclinical assets. We generally out-license rights to product candidates when we believe the program is not a strategic fit for our portfolio development strategy.

We currently have a number of license agreements in place with parties who are pursuing the development of product candidates that were generated by our internal research and discovery efforts or were licensed to us. These agreements demonstrate our history of development of programs that are of interest to others in the industry and our ability to out-license programs that are determined not to be a strategic fit for us.

Abbott Laboratories, Inc. In 2003, we and Abbott entered into a licensing agreement that provides Abbott certain rights to intellectual property related to fully human antibodies capable of binding interleukin-12 (IL-12) or its receptor. Abbott has announced that its anti-IL-12 biologic, ABT-874, is in phase 3 development for psoriasis. ABT-874 is also in early studies for Crohn's disease.

Actinium Pharmaceuticals, Inc. In 2003, we licensed certain rights to Actinium with respect to the development and marketing of forms of derivatives of HuM195, an anti-CD33 antibody, conjugated with alpha emitting radioisotopes, and we are entitled to receive future milestones and royalties under the license agreement with Actinium. Actinium has announced that it is conducting ongoing clinical development activities to support HuM195.

Genentech, Inc. In 2005, we entered into an agreement with Genentech to sub-license development and commercialization rights to Genentech for antibody-drug conjugates (ADC) directed against the TMEFF2 antigen, which is frequently differentially expressed in prostate cancer. Prior to the agreement, our scientists conducted preclinical work to validate the target and characterize the antibody. We believe that Genentech continues clinical development activities to support this antibody.

Ophthotech Corporation In 2008, we and Biogen Idec entered into an exclusive worldwide licensing agreement with Ophthotech, a privately held biopharmaceutical company focused on developing ophthalmic therapies for back-of-the-eye diseases, for our volociximab antibody to treat age-related macular degeneration (AMD). Under the agreement, Ophthotech was granted worldwide development and commercial rights to all ophthalmic uses of volociximab. In November 2008, Ophthotech announced that it treated its first patient in a phase 1 trial for volociximab to treat AMD, and we believe Ophthotech continues to advance volociximab's development in AMD.

Progenics Pharmaceuticals, Inc. In 1999, we entered into a humanization agreement with Progenics whereby we humanized an antibody targeted to the CCR5 receptor (designated by Progenics as PRO 140). Progenics recently completed a phase 1b study of PRO 140, its principal HIV drug candidate.

Seattle Genetics, Inc. In 2005, Seattle Genetics licensed rights to our anti-CD33 program for both unconjugated antibody and antibody-drug conjugate (ADC) applications, subject to the rights we granted to Actinium as noted above. Seattle Genetics is conducting phase 1 and phase 2 clinical development of SGN-33, or lintuzumab, a humanized monoclonal antibody that targets the CD33 antigen, in patients with acute myeloid leukemia or myeloid dysplastic syndrome. Seattle Genetics received orphan drug designation from the FDA for SGN-33 in both diseases. In 2007, Seattle Genetics also licensed rights from us to another preclinical target.

In addition to the agreements listed above, we have a number of humanization agreements into which we have entered, and we may enter into other agreements to license our antibody humanization and optimization technologies in the future.

Further, in 2008, PDL entered into an agreement with EKR Therapeutics, Inc. (EKR) for the sale of certain of its commercial and cardiovascular assets, including a currently marketed antihypertensive product, Cardene®, and the development product, ularitide. In connection with the spin-off, PDL assigned its rights and obligations under the agreement to us, including the contingent consideration from EKR. Under the agreement, we are entitled to milestones and royalties related to sales of new formulations of the Cardene product and to royalties related to future sales of ularitide. Such contingent consideration as of December 31, 2008 was as follows:

$30,000,000 upon achievement of $80,000,000 in net product sales of new formulations of the Cardene product in any 12-consecutive-month period;

$30,000,000 upon achievement of $150,000,000 in net product sales of new formulations of the Cardene product in any 12-consecutive-month period;

a royalty of 10% on future net sales of new formulations of the Cardene product; and

a royalty of 5% on future net sales of any ularitide product.

In November 2008, we received our first royalty payment from EKR on net sales of new formulations of the Cardene product (the Cardene Pre-Mixed Bag), which commercially launched in September 2008. Based on current Cardene Pre-Mixed Bag sales levels, we do not expect to receive either of the $30.0 million milestone payments that we would earn if EKR achieves certain Cardene Pre-Mixed Bag sales thresholds, and we do not expect to receive material amounts of royalties on sales of the Cardene Pre-Mixed Bag. Also, because the ularitide product is still in clinical development, which could fail or be abandoned, we may never receive any ularitide-related royalty revenue and, even if ularitide is successfully developed, the marketing launch of ularitide would not likely occur for several years. Please refer to the risk factor, "We may not receive the contingent consideration related to the sale of the product rights to new formulations of Cardene and the ularitide development-stage

product under our Asset Purchase Agreement with EKR" in Item 1A of this Annual Report for further details.

In addition to our historical out-licensing activity described above, we intend to evaluate opportunities to develop and out-license new, proprietary antibody technologies, which we believe may provide advantages to pharmaceutical and biotechnology companies involved in the development of protein therapeutics.

In-Licensing Agreements

We have in-licensed certain technologies that support the development of our current pipeline products, and we will continue to pursue in-licensing of new technologies that may complement our current capabilities. We also are focused on expanding our pipeline with additional oncology-focused programs and, in connection with such efforts, we are evaluating and may enter in to in-licensing agreements. In addition, we may pursue other means to augment our current pipeline, including, but not limited to, entering into strategic collaboration agreements. See "Overview" section above.

MAJOR CUSTOMERS

We define our customers as our collaboration partners and our licensees from whom we have received and may receive reimbursement for research and development services, license fees, royalties and milestone payments. Note 17, "Revenues by Geographic Area and Significant Customers," in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Annual Report lists our major customers who each provided over 10% of our total operating revenues in each of the last three years. Also discussed in the note are material net foreign revenues by country in 2008, 2007, and 2006.

OUR PATENTS AND OTHER INTELLECTUAL PROPRIETARY RIGHTS

We expend a significant amount of our resources on research and development efforts to discover and develop innovative therapies for severe or life-threatening illnesses and to develop proprietary development technologies. Obtaining, maintaining and protecting the intellectual property rights, including patent rights, developed through our research and development efforts, is essential for our business to succeed. To that end, we actively seek to implement patent strategies to maximize the effectiveness of our intellectual property positions. We have numerous issued U.S and foreign patents and have a variety of patent applications pending in the U.S. and various foreign countries covering, among other things, compositions of matter, drug formulations, methods of use and action, and manufacturing.

While we file and prosecute patent applications to protect our inventions, our pending patent applications may not result in the issuance of patents or our issued patents may not provide competitive advantages. Also, our patent protection may not prevent others from developing competitive products using related or other technology.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation, which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

A number of companies, universities and research institutions have filed patent applications or received patents claiming compositions of matter, drug formulations, methods of use and action and manufacturing, which could relate to our programs. Some of these applications or patents may be competitive with our applications or contain material that could prevent the issuance of patents to us or result in a significant reduction in the scope of our issued patents. Additionally, other companies,

universities and research institutions may obtain patents that could limit our ability to use, import, manufacture, market or sell our products, commonly referred to as our "freedom to operate," or impair our competitive position. As a result, we might be required to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We may not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we may encounter significant delays in product development while we redesign potentially infringing products or methods or may not be able to market our products at all.

The scope, enforceability and effective term of issued patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in biotechnology patents, so that even issued patents may later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. We cannot assure you that the patents we obtain or the unpatented proprietary technology we hold will afford us significant commercial protection or competitive advantage. Additional information regarding risks associated with our patents and other proprietary rights that affect our business is contained under the headings "We must protect our patents and other intellectual property rights to succeed" and "We may need to obtain patent licenses from others in order to manufacture or sell our potential products and we may not be able to obtain these licenses on terms acceptable to us or at all" in Item 1A under the heading "Risk Factors."

In connection with the spin-off, PDL assigned to us (1) the patents and other intellectual property related to the Biotechnology Business; (2) the strategic collaboration, licensing and other agreements, described in the section above entitled "Strategic Collaborations and Licensing Agreements," related to the research, development, commercialization and optimization of human therapeutics, including the human therapeutics under development by PDL, and (3) other agreements pursuant to which third parties have licensed intellectual property rights to PDL. In addition, we obtained certain rights to the Queen et al. patents and the related intellectual property under a non-exclusive cross license agreement we entered into with PDL.

GOVERNMENT REGULATION

The manufacturing, testing, labeling, approval and storage of our products are subject to rigorous regulation by numerous governmental authorities in the United States and other countries at the federal, state and local level, including the FDA. Conduct of non-clinical and clinical studies in support of our products are similarly subject to US and international quality standards and guidelines, and are also subject to inspection from regulatory authorities at their discretion. The process of obtaining approval for initiating approval with a new pharmaceutical product and ultimately getting marketing approval requires expenditure of substantial resources and usually takes several years. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

The process for obtaining FDA approval of drug candidates customarily begins with the filing with the FDA of an IND for the use of a drug candidate to treat a particular indication. If the IND is accepted by the FDA, we would then start human clinical trials to determine, among other things, the proper dose, safety and efficacy of the drug candidate in the stated indication. The clinical trial process is customarily divided into three phases phase 1, phase 2 and phase 3. Each successive phase is generally larger and more time-consuming and expensive than the preceding phase. Throughout each phase we are subject to extensive regulation and oversight by the FDA. Even after a drug is approved and being marketed for commercial use, the FDA may require that we conduct additional trials, including "phase 4" trials, to further study safety or efficacy.

As part of the regulatory approval process, we must demonstrate to the FDA the ability to manufacture a pharmaceutical product before we receive marketing approval. The manufacturing and quality control procedures we and our manufacturing partners must undertake must conform to rigorous standards in order to receive FDA approval and the validation of these procedures is a costly endeavor. Pharmaceutical manufacturers are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the United States, foreign manufacturers must comply with these FDA-approved guidelines. These foreign manufacturers are also subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, state, local and other authorities may also regulate pharmaceutical product manufacturing facilities. Before we are able to manufacture commercial products, we or our contract manufacturer, as the case may be, must meet FDA guidelines.

For the development of pharmaceutical products outside the United States, we and our collaborators are subject to foreign regulatory requirements and, if the particular product is manufactured in the United States, FDA and other U.S. export provisions. Requirements relating to manufacturing, conduct of clinical trials and product licensing vary widely in different countries. We or our licensees may encounter difficulties or unanticipated costs or price controls in our respective efforts to secure necessary governmental approvals. This could delay or prevent us or our licensees from marketing potential pharmaceutical products. In addition, our promotional materials and activities must also comply with FDA regulations and other guidelines.

Both before and after marketing approval is obtained, a pharmaceutical product, its manufacturer and the holder of the Biologics License Application (BLA) or New Drug Application (NDA) for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny approval to a BLA or NDA if applicable regulatory criteria are not satisfied. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which we may market the pharmaceutical product. Further, marketing approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. In addition, under a BLA or NDA, the manufacturer of the product continues to be subject to facility inspections and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or marketing approvals or the imposition of criminal penalties against the manufacturer or BLA or NDA holder.

Additional information regarding the regulatory matters that affect our business is contained in Item 1A under the heading "Risk Factors."

COMPETITION

Potential competitors have developed and are developing mouse, chimeric, human and humanized antibodies or other compounds for treating cancers and immunologic diseases. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that may compete with our antibody technology platform. Competitors may succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborators may also independently develop products that are competitive with products that we have licensed to them. Any product that we or our collaborators succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborators can develop products, complete clinical testing and approval processes, and supply commercial quantities of the

products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources, and the effectiveness of the marketing used with respect to a product will affect its success.

Other competitive factors affecting our business generally include:

- product efficacy and safety;
- timing and scope of regulatory approval;
- product availability, marketing and sales capabilities;
- reimbursement coverage;
- the amount of clinical benefit of our product candidates relative to their cost;
- method of and frequency of administration of any of our product candidates which may be commercialized;
- patent protection of our product candidates;
- the capabilities of our collaborators; and
- the ability to hire qualified personnel.

EMPLOYEES

As of December 31, 2008, we had approximately 327 full-time employees. Of the total, 229 were engaged in research and development and 99 were engaged in general and administrative functions. Approximately 49 of these employees were short-term transition employees as a result of the restructuring activities we undertook in early 2008, and we expect to terminate the employment of all of these transition employees by March 31, 2009. In addition, we announced a further reduction in force in January 2009 pursuant to which we eliminated approximately 80 additional positions. At the conclusion of these restructuring efforts, which we expect to occur by the third quarter of 2009, we expect to have approximately 200 employees. We have recognized, and we will continue to recognize through mid-2009, restructuring charges related to the termination of the transition employees as well as the employees affected by the January 2009 restructuring efforts. See Note 7 and 20 to the Consolidated Financial Statements found elsewhere in this Annual Report for further information related to the nature of our workforce reductions and the related restructuring charges.

Our scientific staff members have diversified experience and expertise in molecular and cell biology, biochemistry, immunology, oncology, protein chemistry, computational chemistry, computer modeling, process engineering and pharmaceutical, analytical, pharmacological, toxicological and other sciences. Our success will depend in large part on our ability to attract and retain skilled and experienced employees. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

ENVIRONMENTAL COMPLIANCE

We seek to comply with environmental statutes and the regulations of federal, state and local governmental agencies. We have put into place processes and procedures and maintain records in order to monitor environmental compliance. We may invest additional resources, if required, to comply with applicable regulations, and the cost of such compliance may increase significantly.

AVAILABLE INFORMATION

For a report of our fiscal year 2008 operating results, total assets, the amount we spent on research and development activities, and our revenues from external customers, including a geographic

breakdown of such revenues, see the Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

We file electronically with the Securities and Exchange Commission (SEC) our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is *www.sec.gov*.

We will make available free of charge on or through our website at *www.facetbiotech.com* our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements, as well as amendments to these reports and statements, as soon as practicable after we have electronically filed such material with, or furnished it to, the SEC. You may also obtain copies of these filings free of charge by contacting our Corporate and Investor Relations Department by calling (650) 454-1000.

ITEM 1A. RISK FACTORS

This Annual Report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "believes," "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Annual Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including the risk factors set forth below, and for the reasons described elsewhere in this Annual Report. All forward-looking statements and reasons why results may differ included in this Annual Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

If our research and development efforts are not successful, we may not be able to effectively develop new products.

We are engaged in research activities intended to, among other things, progress therapeutic candidates into clinical development. In the near-term, we will focus on obtaining new product candidates through various means, including, but not limited to, in-licensing them from or entering in to strategic collaborations with institutions or other biotechnology or pharmaceutical companies. Acquiring rights to products in this manner poses risks, including that we may not be unable to successfully integrate the research, development and commercialization capabilities necessary to bring these products to market. In addition, we may not be able to identify or acquire suitable products to in-license.

Our antibody product candidates are in various stages of development and many are in an early development stage. If we are unsuccessful in our research efforts to identify and obtain rights to new validated targets and develop product candidates that lead to the required regulatory approvals and the successful commercialization of products, our ability to develop new products could be harmed.

Our business strategy is dependent on our ability to in-license or otherwise acquire the rights to develop and commercialize products.

We have determined that for the foreseeable future, the expansion of our existing pipeline in the near term should be accomplished primarily through the in-licensing or other acquisition of additional pre-clinical and clinical oncology programs. Therefore, our future success will be dependent in substantial part upon identifying and in-licensing or otherwise acquiring such therapeutic products from third parties. While we are actively seeking clinical programs that fit within our strategic objectives, the competition for the acquisition of attractive oncology programs is intense, and we cannot assure you that we will be able to in-license or otherwise acquire clinical programs in the future on acceptable terms, if at all. In addition, we may acquire clinical programs for indications in which we have limited expertise and, as a result, we may need to attract and retain additional personnel or expand existing functions to manage the development of these programs. There can be no assurance that we will not meet challenges in integrating potential new programs or personnel to manage those programs, and any such programs could be delayed or fail as a result.

If we are unable to in-license or otherwise acquire development programs on acceptable terms and successfully develop and commercialize them, our business could be harmed.

Unless our clinical studies demonstrate the safety and efficacy of our product candidates, we will not be able to commercialize our product candidates.

To obtain regulatory approval to market and sell any of our existing or future product candidates, we must satisfy the FDA and other regulatory authorities abroad, through extensive preclinical and clinical studies, that our product candidates have an acceptable safety profile and are efficacious. We may not conduct the types of testing eventually required by regulatory authorities to demonstrate an adequate safety profile for the particular indication, or the tests may indicate that the safety profile of our product candidates is unacceptably inferior to therapeutics with comparable efficacy or otherwise unsuitable for use in humans in light of the expected therapeutic benefit of the product candidate. Clinical trials and preclinical testing are expensive, can take many years and have an uncertain outcome. In addition, initial testing in preclinical studies or in phase 1 or phase 2 clinical trials may indicate that the safety profile of a product candidate is adequate for approval, but does not ensure that safety issues may not arise in later trials, or that the overall safety profile for a product candidate will be sufficient for regulatory approval in any particular product indication. We may experience numerous unforeseen events during, or as a result of, the preclinical testing or clinical studies or clinical development, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our testing or trials may produce inconclusive or negative safety results, which may require us to conduct additional testing or trials or to abandon product candidates that we believed to be promising;
- our product candidates may have unacceptable pharmacology, toxicology or carcinogenicity; and
- our product candidates may cause significant adverse effects in patients.

Even if we are able to demonstrate efficacy of any product candidate, any adverse safety events would increase our costs and could delay or prevent our ability to continue the development of or commercialize our product candidates, which would adversely impact our business, financial condition

and results of operations. We are aware that our drug candidates can cause various adverse side effects in humans, some of which are predictable and some of which are unpredictable. We proceed to evaluate the safety and efficacy of these drug candidates based on data we accumulate from preclinical assessments and ongoing clinical studies. We believe that our drug candidates have an acceptable safety profile for the potential indications in which we are currently conducting clinical trials. Data from ongoing or future clinical trials may indicate that a drug candidate causes unanticipated or more significant adverse side effects either used alone or when used in combination with other drugs, in particular patient populations or at increased dosages or frequency of administration. This may lead us to conclude that the drug candidate does not have an acceptable safety profile for a particular patient population or use.

The clinical development of drug products is inherently uncertain and expensive and subject to extensive government regulation.

Our future success depends entirely upon the success of our clinical development efforts. Clinical development, however, is a lengthy, time-consuming and expensive process and subject to significant risks of failure. In addition, we must expend significant amounts to comply with extensive government regulation of the clinical development process.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended use in humans. We have incurred and will continue to incur substantial expense for, and we have devoted and expect to continue to devote a significant amount of time to, preclinical testing and clinical trials. Despite the time and expense incurred, our clinical trials may not adequately demonstrate the safety and effectiveness of our product candidates.

Completion of clinical development generally takes several years or more. The length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly according to the type, complexity and intended use of the product candidate and is difficult to predict. Further, we, the FDA, the EMEA, investigational review boards or data safety monitoring boards may decide to temporarily suspend or permanently terminate ongoing trials. Failure to comply with extensive regulations may result in unanticipated delay, suspension or cancellation of a trial or the FDA's or EMEA's refusal to accept test results. As a result of these factors, we cannot predict the actual expenses that we will incur with respect to preclinical or clinical trials for any of our potential products, and we expect that our expense levels will fluctuate unexpectedly in the future. Despite the time and expense incurred, we cannot guarantee that we will successfully develop commercially viable products that will achieve FDA or EMEA approval or market acceptance, and failure to do so would materially harm our business, financial condition and results of operations.

Early clinical trials such as phase 1 and 2 trials generally are designed to gather information to determine whether further trials are appropriate and, if so, how such trials should be designed. As a result, data gathered in these trials may indicate that the endpoints selected for these trials are not the most relevant for purposes of assessing the product or the design of future trials. Moreover, success or failure in meeting such early clinical trial endpoints may not be dispositive of whether further trials are appropriate and, if so, how such trials should be designed. We may decide, or the FDA or other regulatory agencies may require us, to make changes in our plans and protocols. Such changes may relate, for example, to changes in the standard of care for a particular disease indication, comparability of efficacy and toxicity of potential drug product where a change in the manufacturing process or manufacturing site is proposed, or competitive developments foreclosing the availability of expedited approval procedures. We may be required to support proposed changes with additional preclinical or clinical testing, which could delay the expected time line for concluding clinical trials.

Larger or later stage clinical trials may not produce the same results as earlier trials. Many companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in clinical trials, including advanced clinical trials, even after promising results had been obtained in earlier trials. For example, in August 2007, PDL announced that it would terminate the phase 3 program of its *Nuvion*® (visilizumab) antibody in intravenous steroid-refractory ulcerative colitis because data from treated patients showed insufficient efficacy and an inferior safety profile in the visilizumab arm compared to IV steroids alone.

Even when a drug candidate shows evidence of efficacy in a clinical trial, it may be impossible to further develop or receive regulatory approval for the drug if it causes an unacceptable incidence or severity of side effects, or further development may be slowed by the need to find dosing regimens that do not cause such side effects.

In addition, we may not be able to successfully commence and complete all of our planned clinical trials without significant additional resources and expertise because we have a number of potential products in clinical development. The approval process takes many years, requires the expenditure of substantial resources, and may involve post-marketing surveillance and requirements for post-marketing studies. The approval of a product candidate may depend on the acceptability to the FDA or other regulatory agencies of data from our clinical trials. Regulatory requirements are subject to frequent change. Delays in obtaining regulatory approvals may:

adversely affect the successful commercialization of any drugs that we develop;

impose costly procedures on us;

diminish any competitive advantages that we may attain; and

adversely affect our receipt of any revenues or royalties.

In addition, we may encounter regulatory delays or failures of our clinical trials as a result of many factors, all of which may increase the costs and expense associated with the trial, including:

changes in regulatory policy during the period of product development;

delays in obtaining sufficient supply of materials to enroll and complete clinical studies according to planned timelines;

delays in obtaining regulatory approvals to commence a study;

delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

delays in the enrollment of patients;

lack of efficacy during clinical trials; or

unforeseen safety issues.

Regulatory review of our clinical trial protocols may cause us in some cases to delay or abandon our planned clinical trials. Our potential inability to commence or continue clinical trials, to complete the clinical trials on a timely basis or to demonstrate the safety and efficacy of our potential products, further adds to the uncertainty of regulatory approval for our potential products.

We may be unable to enroll a sufficient number of patients in a timely manner in order to complete our clinical trials.

The rate of completion of clinical trials is significantly dependent upon the rate of patient enrollment. Patient enrollment is a function of many factors, including:

the size of the patient population;

perceived risks and benefits of the drug under study;

availability of competing therapies, including those in clinical development;

availability of clinical drug supply;

availability of clinical trial sites;

design of the protocol;

proximity of and access by patients to clinical sites;

patient referral practices of physicians;

eligibility criteria for the study in question; and

efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

We may have difficulty obtaining sufficient patient enrollment or clinician support to conduct our clinical trials as planned, and we may need to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may result in our being unable to successfully achieve our projected development timelines, or potentially even lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication.

If our collaborations are not successful or are terminated by our collaborators, we may not effectively develop and market some of our product candidates.

We have agreements with biotechnology and other companies to develop, manufacture and market certain of our potential products. In some cases, we rely on our collaborators to manufacture such products and essential components for those products, design and conduct clinical trials, compile and analyze the data received from these trials, obtain regulatory approvals and, if approved, market these licensed products. As a result, we may have limited or no control over the manufacturing, development and marketing of these potential products and little or no opportunity to review the clinical data prior to or following public announcement. In addition, the design of the clinical studies may not be sufficient or appropriate for regulatory review and approval and we may have to conduct further studies in order to facilitate approval.

In September 2005 and August 2008, respectively, we entered into collaboration agreements with Biogen Idec for the joint development of daclizumab in certain indications, including MS, and volociximab (M200) in all indications, and BMS for the co-development of elotuzumab in multiple myeloma and other potential oncology indications. These agreements are particularly important to us. The collaboration agreements provide significant combined resources for the development, manufacture and potential commercialization of covered products. We and our collaborators each assume certain responsibilities and share expenses. Because of the broad scope of the collaborations, we are particularly dependent upon the performance by Biogen Idec and BMS of their respective obligations under the agreements. The failure of Biogen Idec or

BMS to perform their obligations, our failure to perform our obligations, our failure to effectively manage the relationships, or a material contractual dispute between us and either of our collaborators could have a material adverse effect on our prospects or financial results. Moreover, our financial results depend in substantial part upon our

efforts and related expenses for these programs. Our revenues and expenses recognized under each collaboration will vary depending on the work performed by us and our collaborators in any particular reporting period.

We rely on other collaborators, such as contract manufacturers, clinical research organizations, medical institutions and clinical investigators, including physician sponsors, to conduct nearly all of our clinical trials, including recruiting and enrolling patients in the trials. If these parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed or may not obtain regulatory approval for or commercialize our product candidates. If any of the third parties upon whom we rely to conduct our clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, our clinical trials may be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by third party contractors is compromised due to their failure to adhere to applicable laws, our clinical protocols or for other reasons, we may not obtain regulatory approval for or successfully commercialize any of our product candidates. If our relationships with any of these organizations or individuals terminates, we believe that we would be able to enter into arrangements with alternative third parties. However, replacing any of these third parties could delay our clinical trials and could jeopardize our ability to obtain regulatory approvals and commercialize our product candidates on a timely basis, if at all.

Our collaborators can terminate our collaborative agreements under certain conditions, and in some cases on short notice. A collaborator may terminate its agreement with us or separately pursue alternative products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by us, or our collaborative effort. Even if a collaborator continues to contribute to the arrangement, it may nevertheless decide not to actively pursue the development or commercialization of any resulting products. In these circumstances, our ability to pursue potential products could be severely limited.

In 2004 and 2005, we entered into two collaboration arrangements with Roche for the joint development and commercialization of daclizumab for the treatment of asthma and other respiratory diseases and transplant indications. In 2006, Roche notified us of its election to discontinue its involvement in both of these collaboration arrangements. As a result of the termination of this relationship, we suspended the active clinical development of daclizumab in these indications and, consequently, the development expenses related to the development of daclizumab in these indications were reduced from historical and forecasted levels. Under the terms of the agreement governing this collaboration with Roche, the costs of clinical studies and other development costs were shared by Roche through the effective termination dates, so our financial condition was not materially affected as a result of the termination of these collaborations.

Continued funding and participation by collaborators will depend on the continued timely achievement of our research and development objectives, the retention of key personnel performing work under those agreements and on each collaborator's own financial, competitive, marketing and strategic capabilities and priorities. These considerations include:

- the commitment of each collaborator's management to the continued development of the licensed products or technology;
- the relationships among the individuals responsible for the implementation and maintenance of the development efforts; and
- the relative advantages of alternative products or technology being marketed or developed by each collaborator or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully.

Our ability to enter into new relationships and the willingness of our existing collaborators to continue development of our potential products depends upon, among other things, our patent position with respect to such products. If we are unable to successfully maintain our patents we may be unable to collect royalties on existing licensed products or enter into additional agreements.

In addition, our collaborators may independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues or the likelihood of achieving revenues under our agreements with these collaborators.

We must protect our patent and other intellectuaize: 85%; vertical-align: text-top''>® for our FDA-approved indication. While we believe that the reexamination will strengthen the patent, there is no guarantee that the process will be successful since the USPTO reviews the entire prosecution history of a patent during a reexamination and could determine that some or all of the patent claims are invalid. Typically, a reexamination takes approximately 18 months to complete.

We intend to file a 510(k) application with the FDA for an expansion of our BLU-U® label to include severe acne based on the results of our Phase IIb clinical trial, which compared the safety and efficacy of PDT) using our BLU-U® brand light plus vehicle containing Levulan® (aminolevulinic acid HCl) to that of PDT using the BLU-U® plus vehicle without Levulan® (the control group) in patients with moderate to severe facial acne vulgaris. We have also filed a patent application to cover an invention arising from the study.

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

We also own patents covering Nicomide® and the AVAR® products which we have licensed, and have patent applications pending that will cover other products, if those applications issue as patents, including an application on the design of the applicator wand for ClindaReach® pledgets. The Nicomide® patent expires in 2025 and the AVAR® patent expires in 2021.

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

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

In addition, we cannot guarantee that our patents, whether owned or licensed, or any future patents that may issue, will prevent other companies from developing similar or functionally equivalent products. Further, we cannot guarantee that we will continue to develop our own patentable technologies or that our products or

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methods will not infringe upon the patents of third-parties. In addition, we cannot guarantee that any of the patents that may be issued to us will effectively protect our technology or provide a competitive advantage for our products or will not be challenged, invalidated, or circumvented in the future.

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

Even in the absence of composition of matter patent protection for ALA, we may receive financial benefits from: (i) patents relating to the use of such products (like PARTEQ s patents); (ii) patents relating to special compositions and formulations (like the Nicomide® and AVAR® patents); (iii) limited marketing exclusivity that may be available under the Hatch-Waxman Act and any counterpart protection available in foreign countries and (iv) patent term extension under the Hatch-Waxman Act. See the section entitled Business Government Regulation . Effective patent protection also depends on many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of the new drug provisions of the Food, Drug and Cosmetic Act, or similar laws and regulations in other countries.

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

Manufacturing

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

Distribution

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

In January 2006, as amended in September 2007, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc., or Stiefel, covering current and future uses of our proprietary Levulan® Kerastick® for PDT in dermatology. The agreement, grants Stiefel an exclusive right to distribute,

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promote and sell the Levulan® Kerastick® in the western hemisphere from and including Mexico south, and all other countries in the Caribbean, excluding United States territories. We manufacture and supply to Stiefel on an exclusive basis in the territory all of Stiefel s reasonable requirements for the product. The agreement has an initial term of ten years. In September 2007, we amended certain terms of the original Stiefel agreement to reflect our plans to launch in other Latin American countries prior to Brazil. Pursuant to the amendment, Stiefel will make aggregate milestone payments to us of up to $2,250,000, as follows: (i) $375,000 upon launch of the product in either Mexico or Argentina which has been paid; (ii) $375,000 upon receipt of acceptable pricing approval in Brazil which has been paid; (iii) two installments of $375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of $375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. In addition, the transfer price for the product was amended to set a fixed price plus a royalty on net sales, rather than a revenue-sharing arrangement as under the Agreement. We believe that the amended transfer price reduces some of the risk related to currency and market price fluctuations during the ten-year term of the agreement. The parties have certain rights to terminate the agreement prior to the end of the initial term, and Stiefel has an option to extend the term for an additional ten years on mutually agreeable terms and conditions. In the fourth quarter of 2007, the product was launched in Argentina, Chile, Colombia, and Mexico, and in April 2008 the product was launched in Brazil. We began recognizing revenue under the agreement in the fourth quarter of 2007.

The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval. The first contract year for all countries other than Brazil began in October 2007, and for Brazil began in April 2008. For the contract year ended in October 2008 Stiefel did not meet its minimum purchase obligations under the agreement. The agreement provides that within 60 days of the year end, Stiefel is required to pay us the difference between its actual purchases and the contractual minimums (a gross up payment). If Stiefel fails to make the gross up payment, our remedies include, without limitation, appointing one or more distributors in the territory or terminating the agreement. Stiefel did not make the gross up payment within the contractual time period, and the parties are presently discussing actions to be taken, if any, due to the first year shortfall. Also, since Stiefel s sales to third parties during the contract year ended October 2008 were below its minimum purchase obligations, Stiefel has the unilateral right to cancel the agreement.

On January 4, 2007, we entered into an exclusive marketing, distribution and supply agreement with Daewoong covering current and future uses of the Levulan® Kerastick® for PDT in dermatology. The agreement grants Daewoong exclusive rights to distribute, promote and sell the Levulan® Kerastick® in Korea, Taiwan, China, including without limitation Hong Kong, India, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. We will manufacture and supply the product to Daewoong on certain terms and conditions. The agreement has an initial term of ten years (subject to earlier termination and extension provisions). Daewoong will complete final integration and submission on our behalf of all registrations and regulatory filings for the product in the territory. Under the terms of the agreement, Daewoong will make up to $3,500,000 in milestone payments to us, $1,000,000 of which was paid on signing, and $1,000,000 of which was paid upon receipt of Korean regulatory approval of the product. The remaining milestones consist of two installments of $750,000 each for cumulative end-user sales totaling 200,000 units and 500,000 units. In order to maintain its exclusive rights, Daewoong is obligated to purchase a certain number of units of the product and meet certain regulatory timelines. We will manufacture the product in our facility in Wilmington, Massachusetts. We will also receive a minimum transfer price per unit plus a percentage of Daewoong s end-user price above a certain level. In 2007, the product was launched Korea, and we began recognizing revenue under the agreement in the fourth quarter of 2007. In the third quarter of 2008, we amended this agreement to allow Daewoong to distribute our product in Japan on a named-patient basis only in order to test this market. This amendment has a term of two years.

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

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Marketing and Sales

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

As 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. Initially the sales force was comprised of six direct representatives, various independent representatives, and an independent sales distributor, designed to focus on most of our key geographic markets in the United States. As of December 31, 2008 and 2007, we had 40 and 35, respectively, sales representatives and management deployed nationally.

Competition

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

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

PhotoCure has received marketing approval of its ALA precursor (ALA methyl-ester) compound for PDT treatment of AK and basal cell carcinoma, called BCC, in the European Union, New Zealand, Australia, and countries in Scandinavia. In July 2004, PhotoCure received FDA approval in the United States for its AK therapy. We have been informed that PhotoCure has conducted test marketing activities in the U.S. but it has not yet launched its product. 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 us royalties on sales of its ester products to the extent they are covered by our patents in the U.S. and certain other territories. As part of the agreement, PhotoCure paid us a prepaid royalty in the amount of $1 million.

In August 2003, Axcan Pharma Inc. received FDA approval for the use of its product, PHOTOFRIN®[2], for photodynamic therapy in the treatment of high grade dysplasia associated with Barrett s esophagus. This

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

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approval enabled Axcan to be the first company to market a PDT therapy for this indication, for which we designed our proprietary sheath device and have conducted pilot clinical trials.

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

We believe that comparisons of the properties of various photosensitizing PDT drugs will also highlight important competitive issues. We expect that our principal methods of competition with other PDT companies will be based upon such factors as the ease of administration of our photodynamic therapy; the degree of generalized skin sensitivity to light; the number of required doses; the selectivity of our drug for the target lesion or tissue of interest; and the type and cost of our light systems. New drugs or future developments in PDT, laser products or in other drug technologies may provide therapeutic or cost advantages for competitive products. We believe that with increased reimbursement for our PDT-related procedure fee, including a 12% increase that was effective January 2008 and a 6% increase effective January 2009, our treatment is increasingly financially viable for practitioners, and more competitive with alternative AK therapies from a practice management perspective. However, no assurance can be given that developments by other parties will not render our products uncompetitive or obsolete.

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

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

Government Regulation

The manufacture and sale of pharmaceuticals and medical devices in the United States 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

[3] Efudex® is a registered trademark of Valeant Pharmaceuticals International.
[4] Solaraze® is a registered trademark of SkyePharma PLC.
[5] ALDARA® is a registered trademark of Graceway Pharmaceuticals, LLC.

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costs. The steps required before a new drug can be produced and marketed for human use in the United States include:

preclinical studies,

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

human clinical trials, and

the approval of a New Drug Application, or NDA.

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

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

In Phase I, studies are usually conducted on a small number of healthy human volunteers to determine the maximum tolerated dose and any product-related side effects of a product. Phase I studies generally require several months to complete, but can take longer, depending on the drug and the nature of the study. Phase II studies are conducted on a small number of patients having a specific disease to determine the most effective doses and schedules of administration. 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.

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The supplement deals primarily with safety and effectiveness data related to the new indication or dosage. Finally, the FDA requires reporting of certain safety and other information, often referred to as adverse events that become known to a manufacturer of an approved drug. Safety information collected through this process can result in changes to a product s labeling or withdrawal of a product from the market. If an active ingredient of a drug product has been previously approved, drug applications can be filed that may be less time-consuming and costly.

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

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

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

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

The PMA process can be expensive, uncertain and lengthy. A number of other companies have sought premarket approval for devices that have never been approved for marketing. The review time is often significantly extended by

the FDA, which may require more information or clarification of information already provided in the submission. During the review period, an advisory committee likely will be convened to

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review and evaluate the PMA application and provide recommendations to the FDA as to whether the device should be approved for marketing. In addition, the FDA will inspect the manufacturing facility to ensure compliance with cGMP requirements for medical devices prior to approval of the PMA application. If granted, the premarket approval may include significant limitations on the indicated uses for which the product may be marketed, and the agency may require post-marketing studies of the device. 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. For Levulan® PDT, we have received such approval in Canada, and together with Stiefel under our agreement for Latin America, we have received regulatory approval in Argentina, Brazil, Chile, Colombia and Mexico. Also, together with Daewoong, we have received approval in Korea. We expect to apply for approvals in additional territories 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

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

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 securities laws and regulations, including the Sarbanes-Oxley Act of 2002. We may also be subject to other present and possible future local, state, federal and foreign regulations.

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

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

laws and regulations in the future. Furthermore, we cannot assure that current or future environmental laws or regulations will not materially adversely affect our operations, business or assets. Although we believe that our safety procedures for the handling and disposal of such hazardous materials comply with the standards prescribed by current environmental laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such

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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.

Segment Reporting

We operate in two segments, Photodynamic Therapy, or PDT, Drug and Device Products and Non-Photodynamic Therapy, or Non-PDT, Drug Products. Our Levulan® Kerastick® and BLU-U® products comprise our PDT segment, while Nicomide®, ClindaReach® and the other products acquired in the acquisition of Sirius comprise our Non-PDT segment. For more information about our segments, including financial results of each segment, see Note 14 of the Notes to Consolidated Financial Statements.

Information About Geographic Sources of Revenue

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

Employees

At the end of 2008, we had 86 employees, including 2 part-time employees. We also retain numerous independent consultants and temporary employees to support our business needs. We have employment agreements with all of our key executive officers.

Internet Information

Our Internet site is located at www.dusapharma.com. Copies of our reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, may be accessed from our website, free of charge, as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to the SEC. Please note that our Internet address is being provided for reference only and no information contained therein is incorporated by reference into our Exchange Act filings. The public may read or copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Room 1580, Washington DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, including DUSA, that file electronically with the SEC. The address of that site is www.sec.gov.

ITEM 1A. ***RISK FACTORS***

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

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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.

If We Do Not Become Profitable As Expected, We May Need More Capital.

We have approximately $18,884,000 in cash, cash equivalents and marketable securities as of December 31, 2008. Our cash should be sufficient for current operations for at least the next 12 months. While our goal is to become cash flow positive and profitable on a quarterly basis sometime late in 2009, if we are unable to do so, we may have to reduce our headcount, curtail certain variable expenses, or raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

Our Ability To Become Profitable Has Been Delayed Since We No Longer Sell and Distribute Nicomide® As A Prescription Product.

In March 2006, we acquired Nicomide® in connection with our merger with Sirius Laboratories, Inc. Following investigation by the FDA of Actavis Totowa, LLC, the former manufacturer of Nicomide®, in April 2008, Actavis ceased manufacturing several prescription vitamins, including Nicomide®. The FDA considers prescription dietary supplements to be unapproved new drugs. In response to our discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. We are in discussions with the FDA regarding new labeling, including use of the trademark, in order to commercialize Nicomide® as a non-prescription dietary supplement in compliance with DSHEA. Should we re-launch the product with a DSHEA label, we expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic prescription Nicomide® levels, thus delaying our ability to become profitable. We are also considering the sale or license of the product and related patent.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge which we entered into in October 2007 to settle certain patent litigation. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement.

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

If we do not generate sufficient revenues from our approved products, we may be forced to delay or abandon our development program for solid organ transplant recipients or other programs we may wish to initiate. The pharmaceutical development and commercialization process is time consuming and costly, and any delays might result in higher costs which could adversely affect our financial condition. Without sufficient product sales, we would need alternative sources of funding. There is no guarantee that adequate funding sources could be found to continue

the development of our technology. We might be required to commit substantially greater capital than we have available to research and development and we may not have sufficient funds to complete this program.

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

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

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

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

send warning letters, as received by the manufacturer of our BLU-U®,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products, as Actavis Totowa did with Nicomide®,

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

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

require us to recall products,

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

impose restrictions on our operations, and/or

criminally prosecute us.

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

Certain of the products acquired or licensed in connection with the Sirius merger, including Nicomide®, are regulated by FDA under its marketed unapproved drugs compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and,

at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and/or bring these products into compliance with current FDA regulations. As result of discussions with the FDA, we stopped the sale and distribution of Nicomide® and Psoriatec® as prescription products in June 2008. Our license agreement for Psoriatec® expired on September 30, 2008.

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 the BLU-U®, who has received warning letters from the FDA, fail to maintain compliance with FDA regulatory requirements, it would be time consuming and costly to remedy the

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problem(s) or to qualify other sources. These consequences could have a significant adverse effect on our financial condition and operations. As part of our FDA approval for the Levulan® Kerastick® for AK, we were required to conduct two Phase IV follow-up studies. We successfully completed the first study; and submitted our final report on the second study to the FDA in January 2004. The FDA has requested additional information, which was provided to them in June 2008. We are awaiting their response. Additionally, if previously unknown problems with the product, a manufacturer or its facility are discovered in the future, changes in product labeling restrictions or withdrawal of the product from the market may occur. Any such problems could affect our ability to become profitable.

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

Sales of our products are dependent, in large part, on reimbursement from government health and administration authorities, private health insurers, distribution partners and other organizations. As a result of the current global credit and financial market conditions, government authorities and private insurers may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenues.

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

If the Economic Slowdown Affects Our Market, Our Cash Burn Will Increase And Our Ability To Achieve Profitability Will Be Delayed.

We believe that a portion of our revenues are generated by patients that pay for their procedures out-of-pocket. If the recession causes these patients to postpone or cancel their procedures, our revenues could be reduced, and we will be required to use more of our cash. This could cause a delay in our ability to achieve profitability on a sustainable basis.

We Have Significant Losses And Anticipate Continued Losses.

We have a history of operating losses. We expect to have continued losses until sales of our products increase substantially. We incurred net losses of $6,250,000, $14,714,000 and $31,350,000 for the years ended December 31, 2008, 2007 and 2006, respectively. As of December 31, 2008, our accumulated deficit was approximately $141,851,000. 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 Obtain The Necessary Capital To Fund Our Operations, We Will Have To Delay Our Development Program And May Not Be Able To Complete Our Clinical Trials.

While we completed a private placement raising net proceeds of approximately $10.3 million in October 2007, we may need substantial additional funds to fully develop, manufacture, market and sell other potential products. We may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. We cannot predict whether any additional financing will be available at all or on acceptable terms. Depending on the extent of available funding, we may delay, reduce in scope or eliminate our SOTR research and development program. We may also choose to license rights to third parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own which could reduce our potential revenues.

The availability of additional capital to us is uncertain. There can be no assurance that additional funding will be available to us on favorable terms, if at all. Any equity financing, if needed, would likely result in dilution to our existing shareholders and debt financing, if available, would likely involve significant cash

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payment obligations and include restrictive covenants that restrict our ability to operate our business. Failure to raise capital if needed could materially adversely impact our business, our financial condition, results of operations and cash flows.

If We Are Not Successful With The Reexamination Of Our Patent, We Could Lose Market Share.

In January 2009, we filed a request for reexamination with the United States Patent and Trademark Office (USPTO) of one of the patents licensed from Queens University covering certain methods of using our product, Levulan®, for our FDA-approved indication. While we believe that the reexamination will strengthen the patent, there is no guarantee that the process will be successful since the USPTO reviews the entire prosecution history of a patent during a reexamination and could determine that some or all of the patent claims are invalid. Typically, a reexamination takes approximately 18 months to complete. The patent is due to expire in 2013. If the USPTO finds that the patent is invalid, generic competitors could enter the market and we could lose market share. This would adversely affect our financial condition and results of operations and make it more difficult for us to become profitable.

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

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

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

compositions and apparatus for those methods, and

unique physical forms of ALA.

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

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.

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Nicomide® is covered by a United States patent which issued in December 2005. River s Edge Pharmaceuticals, LLC filed an application with the USPTO for the reexamination of the patent which was vacated by the USPTO on March 6, 2008. On October 28, 2007, we entered into a settlement agreement and mutual release, or Settlement Agreement, to dismiss the lawsuit brought by DUSA against River s Edge, asserting a number of claims arising out of River s Edge s alleged infringement of U.S. Patent No. 6,979,468 under which DUSA has marketed, distributed and sold Nicomide®. Under the terms of the Settlement Agreement, River s Edge unconditionally acknowledged the validity and enforceability of the Nicomide® patent.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we will be paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement.

Another company has launched a substitutable niacinamide product, which may cause us to again consider litigation and the validity of the Nicomide® patent could be tested again. Also, new products have been launched that are competing with Nicomide®. These events, together with our decision regarding the marketing of Nicomide will delay our ability to be profitable.

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

While we attempt to protect our proprietary information as trade secrets through agreements with each employee, licensing partner, consultant, university, pharmaceutical company and agent, we cannot guarantee that these agreements will provide effective protection for our proprietary information. It is possible that all of the following issues could negatively impact our ability to be profitable:

these persons or entities might breach the agreements,

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

our competitors will independently develop or otherwise discover our trade secrets.

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

The costs of litigation or any proceeding relating to our intellectual property 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 such as companies that have launched niacinamide products, may infringe one or more of our patents, and cause us to spend significant resources to enforce our patent rights. Also, in a lawsuit against a third-party for infringement of our patents in the United States, that third-party may challenge the validity of our patent(s). We cannot guarantee that a third-party will not claim, with or without merit, that our patents are not valid 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, or be issued a patent claiming technology also claimed by us in a pending United States application(s), we may be required to participate in interference proceedings in the USPTO to determine the priority of the invention. A third-party could also request the declaration of a patent interference between one of our issued United States patents and one of its patent applications. Any interference proceedings likely would require participation by us and/or PARTEQ, could involve substantial legal fees and result in a loss or lessening of our patent protection.

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In October 2008, Winston Laboratories, Inc. filed a notice of demand for arbitration with us alleging that we breached the agreements relating to Psoriatec®. Although we are in settlement discussions, we intend to vigorously defend ourselves, and this proceeding will likely involve considerable legal expenses which could negatively affect our financial results.

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®, And Meted®, Any Supply Or Manufacturing Problems Could Negatively Impact Our Sales As Occurred With Nicomide®.

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

Following investigation by the FDA of Actavis Totowa, LLC, the former manufacturer of Nicomide®, in April 2008 Actavis ceased manufacturing several prescription vitamins, including Nicomide®. The FDA considers prescription dietary supplements to be unapproved new drugs. In response to our discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. We are in discussions with the FDA regarding new labeling, including use of the trademark, in order to commercialize Nicomide® as a non-prescription dietary supplement in compliance with DSHEA. Should we re-launch the product with a DSHEA label, we expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic prescription Nicomide® levels. We are also considering the sale or license of the product and related patent.

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

product yields,

quality control,

component and service availability,

compliance with FDA regulations, and

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

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

We Have Only Limited Experience Marketing And Selling Pharmaceutical Products And No Experience Marketing Dietary Supplements, 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 do not have experience marketing dietary supplement products like Nicomide®. If our sales and marketing efforts fail, then sales of the Levulan® Kerastick®, the BLU-U®, Nicomide® (if FDA labeling issues are resolved) and other products will be adversely affected.

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

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

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

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

potential advantages over alternative treatments,

the ability to offer our product for sale at competitive prices,

relative convenience and ease of administration,

the strength of marketing and distribution support, and

sufficient third-party coverage or reimbursement.

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

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan® Kerastick® for AK therapy will be limited. While we continue to support efforts to improve reimbursement levels to physicians and are working with the major private insurance carriers to improve coverage for our therapy, if our efforts are not successful, broader adoption of our therapy and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK were made over the last five years, some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

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

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

Our Potential Products Are In Early Stages Of Development And May Never Result In Any 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,

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

failure to achieve market acceptance.

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

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

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

We cannot predict whether we will obtain any other regulatory approvals. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan® PDT or photodetection, known as PD, is safe and effective for any new use we are studying as we experienced with our recent acne study. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy.

In response to our discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008, which FDA considers to be an unapproved new drug. We are in discussions with the FDA regarding new labeling, including use of the trademark, in order to allow us or a third-party on our behalf to commercialize Nicomide® as a non-prescription dietary supplement in compliance with DSHEA. Should we re-launch the product with a DSHEA label, we expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic prescription Nicomide® levels. We are also considering the sale or license of the product and related patent.

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

We are a small company with only 86 employees, including 2 part-time employees, as of December 31, 2008. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer, especially in the photodynamic therapy portion of our business. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light device areas.

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

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

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not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

Risks Related To Our Industry

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

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

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

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

We have used various hazardous materials, such as mercury in fluorescent tubes in our research and development activities. We are subject to federal, state and local laws and regulations which govern the use, manufacture, storage, handling and disposal of hazardous materials and specific waste products. 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 Our Products Or Potential Products Noncompetitive Or Obsolete.

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of AKs and acne. Doctors may prefer to use familiar methods, rather than trying our products. Reimbursement issues affect the economic competitiveness of our products as compared to other more traditional therapies.

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

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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 we granted a non-exclusive license to PhotoCure under the patents we license from PARTEQ, for esters of ALA. Furthermore, we granted a non-exclusive license to PhotoCure for its existing formulations of its Hexvix® and Metvix® (known in the United States as Metvixia®) products for any DUSA patents that may issue or be licensed by us in the future. PhotoCure received FDA approval to market Metvixia for treatment of AKs in July 2004 and 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, which will be marketed in the U.S. by a large dermatology company which may start to market Metvixia at any time, would adversely affect our ability to maintain or increase our market.

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

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

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

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

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

the ease of administration of our method of PDT,

the degree of generalized skin sensitivity to light,

the number of required doses,

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

the type and cost of our light systems.

Our primary competition in the acne market includes oral and topical antibiotics, other topical prescription and over-the-counter products, as well as various laser and non-laser light treatments. The market is highly competitive and other large and small companies have more experience than we do which could make

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it difficult for us to penetrate the market. The entry of new products from time to time would likely cause us to lose market share.

Risks Related To Our Stock

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

In order for our common stock to trade on the Nasdaq Global Market, we must continue to meet the listing standards of that market. Among other things, those standards require that our common stock maintain a minimum closing bid price of at least $1.00 per share. Recently, our common stock has traded at prices near and below $1.00. On October 16, 2008, and again on December 19, 2008, Nasdaq suspended the enforcement of rules requiring a minimum $1.00 closing bid price. The suspension will remain in effect through April 20, 2009. If we do not continue to meet Nasdaq s applicable minimum listing standards, Nasdaq could delist us from the Nasdaq Global Market. If our common stock is delisted from the Nasdaq Global Market, we could seek to have our common stock listed on the Nasdaq Capital Market or other Nasdaq markets. However, delisting of our common stock from the Nasdaq Global Market could hinder your ability to sell, or obtain an accurate quotation for the price of, your shares of our common stock. Delisting could also adversely affect the perception among investors of DUSA and its prospects, which could lead to further declines in the market price of our common stock. Delisting would also make it more difficult and expensive for us to raise capital. In addition, delisting might subject us to a Securities and Exchange Commission rule that could adversely affect the ability of broker-dealers to sell or make a market in our common stock, thus hindering your ability to sell your shares.

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

The price of our common stock has been highly volatile. These fluctuations create a greater risk of capital losses for our shareholders as compared to less volatile stocks. From January 1, 2008 to March 10, 2009, the price of our stock has ranged from a low of $0.87 to a high of $2.58. Factors that contributed to the volatility of our stock during this period included:

- quarterly levels of product sales;
- clinical trial results;
- general market conditions;
- patent litigation;
- increased marketing activities or press releases; and
- changes in third-party payor reimbursement for our therapy.

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

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

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

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

As of March 10, 2009, there were outstanding options and warrants to purchase 4,406,000 shares of common stock, with exercise prices ranging from $1.08 to $31.00 per share, and from $2.85 to $6.00 per share, respectively. In addition, there are 91,000 shares of unvested common stock. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. The holders are likely to exercise their securities during a time when we would likely be able to raise capital from the public on terms more favorable than those provided in these securities.

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

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

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

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

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

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

None.

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

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after the 10th year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. In October 2002, we entered into a five-year lease commitment for approximately 2,000 sq. ft., for our wholly-owned subsidiary, DUSA Pharmaceuticals New York, Inc., replacing the space DUSA previously occupied. In October 2007, we entered into a 14 month lease extension for the New York office space, extending the lease through December 2008, with a renewal option for an additional year. We did not exercise our renewal option on the New York office space and the lease expired in December 2008. Commencing in August 2002, we entered into a five year lease for office space for our Toronto location which had accommodated the Toronto office of our former Chairman of the Board and shareholder services representative. In December 2006, we extended the Toronto lease for an additional five year term through August 2012. We closed the Toronto office on October 31, 2008 and have listed the space with a real estate broker for sub-lease.

ITEM 3. ***LEGAL PROCEEDINGS***

In October 2008, we were notified that Winston Laboratories, Inc. had filed a demand for arbitration against the Company. The demand for arbitration arises out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement, which we refer to together as the Agreement, and claims that DUSA breached the Agreement. Winston Laboratories is claiming damages in excess of $2.0 million. The parties are currently in settlement discussions. The Company plans to defend itself vigorously and has not recorded any liability pursuant to the claim at December 31, 2008. For more information about our agreements with Winston Laboratories, see Management s Discussion and Analysis of Financial Condition and Results of Operations Contractual Obligations and Other Commercial Commitments.

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 Global Market under the symbol DUSA. The following are the high and low sales prices for the common stock reported for the quarterly periods shown.

Price range per common share by quarter, 2008:

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

Price range per common share by quarter, 2007:

	First	Second	Third	Fourth
NASDAQ				

High	$ 4.53	$ 5.00	$ 3.15	$ 3.30
Low	$ 3.15	$ 2.75	$ 1.63	$ 1.94

On March 10, 2009, the closing price of our common stock was $1.25 per share on the NASDAQ Global Market. On March 9, 2009, there were 708 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.

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RELATIVE STOCK PERFORMANCE

The graph below compares DUSA Pharmaceuticals, Inc. s cumulative 5-year total stockholder return on common stock with the cumulative total returns of the NASDAQ Market index and the Hemscott Group index. The graph tracks the performance of a $100 investment in our common stock and in each of the indexes (with the reinvestment of all dividends) from December 31, 2003 to December 31, 2008. The comparisons in this graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

COMPARE 5-YEAR CUMULATIVE RETURN
AMONG DUSA PHARMACEUTICALS, INC.,
NASDAQ MARKET INDEX AND HEMSCOTT GROUP INDEX

ASSUMES $100 INVESTED ON DEC. 31, 2003
ASSUMES DIVIDEND REINVESTED
FISCAL YEAR ENDING DEC. 31, 2008

	Cumulative Return Total					
	12/31/03	**12/31/04**	**12/31/05**	**12/31/06**	**12/31/07**	**12/31/08**
DUSA PHARMACEUTICALS, INC.	$ 100.00	$ 283.17	$ 213.27	$ 85.15	$ 40.99	$ 20.79
HEMSCOTT GROUP INDEX	$ 100.00	$ 106.04	$ 117.67	$ 131.43	$ 149.27	$ 118.91
NASDAQ MARKET INDEX	$ 100.00	$ 108.41	$ 110.79	$ 122.16	$ 134.29	$ 79.25

The list of companies in the Hemscott Group Index includes: Adolor Corp, Alexion Pharmaceuticals Inc., Alexza Pharmaceuticals Inc., Allergan Inc., Allos Therapeutics Inc., Amarin Corp Plc, Angiotech Pharmaceuticals, Inc., Ardea Biosciences Inc., Arena Pharmaceuticals Inc., Arqule Inc., ARYx Therapeutics Inc., Avanir Pharmaceuticals, Avi Biopharma Inc., Biodel Inc., Cardiome Pharma Corp, Cephalon Inc., Chattem Inc., Cortex Pharmaceuticals Inc., Cubist Pharmaceuticals Inc., Depomed Inc., Dr Reddy s Laboratories Ltd., Durect Corp, DUSA Pharmaceuticals Inc., Dynavax Technologies Corp, Elite Pharmaceuticals Inc., Endo Pharmaceuticals Holdings Inc., Forest Laboratories Inc., Gentium SpA., Geron Corp, Inspire Pharmaceuticals Inc., Isis Pharmaceuticals Inc., Kendle International Inc., King Pharmaceuticals Inc., Lannett Co. Inc., Ligand Pharmaceuticals Inc., MAP Pharmaceuticals Inc., Marshall Edwards Inc., Medicines Co., Middlebrook Pharmaceuticals Inc., Neurogen Corp., NeurogesX Inc., Nexmed Inc., Nitromed Inc., NovaBay Pharmaceuticals Inc., Novo Nordisk A/S, Opko Health Inc., Orexigen Therapeutics Inc., Pain Therapeutics Inc., Pharmacyclics Inc., Pharmasset Inc., Pharmaxis Ltd., Pozen Inc., Prana Biotechnology Ltd., Regenerx Biopharmaceuticals Inc., Reliv International Inc., Santarus Inc., Sciclone Pharmaceuticals Inc., Sepracor Inc., Shire Plc, Siga Technologies Inc., Simcere Pharmaceutical Group, Somaxon Pharmaceuticals Inc., Sucampo Pharmaceuticals Inc., Supergen Inc., Synvista Therapeutics Inc., Telik Inc., Teva Pharmaceutical Industries Ltd., Tianyin Pharmaceutical Co., Inc., United Therapeutics Corp, Valeant Pharmaceuticals International, Vertex Pharmaceuticals Inc., Warner Chilcott Ltd., and YM Biosciences Inc.

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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,				
	2008	2007	2006(5)	2005	2004
Product revenues	$ 29,545,406	$ 27,662,598	$ 25,582,986	$ 11,337,461	$ 7,987,656
Net loss	(6,250,441)(1)	(14,713,507)(2)	(31,349,507)(3)	(14,998,709)	(15,628,980)
Basic and diluted net loss per common share	$ (0.26)	$ (0.73)	$ (1.65)	$ (0.89)	$ (0.96))

CONSOLIDATED BALANCE SHEET DATA

	Year Ended December 31,				
	2008	2007	2006	2005	2004
Total assets	$ 28,210,454	$ 32,892,240	$ 33,755,813	$ 42,330,631	$ 56,650,888
Long-term obligations(4)	4,838,436	4,501,186	1,199,086		
Shareholders equity	$ 17,712,199	$ 22,106,522	$ 26,333,573	$ 38,028,728	$ 52,507,018

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

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

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

(4) Primarily comprised of deferred revenues related to milestone payments received under distribution agreements and the fair value of the warrants issued in connection with our October 29, 2007 private placement.

(5) The results of operations include operations of Sirius Laboratories, Inc. from the date of acquisition, March 10, 2006.

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

When you read this section of this report, it is important that you also read the financial statements and related notes included elsewhere in this report. This section contains forward-looking statements that involve risks and

uncertainties. Our actual results could differ materially from those we anticipate in these forward-looking statements for many reasons, including the factors described below and in the section entitled Risk Factors .

Overview

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

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

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

Sirius Laboratories, Inc., or Sirius, a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment of acne vulgaris and acne rosacea. Nicomide®, its key product, is a vitamin-mineral product formerly prescribed by dermatologists. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide®, or License Agreement, with River s Edge Pharmaceuticals, LLC, or River s Edge, and an amendment to our Settlement Agreement with River s Edge. See Note 16 of the Notes to Consolidated Financial Statements. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we are being paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. We are also considering other options, including the possible sale of the product and related patent or the launch of a non-prescription dietary supplement in compliance with the Dietary Supplement Health and Education Act, or DSHEA. We are in discussions with the FDA regarding DSHEA labeling including the use of the trademark. Should we re-launch the product with a DSHEA label, we expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic prescription Nicomide® levels.

We are responsible for manufacturing our Levulan® Kerastick® and for the regulatory, sales, marketing, and customer service and other related activities for all of our products, including our Levulan® Kerastick®. Our current objectives include increasing the sales of our products in the United States, Canada, Latin America, and Korea, launching Levulan® with our partners in additional Latin American and Asian countries and continuing our Levulan® PDT clinical development program for immunosuppressed solid organ transplant recipients, or SOTR. To further these objectives, we entered into a marketing and distribution agreement with Stiefel Laboratories, Inc. in January 2006 granting Stiefel an exclusive right to distribute the Levulan® Kerastick® in Mexico, Central and South America. On March 5, 2008, Stiefel notified us that the Brazilian authorities had published the final pricing for the product which was acceptable to Stiefel and to us. Stiefel launched the product in Brazil in April 2008. The product was launched in Argentina, Chile, Colombia and Mexico during the fourth quarter of 2007. Similarly, in January 2007, we entered into a marketing and distribution agreement with Daewoong Pharmaceutical Co., Ltd. and Daewoong s wholly owned subsidiary, DNC Daewoong Derma & Plastic Surgery Network Company, together referred to as Daewoong, granting

Daewoong exclusive rights to distribute the Levulan® Kerastick® in certain Asian countries. In the fourth quarter of 2007, the Korean Food and Drug Administration, or KFDA, approved Levulan® Kerastick® for PDT for the treatment of actinic keratosis, and Daewoong launched our product in Korea. Recently, we granted

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Daewoong the right to distribute our product in Japan on a named-patient basis to test this market. Through the end of 2008, the rate of adoption of our therapy in these markets has been slower than we had anticipated at the outset of these agreements. Our current objectives include increasing the sales of our products in these markets.

We believe that historical issues related to reimbursement negatively impacted the economic competitiveness of our therapy with other AK therapies and hindered its adoption in the past. Though we believe that current Centers for Medicare and Medicaid Services, or CMS, reimbursement levels allow us to be competitive, we continue to support efforts to improve reimbursement levels to physicians. Most major private insurers have approved coverage for our AK therapy; however some private insurers still do not provide adequate coverage. When we learn of these issues, we educate the insurers and are often able to facilitate a change in their coverage policy. We believe that with potential future improvements, along with our education and marketing programs, a more widespread adoption of our therapy should occur over time. We intend to seek reimbursement coverage for use of our BLU-U to treat acne following the analysis of the results of our Phase IIB clinical trial. As a result of the current global credit and financial market conditions, government authorities and private insurers may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenues. See the section below entitled Research and Development Costs .

We are developing Levulan® PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen s University, Kingston, Ontario, Canada. In January, 2009, we filed a request for reexamination with the USPTO of one of the Queen s patents that cover our approved indication for AK. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA®, DUSA Pharmaceuticals, Inc.®, Levulan®, Kerastick®, BLU-U®, Nicomide®, Nicomide-T®, ClindaReach®, Meted®, and Psoriacap® are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world. Numerous other trademark applications are pending.

As of December 31, 2008, we had an accumulated deficit of approximately $141,851,000. 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 our domestic PDT revenue growth rates in 2008 continue in 2009, we expect to become cash flow positive and profitable on a quarterly basis sometime late in 2009. We recorded significant impairment changes of goodwill during the fourth quarter of 2007 and the third quarter of 2008. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our PDT therapy by the medical and consumer constituencies, increased sales of our products and other factors contained in this report.

We recognize that we have to continue to demonstrate the clinical value of our unique therapy, and the related product benefits as compared to other well-established conventional therapies, in order for the medical community to accept our products on a large scale. We are aware that physicians have been using Levulan® with the BLU-U® using short incubation times, and with light devices manufactured by other companies, and for uses other than our FDA-approved use. While we are not permitted to market our products for so-called off-label uses, we believe that these activities are positively affecting the sales of our products.

As of December 31, 2008, we had a staff of 86 employees, including 2 part-time employees, as compared to 83 full-time employees, including 4 part-time employees, at the end of 2007, including marketing and sales, production, maintenance, customer support, and financial operations personnel, as well as those who support research and development programs for dermatology and internal indications. At December 31, 2008, our sales force was comprised of 40 employees. We may add to or reduce our headcount during 2009 as business circumstances deem necessary.

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2008 TRANSACTIONS

During 2008, DUSA entered into a number of transactions:

River s Edge/Nicomide®

We ceased the sale and distribution of Nicomide® as a prescription product in June 2008. On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, and an amendment to our Settlement Agreement and Mutual Release, or Settlement Agreement, described below, with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we are being paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. We are also considering the possible sale of the product and the related patent. Royalty revenues recorded pursuant to the License Agreement are recorded in Product Revenues in the accompanying Consolidated Statements of Operations.

In October 2007, as part of the settlement of litigation between DUSA and River s Edge, we entered into the Settlement Agreement to dismiss the lawsuit brought by us against River s Edge asserting a number of claims arising out of River s Edge s alleged infringement of our Nicomide® patent, U.S. Patent No. 6,979,468, under which we had marketed, distributed and sold Nicomide®. As part of the original terms of the Settlement Agreement, River s Edge agreed to pay us $25.00 for every bottle of NIC 750 above 5,000 bottles that was substituted for Nicomide® after September 30, 2007. The net gain from settlement of litigation for the years ended December 31, 2008 and 2007 was $283,000 and $583,000, respectively. In the accompanying Consolidated Statements of Operations the net gain on settlement is recorded as a separate component of operating expenses.

Winston Laboratories, Inc.

On or about January 30, 2006, Winston Laboratories, Inc., or Winston, and the former Sirius entered into a license agreement relating to a Sirius product, Psoriatec® (known by Winston as Micanol) revising a former agreement. The original 2006 Micanol License Agreement granted an exclusive license, with limitation on rights to sublicense, to all property rights, including all intellectual property and improvements, owned or controlled by Winston to manufacture, sell and distribute products containing anthralin, in the United States. On January 29, 2008, our wholly-owned subsidiary, Sirius, entered into the 2006 Micanol Transition License Agreement with Winston. The Transition License Agreement amends the original 2006 Micanol License Agreement which was due to expire pursuant to its terms on January 31, 2008. The parties entered into the Transition License Agreement to extend the term of the 2006 Micanol License Agreement to September 30, 2008 in order to allow us to sell our last batch of product, to reduce the period of time that we are required to maintain product liability insurance with respect to the distribution and sale of products containing anthralin after the termination of the Transition License Agreement and to confirm the allocation of certain costs and expenses relating to the product during and after the transition period. Psoriatec® is a product that is regulated under the FDA s marketed unapproved drug policy guide. DUSA placed its Psoriatec® inventory on hold and following discussions with the FDA, notified the FDA (in July 2008) that DUSA would cease marketing Psoriatec® at the termination of its license agreement, which expired on September 30, 2008. In October 2008, Winston filed a notice demanding arbitration of claims relating to alleged breach of the License Agreements and seeking damages in excess of $2,000,000. The parties are currently in settlement discussions. The Company does not expect any potential settlement payment to be material to its financial condition or the results of its operations. The Company has not recorded any liability pursuant to the claim at December 31, 2008. For more information, see Item 3. entitled Legal Proceedings.

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National Biological Corporation Amended and Restated Purchase and Supply Agreement

On June 21, 2004, we signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation, or NBC, the principal manufacturer of our BLU-U® light source. This agreement provides for the elimination of certain exclusivity clauses, permits us to order on a purchase order basis without minimums, and includes other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources and the associated technology within the field of PDT. On December 23, 2008, we signed the Second Amendment to the Amended and Restated Purchase and Supply Agreement with NBC, which extends the Agreement until June 30, 2009, and gives us an option to further extend the term for an additional two years subject only to agreement on price terms to be negotiated in good faith. The parties are actively engaged in discussions to further extend the term of the agreement.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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

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

PHOTODYNAMIC THERAPY (PDT) DRUG AND DEVICE PRODUCTS

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

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

Stiefel Laboratories Agreement. In January 2006, as amended in September 2007, we entered into an exclusive marketing, distribution and supply agreement with Stiefel Laboratories, Inc. for Levulan® PDT in

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Latin America. Under the agreement, Stiefel is required to purchase Levulan® Kerastick® from us and make up front, milestone and royalty payments. Stiefel may cancel the agreement if there is a breach of contract, if either party files for bankruptcy, or if its sales during any year are less than its minimum purchase obligations. No upfront or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications. We are obligated under the agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. The agreement establishes a fixed supply price per unit, as well as a royalty based on a percentage of the net sales price to end-users. Under EITF 00-21 the deliverables under the agreement are treated as a single unit of accounting. We determine attribution methods for each of the separate payment streams. Revenues from unit sales of Levulan® Kerastick® are recognized based on end-user demand as we do not have sufficient data to determine product acceptance in the marketplace and therefore do not have the ability to estimate product returns. Royalty revenues are recorded each quarter based on Stiefel s reported net sales for that quarter and are included in product revenues. The agreement also establishes minimum purchase quantities over the first five years following regulatory approval, and since Stiefel s sales to third parties during the contract year ended October 2008 were below its minimum purchase obligations, Stiefel has the right to cancel the agreement.

The non-refundable up-front payments are being recognized into revenues on a straight-line basis commencing upon the first product shipments in a country over the remaining contractual term of the agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2008 and 2007, in accordance with our policy of deferring revenues on new product launches, we have deferred revenues of $389,000 and $206,000, respectively, related to product shipments of Levulan® Kerastick® into Mexico and Argentina that have not yet been sold through to the end user customers. Deferred revenues at December 31, 2008 and 2007 associated with milestone payments received from Stiefel are $621,000 and $345,000, respectively.

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

The non-refundable up-front payments are recognized into revenues on a straight-line basis commencing upon the first product shipment in the territory over the remaining contractual term of the agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2008 and 2007, in accordance with our policy of

deferring revenues on new product launches, we have deferred revenues of $1,144,000 and $762,000, respectively, related to product shipments of Levulan® Kerastick® into Korea that

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have not yet been sold through to the end user customers. Deferred revenues at December 31, 2008 and 2007 associated with milestone payments received from Daewoong are $1,643,000 and $1,848,000, respectively.

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

NON-PDT DRUG PRODUCTS

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

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

We evaluate inventory levels at our wholesaler customers through an analysis that considers, among other things, wholesaler purchases, wholesaler shipments to retailers, available end-user prescription data obtained from third parties and on-hand inventory data received directly from our three largest wholesaler customers. We believe that this evaluation of wholesaler inventory levels, allows us to make reasonable estimates for our applicable revenue related reserves. Additionally, our products are sold to wholesalers with a product shelf life that allows sufficient time for our wholesaler customers to sell the products in their inventory through to retailers and, ultimately, to end-user consumers prior to product expiration. For new product launches where we do not have the ability to reliably estimate returns, revenue is recognized based on end-user demand, which is typically based on dispensed subscription data, or ship-through data as reported by our international distribution partners. When inventories have been reduced to targeted stocking levels at wholesalers or distribution partners, and we have sufficient data to determine product acceptance in the marketplace which allows us to estimate product returns, we recognize revenue upon shipment, net of discounts and allowances.

SALES RETURNS

We account for sales returns in accordance with Financial Accounting Standards Board (FASB) Statement No. 48, *Revenue Recognition When Right of Return Exists*, by establishing an accrual in an amount equal to our estimate of sales recorded for which the related products are expected to be returned. We determine the estimate of the sales return accrual primarily based on historical experience regarding sales and related returns and incorporating other factors that could impact sales returns in the future. These other factors include levels of inventory in the distribution channel, estimated shelf life, product recalls, product discontinuances, price changes of competitive products, introductions of generic products and introductions of competitive new products. Our policy is to accept returns when product is within six months of expiration. We consider all of these factors and adjust the accrual periodically to reflect actual experience. In the PDT Drug and Device Products segment, product sales made through distributors, historically, had been recorded as deferred revenue until the product was sold by the distributors to the end users

because we did not have sufficient history with our distributors to be able to reliably estimate returns.

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CHARGEBACKS, REBATES AND DISCOUNTS

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

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

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

Valuation Of Long-lived, Intangible Assets and Goodwill We review long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If it is determined that the carrying value of long-lived or intangible assets may not be recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis. At December 31, 2008 and 2007, respectively, total property, plant and equipment had a net carrying value of $1,938,000 and $2,143,000, including $1,313,000 at December 31, 2008 associated with our manufacturing facility. As of December 31, 2008 and 2007, respectively, we had intangible assets totaling $10,000 and $54,000 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. The payment to the light source supplier was fully amortized during 2008.

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius Laboratories, Inc. All goodwill and intangible assets recorded in connection with the Sirius acquisition have been charged to the accompanying statements of operations as impairments as of December 31, 2008. We agreed to pay additional consideration in future periods to the former Sirius shareholders based upon the achievement of total cumulative sales milestones for the Sirius products over the period ending 50 months from the date of close. The first cumulative sales milestone was achieved during the three-month period ended September 30, 2008, and accordingly a cash payment in the amount of $1.5 million was paid to the former Sirius shareholders during the third quarter of 2008. The payment was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period.

During the fourth quarter of 2007, we performed our annual test for goodwill impairment as required by FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). We used December 1st as the date of our annual goodwill impairment test. Based on the review, we recorded an impairment charge to goodwill of $6.8 million, which was all associated with the Non-PDT Drug Products reporting unit and

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represented the entire goodwill balance. As discussed in more detail in Note 3 to the Consolidated Financial Statements, the impairment charge is primarily related to our revised estimate of cash flows associated with the Sirius products and product pipeline. Decisions related to the product pipeline are based on a number of factors, most importantly, our development partner s, Altana, Inc. s, receipt of a non-approvable letter from the FDA in the fourth quarter of 2007 with respect to its ANDA supplement covering one of the potential products we acquired from Sirius. We paid and/or accrued $500,000 in milestone payments in the fourth quarter of 2007 as a result of our decision not to pursue this product or any additional potential products from the acquisition.

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

Share-Based Compensation 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. In accordance with FASB Statement No. 123(R), *Share-Based Payment* (SFAS 123(R)), we recognize the expense attributable to stock awards that are granted or vest in periods ending subsequent to the adoption of SFAS 123(R) in the accompanying Consolidated Statements of Operations. For more information about our share-based compensation, see Note 10 to the Consolidated Financial Statements.

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

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

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Results of Operations

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

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

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

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

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

For the year ended December 31, 2008, BLU-U® revenues were $1,860,000, essentially flat in comparison with 2007 BLU-U® revenues of $1,868,000. The slight decrease in 2008 BLU-U® revenues were driven by slightly lower sales volumes which were offset by an increase in our average selling price. In the year ended December 31, 2008, there were 229 units sold, versus 232 units in 2007. The 2008 total consists of 224 units sold in the United States and 5 in Korea by Daewoong. The 2007 total consists of 206 sold in the United States, 16 sold in Canada and 10 in Korea. Our average net selling price for the BLU-U® increased to 7,861 for the year ended December 31, 2007 from $7,595 for 2007. Our BLU-U® evaluation program allows customers to take delivery for a limited number of BLU-U® units for a period of up to four months for private practitioners and up to one year for hospital clinics, before a purchase decision is required. At December 31, 2008, there were approximately 58 units in the field pursuant to this evaluation program, compared to 31 units

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in the field at December 31, 2007. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of three years.

Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our acquisition of Sirius. Total Non-PDT drug product revenues for the year ended December 31, 2008 were $5,615,000, compared to $9,388,000 for the year ended December 31, 2007. The substantial majority of the Non-PDT product revenues were from sales of Nicomide® and Nicomide® related royalties. In April 2008, we were notified by Actavis Totowa, LLC, the manufacturer of Nicomide®, that Actavis would cease manufacturing several prescription vitamins, including Nicomide®, due to continuing discussions with the FDA. As we previously disclosed, Actavis Totowa had received notice that the FDA considers prescription dietary supplements to be unapproved new drugs. In response to this notification and subsequent discussions with the FDA, we stopped the sale and distribution of Nicomide® as a prescription product in June 2008. We are in discussions with the FDA regarding new labeling, compliant with DSHEA, including use of the trademark. Should we re-launch the product with a DSHEA label, we expect both the price and volume of the Nicomide® DSHEA labeled product to be considerably less than historic prescription Nicomide® levels. We are also considering other options, including the possible sale of the product and related patent or the launch of a non-prescription dietary supplement in compliance with DSHEA.

On August 12, 2008, we entered into a worldwide non-exclusive patent License Agreement to our patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to our Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, we are being paid a share of the net revenues, as defined in the License Agreement, of River s Edge s licensed product sales under the License Agreement. Nicomide® sales in 2008 were negatively impacted by residual levels of NIC 750, that were substituted for Nicomide®, remaining in the distribution channel subsequent to the settlement with River s Edge. The Settlement Agreement is described in Note 16 to the Consolidated Financial Statements.

The increase in our total revenues in 2008 results from increased PDT segment revenues in the United States, as well as our PDT product launches in Korea and the rest of the world. However, we must continue to increase sales from these levels in order for us to become profitable. PhotoCure received FDA approval to market Metvixia® for treatment of AKs in July 2004, and this product, which would be directly competitive with our Levulan® Kerastick® product, could be launched at any time. While we are entitled to royalties from PhotoCure on its net sales of Metvixia®, a large dermatology company has the marketing rights in the U.S., which may adversely affect our ability to maintain or increase our Levulan® market. Nonetheless, we remain confident that sales should continue to increase through increased consumption of our PDT segment products by our existing customers, as well as the addition of new customers. We expect to be able to grow our PDT segment revenues in the United States during 2009, due in part to the 6% increase in reimbursement of our PDT-related procedure fee, which became effective January 1, 2009, as well as our price increases, which were effective October 1, 2008 and January 1, 2009. Although we expect growth in our PDT segment revenues, a portion of our customer base, i.e., those focusing on the cosmetic market, are more susceptible to the uncertain economic conditions facing our markets, and reduced sales to that customer base could be expected until the economy recovers. The vast majority of our international sales and medi-spa sales falls into this market. We expect our Non-PDT revenues for 2009 to be significantly reduced compared to 2008 since we are no longer manufacturing and marketing Nicomide® as a prescription product. We are evaluating alternative manufacturing, labeling and distribution strategies in order to re-launch Nicomide® on the market and we are also considering opportunities to sell the product. Also see the section entitled Risk Factors Any Failure to Comply with Government Regulations in the United States and Elsewhere Will Limit Our Ability to Market Our Products And Become Profitable.

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

	Year Ended December 31,		
	2008	2007	Increase/ (Decrease)
Levulan® Kerastick® Cost of Product Revenues and Royalties			
Direct Levulan® Kerastick® Product costs	$ 2,541,000	$ 2,384,000	$ 157,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	229,000	280,000	(51,000)
Royalty and supply fees(1)	966,000	717,000	249,000
Subtotal Levulan® Kerastick® Cost of Product Revenues and Royalties	3,736,000	3,381,000	355,000
BLU-U® Cost of Product Revenues			
Direct BLU-U® Product Costs	822,000	733,000	89,000
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	794,000	836,000	(42,000)
Subtotal BLU-U® Cost of Product Revenues	1,616,000	1,569,000	47,000
TOTAL PDT DRUG & DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	5,352,000	4,950,000	402,000
Non-PDT Drug Cost of Product Revenues and Royalties	1,773,000	2,879,000	(1,106,000)
TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES AND ROYALTIES	1,773,000	2,879,000	(1,106,000)
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	$ 7,125,000	$ 7,829,000	$ (704,000)

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

Margins Total product margins for 2008 were $22,420,000, or 76%, as compared to $19,833,000, or 72% for 2007, as shown below:

	Year Ended December 31,				
	2008		2007		Increase/ (Decrease)
Levulan® Kerastick® Gross Margin	$ 18,334,000	83%	$ 13,025,000	79%	$ 5,309,000

BLU-U® Gross Margin	244,000	13%	299,000	16%	(55,000)
Total PDT Drug & Device Gross Margin	$ 18,578,000	78%	$ 13,324,000	73%	$ 5,254,000
Total Non-PDT Drug Gross Margin	3,842,000	68%	6,509,000	69%	(2,667,000)
TOTAL GROSS MARGIN	$ 22,420,000	76%	$ 19,833,000	72%	$ 2,587,000

For the year ended December 31, 2008, total PDT Drug and Device Product Margins were 78% versus 73% for the year ended December 31, 2007. The incremental margin was driven primarily by positive margin gains on the Kerastick® product.

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Kerastick® gross margins for the year ended December 31, 2008 were 83%, versus 79% for the year ended December 31, 2007. The increase in margin is mainly attributable to an increase in our average unit selling price and lower overall manufacturing costs due to increased production volumes. Our long-term goal is to achieve higher gross margins on Kerastick® sales which will be significantly dependent on increased volume. We believe that we can achieve improved gross margins on our Kerastick® during 2009 due to the anticipated increased volumes from continued growth.

BLU-U® margins for the year ended December 31, 2008 were 13%, versus 16% for the year ended December 31, 2007. The decrease in gross margin is a result of an increase in our direct BLU-U® product costs, offset in part by an increase in our average selling price per unit. Our short-term strategy is to at a minimum break even on device sales in an effort to drive Kerastick® sales volumes.

Non-PDT Drug Product Margins reflect the gross margin generated by the products acquired as part of our merger with Sirius. Total margin for the year ended December 31, 2008 was 68% compared with 69% for the year ended December 31, 2007. During 2008, Non-PDT Product margins were negatively impacted by our discontinuance of sales of Nicomide® as a prescription product.

Research and Development Costs Research and development costs for 2008 were $6,643,000 as compared to $5,977,000 in 2007. The increase in 2008 compared to 2007 was due primarily to increased spending on our Phase IIb clinical trial on acne and a $0.6 million Prescription Drug User Fee Act (PDUFA) charge related to our approved AK indication. In October 2008, we announced the results from our Phase IIb clinical trial to compare the safety and efficacy of PDT using DUSA s BLU-U® brand light plus vehicle containing Levulan® (aminolevulinic acid HCl) to that of PDT using the BLU-U® plus vehicle without Levulan® (the control group) in patients with moderate to severe facial acne vulgaris. While both groups showed a statistically significant reduction in lesions from baseline, the results did not demonstrate statistically significant difference between the control and Levulan PDT groups. Therefore, DUSA will not pursue further clinical development of Levulan® PDT with BLU-U® for moderate to severe acne. However, we do expect to continue to support investigator initiated studies in moderate to severe acne with Levulan and various light sources. We intend to file a 510(k) application with the FDA for an expansion of our BLU-U® label to include severe acne and we have filed a patent application to cover an invention arising from the study.

We are planning to initiate a proof-of-concept clinical trial, which we expect will include up to 40 patients, at up to ten clinical sites across the United States, for the treatment of actinic keratoses and chemoprevention of non-melanoma skin cancers in immunosuppressed solid organ transplant recipients, or SOTR, who have demonstrated that they are at risk of developing multiple squamous cell carcinomas. We expect that our research and development costs will remain at 2008 levels since we will not have expenditures relating to the acne trial which ended during 2008.

Marketing and Sales Costs Marketing and sales costs for the year ended December 31, 2008 were $13,112,000 as compared to $13,311,000 for the year ended December 31, 2007. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling $9,327,000 for the year ended December 31, 2008, compared to $8,386,000 in the year ended December 31, 2007. The increase in this category was due mainly to increased salaries and commissions earned in 2008 in comparison to 2007 due to improved performance against internal corporate goals during 2008. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling $3,653,000 for the year ended December 31, 2008, compared to $4,685,000 for the year ended December 31, 2007. The decrease in this category in 2008 is due primarily to absence in 2008 of expenses incurred in 2007 related to the launch of ClindaReach®. We expect marketing and sales costs for 2009 to be relatively flat in comparison to 2008, and to decrease as a percentage of revenues.

General and Administrative Costs General and administrative costs for the year ended December 31, 2008 were $9,188,000 as compared to $10,311,000 for the year ended December 31, 2007. The decrease is mainly attributable to a decrease in legal expenses, which were incurred in 2007 due to the River s Edge litigation, offset in part by increased compensation costs, which include the severance and stock compensation costs related to the departure of an officer during the year (see Note 15). General and administrative expenses

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are highly dependent on our legal and other professional fees, which can vary significantly from period to period. We may incur significant legal fees in 2009 due to the arbitration process which has been commenced by Winston Laboratories. See Item 3 Legal Proceedings; however, in total we expect general and administrative costs to remain relatively flat in 2009 compared with 2008.

Impairment of Goodwill In the third quarter of 2008 we made a contingent payment to the former shareholders of Sirius Laboratories in the amount of $1.5 million and in the same period deemed the resulting goodwill to be impaired. During the fourth quarter of 2007, we performed our annual test for goodwill impairment as required by FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). Based on the review, we recorded an impairment charge to goodwill of $6.8 million. The impairment charges were primarily related to our revised estimate of cash flows associated with Nicomide® and the other Sirius products, including the lack of a product pipeline.

Net gain from Settlement of Litigation During the fourth quarter of 2007, we entered into a Settlement Agreement and Mutual Release with River s Edge Pharmaceuticals, LLC. Under the terms of the Settlement Agreement, River s Edge made a lump-sum settlement payment to DUSA in the amount of $425,000 for damages and paid to DUSA $25.00 for every prescription of NIC 750 above 5,000 prescriptions that were substituted for Nicomide® from September 30, 2007 through June 30, 2008. During the years ended December 31, 2008 and 2007 the net gain from settlement of litigation was $283,000 and $583,000, respectively. These payments under the Settlement Agreement ceased due to an amendment effective as of July 3, 2008.

Gain on change in fair value of warrants The warrants issued to investors in connection with the October 29, 2007 private placement were recorded initially at fair value and are marked to market each reporting period. The decrease in the liability during 2008 and 2007 was $826,000 and $687,000, respectively, which resulted in a non-cash gain in both periods. The decrease in fair value was due primarily to decreases in our stock price.

Other Income, Net Other income for the year ended December 31, 2008 increased to $663,000, as compared to $554,000 in 2007. The increase in 2008 reflects an increase in our average invested cash balances during 2008 as compared to 2007 as a result of the October 2007 private placement.

Income Taxes There is no provision for income taxes due to ongoing operating losses. As of December 31, 2008, we had net operating loss carryforwards of approximately $89,696,000 and tax credit carryforwards of approximately $1,493,000 for Federal tax purposes. These amounts expire at various times through 2028. We have provided a full valuation allowance against the net deferred tax assets at December 31, 2008 and 2007.

Net Loss For 2008, we recognized a net loss of $6,250,000, or $0.26 per share, as compared to $14,714,000, or $0.73 per share, for 2007. The decrease in net loss is attributable to the reasons discussed above.

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Results of Operations

Year Ended December 31, 2007 As Compared to the Year Ended December 31, 2006

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

	Year Ended December 31,		
	2007	2006	Increase/ (Decrease)
PDT PRODUCT REVENUES			
LEVULAN® KERASTICK® PRODUCT REVENUES			
United States	$ 15,139,000	$ 12,425,000	$ 2,714,000
Canada	740,000	1,147,000	(407,000)
Korea	436,000		436,000
Rest of world	92,000		92,000
Subtotal Levulan® Kerastick® product revenues	16,407,000	13,572,000	2,835,000
BLU-U® PRODUCT REVENUES			
United States	1,724,000	2,292,000	(568,000)
Canada	94,000	233,000	(139,000)
Korea	50,000		50,000
Subtotal BLU-U® product revenues	1,868,000	2,525,000	(657,000)
TOTAL PDT PRODUCT REVENUES	18,275,000	16,097,000	2,178,000
TOTAL NON-PDT DRUG PRODUCT REVENUES	9,388,000	9,486,000	(98,000)
TOTAL PRODUCT REVENUES	$ 27,663,000	$ 25,583,000	$ 2,080,000

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

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

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

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evaluation program, compared to 40 units in the field at December 31, 2006. The units are classified as inventory in the financial statements and are being amortized during the evaluation period to cost of goods sold using an estimated life for the equipment of three years.

Non-PDT Drug Product Revenues reflect the revenues generated by the products acquired as part of our March 10, 2006 acquisition of Sirius. Total revenues for the year ended December 31, 2007 were $9,388,000, compared to $9,486,000 for the period from March 10, 2006 (date of acquisition) through December 31, 2006. The substantial majority of the Non-PDT product revenues were from sales of Nicomide®. Nicomide® sales in 2007 were significantly negatively impacted by the introduction into the market of NIC 750, a niacinamide product that was substituted for Nicomide®, which was re-launched in March 2007 following the dissolution by the court of a preliminary injunction. We have since reached a settlement agreement with River s Edge, the manufacturer of NIC 750. The settlement agreement is described further in Item 3. Legal Proceedings River s Edge.

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

Cost Of Product Revenues and Royalties Cost of product revenues and royalties for the year ended December 31, 2007 were $7,829,000 as compared to $26,116,000 for the year ended December 31, 2006 (including an impairment of intangible assets totaling $15,746,000). A summary of the components of cost of product revenues and royalties is provided below:

	Year Ended December 31,		
	2007	2006	Increase/ (Decrease)
Levulan® Kerastick® Cost of Product Revenues and Royalties			
Direct Levulan® Kerastick® Product costs	$ 2,384,000	$ 1,944,000	$ 440,000
Other Levulan® Kerastick® production costs including internal costs assigned to support products, net	280,000	837,000	(557,000)
Royalty and supply fees(1)	717,000	659,000	58,000
Subtotal Levulan® Kerastick® Cost of Product Revenues and Royalties	3,381,000	3,440,000	(59,000)
BLU-U® Cost of Product Revenues			
Direct BLU-U® Product Costs	733,000	1,131,000	(398,000)
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	836,000	1,015,000	(179,000)
Subtotal BLU-U® Cost of Product Revenues	1,569,000	2,146,000	(577,000)
TOTAL PDT DRUG & DEVICE COST OF PRODUCT REVENUES AND ROYALTIES	4,950,000	5,586,000	(636,000)
Impairment of Intangible Assets(2)		15,746,000	(15,746,000)
Non-PDT Drug Cost of Product Revenues and Royalties	2,879,000	4,784,000	(1,905,000)
	2,879,000	20,530,000	(17,651,000)

TOTAL NON-PDT DRUG COST OF PRODUCT REVENUES AND ROYALTIES			
TOTAL COST OF PRODUCT REVENUES AND ROYALTIES	$ 7,829,000	$ 26,116,000	$ (18,287,000)

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

2) An impairment resulting from our review of the carrying amount of our intangible assets of $15,746,000.

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

	Year Ended December 31,				
	2007		2006		Increase/ (Decrease)
Levulan® Kerastick® Gross Margin	$ 13,025,000	79%	$ 10,132,000	75%	$ 2,893,000
BLU-U® Gross Margin	299,000	16%	379,000	15%	(80,000)
Total PDT Drug & Device Gross Margin	$ 13,324,000	73%	$ 10,511,000	65%	$ 2,813,000
Total Non-PDT Drug Gross Margin	6,509,000	69%	(11,044,000)	(116)%	17,553,000
TOTAL GROSS MARGIN	$ 19,833,000	72%	$ (533,000)	(2)%	$ 20,366,000

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

Kerastick® gross margins for the year ended December 31, 2007 were 79%, versus 75% for the year ended December 31, 2006. The increase in margin was mainly attributable to an increase in our average unit selling price and lower overall manufacturing costs due to increased production volumes.

BLU-U® margins for the year ended December 31, 2007 were 16%, versus 15% for the year ended December 31, 2006. The increase in gross margin was a result of an increase in the average selling price per unit as well as the impact of a one-time sales promotion where we sold a limited number of earlier generation devices with zero cost basis.

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

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

In addition to the non-recurring $1.6 million in-process research and development charge, the remaining decrease in 2007 compared to 2006 was due primarily to lower compensation costs for personnel attributable to research and development activities in the form of lower bonuses in 2007, a decrease in share-based compensation expense, reduced spending on Barrett s Esophagus, and the elimination of spending on photodamaged skin, all offset by

increased spending on our Phase IIb clinical trial on acne, which commenced in March 2007.

Research and development expenses reflect the costs of our Phase IIb clinical trial for acne, which commenced in March 2007. The current Phase II trial was conducted at 14 sites and involved approximately 260 patients. In November 2004, we signed a clinical trial agreement with the NCI DCP for the treatment of oral cavity dysplasia. DUSA and the NCI DCP worked together to prepare the overall clinical development plan for Levulan® PDT in this indication, starting with Phase I/II trials. The NCI DCP used its resources to file its own investigational new drug application with the FDA, and approval to initiate the study was received. Our costs related to this study will be limited to providing Levulan®, leasing lasers and the necessary training for the investigators involved. All other costs of this study are the responsibility of the NCI DCP. We have options on any new intellectual property.

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Marketing and Sales Costs Marketing and sales costs for the year ended December 31, 2007 were $13,311,000 as compared to $12,645,000 for the year ended December 31, 2006. These costs consisted primarily of expenses such as salaries and benefits for the marketing and sales staff, commissions, and related support expenses such as travel, and telephone, totaling $8,386,000 for the year ended December 31, 2007, compared to $8,672,000 in the year ended December 31, 2006. The decrease in this category was due to lower commissions earned in 2007 in comparison to 2006 due to lower performance against internal corporate goals. The remaining expenses consisted of tradeshows, miscellaneous marketing and outside consultants totaling $4,685,000 for the year ended December 31, 2007, compared to $3,603,000 for the year ended December 31, 2006. The increase in this category is due primarily to additional expenses related to the launch of ClindaReach®, and increased expenses related to reimbursement improvement initiatives.

General and Administrative Costs General and administrative costs for the twelve months ended December 31, 2007 were $10,311,000 as compared to $11,196,000 for the year ended December 31, 2006. The decrease was mainly attributable to lower compensation in the form of bonuses for 2007, decreases in legal and share-based compensation expenses; offset partially by an increase in other professional services fees. General and administrative expenses are highly dependent on our legal and other professional fees, which vary significantly from period to period particularly in light of our litigation strategy to protect our intellectual property.

Impairment of Goodwill During the fourth quarter of 2007, we performed our annual test for goodwill impairment as required by SFAS 142. Based on the review, we recorded an impairment charge to goodwill of $6.8 million. The impairment charge was primarily related to our revised estimate of cash flows associated with the Sirius products and product pipeline.

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

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

These payments under the Settlement Agreement ceased due to an amendment, effective as of July 3, 2008.

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

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

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

Net Loss For 2007, we recognized a net loss of $14,714,000, or $0.73 per share, as compared to $31,350,000, or $1.65 per share, for 2006.

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Quarterly Results of Operations

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2008 and 2007, respectively:

	Quarterly Results for Year Ended December 31, 2008			
	March 31	June 30	SEPT 30(1)	Dec 31
Product revenues	$ 7,929,500	$ 8,112,239	$ 5,726,071	$ 7,777,596
Gross margin	6,229,183	6,324,545	4,264,043	5,602,540
Net loss	(1,284,141)	(138,791)	(2,836,855)	(1,990,654)
Basic and diluted loss per common share	$ (0.05)	$ (0.01)	$ (0.12)	$ (0.08)

	Quarterly Results for Year Ended December 31, 2007			
	March 31	June 30	Sept 30	DEC 31(2)
Product revenues	$ 6,676,840	$ 6,862,198	$ 5,784,194	$ 8,339,366
Gross margin	4,520,688	5,085,707	4,210,297	6,016,622
Net loss	(3,370,928)	(2,477,407)	(1,877,782)	(6,987,390)
Basic and diluted loss per common share	$ (0.17)	$ (0.13)	$ (0.10)	$ (0.31)

(1) In the third quarter of 2008, we recorded an impairment charge to our goodwill balance of $1.5 million.

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

Liquidity and Capital Resources

At December 31, 2008, we had approximately $18,884,000 of total liquid assets, comprised of $3,881,000 of cash and cash equivalents and marketable securities available-for-sale totaling $15,003,000. We believe that our liquidity will be sufficient to meet our cash requirements for at least the next twelve months based on our projections of revenues and spending over that timeframe. We have invested our funds in liquid investments, so that we will have ready access to these cash reserves, as needed, for the funding of development plans on a short-term and long-term basis. As of December 31, 2008, these securities had a weighted average yield of 3.77% and maturity dates ranging from January 2009 to January 2013. Our net cash used in operations in 2008 was $2,303,000 versus $4,986,000 for 2007. The year-over-year improvement is primarily attributable to growth in revenues and gross margins in our PDT operating segment. As of December 31, 2008, working capital (total current assets minus total current liabilities) was $20,278,000, as compared to $24,021,000 as of December 31, 2007. Total current assets decreased by $4.4 million during the 2008 due primarily to decreases in cash and cash equivalents, marketable securities and accounts receivable, offset by an increase in inventory. Total current liabilities decreased by $0.6 million during the same period due primarily to decreases in accounts payable and deferred revenue, offset by an increase in accrued compensation. In response to the instability in the global financial markets, we regularly review our marketable securities holdings, and have reduced or avoided investing in securities deemed to have increased risk. We do not hold any asset-backed or auction rate securities.

Since our inception, we have generated significant losses while we have advanced our product candidates into preclinical and clinical trials, development and commercialization. We have funded our operations primarily through

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

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If our domestic PDT growth rate in 2008 continues in 2009, we expect to become cash flow positive and profitable on a quarterly basis sometime late in 2009. If we are unable to do so, we may have to reduce our headcount, reduce spending in other areas, or raise funds through financing transactions. We cannot predict whether financing will be available at all or on reasonable terms.

We agreed to pay additional consideration to the former shareholders of Sirius in future periods, based upon the attainment of pre-determined total cumulative sales milestones for the Sirius products over the period ending 50 months from the date of close. 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:
$35.0 million	$ 1.0 million
$45.0 million	$ 1.0 million
Total	$ 2.0 million

The first cumulative sales milestone at $25.0 million was achieved during the third quarter of 2008, and a cash payment in the amount of $1.5 million was paid to the former Sirius shareholders during that period. The payment was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period.

We may seek 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 2009, we are focusing primarily on increasing the sales of the Levulan® Kerastick®, the BLU-U® and ClindaReach®. DUSA has no off-balance sheet financing arrangements.

Contractual Obligations and Other Commercial Commitments

L. PERRIGO COMPANY

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

MERGER WITH SIRIUS LABORATORIES, INC.

In March 2006, we closed our merger to acquire all of the common stock of Sirius Laboratories Inc. in exchange for cash and common stock worth up to $30,000,000. Of the up to $30,000,000, up to $5,000,000, ($1,500,000 of which would be paid in cash, and $3,500,000 of which would be paid in cash or common stock) may be paid based on a combination of new product approvals or launches, and achievement of certain pre-determined total cumulative sales milestones for Sirius products. With the launch of ClindaReach®, one of the new Sirius products, we were obligated to make a cash payment of $500,000 to the former shareholders of Sirius. Also, as a consequence of the decision not to

launch the product under development with Altana and pursuant to the terms of the merger agreement with Sirius, DUSA paid $250,000 on a pro rata basis to the former Sirius shareholders. Similarly, with the decision by DUSA in early 2008 not to develop a third product from a list of product candidates acquired as part of the merger, another $250,000 was paid on a pro rata basis to the former Sirius shareholders. The payments for ClindaReach® and the other two product decisions satisfy DUSA s obligations for the $1,500,000 portion of the purchase price mentioned above. In the third quarter of 2008, the first of the pre-determined total cumulative sales milestones for Sirius products was achieved, and

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accordingly, we made a cash payment of $1,500,000 to the former Sirius shareholders in consideration of the milestone achievement.

PARTEQ AGREEMENT

We license certain patents underlying our Levulan® PDT/PD systems under a license agreement with PARTEQ Research and Development Innovations, or PARTEQ. Under the agreement, we have been granted an exclusive worldwide license, with a right to sublicense, under PARTEQ patent rights, to make, have made, use and sell certain products, including ALA. The agreement covers certain use patent rights. When we sell our products directly, we have agreed to pay to PARTEQ royalties of 6% and 4% on 66% of the net selling price in countries where patent rights do and do not exist, respectively. In cases where we have a sublicensee, we will pay 6% and 4% when patent rights do and do not exist, respectively, on our net selling price less the cost of goods for products sold to the sublicensee, and 6% of payments we receive on sales of products by the sublicensee. We are also obligated to pay to PARTEQ 5% of any lump sum sublicense fees received, such as milestone payments, excluding amounts designated by the sublicensee for future research and development efforts.

For the years ended December 31, 2008, 2007 and 2006, actual royalties based on product sales were approximately $873,000, $620,000, and $522,000, respectively. Annual minimum royalties to PARTEQ must total at least CDN $100,000 (U.S. $82,000 as of December 31, 2008).

NATIONAL BIOLOGICAL CORPORATION AMENDED AND RESTATED PURCHASE AND SUPPLY AGREEMENT

On June 21, 2004, we signed an Amended and Restated Purchase and Supply Agreement with National Biological Corporation, or NBC, one of the manufacturers of our BLU-U® light source. This agreement provides for the elimination of certain exclusivity clauses, permits us to order on a purchase order basis without minimums, and includes other modifications of the original agreement providing both parties greater flexibility related to the development and manufacture of light sources and the associated technology within the field of PDT. On December 23, 2008, we signed the Second Amendment to the Amended and Restated Purchase and Supply Agreement, which extends the Agreement until June 30, 2009, and gives us an option to extend for an additional two years subject only to agreement on price terms to be negotiated in good faith. The parties are actively engaged in discussions to extend the term of the agreement.

SOCHINAZ SA

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

LEASE AGREEMENTS

We have entered into lease commitments for office space in Wilmington, Massachusetts, 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. In the fourth quarter of 2008, we vacated the Toronto, Ontario office and have listed the space with a real estate broker for potential sublease. We previously had a lease in Valhalla, New York, which expired on December 31, 2008 and was not renewed.

RESEARCH AGREEMENTS

We have entered into various agreements for research projects and clinical studies. As of December 31, 2008, future payments to be made pursuant to these agreements, under certain terms and conditions, totaled approximately $1,532,000. Included in this future payment is a master service agreement, effective June 15, 2001, with Therapeutics, Inc. for an initial term of two years, with annual renewal periods thereafter, to engage Therapeutics to manage the clinical development of our products in the field of dermatology. The

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agreement was renewed on June 15, 2008 for a one year period. Therapeutics is entitled to receive a bonus valued at $50,000, in cash or stock at our discretion, upon each anniversary of the effective date.

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, 2008:

	Total	1 Year or less	2-3 Years	4-5 Years	After 5
Operating lease obligations	$ 1,662,000	$ 449,000	$ 944,000	$ 269,000	$
Purchase obligations (1, 2)	3,657,000	3,025,000	632,000		
Minimum royalty obligations (3)	665,000	332,000	189,000	144,000	
Total obligations	$ 5,984,000	$ 3,806,000	$ 1,765,000	$ 413,000	$

1) Research and development projects include various commitments including obligations related to clinical development.

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 and Perrigo described above.

Rent expense incurred under these operating leases was approximately $447,000, $476,000, and $477,000 for the years ended December 31, 2008, 2007, and 2006, respectively.

Recently Issued Accounting Guidance for Future Adoption

In December 2007, the Financial Accounting Standards Board (FASB) issued Statement No. 141(R), *Business Combinations* (SFAS 141(R)). SFAS 141(R) amends FASB Statement No. 141 and provides revised guidance for recognizing and measuring assets acquired and liabilities assumed in a business combination. SFAS 141(R) also requires that transaction costs in a business combination be expensed as incurred. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141(R) is effective on a prospective basis for our financial statements beginning on January 1, 2009. Accordingly, any future business combination we enter into would be subject to SFAS 141(R).

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force (EITF) on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy

election. Further, EITF 07-1 clarified the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF Issue No. 01-9, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products). EITF 07-1 is effective for us beginning on January 1, 2009. EITF 07-1 is not expected to have a material effect on our consolidated financial statements.

In 2007, the FASB also issued Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* (SFAS 160). SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method will significantly change the accounting for transactions with minority interest holders. The provisions of this standard are effective beginning January 1, 2009. The adoption of this standard is not expected to have an effect on our consolidated financial position and results of operations.

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In March 2008, the FASB issued Statement No. 161 (SFAS 161), *Disclosures about Derivative Instruments and Hedging Activities, as an amendment to SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities*. SFAS 161 requires that objectives for using derivative instruments be disclosed in terms of underlying risk and accounting designation. The fair value of derivative instruments and their gains and losses will need to be presented in tabular format in order to present a more complete picture of the effects of using derivative instruments. SFAS 161 is effective for financial statements issued for periods beginning after November 15, 2008. The adoption of this pronouncement is not expected to have a material impact on our financial statements.

Inflation

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

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

Interest Rates

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our investments consist of United States government securities and high grade corporate bonds. All investments are carried at market value, which approximates cost. In response to the instability in the global financial markets, we have regularly reviewed our marketable securities holdings, and have reduced or avoided investing in securities deemed to have increased risk.

As of December 31, 2008, the weighted average rate of return on our investments was 3.77%. If market interest rates were to increase immediately and uniformly by 100 basis points from levels as of December 31, 2008, the fair market value of the portfolio would decline by $159,000. Declines in interest rates could, over time, reduce our interest income.

Derivative Financial Instruments

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

Currency Exchange Rates

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

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

each reporting period.

Other exchange rates that we are subject to, such as the Canadian dollar, are not material to our operations.

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Forward-Looking Statements Safe Harbor

This report, including the Management s Discussion and Analysis of Financial Condition and Results of Operations, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 21E of the Securities Exchange Act of 1934 which represent our expectations or beliefs concerning future events, including, but not limited to management s statements regarding our strategies and core objectives for 2009, our expectations concerning the introduction of generic substitutes for Nicomide® and such products impact on sales of Nicomide®, our use of estimates and assumptions in the preparation of our financial statements and policies and impact on us of the adoption of certain accounting standards, the impact of compounding pharmacies, management s beliefs regarding the unique nature of Levulan® and its use and potential use, expectations regarding the timing of results of clinical trials, future development of Levulan® and our other products and other potential indications, statements regarding the manufacture of Nicomide® in the future, beliefs concerning manufacture of the BLU-U®, intention to pursue licensing, marketing, co-promotion, collaboration or acquisition opportunities, status of clinical programs for all other indications and beliefs regarding potential efficacy and marketing, our beliefs regarding the safety, simplicity, reliability and cost-effectiveness of certain light sources, our expectations regarding product launches in other countries, expectations regarding additional market expansion, expectations for commercialization of Levulan® Kerastick® in Asian countries, expectations regarding the marketing and distribution of Levulan® Kerastick® by Daewoong Pharmaceutical Co., Ltd. and Stiefel Laboratories, Inc., beliefs regarding the suitability of clinical data, expectations regarding the confidentiality of our proprietary information, statements of our intentions to seek additional U.S. and foreign regulatory approvals, and to market and increase sales outside the U.S., beliefs regarding regulatory classifications, filings, timelines, off-label use and environmental compliance, beliefs concerning patent disputes and litigation, intentions to defend our patent estate, beliefs regarding the patent reexamination process, 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 or decreases in the prices we charge for our products, our beliefs regarding the size of the market for our products and our product candidates, expectations of increases or decreases in cost of product sales, expected use of cash resources, requirements of cash resources for our future liquidity, beliefs regarding investments and economic conditions, expectations regarding outstanding options and warrants and our dividend policy, anticipation of increases or decreases in personnel, beliefs regarding the effect of reimbursement policies on revenues and acceptance of our therapies, expectations for future strategic opportunities and research and development programs and expenses, expectations for continuing operating losses and competition, including from Metvixia, expectations regarding the adequacy and availability of insurance, expectations regarding general and administrative costs, expectations regarding sales and marketing costs and research and development costs, levels of interest income and our capital resource needs, intention to raise additional funds to meet capital requirements and the potential dilution and impact on our business, potential for additional inspection and testing of our manufacturing facilities or additional FDA actions, beliefs regarding the adequacy of our inventory of Kerastick® and BLU-U® units and of Nicomide®, our manufacturing capabilities and the impact of inventories on revenues, beliefs regarding interest rate risks to our investments and effects of inflation, beliefs regarding the impact of any current or future legal proceedings or arbitration proceedings, dependence on key personnel, and beliefs concerning product liability insurance, the enforceability of our patents, the impact of generic products, our beliefs regarding our sales and marketing efforts, competition with other companies, the adoption of our products, our beliefs regarding the use of our products and technologies by third parties, our beliefs regarding our compliance with applicable laws, rules and regulations, our beliefs regarding available reimbursement for our products, our beliefs regarding the current and future clinical development and testing of our potential products and technologies and the costs thereof, the volatility of our stock price, the impact of our rights plan, the possibility that the holders of options and warrants will purchase our common stock by exercising these securities, timing and future development plans with respect to the NCI clinical trials, beliefs regarding legal strategies or regulatory authorities actions to stop compounding pharmacies, expectations of price and volume of Nicomide® as a DSHEA-labeled product, expectations related to the change in revenues of our PDT and Non-PDT products, expectations regarding the payment of remaining milestones to former Sirius shareholders,

intention to sublease the Toronto offices, plans to re-launch Nicomide® under DSHEA compliant labeling, beliefs regarding

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market share, beliefs regarding profitability, beliefs regarding the change in growth in our PDT Drug and Device Products segment, expectations regarding the BLU-U® evaluation program and purchases of our products resulting therefrom, expectations regarding our manufacturing facility, beliefs regarding our SOTR research and development program, beliefs regarding settlement discussions with Winston Laboratories, Inc. and possibilities regarding Nasdaq listing. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, changing market and regulatory conditions, actual clinical results of our trials, the impact of competitive products and pricing, the timely development, FDA and foreign regulatory approval, and market acceptance of our products, environmental risks relating to our products, reliance on third-parties for the production, manufacture, sales and marketing of our products, the availability of products for acquisition and/or license on terms agreeable to us, sufficient sources of funds, the securities regulatory process, the maintenance of our patent portfolio and ability to obtain competitive levels of reimbursement by third-party payors, none of which can be assured. Results actually achieved may differ materially from expected results included in these statements as a result of these or other factors.

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

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

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 Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to the issuer s management, including its principal executive and principal financial officers or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

Changes In Internal Control Over Financial Reporting. The Chief Executive Officer and Chief Financial Officer have concluded that there have been no changes in the Company s internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

ITEM 9B. ***OTHER INFORMATION***

None.

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PART III

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

The information required by Item 10 is hereby incorporated by reference to the sections entitled Nominees, Executive Officers who are not Directors, Compliance with Section 16(a) of the Exchange Act , Meetings and Committees of the Board , and Code of Ethics Applicable to Senior Officers of the Registrant s 2009 Proxy Statement.

ITEM 11. ***EXECUTIVE COMPENSATION***

The information required by Item 11 is hereby incorporated by reference to the sections entitled Director Compensation, Executive Compensation, Summary Compensation Table, Grants of Plan-Based Awards, Outstandi Equity Awards at Fiscal Year-End, Option Exercises and Stock Vested, NonQualified Deferred Compensation, Compensation Discussion and Analysis, and Board Compensation Committee Report of Registrant s 2009 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 2009 Proxy Statement.

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

The information required by Item 13 is hereby incorporated by reference to the section entitled Certain Relationships and Related Transactions and Meetings and Committees of the Board of the Registrant s 2009 Proxy Statement.

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

The information required by Item 14 is hereby incorporated by reference to the section entitled Ratification and Selection of Auditors of the Registrant s 2009 Proxy Statement.

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

A. List of Financial Statements

B. Exhibits filed as part of this Report

2(a.1)*	Merger Agreement by and among the Registrant, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005 filed as Exhibit 2(a.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; and
2(a.2)	First Amendment to Merger Agreement by and among the Registrant, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006 filed as Exhibit 2(a.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference.

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3(a.1)	Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant s Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference;
3(a.2)	Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference; and
3(b)	By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant s current report on Form 8-K, filed on November 2, 2007, and is incorporated herein by reference.
4(a)	Common Stock specimen, filed as Exhibit 4(a) to the Registrant s Form 10-K for the fiscal year ended December 31, 2002, and is incorporated herein by reference;
4(b)	Form of D. Geoffrey Shulman s Class B Warrant, filed as Exhibit 4(b) to the Registrant s Form 10-K for the fiscal year ended December 31, 2007, and is incorporated herein by reference;
4(c)	Rights Agreement filed as Exhibit 4.0 to Registrant s Current Report on Form 8-K filed October 11, 2002, and is incorporated herein by reference;
4(d)	Rights Certificate relating to the rights granted to holders of common stock under the Rights Agreement filed as Exhibit 4.0 to Registrant s Current Report on Form 8-K filed October 11, 2002, and is incorporated herein by reference;
4(e)	Form of Common Stock Purchase Warrant, dated October 29, 2007 filed as Exhibit 4.2 to the Registrant s Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference; and
4(f)	Registration Rights Agreement, dated October 29, 2007, by and between the Registrant and each of the respective selling shareholders named therein filed as Exhibit 4.3 to the Registrant s Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference.
10(a)	License Agreement between the Registrant, PARTEQ and Draxis Health Inc. dated August 27, 1991, filed as Exhibit 10.1 to the Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
10(b)	ALA Assignment Agreement between the Registrant, PARTEQ, and Draxis Health Inc. dated October 7, 1991, filed as Exhibit 10.2 to the Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
10(b.1)	Amended and Restated Assignment Agreement between the Registrant and Draxis Health, Inc. dated April 16, 1999, filed as Exhibit 10(b.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
10(b.2)	Termination and Transfer Agreement between the Registrant and Draxis Health Inc. dated as of February 24, 2004, filed as Exhibit 10(b.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(c)	Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated October 1, 1991, filed as Exhibit 10.4 to the Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference; +
10(d.1)	Amendment to Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated April 14, 1994, filed as Exhibit 10.4 to the Registrant s Registration Statement on Form S-2, No. 33-98030, and is incorporated herein by reference; +
10(d.2)	Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated March 20, 1997, filed as Exhibit 10(d.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
10(d.3)	Consulting Agreement and General Release of D. Geoffrey Shulman, MD, FRCPC dated as of December 1, 2008; +

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10(e)	Amended and Restated License Agreement between the Registrant and PARTEQ dated March 11, 1998, filed as Exhibit 10(e) to the Registrant s Form 10-K/A filed on June 18, 1999, portions of Exhibit A have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(f)	Incentive Stock Option Plan, filed as Exhibit 10.11 of Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference; +
10(g)	1994 Restricted Stock Option Plan, filed as Exhibit 1 to Registrant s Schedule 14A definitive Proxy Statement dated April 26, 1995, and is incorporated herein by reference; +
10(h)	1996 Omnibus Plan, as amended, filed as Appendix A to Registrant s Schedule 14A Definitive Proxy Statement dated April 26, 2001, and is incorporated herein by reference; +
10(h.1)	1996 Omnibus Plan, as amended on May 1, 2003, filed as Exhibit 10(h.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference; +
10(h.2)	1996 Omnibus Plan, as amended April 23, 2004, filed as Appendix A to Registrant s Schedule 14A definitive Proxy Statement dated April 28, 2004, and is incorporated herein by reference; +
10(i)	Purchase and Supply Agreement between the Registrant and National Biological Corporation dated November 5, 1998, filed as Exhibit 10(i) to the Registrant s Form 10-K/A filed on June 18, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(i.1)	Amended and Restated Purchase and Supply Agreement between the Registrant and National Biological Corporation dated as of June 21, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed August 11, 2004, and is incorporated herein by reference;
10(j)	Supply Agreement between the Registrant and Sochinaz SA dated December 24, 1993, filed as Exhibit 10(q) to Registrant s Form 10-K/A filed on March 21, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(j.1)	First Amendment to Supply Agreement between the Registrant and Sochinaz SA dated July 7, 1994, filed as Exhibit 10(q.1) to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
10(j.2)	Second Amendment to Supply Agreement between the Registrant and Sochinaz SA dated as of June 20, 2000, filed as Exhibit 10.1 to Registrant s Current Report on Form 8-K dated June 28, 2000, and is incorporated herein by reference;
10(j.3)	Third Amendment to Supply Agreement between the Registrant and Sochinaz SA dated July 29, 2005, filed as Exhibit 10.1 to the Registrant s Form 10-Q filed on August 3, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(k)	Master Service Agreement between the Registrant and Therapeutics, Inc. dated as of October 4, 2001, filed as Exhibit 10(b) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(l)	License and Development Agreement between the Registrant and photonamic GmbH & Co. KG dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;

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10(m)	Supply Agreement between the Registrant and medac GmbH dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(n)	License and Supply Agreement dated August 7, 2007 among the Registrant, photonamic GmbH & Co. KG and medac, GmbH, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10 to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2007 and is incorporated herein by reference
10(o)	Securities Purchase Agreement dated as of February 27, 2004, by and among the Registrant and certain investors, filed as Exhibit 10.1 to the Registrant s current report on Form 8-K, filed on March 2, 2004, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(p)	Registration Rights Agreement dated as of February 27, 2004 by and among the Registrant and certain investors, filed as Exhibit 10.2 to the Registrant s current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
10(q)	Form of Additional Investment Right dated as of February 27, 2004, filed as Exhibit 10.3 to the Registrant s current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
10(r)	License, Promotion, Distribution and Supply Agreement between the Registrant and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;
10(s)	Employment Agreement of Scott L. Lundahl dated as of June 23, 1999 filed as Exhibit 10(u) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(s.1)	Amendment No. 1 to Employment Agreement of Scott Lundahl dated as of April 10, 2008; +
10(t)	Amended Employment Agreement of Stuart L. Marcus, MD, PhD dated December 9, 1999 filed as Exhibit 10(v) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(t.1)	Amendment No. 2 to Employment Agreement of Stuart L. Marcus, MD, PhD dated as of April 10, 2008; +
10(u)	Employment Agreement of Mark C. Carota dated as of February 14, 2000 filed as Exhibit 10(w.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(u.1)	First Amendment to Employment Agreement of Mark C. Carota dated October 31, 2001 filed as Exhibit 10(w.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(u.2)	Amendment No. 2 to Employment Agreement of Mark C. Carota dated as of April 10, 2008; +
10(v)	Amendment to Employment Agreement of Richard Christopher dated as of October 18, 2006 filed as Exhibit 10.A to the Registrant s Form 10-Q for the fiscal quarter ended September 30, 2004, and is incorporated herein by reference;
10(w)	Employment Agreement of Richard Christopher dated as of January 1, 2004 filed as Exhibit 10(y) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(w.1)	Amendment to Employment Agreement of Richard Christopher dated as of April 10, 2008; +
10(x)	Employment Agreement of Robert F. Doman dated as of March 15, 2005 filed as Exhibit 10(z) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +

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10(x.1)	First Amendment to Employment Agreement of Robert F. Doman dated November 26, 2008; +
10(aa)	Compensation Policy Applicable to the Registrant s Non-Employee Directors filed as Exhibit 10(cc) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; and +
10(bb)	Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated May 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(cc)	Amendment and Extension of the Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(dd)	Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(ee)	Amendment and Extension of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.D to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
10(ff)	Second Amendment of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.E to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
10(gg)	Supply Agreement between Sirius Laboratories, Inc. and L. Perrigo Registrant dated October 21, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.F to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
10(hh)	2006 Micanol License Agreement between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.G to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference; and
10(hh.1)	2006 Micanol Transition License Agreement, dated as of January 29, 2008, by and between Winston Laboratories, Inc. and Sirius Laboratories, Inc. portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.1 to the Registrant s Current Report on Form 8-K, filed on January 31, 2008, and is incorporated herein by reference;
10(ii)	Development, License and Supply Agreement between Sirius Laboratories, Inc. and Altana Inc. dated June 13, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and as filed as Exhibit 10.H to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference.
10(jj)	Employment Agreement of William O Dell dated as of April 4, 2006 filed as Exhibit 10(ii) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;

10(jj.1) Amendment No. 1 to Employment Agreement of William O Dell dated as of April 10, 2008; +

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10(kk)	Patent License Agreement between the Registrant and PhotoCure ASA, dated as of May 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10.A to the Registrant s Form 10-Q for the fiscal quarter ended June 30, 2006, and is incorporated herein by reference;
10(ll)	Separation Agreement between the Registrant and Paul Sowyrda, dated as of August 31, 2006 filed as Exhibit 10(kk) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(mm)	Employment Agreement of Michael Todisco dated as of September 20, 2006 filed as Exhibit 10(11) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(mm.1)	Amendment No. 1 to Employment Agreement of Michael Todisco dated as of April 10, 2008; +
10(nn)	Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 4, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(mm) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(nn.1)	First Amendment to Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 10, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(nn) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(oo)	DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, filed as Appendix A to Registrants s Schedule 14A definitive Proxy Statement dated April 24, 2006, and is incorporated herein by reference; +
10(pp)	DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, as amended October 18, 2006 filed as Exhibit 10(pp) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
10(qq)	DUSA Pharmaceuticals, Inc. 2006 Deferred Compensation Plan, October 18, 2006 filed as Exhibit 10(qq) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
10(rr)	Marketing, Distribution and Supply Agreement between the Registrant and Stiefel Laboratories, Inc., dated as of January 12, 2006, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(aa) to the Registrant s Form 10-K for the fiscal year ended December 31, 2005, and is incorporated herein by reference;
10(rr.1)	Amendment to the Marketing, Distribution and Supply Agreement dated September 26, 2007, between the Registrant and Stiefel Laboratories, Inc. portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(a) to the Registrant s Form 10-Q for the fiscal quarter ended September 30, 2007, and is incorporated herein by reference;
10(ss)	Securities Purchase Agreement, dated October 29, 2007, by and among the Registrant and each of the selling shareholders named therein portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10.1 to the Registrant s Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference;
10(tt)	Settlement Agreement and Mutual Release, including License Agreement dated October 28, 2007 between Registrant and River s Edge Pharmaceuticals LLC, filed as Exhibit 10(tt) to the Registrant s

Form 10-K for the fiscal year ended December 31, 2007, and is incorporated herein by reference; and

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10(uu)	License Agreement between the Registrant and River s Edge Pharmaceuticals LLC entered into August 12, 2008 portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2008, and is incorporated herein by reference.
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 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.
99.1	Press Release.

+ Management contract or compensatory plan or arrangement.

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of DUSA Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2008. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 11, 2009

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DUSA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	2007
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 3,880,673	$ 4,713,619
Marketable securities, at fair value	15,002,830	18,311,650
Accrued interest receivable	155,728	97,243
Accounts receivable, net of allowance for doubtful accounts of $98,000 and $158,000 in 2008 and 2007, respectively	2,367,803	2,667,178
Inventory	2,812,825	2,672,105
Prepaid and other current assets	1,718,073	1,843,873
TOTAL CURRENT ASSETS	25,937,932	30,305,668
Restricted cash	173,844	170,510
Property, plant and equipment, net	1,937,978	2,142,658
Deferred charges and other assets	160,700	273,404
TOTAL ASSETS	$ 28,210,454	$ 32,892,240
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 305,734	$ 1,213,867
Accrued compensation	1,515,912	491,529
Other accrued expenses	3,226,571	3,322,642
Deferred revenue	611,602	1,256,494
TOTAL CURRENT LIABILITIES	5,659,819	6,284,532
Deferred revenues	4,157,305	2,918,850
Warrant liability	436,458	1,262,600
Other liabilities	244,673	319,736
TOTAL LIABILITIES	10,498,255	10,785,718
COMMITMENTS AND CONTINGENCIES (NOTE 16)		
SHAREHOLDERS EQUITY		
Capital Stock Authorized: 100,000,000 shares; 40,000,000 shares designated as common stock, no par, and 60,000,000 shares issuable in series or classes; and 40,000 junior Series A preferred shares. Issued and outstanding: 24,089,452 and 24,076,110 shares of common stock, no par, at December 31, 2008 and December 31, 2007, respectively	151,663,943	151,648,943
Additional paid-in capital	7,514,900	5,885,353
Accumulated deficit	(141,850,925)	(135,600,484)

Accumulated other comprehensive income	384,281	172,710
TOTAL SHAREHOLDERS EQUITY	17,712,199	22,106,522
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 28,210,454	$ 32,892,240

See the accompanying Notes to the Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2008	**2007**	**2006**
Product revenues	$ 29,545,406	$ 27,662,598	$ 25,582,986
Cost of product revenues			
Cost of product revenues and royalties	7,125,095	7,829,284	10,369,957
Impairment of intangible assets			15,746,032
Total cost of product revenues	7,125,095	7,829,284	26,115,989
GROSS MARGIN	22,420,311	19,833,314	(533,003)
Operating costs			
Research and development	6,643,207	5,976,728	6,213,851
In-process research and development			1,600,000
Marketing and sales	13,111,652	13,311,314	12,644,654
General and administrative	9,187,826	10,311,290	11,195,726
Impairment of goodwill	1,500,000	6,772,505	
Net gain from settlement of litigation	(282,775)	(582,866)	
TOTAL OPERATING COSTS	30,159,910	35,788,971	31,654,231
LOSS FROM OPERATIONS	(7,739,599)	(15,955,657)	(32,187,234)
Gain on change in fair value of warrants	826,142	687,300	
Other income, net	663,016	554,850	837,727
NET LOSS	$ (6,250,441)	$ (14,713,507)	$ (31,349,507)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (0.26)	$ (0.73)	$ (1.65)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	24,079,414	20,292,729	19,006,609

See the accompanying Notes to the Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

	Common Stock Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accum. Other Comprehensive Income (Loss)	Total
Balance, January 1, 2006	17,041,197	$ 125,626,163	$ 2,035,783	$ (89,537,470)	$ (95,748)	$ 38,028,728
Comprehensive loss:						
Net loss				(31,349,507)		(31,349,507)
Net unrealized gain on marketable securities available-for-sale					36,375	36,375
Total comprehensive loss						(31,313,132)
Issuance of common stock upon acquisition of Sirius Laboratories, Inc.	2,396,245	17,203,449				17,203,449
Share-based compensation expense			2,284,842			2,284,842
Exercises of options	42,625	129,686				129,686
Balance, December 31, 2006	19,480,067	$ 142,959,298	$ 4,320,625	$ (120,886,977)	$ (59,373)	$ 26,333,573
Comprehensive loss:						
Net loss				(14,713,507)		(14,713,507)
Net unrealized gain on marketable securities available-for-sale					232,083	232,083
Total comprehensive loss						(14,481,424)
Adjustment to equity issuance costs for the acquisition of Sirius Laboratories, Inc.		250,590				250,590
Share-based compensation expense			1,564,728			1,564,728

Exercises of options	15,000	40,651				40,651
Issuance of common stock in private placement, net of issuance costs and fair value of warrants at issuance	4,581,043	8,398,404				8,398,404
Balance, December 31, 2007	24,076,110	$ 151,648,943	$ 5,885,353	$ (135,600,484)	$ 172,710	$ 22,106,522
Comprehensive loss:						
Net loss				(6,250,441)		(6,250,441)
Net unrealized gain on marketable securities available-for-sale					211,571	211,571
Total comprehensive loss						(6,038,870)
Share-based compensation expense			1,640,547			1,640,547
Exercises of options	2,500	4,000				4,000
Vesting of common stock grants	11,000	11,000	(11,000)			
Retirement of shares from liability escrow account	(158)					
Balance, December 31, 2008	24,089,452	$ 151,663,943	$ 7,514,900	$ (141,850,925)	$ 384,281	$ 17,712,199

See the accompanying Notes to the Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2008	**2007**	**2006**
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (6,250,441)	$ (14,713,507)	$ (31,349,507)
Adjustments to reconcile net loss to net cash used in operating activities:			
(Accretion) amortization of premiums and discounts on marketable securities, available-for-sale	(114,995)	(199,164)	35,167
Realized loss (gain) on sale of marketable securities, available-for-sale	50,338	14,617	(14,015)
Share-based compensation	1,640,547	1,564,728	2,284,842
In-process research and development charge			1,600,000
Depreciation and amortization	570,098	671,387	3,908,532
Gain on change in fair value of warrants	(826,142)	(687,300)	
Deferred revenues recognized	(1,064,362)	(1,576,091)	(43,913)
Impairment of intangible assets			15,746,032
Impairment of goodwill	1,500,000	6,772,505	
Changes in other assets and liabilities impacting cash flows from operations:			
Accrued interest receivable	(58,485)	61,131	195,076
Accounts receivable	299,375	(606,613)	24,732
Inventory	(140,720)	(328,633)	(263,857)
Prepaid and other current assets	125,800	(308,054)	(802,000)
Deferred charges and other assets	112,704	671,316	(781,148)
Accounts payable	(908,133)	564,344	(888,001)
Accrued compensation and other accrued expenses	1,178,312	(1,701,599)	620,779
Deferred revenues	1,657,925	4,701,080	999,985
Other liabilities	(75,064)	113,735	431
NET CASH USED IN OPERATING ACTIVITIES	(2,303,243)	(4,986,118)	(8,726,865)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES			
Cash paid for acquisition, net of cash received			(7,767,006)
Cash paid for contingent consideration	(1,750,000)	(750,000)	
Purchases of marketable securities	(27,093,757)	(23,740,590)	(9,619,879)
Proceeds from maturities and sales of marketable securities	30,678,809	20,788,766	25,271,393
Restricted cash	(3,334)	(7,705)	(18,264)
Purchases of property, plant and equipment	(365,421)	(246,760)	(212,669)
NET CASH PROVIDED BY(USED IN) INVESTING ACTIVITIES	1,466,297	(3,956,289)	7,653,575
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			

Issuance of common stock in private placement, net of costs		10,348,304	
Proceeds from exercise of options	4,000	40,651	129,686
NET CASH PROVIDED BY FINANCING ACTIVITIES	4,000	10,388,955	129,686
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(832,946)	1,446,548	(943,604)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	$ 4,713,619	$ 3,267,071	$ 4,210,675
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 3,880,673	$ 4,713,619	$ 3,267,071

See the accompanying Notes to the Consolidated Financial Statements.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1) NATURE OF BUSINESS

DUSA Pharmaceuticals, Inc. (DUSA or the Company) is a vertically-integrated dermatology company that is developing and marketing Levulan® photodynamic therapy (PDT) and other products for common skin conditions. The Company s marketed products include among others Levulan® Kerastick® 20% Topical Solution with PDT, the BLU-U® brand light source, and certain products acquired in the March 10, 2006 merger with Sirius Laboratories, Inc.

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

Sirius Laboratories, Inc. (Sirius), a dermatology specialty pharmaceuticals company, was founded in 2000 with a primary focus on the treatment acne vulgaris and rosacea. Nicomide®, its key product, is a vitamin mineral product which is prescribed by dermatologists. The Company stopped the sale and distribution of Nicomide® as a prescription product in June 2008 following a series of discussions and communications with the FDA. On August 12, 2008, the Company entered into a worldwide non-exclusive patent License Agreement to license its patent covering Nicomide® to River s Edge Pharmaceuticals, LLC, (River s Edge), and an amendment to our Settlement Agreement with River s Edge, which we entered into in October 2007 to settle certain patent litigation. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. ClindaReach® was in development prior to the merger and the Company successfully launched the product in March 2007.

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

2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

c) Cash and Cash Equivalents Cash equivalents include short-term highly liquid money market funds. All other investments are classified as marketable securities. The Company maintained cash of $174,000 and $171,000 at December 31, 2008 and 2007, respectively, in a separate bank account in support of a letter of credit of $167,000 that was issued in lieu of a security deposit on the lease for its manufacturing facility in Wilmington, Massachusetts. The cash is presented in restricted cash as a non-current asset in the Consolidated Balance Sheets.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

d) Marketable Securities The Company records marketable securities at fair value as available-for-sale with unrealized holding gains (losses) recorded in accumulated other comprehensive income (loss). The Company records other-than-temporary impairment charges for investments that are in an unrealized loss position at the end of the period since the Company s portfolio is managed by a third-party investment advisor that has discretionary authority to sell the investments. The other-than-temporary impairment charge was $78,000, $16,000, and $0 for the years ended December 31, 2008, 2007 and 2006, respectively, and is included in other income in the accompanying Consolidated Statements of Operations. The Company amortizes or accretes the premiums and discounts paid for the securities into interest income over the period to maturity of the securities. As the Company s marketable securities are available to fund operations and as management expects to sell a portion of its marketable securities in the next fiscal year in order to meet its working capital requirements, all marketable securities are classified as current assets.

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

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

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

h) Goodwill and Other Intangible Assets Goodwill and intangible assets with indefinite lives are not amortized but are reviewed annually for impairment or more frequently if impairment indicators arise. Separable intangible assets that are not deemed to have indefinite lives will continue to be amortized over their useful lives. The Company has adopted December 1st as the date of the annual impairment test for goodwill. At December 31, 2008, the Company has no goodwill or intangible assets.

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

For revenues associated with contractual agreements with multiple deliverables, the Company applies the revenue recognition criteria outlined in Securities and Exchange Commission (SEC) Staff Accounting Bulletin Topic 13,

Revenue Recognition (SAB Topic 13) and Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* , (EITF 00-21). Accordingly, revenues from contractual agreements are recognized based on the performance requirements of those agreements. As prescribed by EITF 00-21, the Company analyzes each contract in order to separate each deliverable into

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

separate units of accounting, if applicable, and then recognizes revenue for those separated units at their fair values as earned in accordance with the SAB Topic 13 or other applicable revenue recognition guidance.

PHOTODYNAMIC THERAPY (PDT) DRUG AND DEVICE PRODUCTS

Revenues on the Levulan® Kerastick® and BLU-U® product sales in the U.S. and Canada are recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collection is 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 had sufficient history to reliably estimate returns from distributors beginning January 1, 2006. This change in estimate was not material to the Company s revenues or results of operations. We offer programs that allow physicians access to our BLU-U® device for a trial period. No revenue is recognized on these units until the physician elects to purchase the equipment and all other revenue recognition criteria are met.

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

Stiefel Laboratories Agreement. In January 2006, as amended in September 2007, the Company entered into an exclusive marketing, distribution and supply agreement (the Stiefel Agreement) with Stiefel Laboratories, Inc. (Stiefel) for Levulan® PDT in Latin America (see Note 11). Under the Stiefel Agreement, Stiefel is required to purchase Levulan® Kerastick® from the Company and make up front, milestone and royalty payments. Stiefel may cancel the Stiefel Agreement if there is a breach of contract, if either party files for bankruptcy, if its sales during any year are less than its minimum purchase obligations, or, as to Brazil only, if acceptable pricing approval, as defined in the Agreement, is not obtained. No upfront or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications. The Company is obligated under the Stiefel Agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. The Stiefel Agreement establishes a fixed supply price per unit, as well as a royalty based on a percentage of the net sales price to end-users. Under EITF 00-21 the deliverables under the Stiefel Agreement are treated as a single unit of accounting. The Company determines attribution methods for each of the separate payment streams. Revenues from unit sales of Levulan® Kerastick® are recognized based on end-user demand as the Company does not have sufficient data to determine product acceptance in the marketplace and therefore does not have the ability to estimate product returns. Royalty revenues are recorded each quarter based on Stiefel s reported net sales for that quarter and are included in product revenues.

The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval. The first contract year for all countries other than Brazil began in October 2007, and for Brazil began in April 2008. For the contract year ended in October 2008 Stiefel did not meet its minimum purchase obligations under the agreement. The agreement provides that within 60 days of the year end, Stiefel is required to pay us the difference between its actual purchases and the contractual minimums (a gross up payment). If Stiefel fails to make the gross up payment, our remedies include, without limitation, appointing one or more distributors in the territory or terminating the agreement. Stiefel did not make the gross up payment within the contractual time period, and the parties are

presently discussing actions to be taken, if any, due to the first year shortfall. Also, since Stiefel s sales to third parties during the contract year ended October 2008 were below its minimum purchase obligations, Stiefel has the unilateral right to cancel the contract.

The non-refundable up-front payments are being recognized into revenues on a straight-line basis commencing upon the first product shipments in a country over the remaining contractual term of the Stiefel

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2008 and 2007, in accordance with the Company s policy of deferring revenues on new product launches, the Company has deferred revenues of $389,000 and $206,000, respectively, related to product shipments of Levulan® Kerastick® into Latin America that have not yet been sold through to end user customers. Deferred revenues at December 31, 2008 and 2007 associated with milestone payments received from Stiefel were $621,000 and $345,000, respectively.

Daewoong Agreement. On January 4, 2007, the Company entered into an exclusive marketing, distribution and supply agreement (the Daewoong Agreement) with Daewoong Pharmaceuticals (Daewoong) for Levulan (R) PDT in Korea (see Note 12). Under the Daewoong Agreement, Daewoong is required to purchase Levulan® Kerastick® from the Company and make up-front and milestone payments. Daewoong may cancel the Daewoong Agreement only if there is a breach of contract or if either party files for bankruptcy. Under the terms of the agreement, Daewoong will make up to $3,500,000 in milestone payments to DUSA, $1,000,000 of which was paid upon contract execution during the first quarter of 2007 and another $1,000,000 of which was paid during the fourth quarter of 2007 upon achieving regulatory approval in Korea. The milestone payments are non-refundable. Product shipments are subject to return and refund only if the product does not comply with technical specifications. The Company is obligated under the Daewoong Agreement to provide multiple deliverables; the primary deliverables being license/product distribution rights and commercial product supply. The Daewoong Agreement establishes a fixed supply price per unit, as well as an Excess Purchase Price component if the Average Selling Price to end-users exceeds a certain threshold. Under EITF 00-21 the deliverables under the Agreement are treated as a single unit of accounting. The Company determines attribution methods for each of the separate payment streams. Revenues from unit sales of Levulan® Kerastick® are recognized based on end-user demand as the Company does not have sufficient data to determine product acceptance in the marketplace and therefore does not have the ability to estimate product returns. Excess purchase price revenues are recorded each quarter based on Daewoong s reported net sales for that quarter and are included in product revenues. The Daewoong Agreement also establishes minimum purchase quantities over the first five years following regulatory approval in Korea.

The non-refundable up-front payments are recognized into revenues on a straight-line basis commencing upon the first product shipment in the territory over the remaining contractual term of the Agreement, which is 10 years. Milestone payments based on cumulative units shipped into a country will initially be deferred and then recognized on a straight-line basis over the then remaining contractual term, with a cumulative catch-up based on the number of years into the contract such milestone is attained. As of December 31, 2008 and 2007, in accordance with the Company s policy of deferring revenues on new product launches, the Company has deferred revenues of $1,144,000 and $762,000, respectively, related to product shipments of Levulan® Kerastick® into Korea that have not yet been sold through to end user customers. Deferred revenues at December 31, 2008 and 2007 associated with milestone payments received from Daewoong are $1,643,000 and $1,848,000, respectively.

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

Photocure is obligated to pay the Company royalties on sales of its ester products to the extent they are covered by its patents in the U.S. and certain other territories. As part of the agreement, PhotoCure paid the Company a prepaid royalty in the amount of $1.0 million in 2006. Revenues recognized pursuant to the

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Photocure Agreement have not been material to date. The balance of the prepaid royalty under the Photocure Agreement is included in deferred revenues in the accompanying Consolidated Balance Sheets.

NON-PDT DRUG PRODUCTS

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

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

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

For new product launches where the Company does not have the ability to reliably estimate returns, revenue is recognized based on end-user demand, which is typically based on dispensed subscription data, or ship-through data as reported by the Company s international distribution partners. When inventories have been reduced to targeted stocking levels at wholesalers or distribution partners, and the Company has sufficient data to determine product acceptance in the marketplace which allows the Company to estimate product returns, the Company recognizes revenue upon shipment, net of discounts and allowances.

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

CHARGEBACKS, REBATES AND DISCOUNTS Chargebacks typically occur when suppliers enter into contractual pricing arrangements with end-user customers, including certain federally mandated programs, who then purchase from wholesalers at prices below what the supplier charges the wholesaler. Since the Company only offers discounts

to end-user customers under federally mandated programs, chargebacks have not been significant to the Company. The Company s rebate programs can generally be categorized into the following two types: Medicaid rebates and consumer rebates. Medicaid rebates are amounts owed based on legal requirements with public sector benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Consumer rebates are amounts owed as a result of mail-in coupons that are distributed by health care providers to consumers at the time a prescription is written.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	For the Year Ended December 31, 2008:				
	Balance at January 1, 2008	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, 2008
Accrued Expenses:					
Returns and allowances	$ 546,000	$ 916,000	$	$ (962,000)	$ 500,000
Chargebacks and rebates	$ 200,000	$ 408,000	$	$ (578,000)	$ 30,000

	For the Year Ended December 31, 2007:				
	Balance at January 1, 2007	Provision Related to Sales Made in the Current Period	Provision for Sales Made in Prior Periods	Actual Returns or Credits in the Current Period	Balance at December 31, 2007
Accrued Expenses:					
Returns and allowances	$ 632,000	$ 708,000	$	$ (794,000)	$ 546,000
Chargebacks and rebates	$ 26,000	$ 675,000	$	$ (501,000)	$ 200,000

j) Warranty costs The Company accrues for estimated future warranty costs on its BLU-U® sales at the time of sale. The Company s products are subject to rigorous regulation and quality standards. Warranty costs, which are included in cost of product revenues, were $89,000, $73,000 and $61,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

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

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

costs are expensed as incurred.

m) Income Taxes The Company recognizes deferred income tax assets and liabilities for the expected future tax consequences for events that have been included in the Company s financial statements or tax returns. Deferred tax assets and liabilities are based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which these differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

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

The Company adopted the provisions of FIN 48 on January 1, 2007. As of December 31, 2008 and 2007 the total amount of unrecognized tax benefits was $1,483,000 and $1,739,000, respectively, all of which, if

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recognized, would affect the effective tax rate prior to the adjustment for the Company s valuation allowance. As a result of the implementation of FIN 48, the Company did not recognize an increase in tax liability for the unrecognized tax benefits because the Company has recorded a tax net operating loss carryforward that would offset this liability.

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

n) Basic and Diluted Net Loss Per Common Share Basic net loss per common share is based upon the weighted average number of common shares outstanding during each period. Stock options, unvested common stock grants and warrants are not included in the computation of the weighted average number of common shares outstanding for dilutive net loss per common share during each of the periods presented in the Consolidated Statements of Operations, as the effect would be antidilutive. For the years ended December 31, 2008, 2007, and 2006, stock options, unvested common stock grants, warrants and rights totaling approximately 4,497,000, 4,250,000, and 3,031,000 shares, respectively, have been excluded from the computation of diluted net loss per share. The 2,396,087 shares issued in the Sirius acquisition are included in the weighted average number of shares outstanding from the date of issuance, March 10, 2006.

o) Share-Based Compensation The Company measures all employee share-based compensation awards using a fair value based method and records share-based compensation expense in its financial statements over the vesting period of the award.

p) Comprehensive Loss The Company has reported accumulated 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 The Company has two reportable segments, Photodynamic Therapy (PDT) Drug and Device Products and Non-Photodynamic Therapy (Non-PDT) Drug Products. Operating segments are defined as components of the Company for which separate financial information is available to manage resources and evaluate performance regularly by the chief operating decision maker. The Company does not allocate research and development, selling and marketing and general and administrative expenses or long-lived assets to its reportable segments, because these activities are managed at a corporate level.

r) Fair Value Measurements Effective January 1, 2008, the Company implemented FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The adoption of SFAS 157 did not have an impact on the Company s financial results. As defined in SFAS 157, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, prepayment speeds, default rates, loss severity, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Financial instruments in this category include corporate debt and government-backed securities.

Level 3 is comprised of financial instruments whose fair value is estimated based on internally developed models or methodologies utilizing significant inputs that are generally less readily observable. The following table presents information about the Company s assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2008, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Level 2
Assets:	
United States government-backed securities	$ 12,313,000
Corporate debt securities	2,690,000
Total assets	$ 15,003,000

	Level 3
Liabilities:	
Warrant liability	$ 436,000
Total liabilities	$ 436,000

Changes in Level 3 Recurring Fair Value Measurements:

The table below includes a rollforward of the balance sheet amounts for the year ended December 31, 2008 for the warrant liability, which is classified as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable parameters to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable components, observable components (that is, components that are actively quoted and can be validated to external sources). Accordingly, the gains and losses in the table below include changes in fair value due in part to observable factors that are part of the methodology.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Year Ended December 31, 2008

	Fair Value at December 31, 2007	Total Unrealized Gains	Purchases, Sales, Issuances, Settlements, net	Transfers In and/or Out of Level 3	Fair Value at December 31, 2008	Change in Unrealized Gains Related to Financial Instruments Held at December 31, 2008
Warrant Liability	$ 1,263,000	$ 826,000	$	$	$ 436,000	$ 826,000

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s) Concentrations The Company invests cash in accordance with a policy objective that seeks to preserve both liquidity and safety of principal. The Company manages the credit risk associated with its investments in marketable securities by investing in U.S. government securities and investment grade corporate bonds. The Company is also exposed to concentration of credit risk related to accounts receivable that are generated from its distributors and customers. To manage credit risk, the Company performs regular credit evaluations of its customers and provides allowances for potential credit losses, when applicable. Concentrations in the Company s total revenues for 2008, 2007, and 2006, and accounts receivable as of December 31, 2008 and December 31, 2007 were as follows:

	% of Revenue for Year Ended December 31,			% of Accounts Receivable as of December 31,	
	2008	2007	2006	2008	2007
Customer A	2%	4%	5%	11%	5%
Customer B	7%	11%	12%	%	10%
Customer C	6%	15%	18%	%	12%
Customer D	3%	6%	7%	%	7%
Customer E	3%	2%	%	1%	26%
Customer F	2%	%	%	9%	%
Other customers	77%	62%	58%	79%	40%
Total	100%	100%	100%	100%	100%

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

t) Derivative Financial Instruments The Company has issued common stock warrants in connection with the October 2007 private placement (See Note 10). The warrants are accounted for as derivative liabilities at fair value in accordance with FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133). The warrants do not meet the criteria in paragraph 11(a) of SFAS 133 that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified as a component of stockholders equity. Changes in fair value of derivative liabilities are recorded in the Consolidated Statements of Operations under the caption Gain on change in fair value of warrants.

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

In connection with the October 2007 private placement, the Company filed a registration statement with the SEC, which was declared effective by the SEC on January 24, 2008, for the registration of the total number of shares sold to

the investors and shares issuable upon the exercise of warrants. The Company is required under the agreement to use commercially reasonable efforts to cause the registration to remain continuously effective until such time when all of the registered shares are sold. In the event the Company fails to meet the requirements in regards to the registration statement, it will be obligated to pay the investors, as partial liquidated damages and not as a penalty, an amount in cash equal to 1% of the aggregate purchase price paid by investors for each monthly period that the registration statement is not effective, up to 12%. The Company follows EITF Issue No. 00-19-2, *Accounting for Registration Payment Arrangements* (EITF 00-19-

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2), which specifies that registration payment arrangements should play no part in determining the initial classification of, and subsequent accounting for, securities to which the payments relate. Contingent obligations in a registration payment arrangement are separately analyzed under FASB Statement No. 5, *Accounting for Contingencies*. If the Company determines a payment under this registration rights arrangement is probable and can be reasonably estimated, a liability will be recorded. As of December 31, 2008, the Company concluded the likelihood of having to make any payments under the arrangements was remote, and therefore did not record any related contingent liability as of December 31, 2008.

u) Recently Issued Accounting Pronouncements for Future Adoption In December 2007, the FASB issued Statement No. 141(R), *Business Combinations* (SFAS 141(R)). SFAS 141(R) amends FASB Statement No. 141 and provides revised guidance for recognizing and measuring assets acquired and liabilities assumed in a business combination. SFAS 141(R) also requires that transaction costs in a business combination be expensed as incurred. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141(R) is effective on a prospective basis for the Company s financial statements beginning on January 1, 2009. Accordingly, any future business combination the Company enters into would be subject to SFAS 141(R).

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*. EITF 07-1 is effective for the Company beginning on January 1, 2009. EITF 07-1 is not expected to have a material effect on the Company s consolidated financial statements.

In 2007, the FASB also issued Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* (SFAS 160). SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method will significantly change the accounting for transactions with minority interest holders. The provisions of this standard are effective beginning January 1, 2009. The adoption of this standard is not expected to have an effect on the Company s consolidated financial position and results of operations.

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities, as an amendment to SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities* (SFAS 161). SFAS 161 requires that objectives for using derivative instruments be disclosed in terms of underlying risk and accounting designation. The fair value of derivative instruments and their gains and losses will need to be presented in tabular format in order to present a more complete picture of the effects of using derivative instruments. SFAS 161 is effective for financial statements issued for periods beginning after November 15, 2008. The adoption of this pronouncement is not expected to have a material impact on the Company s financial statements.

3) BUSINESS ACQUISITION

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius Laboratories, Inc (Sirius). The Company agreed to pay additional consideration in future periods to the former Sirius shareholders based upon the achievement of total cumulative sales milestones for the Sirius products over the period ending 50 months from the date of close. The first cumulative sales milestone was achieved during

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2008, and accordingly a cash payment in the amount of $1.5 million was paid to the former Sirius shareholders during the period. The payment made during 2008 was recorded initially as goodwill and then subsequently deemed impaired and expensed during the same period as described below.

If the remaining sales milestones are attained, they will be paid in either common stock or cash, at the Company s sole discretion. The remaining cumulative sales milestones and related consideration are, as follows:

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

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

In performing the first step of the goodwill impairment test, management determined there was an indicator of impairment in the Non-PDT goodwill because the carrying value of the reporting unit exceeded its estimated fair value. In performing the second step of the goodwill impairment test, the Company allocated the estimated fair values of the Non-PDT reporting unit determined in step one of the impairment test, to the assets and liabilities as if a new acquisition were being accounted for in accordance with SFAS 141. Determining the fair value of the reporting unit under the first step of the goodwill impairment test and determining the fair value of individual assets and liabilities of a reporting unit under the second step of the goodwill impairment test is judgmental in nature and often involves the use of significant estimates and assumptions. Since the fair value of the Non-PDT reporting unit was derived from projected revenues associated solely with developed technologies, which were identified as intangible assets in the original purchase accounting allocation and subsequently written down to zero in 2006, the fair value of the reporting

unit was hypothetically all allocated to developed technologies, with no remaining value to assign to goodwill. The result was a write-down of $1.5 million paid to the former Sirius shareholders during the year ended December 31, 2008 which was initially recorded as goodwill.

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

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the product pipeline were based on a number of factors, most importantly, DUSA s development partner s, Altana, Inc. s, receipt of a non-approvable letter from the FDA with respect to its ANDA supplement covering one of the potential products we acquired from Sirius.

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

4) MARKETABLE SECURITIES

The Company s investment securities consist of securities of the U.S. government and its agencies, and investment grade corporate bonds. The Company has historically classified all investment securities as available-for-sale and recorded such investments at fair market value. Since the Company s investments are managed by a third-party investment advisor pursuant to a discretionary arrangement, for securities with unrealized losses during 2008 and 2007, which totaled $78,000 and $16,000, respectively, an other-than-temporary impairment was considered to have occurred and the cost basis of such securities were written down to their fair values with the amount of the write-down included in earnings as realized losses, which are included in other income in the accompanying Consolidated Statements of Operations. As of December 31, 2008, current yields range from 1.63% to 6.47% and maturity dates ranged from January 2009 to January 2013. The estimated fair value and cost of marketable securities at December 31, 2008 and December 31, 2007 are as follows:

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government-backed securities	$ 11,956,000	$ 357,000	$	$ 12,313,000
Corporate debt securities	2,662,000	28,000		2,690,000
Total marketable securities available-for-sale	$ 14,618,000	$ 385,000	$	$ 15,003,000

	December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
United States government-backed securities	$ 16,429,000	$ 163,000	$	$ 16,592,000
Corporate debt securities	1,710,000	10,000		1,720,000
Total marketable securities available-for-sale	$ 18,139,000	$ 173,000	$	$ 18,312,000

The change in net unrealized gains and losses on such securities for the years ended December 31, 2008, 2007 and 2006 was $212,000, $232,000, and $36,000, respectively, and has been recorded in accumulated other comprehensive income (loss), which is reported as part of shareholders equity in the Consolidated Balance Sheets. Realized (losses) gains on sales of marketable securities were $(50,000), $(15,000) and $14,000 in 2008, 2007 and 2006, respectively.

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5 INVENTORY

Inventory consisted of the following at December 31:

	2008	2007
Finished goods	$ 1,348,000	$ 1,625,000
BLU-U® evaluation units	166,000	131,000
Work in process	698,000	409,000
Raw materials	601,000	507,000
	$ 2,813,000	$ 2,672,000

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

6) PROPERTY, PLANT AND EQUIPMENT

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

	Useful Life (In years)	2008	2007
Computer equipment and software	3	$ 2,815,000	$ 2,698,000
Furniture, fixtures and equipment	5	1,154,000	959,000
Manufacturing facility	Term of lease	2,204,000	2,204,000
Manufacturing equipment	5	2,332,000	2,283,000
Leasehold improvements	Lesser of useful life or term of lease	845,000	845,000
		9,350,000	8,989,000
Accumulated depreciation and amortization		(7,412,000)	(6,846,000)
		$ 1,938,000	$ 2,143,000

Depreciation and amortization related to property, plant and equipment was $570,000, $671,000, and $722,000 for 2008, 2007, and 2006, respectively.

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7) OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following at December 31:

	2008	2007
Research and development costs	$ 190,000	$ 293,000
Marketing and sales costs	191,000	334,000
Reserve for sales returns and allowances	500,000	546,000
Reserve for chargebacks and rebates	30,000	200,000
Other product related costs	824,000	873,000
Legal and other professional fees	467,000	484,000
Employee benefits	278,000	236,000
Accrued FDA fees	589,000	
Other expenses	158,000	357,000
	$ 3,227,000	$ 3,323,000

8) INCOME TAXES

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

	2008	2007
DEFERRED TAX ASSETS		
Current		
Reserves	$ 230,000	$ 349,000
Accrued Charges	356,000	219,000
Total current deferred tax assets	586,000	568,000
Non-current		
Operating loss carryforwards	32,176,000	32,023,000
Capitalized R&D	8,224,000	8,138,000
Research and development tax credit carryforwards	1,582,000	1,483,000
Deferred revenue	1,221,000	379,000
Intangible assets	226,000	264,000
Accrued charges	263,000	207,000
Stock-based compensation	1,753,000	1,202,000
Fixed assets	773,000	617,000
Total noncurrent deferred tax assets	46,218,000	44,313,000

Net deferred tax assets before allowance	46,804,000	44,881,000
Valuation allowance	(46,804,000)	(44,881,000)
Total	$	$

During the years ended December 31, 2008, 2007, and 2006, the valuation allowance was increased by approximately $1,923,000, $861,000, and $4,582,000, 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 $1,923,000 is primarily comprised of an increase due to the current year change in temporary differences of

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

$1,671,000, an increase in R&D credit carryforwards of $99,000 and an increase in the net operating loss carryforwards $153,000.

Future releases of valuation allowances related to stock option deductions in the amount of $2,166,000 will be credited to additional paid-in-capital.

As of December 31, 2008, the Company has Federal net operating loss carryforwards for tax purposes of approximately $89,696,000 and research and development tax credits of approximately $1,493,000, both of which, if not utilized, will expire on various dates through 2028 as follows:

	Operating Loss Carryforwards	Research and Development Tax Credits
2010	$ 2,325,000	$
2011	6,638,000	
2012	6,841,000	
2013		
2014		
2015		
2016		
2017		
2018	5,738,000	
2019		
2020		110,000
2021	3,143,000	288,000
2022	16,018,000	308,000
2023	12,872,000	147,000
2024	10,498,000	195,000
2025	13,425,000	182,000
2026	5,923,000	164,000
2027	5,321,000	25,000
2028	954,000	74,000
	$ 89,696,000	$ 1,493,000

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	2008	%	2007	%	2006	%
Income tax benefit at statutory rate	$ (2,125,000)	(34.0)	$ (5,003,000)	(34.0)	$ (10,659,000)	(34.0)
State taxes	(113,000)	(1.8)	59,000	0.4	(1,632,000)	(5.2)
Tax credit carryforwards	(73,000)	(1.2)			(141,000)	(0.5)
Charges for in-process research and development					627,000	2.0
Goodwill impairment	510,000	8.2	2,303,000	15.6		
Warrant valuation adjustment	(281,000)	(4.5)	(234,000)	(1.6)		
Change in valuation allowance including revisions of prior year estimates	1,923,000	30.8	2,831,000	19.2	11,747,000	37.5
Other	159,000	2.5	44,000	0.4	58,000	0.2
Effective tax rate	$		$		$	

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

The Company adopted the provisions of FIN 48 on January 1, 2007. As of December 31, 2008 and 2007, the Company s total amount of unrecognized tax benefits was $1,483,000 and $1,739,000, respectively, which, if recognized, would affect the effective tax rate prior to the adjustment for the Company s valuation allowance. As a result of the implementation of FIN 48, the Company did not recognize an increase in tax liability for the unrecognized tax benefits because the Company has recorded a tax net operating loss carryforward that would offset this liability.

The change in unrecognized tax benefits for the 12 months ended December 31, 2008 and 2007 is as follows:

	2008	2007
Balance at January 1,	$ 1,739,000	$ 1,803,000
Decrease for tax positions related to prior years	(190,000)	
Reductions for expiration of statue of limitations	(66,000)	(64,000)
Balance at December 31,	$ 1,483,000	$ 1,739,000

The Company recognizes interest and penalties related to unrecognized tax benefits in operating expenses. Since a full valuation allowance was recorded against the Company s net deferred tax assets and the unrecognized tax benefits determined under FIN 48 would not result in a tax liability, the Company has not accrued for any interest and penalties relating to these unrecognized tax benefits. The Company does not expect substantial changes in its unrecognized tax benefits or positions over the next 12 months.

Tax years ended December 31, 2005, 2006, 2007 and 2008 remain subject to examination by major tax jurisdictions, which are Federal and the Commonwealth of Massachusetts. However, since the Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, the years in which such losses originated may also be subject to review by relevant taxing authorities if utilized.

The Company has performed an analysis of its changes in ownership under Internal Revenue Code Section 382 and has determined that no Federal or state net operating loss carryforwards are limited and unavailable to offset future taxable income, resulting in no reduction of the related deferred tax asset and

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

valuation allowance as of December 31, 2008. As of December 31, 2007, the same analysis resulted in approximately $4,100,000 of state net operating loss carryforwards being considered limited and unavailable to offset future taxable income resulting in a reduction of the related deferred tax asset account and valuation allowance of approximately $187,000 at December 31, 2007.

9) SHAREHOLDERS EQUITY

Common Stock Issuances On October 29, 2007, the Company entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement with certain accredited investors for the private placement of 4,581,043 shares of the Company s common stock at a purchase price of $2.40 per share which resulted in gross proceeds of $11,000,000. The Company also issued warrants to purchase an additional 1,145,259 shares of common stock (see Note 10). The shares that were issued and the shares underlying the warrants were registered with the Securities and Exchange Commission on a Form S-3 registration statement, which became effective on January 24, 2008. The Company paid the placement agent its fee, including expenses, of $695,000 for its services in connection with the transaction.

On March 10, 2006, the Company acquired all of the outstanding common stock of Sirius in exchange for cash and 2,396,087 shares of DUSA common stock.

In the fourth quarter of 2008, 11,000 shares of unvested common stock grants vested upon the departure of the Company s former Chief Strategic Officer and Chairman of its Board of Directors.

10) STOCK OPTIONS AND WARRANTS

Stock Warrants

On October 29, 2007, the Company sold, through a private placement, 4,581,043 shares of our common stock and warrants to purchase 1,145,259 shares of common stock with an exercise price of $2.85. The warrants have a 5.5 year term and became exercisable on April 30, 2008. As described in Note 2, the warrants are recorded as a derivative liability at fair value. Upon issuance of the warrants on October 29, 2007, the Company recorded the warrant liability at its initial fair value of $1,950,000. Warrants that are classified as a liability are revalued at each reporting date until the warrants are exercised or expire with changes in the fair value reported in the Company s Consolidated Statements of Operations as gain or loss on fair value of warrants. At December 31, 2008 and 2007, the aggregate fair value of these warrants was $437,000 and $1,263,000, respectively, resulting in non-cash gains of $826,000 and $687,000 in 2008 and 2007, respectively. Assumptions used for the Black-Scholes option-pricing models as of December 31, 2008 and 2007 are as follows:

	December 31,	
	2008	**2007**
Expected volatility	75.0%	67.3%
Remaining contractual term (years)	4.33	5.33
Risk-free interest rate	1.55%	3.45%

Expected dividend yield	0%	0%
Common stock price	$ 1.05	$ 2.07

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

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Share-based Awards

Under the Company s 2006 Equity Compensation Plan (the 2006 Plan), the Company may grant stock-based awards in amounts not to exceed the lesser of: (i) 20% of the total number of shares of the Company s common stock issued and outstanding at any given time less the number of shares issued and outstanding under any other equity compensation plan of the Company at such time; or (ii) 4,815,690 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 NSOs on June 30 of each year. Grants to directors immediately vest on the date of the grant.

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

The 2006 Plan replaced the Company s 1996 Omnibus Plan (the 1996 Plan), which expired on June 6, 2006. A summary of stock option activity in both the 1996 Plan and the 2006 Plan, for 2008 follows:

		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, beginning of year	2,855,125	$ 10.76		
Options granted	312,000	$ 2.16		
Options forfeited	(19,687)	$ 5.27		

Options expired	(133,875)	$ 10.79			
Options exercised	(2,500)	$ 1.60			
Outstanding, end of year	3,011,063	$ 9.91	3.90	$	0.00
Exercisable, end of year	2,385,689	$ 11.34	3.31	$	0.00
Options vested and expected to vest, end of year	2,958,716	$ 10.04	3.86	$	0.00

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A summary of stock options outstanding at December 31, 2008 follows:

Range of Exercise Prices	Outstanding as of December 31, 2008	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable as of December 31, 2008	Weighted Average Exercise Price
$1.08-$3.00	608,500	5.13	$ 2.30	355,500	$ 2.39
$3.08-$6.75	765,125	4.66	$ 4.63	486,625	$ 4.70
$6.90-$9.92	721,250	3.42	$ 9.02	695,000	$ 9.10
$10.00-27.31	624,188	3.59	$ 14.98	556,564	$ 15.35
$31.00	292,000	1.17	$ 31.00	292,000	$ 31.00
	3,011,063	3.90	$ 9.91	2,385,689	$ 11.34

The total intrinsic value for stock options exercised in 2008, 2007 and 2006 was approximately $1,000, $31,000 and $100,000, respectively. At December 31, 2008, total unrecognized estimated compensation cost related to non-vested stock options and granted prior to that date was $1,219,000, which is expected to be recognized over a weighted average period of 2.3 years.

The amount of cash received from the exercise of stock options in 2008, 2007 and 2006 was approximately $4,000, $41,000 and $130,000, respectively, and the related tax benefit was approximately $1,000, $31,000 and $69,000 in 2008, 2007 and 2006, respectively.

During the second quarter of 2008, the Company issued 102,000 unvested shares of common stock to its officers. The unvested shares of common stock vest over 4 years at a rate of 25% per year. The fair value on the date of grant was $2.20 per share. In the fourth quarter of 2008, upon the departure of one of the Company s officers, 11,000 of the shares vested and are included in issued and outstanding shares on the accompanying Consolidated Balance Sheets at December 31, 2008. At December 31, 2008 the total amount of unrecognized compensation expense related to grants of unvested common stock was $157,000, which will be recognized over a period of 3.5 years.

SHARE-BASED COMPENSATION INFORMATION UNDER SFAS 123(R)

The weighted-average estimated fair value of employee stock options granted during the years ended December 31, 2008, 2007 and 2006 was $1.41, $1.97 and $4.61 per share, respectively, using the Black-Scholes option valuation model with the following weighted-average assumptions (annualized percentages):

	Year Ended December 31,		
	2008	2007	2006

Volatility	70.4%	62.2%	63.7%
Risk-free interest rate	2.98 - 3.6%	4.01% - 4.92%	4.31% - 5.21%
Expected dividend yield	0%	0%	0%
Expected life-directors and officers	6.3 years	5.9 years	5.9 - 8.5 years
Expected life-non-officer employees	5.9 years	5.5 years	5.5 - 6.3 years

The Company used historical volatility in the Company s stock for the expected volatility assumption input to the Black-Scholes model measured over a look back period commensurate with the expected life of the options. The decision to use historical volatility data to estimate expected volatility was based upon the lack of actively traded options in the Company s stock, and the Company s assessment that historical volatility is the most representative measure of future stock price trends.

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

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 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 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 2008 and 2007, forfeiture rates were estimated to be approximately 2.71% and 2.95%, respectively, for officers and directors and 9.35% and 8.10%, respectively, for non-officer employees.

Total share-based compensation expense, related to all of the Company s share-based awards, recognized for the years ended December 31, 2008, 2007 and 2006 is included in the following line items:

	Year Ended December 31,		
	2008	2007	2006
Cost of product revenues	$ 77,000	$ 99,000	$ 81,000
Research and development	457,000	373,000	621,000
Selling and marketing	131,000	241,000	370,000
General and administrative	976,000	852,000	1,213,000
Share-based compensation expense	$ 1,641,000	$ 1,565,000	$ 2,285,000

As a result of the departure of one of the Company s officers (see Note 15) during the fourth quarter of 2008, the Company accelerated the vesting on all of the former officer s stock options and grants of unvested common stock. As a result of the acceleration of vesting the Company recorded share-based compensation expense of $286,000.

11) STIEFEL AGREEMENT

In January 2006, as amended in September 2007, DUSA licensed to Stiefel the exclusive Latin American rights to market Levulan® PDT for payments by Stiefel of up to $2,250,000. The Company also manufactures and supplies finished product for Stiefel, which the Company began shipping in September 2007. In consideration for the transaction Stiefel agreed to pay the Company as follows: (i) $375,000 upon launch of the product in either Mexico or Argentina; (ii) $375,000 upon receipt of acceptable pricing approval in Brazil; (iii) two installments of $375,000 each for cumulative end-user sales in Brazil totaling 150,000 units and 300,000 units, and (iv) two installments of $375,000 each for cumulative sales in countries excluding Brazil totaling 150,000 units and 300,000 units. Stiefel launched the product in October 2007 in Mexico and Argentina and in April 2008 in Brazil. The Company is deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the fourth quarter of 2015, which is the term of the Stiefel Agreement. Stiefel pays a fixed price per unit for the inventory as well as a royalty based on a percentage of the net sales price to end-users. During 2008 and 2007, the Company s sales of Levulan® Kerastick® to Stiefel were $304,000 and $248,000, respectively. At December 31, 2008 and 2007 the total revenues deferred associated with shipments to Stiefel were $389,000 and $206,000, respectively, in accordance with the Company s policy of deferring revenues during a

product s launch phase and recognizing revenues based on end-user demand. Deferred revenues at December 31, 2008 and 2007 associated with milestone payments received from Stiefel were $621,000 and $345,000, respectively.

The agreement with Stiefel also establishes minimum purchase quantities over the first five years following regulatory approval. The first contract year for all countries other than Brazil began in October 2007, and for Brazil began in April 2008. For the contract year ended in October 2008 Stiefel did not meet its minimum purchase obligations under the agreement. The agreement provides that within 60 days of the year end, Stiefel is required to pay the Company the difference between its actual purchases and the contractual

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

minimums (a gross up payment). If Stiefel fails to make the gross up payment, the Company s remedies include, without limitation, appointing one or more distributors in the territory or terminating the agreement. Stiefel did not make the gross up payment within the contractual time period, and the parties are presently discussing actions to be taken, if any, due to the first year shortfall. Also, since Stiefel s sales to third parties during the contract year ended October 2008 were below its minimum purchase obligations, Stiefel has the unilateral right to cancel the contract.

12) DAEWOONG AGREEMENT

In January 2007 the Company licensed to Daewoong the exclusive Korean rights to market Levulan® PDT for payments by Daewoong of up to $3,500,000. The Company also manufactures and supplies finished product for Daewoong, which the Company began shipping in October 2007. In consideration for the transaction Daewoong agreed to pay the Company as follows: (i) $1,000,000 upon contract signing; (ii) $1,000,000 upon achieving regulatory approval in Korea; and (iii) two installments of $750,000 each for cumulative end-user sales totaling 200,000 units and 500,000 units. Daewoong launched the product in November 2007 in Korea. The Company is deferring and recognizing the up-front and regulatory approval milestones as license revenues on a straight-line basis, beginning with product launch in the Territory through the fourth quarter of 2016, which is the term of the Daewoong Agreement. Daewoong pays a fixed price per unit for the inventory and an Excess Purchase Price, as defined in the Agreement, if the Average Selling Price to end-users during any calendar quarter exceeds a certain threshold. During 2008 and 2007, DUSA s sales of Levulan® Kerastick® to Daewoong were $998,000 and $1,100,000, respectively. At December 31, 2008 and 2007 the total revenues deferred associated with shipments to Daewoong were $1,144,000 and $762,000, respectively, in accordance with the Company s policy of deferring revenues during a product s launch phase and recognizing revenues based on end-user demand. Deferred revenues at December 31, 2008 and 2007 associated with milestone payments received from Daewoong were $1,643,000 and $1,848,000, respectively. The agreement with Daewoong also establishes minimum purchase quantities over the first five years following regulatory approval.

13) RETIREMENT AND DEFERRED COMPENSATION PLANS

The Company has a tax-qualified employee savings and retirement 401(k) Profit Sharing Plan (the 401(k) Plan), covering all qualified employees. Participants may elect a salary deferral of at least 1% as a contribution to the 401(k) Plan, up to the statutorily prescribed annual limit for tax-deferred contributions. Effective February 1, 2003, the Company matches a participant s contribution up to 1.25% of a participant s salary (the Match), subject to certain limitations of the 401(k) Plan. Participants will vest in the Match at a rate of 25% for each year of service to the Company. The Company s matching contributions in 2008, 2007 and 2006 were $64,000, $59,000 and $49,000, respectively.

In October 2006, the Company adopted the DUSA Pharmaceuticals, Inc. Non-Qualified Deferred Compensation Plan (the Plan), a non-qualified supplemental retirement plan maintained primarily for the purpose of providing deferred compensation for a select group of management or highly compensated employees and members of the Board of Directors of the Company (the Participants). Participants may defer up to 80% of their compensation. A Participant will be 100% vested in all of the amounts he or she defers as well as in the earnings attributable to a Participant s deferred account. A Participant may elect to receive distributions from the deferred account at various times, either in a lump sum or in up to ten annual installments. Included in other liabilities is $80,000 and $127,000 at December 31, 2008 and 2007, respectively, representing the Company s obligation under the Plan. DUSA s obligation to pay the

Participant an amount from his or her deferred account is an unsecured promise and benefits shall be paid out of the general assets of the Company. The Company has purchased corporate owned life insurance to serve as the funding vehicle for the Plan. The cash surrender value of the life insurance policy is recorded in deferred charges and other assets and totaled $83,000 and $124,000 at December 31, 2008 and 2007, respectively.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14) SEGMENT REPORTING

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

	Year Ended December 31,		
	2008	2007	2006
		(In thousands)	
REVENUES			
PDT drug & device product revenues	$ 23,930,000	$ 18,275,000	$ 16,097,000
Non-PDT drug product revenues	5,615,000	9,388,000	9,486,000
Total revenues	29,545,000	27,663,000	25,583,000
COSTS OF REVENUES			
PDT drug & device cost of product revenues and royalties	5,352,000	4,950,000	5,586,000
Non-PDT drug cost of product revenues and royalties	1,773,000	2,880,000	4,784,000
Impairment of intangible assets			15,746,000
Total non-PDT drug cost of product revenues and royalties	1,773,000	2,880,000	20,530,000
Total costs of product revenues and royalties	7,125,000	7,830,000	26,116,000
GROSS MARGINS			
PDT drug and device product gross margin	18,578,000	13,325,000	10,511,000
Non-PDT drug product gross margin	3,842,000	6,508,000	(11,044,000)
Total gross margins	$ 22,420,000	$ 19,833,000	$ (533,000)

During the years ended December 31, 2008, 2007 and 2006, the Company derived revenues from the following geographies based on the location of the customer (as a percentage of product revenues):

	Year Ended December 31,		
	2008	2007	2006
United States	94%	95%	96%
Canada	2%	3%	4%

Korea	3%	2%	%
Rest-of-world	1%	%	%
Total	100%	100%	100%

Asset information by reportable segment is not reported to or reviewed by the chief operating decision maker and, therefore, the Company has not disclosed asset information for each reportable segment. As discussed in Note 3, the Company recorded goodwill impairment charges of $1,500,000 and $6,800,000 in 2008 and 2007, respectively, and an intangible asset impairment charge of $15,700,000 in 2006, all of which were assets related to the Non-PDT segment.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15) DEPARTURE OF OFFICER

During the fourth quarter of 2008, the Company reported the departure of Dr. Shulman, the Company s founder, Chief Strategic Officer, and Chairman of the Board. Dr. Shulman has resigned from full-time management and his officer position and has agreed to become a part time consultant to DUSA. As a consequence of the departure, the Company and Dr. Shulman agreed to terminate Dr. Shulman s Employment Agreement and entered into a two-year consulting agreement effective December 1, 2008 (the Consulting Agreement).

Under the terms of the Employment Agreement, Dr. Shulman received twelve months severance in the amount of $379,080, which was paid and expensed during 2008. Also, Dr. Shulman became vested in all of his stock options and grants of unvested common stock. Dr. Shulman has the right to exercise all such options for one year. The Company recorded a non-cash stock compensation charge of $286,000 during 2008 related to the acceleration of vesting. Pursuant to the Consulting Agreement, Dr. Shulman will devote his best efforts (health permitting) on a part-time basis to further the goals of DUSA. His duties will include, among others, consulting on matters requested by the Company s Chief Executive Officer, and monitoring the dermatology community with respect to photodynamic therapy and photodetection technologies and products and other issues of interest to the Company. Dr. Shulman will receive annual consulting fees of $175,000, which will be accrued and paid on a monthly basis over its term. Furthermore, DUSA has agreed to reimburse Dr. Shulman for direct medical-related expenses and prescription drug expenses to the extent not covered by Dr. Shulman s health plans up to $50,000 per year for the period from March 1, 2008 through February 28, 2013. These payments will be accrued by the Company as incurred and billed by Dr. Shulman. The Consulting Agreement may be renewed by mutual agreement of the parties at the end of the two year period.

16) COMMITMENTS AND CONTINGENCIES

LEGAL MATTERS:

RIVER S EDGE LITIGATION SETTLEMENT

As part of the settlement of litigation between DUSA and River s Edge Pharmaceuticals, LLC in October 2007, the parties entered into a Settlement Agreement and Mutual Release (the Settlement Agreement) to dismiss the lawsuit brought by DUSA against River s Edge asserting a number of claims arising out of River s Edge s alleged infringement of the Company s Nicomide® patent, U.S. Patent No. 6,979,468, under which DUSA has marketed, distributed and sold Nicomide®. As part of the terms of this agreement, River s Edge agreed to pay to DUSA $25.00 for every bottle of NIC 750 above 5,000 bottles that was substituted for Nicomide® after September 30, 2007. The net gain from settlement of litigation for 2008 and 2007 is $283,000 and $583,000, respectively and is recorded in the accompanying Consolidated Statement of Operations as a separate component of operating expenses.

On August 12, 2008, the Company entered into a worldwide non-exclusive patent License Agreement to its patent covering Nicomide® with River s Edge Pharmaceuticals, LLC and an amendment to its Settlement Agreement with River s Edge. The amendment to the Settlement Agreement allows River s Edge to manufacture and market a prescription product that could be substitutable for Nicomide® pursuant to the terms of the License Agreement and changes certain payment obligations of River s Edge for sales of its substitutable product. In consideration for granting the license, the Company will be paid a share of the net revenues, as defined in the License Agreement, of River s

Edge s licensed product sales under the License Agreement. At the same time, we are also considering the possible sale of the product and the related patent. Royalty revenues recorded pursuant to the License Agreement are recorded in Product Revenues in the accompanying Consolidated Statements of Operations.

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

WINSTON LABORATORIES ARBITRATION

In October 2008, the Company was notified that Winston Laboratories, Inc. had filed a demand for arbitration against the Company. The demand for arbitration arises out of the 2006 Micanol License Agreement and subsequent 2006 Micanol Transition License Agreement (together, the Agreement) and claims that DUSA breached the Agreement. Winston Laboratories is claiming damages in excess of $2,000,000. The parties are currently in settlement discussions. The Company does not expect any potential settlement to be material to its financial condition or the results of its operations. The Company has not recorded any liability pursuant to the claim at December 31, 2008.

The Company has not accrued any amounts for potential contingencies as of December 31, 2008.

LEASE ARRANGEMENTS

The Company leases its facilities under operating leases. The Company s lease arrangements have terms which expire through 2012. Total rent expense under operating leases was approximately $447,000, $476,000 and $477,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Future minimum payments under lease arrangements at December 31, 2008 are as follows:

Years Ending December 31,		**Operating Lease Obligations**
2009	$	449,000
2010		464,000
2011		480,000
2012		269,000
2013		
Thereafter		
Total	$	1,662,000

In December 2001, we entered into a 15 year lease covering the facility in Wilmington, Massachusetts through November 2016. We have the ability to terminate the Wilmington lease after the 10th year (2011) of the lease by providing the landlord with notice at least seven and one-half months prior to the date on which the termination would be effective. In December 2006, we extended the Toronto lease for an additional five year term through August 2012. We closed the Toronto office on October 31, 2008 and have listed the space with a real estate broker for sub-lease.

17) SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

Supplementary Information:

Quarterly Results for Year Ended December 31, 2008

	March 31	June 30	September 30(1)	December 31	Total
Product revenues	$ 7,929,500	$ 8,112,239	$ 5,726,071	$ 7,777,596	$ 29,545,406
Gross margin	6,229,183	6,324,545	4,264,043	5,602,540	22,420,311
Net loss	(1,284,141)	(138,791)	(2,836,855)	(1,990,654)	(6,250,441)
Basic and diluted loss per common share	$ (0.05)	$ (0.01)	$ (0.12)	$ (0.08)	$ (0.26)

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DUSA PHARMACEUTICALS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Quarterly Results for Year Ended December 31, 2007				
	March 31	June 30	September 30	December 31(2)	Total
Product revenues	$ 6,676,840	$ 6,862,198	$ 5,784,194	$ 8,339,366	$ 27,662,598
Gross margin	4,520,688	5,085,707	4,210,297	6,016,622	19,833,314
Net loss	(3,370,928)	(2,477,407)	(1,877,782)	(6,987,390)	(14,713,507)
Basic and diluted loss per common share	$ (0.17)	$ (0.13)	$ (0.10)	$ (0.31)	$ (0.73)

(1) In the third quarter of 2008, the Company recorded a goodwill impairment charge of $1,500,000.

(2) In the fourth quarter of 2007, the Company recorded a goodwill impairment charge of $6,800,000.

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SIGNATURES

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

(Registrant)
DUSA Pharmaceuticals, Inc.

By (Signature and Title)

/s/ Robert F. Doman

President and Chief Executive Officer

Date: March 11, 2009

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

/s/ Robert F. Doman	President and Chief Executive Officer (principal executive officer)	March 11, 2009 Date
Robert F. Doman		
/s/ Richard C. Christopher	Vice President, Finance and Chief Financial Officer (principal financial office)	March 11, 2009 Date
Richard C. Christopher		
/s/ John H. Abeles	Director	March 11, 2009 Date
John H. Abeles		
/s/ David Bartash	Director	March 11, 2009 Date
David Bartash		
/s/ Jay M. Haft, Esq.	Chairman of the Board	March 11, 2009 Date
Jay M. Haft, Esq.		
/s/ Richard C. Lufkin	Director	March 11, 2009 Date
Richard C. Lufkin		
/s/ Magnus Moliteus	Director	March 11, 2009 Date
Magnus Moliteus		

/s/ Alexander W. Casdin	Director	March 11, 2009
		Date
Alexander W. Casdin		

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EXHIBIT INDEX

2(a.1)*	Merger Agreement by and among the Registrant, Sirius Laboratories, Inc., and the shareholders of Sirius dated as of December 30, 2005 filed as Exhibit 2(a.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; and
2(a.2)	First Amendment to Merger Agreement by and among the Registrant, Sirius Laboratories, Inc. and the shareholders of Sirius, dated as of February 6, 2006 filed as Exhibit 2(a.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference.
3(a.1)	Certificate of Incorporation, as amended, filed as Exhibit 3(a) to the Registrant s Form 10-K for the fiscal year ended December 31, 1998, and is incorporated herein by reference;
3(a.2)	Certificate of Amendment to the Certificate of Incorporation, as amended, dated October 28, 2002 and filed as Exhibit 99.3 to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, filed November 12, 2002, and is incorporated herein by reference; and
3(b)	By-laws of the Registrant, filed as Exhibit 3.1 to the Registrant s current report on Form 8-K, filed on November 2, 2007, and is incorporated herein by reference.
4(a)	Common Stock specimen, filed as Exhibit 4(a) to the Registrant s Form 10-K for the fiscal year ended December 31, 2002, and is incorporated herein by reference;
4(b)	Form of D. Geoffrey Shulman s Class B Warrant, filed as Exhibit 4(b) to the Registrant s Form 10-K for the fiscal year ended December 31, 2007, and is incorporated herein by reference;
4(c)	Rights Agreement filed as Exhibit 4.0 to Registrant s Current Report on Form 8-K filed October 11, 2002, and is incorporated herein by reference;
4(d)	Rights Certificate relating to the rights granted to holders of common stock under the Rights Agreement filed as Exhibit 4.0 to Registrant s Current Report on Form 8-K filed October 11, 2002, and is incorporated herein by reference;
4(e)	Form of Common Stock Purchase Warrant, dated October 29, 2007 filed as Exhibit 4.2 to the Registrant s Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference; and
4(f)	Registration Rights Agreement, dated October 29, 2007, by and between the Registrant and each of the respective selling shareholders named therein filed as Exhibit 4.3 to the Registrant s Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference.
10(a)	License Agreement between the Registrant, PARTEQ and Draxis Health Inc. dated August 27, 1991, filed as Exhibit 10.1 to the Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
10(b)	ALA Assignment Agreement between the Registrant, PARTEQ, and Draxis Health Inc. dated October 7, 1991, filed as Exhibit 10.2 to the Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference;
10(b.1)	Amended and Restated Assignment Agreement between the Registrant and Draxis Health, Inc. dated April 16, 1999, filed as Exhibit 10(b.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
10(b.2)	Termination and Transfer Agreement between the Registrant and Draxis Health Inc. dated as of February 24, 2004, filed as Exhibit 10(b.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(c)	Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated October 1, 1991, filed as Exhibit 10.4 to the Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference; +
10(d.1)	Amendment to Employment Agreement of D. Geoffrey Shulman, MD, FRCPC dated April 14, 1994, filed as Exhibit 10.4 to the Registrant s Registration Statement on Form S-2, No. 33-98030, and is

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

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10(d.3)	Consulting Agreement and General Release of D. Geoffrey Shulman, MD, FRCPC dated as of December 1, 2008; +
10(e)	Amended and Restated License Agreement between the Registrant and PARTEQ dated March 11, 1998, filed as Exhibit 10(e) to the Registrant s Form 10-K/A filed on June 18, 1999, portions of Exhibit A have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(f)	Incentive Stock Option Plan, filed as Exhibit 10.11 of Registrant s Registration Statement on Form S-1, No. 33-43282, and is incorporated herein by reference; +
10(g)	1994 Restricted Stock Option Plan, filed as Exhibit 1 to Registrant s Schedule 14A definitive Proxy Statement dated April 26, 1995, and is incorporated herein by reference; +
10(h)	1996 Omnibus Plan, as amended, filed as Appendix A to Registrant s Schedule 14A Definitive Proxy Statement dated April 26, 2001, and is incorporated herein by reference; +
10(h.1)	1996 Omnibus Plan, as amended on May 1, 2003, filed as Exhibit 10(h.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2003, and is incorporated herein by reference; +
10(h.2)	1996 Omnibus Plan, as amended April 23, 2004, filed as Appendix A to Registrant s Schedule 14A definitive Proxy Statement dated April 28, 2004, and is incorporated herein by reference; +
10(i)	Purchase and Supply Agreement between the Registrant and National Biological Corporation dated November 5, 1998, filed as Exhibit 10(i) to the Registrant s Form 10-K/A filed on June 18, 1999, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(i.1)	Amended and Restated Purchase and Supply Agreement between the Registrant and National Biological Corporation dated as of June 21, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed August 11, 2004, and is incorporated herein by reference;
10(j)	Supply Agreement between the Registrant and Sochinaz SA dated December 24, 1993, filed as Exhibit 10(q) to Registrant s Form 10-K/A filed on March 21, 2000, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(j.1)	First Amendment to Supply Agreement between the Registrant and Sochinaz SA dated July 7, 1994, filed as Exhibit 10(q.1) to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, and is incorporated herein by reference;
10(j.2)	Second Amendment to Supply Agreement between the Registrant and Sochinaz SA dated as of June 20, 2000, filed as Exhibit 10.1 to Registrant s Current Report on Form 8-K dated June 28, 2000, and is incorporated herein by reference;
10(j.3)	Third Amendment to Supply Agreement between the Registrant and Sochinaz SA dated July 29, 2005, filed as Exhibit 10.1 to the Registrant s Form 10-Q filed on August 3, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(k)	Master Service Agreement between the Registrant and Therapeutics, Inc. dated as of October 4, 2001, filed as Exhibit 10(b) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001, filed November 8, 2001, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(l)	License and Development Agreement between the Registrant and photonamic GmbH & Co. KG dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is

incorporated herein by reference;

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10(m)	Supply Agreement between the Registrant and medac GmbH dated as of December 30, 2002, filed as Exhibit 10(r) to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(n)	License and Supply Agreement dated August 7, 2007 among the Registrant, photonamic GmbH & Co. KG and medac, GmbH, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10 to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2007 and is incorporated herein by reference
10(o)	Securities Purchase Agreement dated as of February 27, 2004, by and among the Registrant and certain investors, filed as Exhibit 10.1 to the Registrant s current report on Form 8-K, filed on March 2, 2004, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(p)	Registration Rights Agreement dated as of February 27, 2004 by and among the Registrant and certain investors, filed as Exhibit 10.2 to the Registrant s current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
10(q)	Form of Additional Investment Right dated as of February 27, 2004, filed as Exhibit 10.3 to the Registrant s current report on Form 8-K, filed on March 2, 2004, and is incorporated herein by reference;
10(r)	License, Promotion, Distribution and Supply Agreement between the Registrant and Coherent-AMT dated as of March 31, 2004 filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2004, filed May 4, 2004, and is incorporated herein by reference;
10(s)	Employment Agreement of Scott L. Lundahl dated as of June 23, 1999 filed as Exhibit 10(u) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(s.1)	Amendment No. 1 to Employment Agreement of Scott L. Lundahl dated as of April 10, 2008; +
10(t)	Amended Employment Agreement of Stuart L. Marcus, MD, PhD dated December 9, 1999 filed as Exhibit 10(v) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(t.1)	Amendment No. 2 to Employment Agreement of Stuart L. Marcus, MD, PhD dated as of April 10, 2008; +
10(u)	Employment Agreement of Mark C. Carota dated as of February 14, 2000 filed as Exhibit 10(w.1) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(u.1)	First Amendment to Employment Agreement of Mark C. Carota dated October 31, 2001 filed as Exhibit 10(w.2) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(u.2)	Amendment No. 2 to Employment Agreement of Mark C. Carota dated as of April 10, 2008; +
10(v)	Amendment to Employment Agreement of Richard Christopher dated as of October 18, 2006 filed as Exhibit 10.A to the Registrant s Form 10-Q for the fiscal quarter ended September 30, 2004, and is incorporated herein by reference;
10(w)	Employment Agreement of Richard Christopher dated as of January 1, 2004 filed as Exhibit 10(y) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +
10(w.1)	Amendment No. 2 to Employment Agreement of Richard Christopher dated as of April 10, 2008; +
10(x)	Employment Agreement of Robert F. Doman dated as of March 15, 2005 filed as Exhibit 10(z) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; +

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10(x.1)	First Amendment to Employment Agreement of Robert F. Doman dated as of November 26, 2008; +
10(aa)	Compensation Policy Applicable to the Registrant s Non-Employee Directors filed as Exhibit 10(cc) to the Registrant s Form 10-K for the fiscal year ended December 31, 2004, and is incorporated herein by reference; and+
10(bb)	Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated May 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(cc)	Amendment and Extension of the Supply Agreement between Sirius Laboratories, Inc. and Amide Pharmaceuticals, Inc. dated February 8, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(dd)	Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated September 18, 2001, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and is incorporated herein by reference;
10(ee)	Amendment and Extension of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated February 16, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.D to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
10(ff)	Second Amendment of the Supply and Development Agreement between Sirius Laboratories, Inc. and Harmony Laboratories dated March 10, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.E to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
10(gg)	Supply Agreement between Sirius Laboratories, Inc. and L. Perrigo Registrant dated October 21, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.F to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference;
10(hh)	2006 Micanol License Agreement between Sirius Laboratories, Inc. and Winston Laboratories, Inc. effective as of January 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.G to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference; and
10(hh.1)	2006 Micanol Transition License Agreement, dated as of January 29, 2008, by and between Winston Laboratories, Inc. and Sirius Laboratories, Inc. portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b)-2 of the Securities Exchange Act of 1934, as amended, as filed as Exhibit 10.1 to the Registrant s Current Report on Form 8-K, filed on January 31, 2008, and is incorporated herein by reference;
10(ii)	Development, License and Supply Agreement between Sirius Laboratories, Inc. and Altana Inc. dated June 13, 2005, portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and as filed as Exhibit 10.H to the Registrant s Form 10-Q for the fiscal quarter ended March 31, 2006, and is incorporated herein by reference.
10(jj)	Employment Agreement of William O Dell dated as of April 4, 2006 filed as Exhibit 10(ii) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;

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10(jj.1)	Amendment No. 1 to Employment Agreement of William O Dell dated as of April 10, 2008; +
10(kk)	Patent License Agreement between the Registrant and PhotoCure ASA, dated as of May 30, 2006, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10.A to the Registrant s Form 10-Q for the fiscal quarter ended June 30, 2006, and is incorporated herein by reference;
10(ll)	Separation Agreement between the Registrant and Paul Sowyrda, dated as of August 31, 2006 filed as Exhibit 10(kk) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(mm)	Employment Agreement of Michael Todisco dated as of September 20, 2006 filed as Exhibit 10(11) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(mm.1)	Amendment No. 1 to Employment Agreement of Michael Todisco dated as of April 10, 2008; +
10(nn)	Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 4, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(mm) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(nn.1)	First Amendment to Marketing, Distribution and Supply Agreement between the Registrant, Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Registrant dated January 10, 2007, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(nn) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference;
10(oo)	DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, filed as Appendix A to Registrants s Schedule 14A definitive Proxy Statement dated April 24, 2006, and is incorporated herein by reference; +
10(pp)	DUSA Pharmaceuticals, Inc. 2006 Equity Compensation Plan, as amended October 18, 2006 filed as Exhibit 10(pp) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
10(qq)	DUSA Pharmaceuticals, Inc. 2006 Deferred Compensation Plan, October 18, 2006 filed as Exhibit 10(qq) to the Registrant s Form 10-K for the fiscal year ended December 31, 2006, and is incorporated herein by reference; +
10(rr)	Marketing, Distribution and Supply Agreement between the Registrant and Stiefel Laboratories, Inc., dated as of January 12, 2006, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(aa) to the Registrant s Form 10-K for the fiscal year ended December 31, 2005, and is incorporated herein by reference;
10(rr.1)	Amendment to the Marketing, Distribution and Supply Agreement dated September 26, 2007, between the Registrant and Stiefel Laboratories, Inc. portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(a) to the Registrant s Form 10-Q for the fiscal quarter ended September 30, 2007, and is incorporated herein by reference;
10(ss)	Securities Purchase Agreement, dated October 29, 2007, by and among the Registrant and each of the selling shareholders named therein portions of which have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10.1 to the Registrant s Registration Statement on Form S-3, No. 333-147614, and is incorporated herein by reference;
10(tt)	

Settlement Agreement and Mutual Release, including License Agreement dated October 28, 2007 between Registrant and River s Edge Pharmaceuticals LLC, filed as Exhibit 10(tt) to the Registrant s Form 10-K for the fiscal year ended December 31, 2007, and is incorporated herein by reference; and

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10(uu)	License Agreement between the Registrant and River s Edge Pharmaceuticals LLC entered into August 12, 2008 portions of which have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 10(a) to the Registrant s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2008, and is incorporated herein by reference.
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 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.
99.1	Press Release

+ Management contract or compensatory plan or arrangement.

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