

DUSA PHARMACEUTICALS INC

Form S-3/A

January 22, 2008

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As filed with the Securities and Exchange Commission on January 22, 2008

Registration No. 333- 147614

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
PRE-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-3
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
DUSA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)**

New Jersey
(State or Other Jurisdiction
of Incorporation or Organization)

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

**25 Upton Drive
Wilmington, Massachusetts 01887
(978) 657-7500**

(Address, Including Zip Code, and Telephone Number, Including Area Code of Principal Executive Offices)

**Robert F. Doman, President and CEO
DUSA Pharmaceuticals, Inc.
25 Upton Drive
Wilmington, Massachusetts 01887
(978) 657-7500**

(Address, Including Zip Code, and Telephone Number, Including Area Code of Agent For Service)

**Copies to:
Nanette W. Mantell, Esq.
Reed Smith LLP
136 Main Street Suite 250
Princeton, New Jersey 08543-7839
(609) 987-0050**

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following

box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a Registration Statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a Registration Statement filed pursuant to General Instruction I.D. to register additional securities or classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Shares of common stock without par value ⁽¹⁾	4,581,043	\$2.12 ⁽²⁾	\$9,711,811.16	\$298.15
Shares of common stock without par value ⁽³⁾	1,145,259	\$2.85 ⁽⁴⁾	\$3,263,988.15	\$100.20
TOTAL REGISTRATION FEE*				\$398.35

(1) Represents shares issued to certain Selling Shareholders in a private placement completed October 29, 2007 under Rule 506 of Regulation D of the Securities Act of 1933, as amended, pursuant to a securities purchase agreement.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) of the Securities Act, based upon the average of the high and low price as reported on The NASDAQ National Market on November 21, 2007.

- (3) Issuable to the Selling Shareholders upon the exercise of warrants to purchase common stock.
- (4) Calculated pursuant to Rule 457(g)(1) of the Securities Act of 1933, as amended, based upon the exercise price of \$2.85, for the warrants issued to the Selling Shareholders in the private placement.

Pursuant to Rule 416(a) under the Securities Act, this registration statement also covers any additional securities that may be offered or issued in connection with any stock split, stock dividend or similar transaction.

*\$398.35 previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Prospectus

Subject to Completion, Dated January 22, 2008

5,726,302 Shares

DUSA PHARMACEUTICALS, INC.

Common Stock

This prospectus relates to the offer and sale, from time to time, of up to 5,726,302 shares of our common stock, no par value per share, including shares of common stock issuable upon the exercise of outstanding warrants, held by the Selling Shareholders listed on page 19 of this prospectus. The Selling Shareholders acquired the common stock from us in a private placement completed on October 29, 2007 and is more fully described on page 18 of this prospectus under "Selling Shareholders". We will not receive any of the proceeds from the sale of these shares of our common stock by the Selling Shareholders.

The Selling Shareholders may resell or dispose of the shares of our common stock, or interests therein, from time to time, at prevailing market prices at the time of sale or at prices negotiated with purchasers, to or through underwriters, broker-dealers, agents, or through any other means described in this prospectus under the section entitled "Plan of Distribution". The Selling Shareholders will bear all commissions and discounts, if any, attributable to the sale or disposition of the shares, or interests therein. We will bear all costs, expenses and fees in connection with the registration of the shares.

Our common stock is traded on the NASDAQ Global Market under the symbol "DUSA". The last reported sale price of our common stock on January 18, 2008 was \$1.99 per share.

Investing in the common stock involves a high degree of risk.

See Risk Factors beginning on page 4.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is January [], 2008

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DUSA PHARMACEUTICALS, INC.

About DUSA

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

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

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

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

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

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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. The product was launched in Mexico and Argentina in late September 2007. Similarly, we entered into a marketing and distribution agreement with Daewoong Pharmaceutical Co., Ltd. and DNC Daewoong Derma & Plastic Surgery Network Company, or collectively, Daewoong, granting Daewoong exclusive rights to distribute the Levulan[®] Kerastick[®] in certain Asian countries. Subsequent to September 30, 2007 the Korean Food and Drug Administration, or KFDA, approved Levulan[®] Kerastick[®] for PDT for the treatment of actinic keratosis. Daewoong launched our product during the fourth quarter of 2007.

We are developing Levulan[®] PDT and PD under an exclusive worldwide license of patents and technology from PARTEQ Research and Development Innovations, the licensing arm of Queen's University, Kingston, Ontario, Canada. We also own or license certain other patents relating to methods for using pharmaceutical formulations which contain our drug and related processes and improvements. In the United States, DUSA[®], DUSA Pharmaceuticals, Inc.[®], Levulan[®], Kerastick[®], BLU-U[®] Nicomide[®], Nicomide-T[®], Meted[®], Psoriacap[®] and Psoriatec[®] 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 September 30, 2007, our accumulated deficit was approximately \$128,613,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis. We expect to continue to incur operating losses until sales of our products increase substantially. As discussed above, we expect to record a significant impairment charge of goodwill during the fourth quarter of 2007. Achieving our goal of becoming a profitable operating company is dependent upon greater acceptance of our PDT therapy by the medical and consumer constituencies, increased sales of our products and other factors contained in this prospectus and in the filings we make with the Securities and Exchange Commission, or SEC.

As of September 30, 2007, we had a staff of 86 employees, including 4 part-time employees, as compared to 85 full-time employees, including 2 part-time employees at the end of 2006, who worked across all operating functions at DUSA.

Our principal executive offices are located at 25 Upton Drive, Wilmington, Massachusetts, 01887 and our telephone number is (978) 657-7500. Unless the context otherwise requires, the terms we, our, us, the company and

DUSA refer to DUSA Pharmaceuticals, Inc., a New Jersey corporation, and not to the Selling Shareholders.

Recent Event

We are in the process of performing our annual test for goodwill impairment as required by Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets (SFAS 142). We use December 1st as the date of our annual goodwill impairment test. The preliminary results of the impairment test have been reviewed and discussed by management. Based on this preliminary review, we expect that we will be required to recognize a non-cash goodwill impairment charge in the fourth quarter of 2007 in the range of \$6.5 million – \$ 6.8 million, a range which includes additional milestone payments made or accrued since September 30, 2007. The final amount of the goodwill impairment will be determined upon the completion of step two of the goodwill impairment test, which requires us to compare the implied fair value goodwill (as determined by calculating the fair value of all assets and liabilities of the reporting unit) with the carrying amount of that goodwill. The carrying value of the goodwill as of September 30, 2007 was \$6,272,500. The expected goodwill impairment charge is primarily related to the Company's 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, recent receipt of a non-approvable letter from the U.S. Food and Drug Administration (FDA) with respect to its abbreviated new drug application (ANDA) supplement covering one of the potential products we acquired from Sirius. We no longer expect to launch this product.

About the Offering and this Prospectus

On October 29, 2007, we entered into a securities purchase agreement, common stock purchase warrants, and a registration rights agreement with certain accredited investors for the private placement of 4,581,043 shares of our common stock at a purchase price of \$2.40 per share which resulted in gross proceeds to us of \$11,000,000, and warrants to purchase an additional 1,145,259 shares of common stock. The warrants become exercisable on April 30,

2008, have a term of 5 years from April 30, 2008, and have an exercise price of \$2.85 per share. We committed to register the shares, including the shares underlying the warrants, with the Securities and Exchange Commission, or SEC, on a Form S-3 registration statement. If the registration statement does not become effective within a stated period of time, then the investors are entitled to receive a cash payment of 1% of the aggregate purchase price they paid for their respective shares of common stock for each month that the registration statement is delayed beyond the time periods stated in the agreements with the investors, up to a maximum of 12% of such aggregate purchase price. We paid the placement agent its fee, including expenses, of \$695,000 for its services in connection with the transaction.

We will not receive any proceeds from the resale of the common stock by the Selling Shareholders. We have agreed to bear all expenses of registration of the common stock offered by this prospectus.

This prospectus is part of a registration statement that we have filed with the SEC. The Selling Shareholders may, from time to time, sell the common stock described in this prospectus. We may prepare a

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prospectus supplement at any time to add, update or change the information contained in this prospectus. This prospectus does not contain all the information you can find in the registration statement or the exhibits filed with or incorporated by reference into the registration statement. Whenever a reference is made in this prospectus to an agreement or other document of ours, be aware that such reference is not necessarily complete and you should refer to the exhibits that are filed with or incorporated by reference in the registration statement for a copy of the agreement or other document. You should read this prospectus and any prospectus supplement together with the registration statement, the exhibits filed with or incorporated by reference into the registration statement and the additional information described under the section of this prospectus entitled "Where You Can Find More Information."

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

Risks Related To DUSA

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

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

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

If another company launches a substitutable niacinamide product, or if the USPTO finds that the Nicomide® patent is invalid, our revenues from sales of Nicomide® will decrease, perhaps permanently, and our ability to become profitable will be more difficult.

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

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

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

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

control of marketing activities, including advertising and labeling.

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

send us warning letters,

impose fines and other civil penalties on us,

seize our products,

suspend our regulatory approvals,

cease the manufacture of our products

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

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

require us to recall products,

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

impose restrictions on our operations, and/or

criminally prosecute us.

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

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide®. The FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, the FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with the FDA to begin that process. The FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and the FDA may bring an action against a drug or a firm when the FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide® could not be marketed as a dietary supplement with its current labeling. There can be no

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assurance that the FDA will continue this policy or not take a contrary position with Nicomide®. If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide® as an over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval. Any such action by the FDA could have a material impact on our Non-PDT Drug Product revenues. Label changes eliminating claims of certain medicinal benefits could make it more difficult to market these products and could therefore, negatively affect our revenues and profits.

Manufacturing facilities are subject to ongoing periodic inspection by the FDA, including unannounced inspections. We cannot guarantee that our third-party supply sources, or our own Kerastick® facility, will continue to meet all applicable FDA regulations. If we, or any of our manufacturers, including without limitation, the manufacturer of Nicomide®, who has received warning letters from the FDA, fail to maintain compliance with FDA regulatory requirements, it would be time consuming and costly to remedy the problem(s) or to qualify other sources. These consequences could have a significant adverse effect on our financial condition and operations.

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

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

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

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

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

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

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judgment against one compounding pharmacy, and settled other suits favorably to us, we do not know whether these lawsuits will prevent others from infringing our patents or whether we will be successful in stopping these activities which we believe are negatively affecting our revenues.

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

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

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

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

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

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

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

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

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

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We have recently been advised that the sole manufacturer of our product, Psoriatec[®], may have produced batches that are not meeting stability specifications. We are currently conducting testing of these batches and may have to recall the product that is in the distribution channel which will impact our sales of this product. We do not expect the costs of the potential recall, if any, to be material. The license agreement for Psoriatec is due to expire on January 31, 2008 and we do not intend to renew the license.

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

product yields,

quality control,

component and service availability,

compliance with FDA regulations, and

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

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

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

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

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

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan[®] Kerastick[®] for AK therapy will be limited. While we continue to support efforts to improve reimbursement levels to physicians and are working with the major private insurance carriers to improve coverage for our therapy, if our efforts are not successful, a broader adoption of our therapy and sales of our products could be negatively impacted. Although positive reimbursement changes related to AK were made in 2005 and again in 2007, some physicians still believe that reimbursement levels do not fully reflect the required efforts to routinely execute our therapy in their practices.

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

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

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

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

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

potential advantages over alternative treatments;

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

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

We Have Significant Losses And Anticipate Continued Losses

We have a history of operating losses. We expect to have continued losses until sales of our products increase substantially. We incurred net losses of \$1,878,000 and \$7,726,000 for the three and nine-month periods ended September 30, 2007, respectively. As of September 30, 2007, our accumulated deficit was approximately \$128,613,000. We cannot predict whether any of our products will achieve significant enough market acceptance or generate sufficient revenues to enable us to become profitable on a sustainable basis.

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

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

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

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

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

Nicomide® is covered by a United States patent which issued in December 2005. River s Edge Pharmaceuticals, LLC filed an application with the U.S. Patent and Trademark Office, or USPTO, for the reexamination of the patent. The USPTO accepted the application for reexamination of the patent and the parties have submitted their responses to the first office action. On November 19, 2007, the USPTO issued an Order to Show Cause providing River s Edge with one month or 30 days, whichever is longer, to demonstrate to the USPTO why it should not terminate the reexamination process in light of the dismissal of the patent litigation. River s Edge did not respond. If the USPTO finds that the patent is invalid, generic products will be able to lawfully compete with Nicomide®. Also, recently two new products have been launched that could compete with Nicomide®. These events could cause us to lose significant revenues and put our ability to be profitable at risk.

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

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

these persons or entities might breach the agreements,

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

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

We Have Only 3 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

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risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

delays in product development, clinical testing or manufacturing,

unplanned expenditures in product development, clinical testing or manufacturing,

failure in clinical trials or failure to receive regulatory approvals,

emergence of superior or equivalent products,

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

failure to achieve market acceptance.

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

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

All of our potential Levulan[®] products will require the approval of the FDA before they can be marketed in the United States. If we fail to obtain the required approvals (as we did for the product we were developing with Altana mentioned above in the section entitled *About DUSA* and in the Form 8-K we filed on January 18, 2008) for these products our revenues will be limited. Before an application to the FDA seeking approval to market a new drug, called an NDA, can be filed, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually 1 to 3 years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan[®] PDT products are based on relatively new technology. To the best of our knowledge, the FDA has approved only 3 drugs for use in photodynamic therapy, including Levulan[®]. This factor may lengthen the approval process. We face much trial and error and we may fail at numerous stages along the way.

We cannot predict whether we will obtain approval for any of our potential products. Data obtained from preclinical testing and clinical trials can be susceptible to varying interpretations which could delay, limit or prevent regulatory approvals. Future clinical trials may not show that Levulan[®] PDT or photodetection, known as PD, is safe and effective for any new use we are studying. In addition, delays or disapprovals may be encountered based upon additional governmental regulation resulting from future legislation or administrative action or changes in FDA policy. During September 2005, the FDA issued guidance for the pharmaceutical industry regarding the development of new drugs for acne vulgaris treatment. We are developing Levulan[®] PDT for acne. We have received comments on our acne development program from the FDA statistical reviewer assigned to our investigational new drug application or IND. In this letter, the reviewer stated concern about whether we will have sufficient data to select an appropriate dosing regimen for Phase III trials. We believe that we have the data to indicate that sufficient drug dose ranging has been done; however, if the FDA does not accept our rationale, additional clinical trials and/or formulation development work may be required for the acne development program, which may extend the expected development time lines for such program. The FDA may issue additional guidance in the future, which may result on additional costs and delays. We must also obtain foreign regulatory clearances before we can market any potential products in foreign markets. The foreign regulatory approval process includes all of the risks associated with obtaining FDA marketing approval and may impose substantial additional costs.

Certain of the products acquired in connection with the Sirius merger must meet certain minimum manufacturing and labeling standards established by the FDA and applicable to products marketed without approved marketing applications including Nicomide[®]. FDA regulates such products under its marketed unapproved drugs compliance policy guide entitled, *Marketed New Drugs without Approved NDAs or ANDAs*. Under this policy,

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FDA recognizes that certain unapproved products, based on the introduction date of their active ingredients and the lack of safety concerns, have been marketed for many years and, at this time, will not be the subject of any enforcement action. The FDA has recently taken a more proactive role and is strongly encouraging manufacturers of such products to submit applications to obtain marketing approval and we have begun discussions with FDA to begin that process. FDA's enforcement discretion policy does not apply to drugs or firms that may be in violation of regulatory requirements other than preapproval submission requirements and FDA may bring an action against a drug or a firm when FDA concludes that such other violations exist. The contract manufacturer of Nicomide® has received notice that the FDA considers prescription dietary supplements to be unapproved new drugs that are misbranded and that cannot be legally marketed, and has received notice that the FDA believes Nicomide could not be marketed as a dietary supplement with its current labeling. There can be no assurance that the FDA will continue this policy or not take a contrary position with Nicomide®. If the FDA were to take further action, we may be required to make certain labeling changes and market Nicomide® as over-the-counter product or as a dietary supplement under applicable legislation, or withdraw the product from the market, unless and until we submit a marketing application and obtain FDA marketing approval.

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

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

We are a small company with only 86 employees, including 4 part-time employees as of September 30, 2007. We are highly dependent on several key officer/employees with specialized scientific and technical skills without whom our business, financial condition and results of operations would suffer, especially in the photodynamic therapy portion of our business. The photodynamic therapy industry is still quite small and the number of experts is limited. The loss of these key employees could cause significant delays in achievement of our business and research goals since very few people with their expertise could be hired. Our growth and future success will depend, in large part, on the continued contributions of these key individuals as well as our ability to motivate and retain other qualified personnel in our specialty drug and light device areas.

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

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

Risks Related To Our Industry

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

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

The development, manufacture and sale of medical products expose us to product liability claims related to the use or misuse of our products. Product liability claims can be expensive to defend and may result in significant judgments against us. A successful claim in excess of our insurance coverage could materially harm our business, financial condition and results of operations. Additionally, we cannot guarantee that continued product liability

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insurance coverage will be available in the future at acceptable costs. If the cost is too high, we may have to self-insure.

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

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

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

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

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

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

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

price reductions,

lower levels of third-party reimbursements,

failure to achieve market acceptance, and

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

On May 30, 2006, we entered into a patent license agreement with PhotoCure ASA whereby DUSA granted a non-exclusive license to PhotoCure under the patents DUSA licenses from PARTEQ, the licensing arm of

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Queens University, Kingston, Ontario Canada for esters of aminolevulinic acid (ALA). ALA is the active ingredient in DUSA's Levulan® products. Furthermore, DUSA 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 DUSA in the future. PhotoCure received FDA approval to market Metvixia for treatment of AKs in July 2004 and it would be directly competitive with our Levulan® 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.

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

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

Generic Manufacturers May Launch Products at Risk of Patent Infringement

If generic manufacturers, like River's Edge, launch products to compete with Nicomid® in spite of our patent position, or if the United States Patent and Trademark Office determines that our patent is invalid, these manufacturers may erode our market and negatively impact our sales revenues, liquidity and operations.

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

We 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:

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

Our primary competition in the acne and rosacea markets include oral and topical antibiotics, other topical prescription and over-the-counter products, as well as various laser and non-laser light treatments. The market is highly competitive and other large and small companies have more experience than we do which could make it difficult for us to penetrate the market. We are also aware of new products that were launched recently which will compete with Nicomide® which could negatively impact our market share. In addition, other generic companies may also decide to enter the market while our patent reexamination process is proceeding, or thereafter if the USPTO finds that our Nicomide patent is invalid. On November 19, 2007, the USPTO issued an Order to Show Cause providing River s Edge with one month or 30 days, whichever is longer, to demonstrate to the USPTO why it should not terminate the reexamination process in light of the dismissal of the patent litigation. River s Edge did not respond. The entry of new products from time to time would likely cause us to lose market share.

Risks Related To Our Stock

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

All of the shares of DUSA s common stock which were issued to the former Sirius shareholders were subject to a lock-up provision under the terms of the merger agreement. On March 10, 2007, the lock-up provision on 1,380,151 shares was lifted. These shares have been registered and are freely tradable. If these shareholders decide to sell their shares, the price of the shares on NASDAQ could be depressed. If the shares of DUSA s common stock which were issued in the recent private placement are sold following the effective date of the registration statement which we are obligated to file, the price of our shares could be depressed.

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

As of January 15, 2008 there were outstanding options and warrants to purchase 4,250,259 shares of common stock, with exercise prices ranging from U.S. \$1.60 to \$31.00 per share, and of CDN \$6.79 per share, respectively. The holders of the options and warrants have the opportunity to profit if the market price for the common stock exceeds the exercise price of their respective securities, without assuming the risk of ownership. The holders are likely to exercise their securities when we would probably be able to raise capital from the public on terms more favorable than those provided in these securities.

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

The price of our common stock has been highly volatile. These fluctuations create a greater risk of capital losses for our shareholders as compared to less volatile stocks. From January 1, 2006 to January 15, 2008, the price of our stock has ranged from a low of \$1.63 to a high of \$11.12. Factors that contributed to the volatility of our stock during this period included:

quarterly levels of product sales;
clinical trial results;

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

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

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

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

The rights plan provides for the distribution of one right as a dividend for each outstanding share of our common stock to holders of record as of October 10, 2002. Each right entitles the registered holder to purchase one one-thousandths of a share of preferred stock at an exercise price of \$37.00 per right. The rights will be exercisable subsequent to the date that a person or group either has acquired, obtained the right to acquire, or commences or discloses an intention to commence a tender offer to acquire, 15% or more of our outstanding common