

DUSA PHARMACEUTICALS INC
Form S-3
March 24, 2004

As filed with the Securities and Exchange Commission on March 24, 2004

Registration No. 333 - _____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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 of Principal Executive Offices)

**Dr. D. Geoffrey Shulman, President
DUSA Pharmaceuticals, Inc.
25 Upton Drive
Wilmington, Massachusetts 01887
(978) 657-7500**
(Name and Address 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 delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

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⁾	2,250,000	\$9.98 ⁽²⁾	\$22,455,000	\$2,845.05
Shares of common stock without par value ⁽³⁾	135,000	\$9.98 ⁽²⁾	\$1,347,300	\$170.70
Shares of common stock without par value ⁽⁴⁾	337,500	\$11.00 ⁽⁵⁾	\$3,712,500	\$470.37
Shares of common stock without par value ⁽⁶⁾	20,250	\$9.98 ⁽²⁾	\$202,095	\$25.61
TOTAL REGISTRATION FEE				\$3,511.73

(1) Represents shares issued to certain selling shareholders in a private placement completed March 2, 2004 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 of 1933, as amended, based upon the average of the high and low price as reported on The NASDAQ National Market on March 18, 2004.

(3) Represents shares issued to the placement agent and designees of the placement agent, a registered broker-dealer, as fees and commissions in connection with the private placement.

(4) Represents shares issuable upon exercise of additional investment rights granted to the selling shareholders in a private placement completed March 2, 2004 under Rule 506 of Regulation D of the Securities Act of 1933, as amended, pursuant to a securities purchase agreement.

(5) Calculated pursuant to Rule 457(g)(1) of the Securities Act of 1933, as amended, based upon the exercise price, \$11.00, of the additional investment rights granted to the investors.

(6) Represents shares issuable to the placement agent and/or designees of the placement agent, a registered broker-dealer, as fees and commissions in connection with the exercise and sale of shares underlying the additional investment rights.

Pursuant to Rule 416(a) under the Securities Act of 1933, 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.

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.

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 March 24, 2004

2,742,750 Shares

DUSA PHARMACEUTICALS, INC.

Common Stock

This prospectus relates to an offering of 2,742,750 shares of common stock by the selling shareholders listed on page 10.

**Investing in the common stock involves a high degree of risk.
See Risk Factors beginning on page 1.**

Our common stock is traded on The NASDAQ National Market under the symbol "DUSA."

The last reported sale price of our common stock on NASDAQ on March 23, 2004 was \$10.35 per share.

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

The date of this prospectus is March 1, 2004

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DUSA PHARMACEUTICALS, INC.

We are a pharmaceutical company developing drugs in combination with light devices to treat or detect a variety of conditions in processes known as photodynamic therapy or photodetection. We are engaged primarily in the research, development and marketing of our first drug, the Levulan® brand of aminolevulinic acid HCl, or ALA, with light, for use in a broad range of medical conditions.

- When we use Levulan® and follow it with exposure to light to treat a medical condition it is known as Levulan® photodynamic therapy or Levulan® PDT.
- When we use Levulan® and follow it with exposure to light to detect medical conditions it is known as Levulan® photodetection or Levulan® PD.

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 Queens University, Kingston, Ontario, Canada. We also own or license certain 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® and BLU-U® are registered trademarks. Several of these trademarks are also registered in Europe, Australia, Canada, and in other parts of the world.

Our first products, the Levulan® Kerastick® 20% Topical Solution with PDT and the BLU-U® brand light source were launched in the United States in September 2000 for the treatment of actinic keratoses, or AKs, of the face or scalp under a marketing, development and supply agreement with Schering AG, our former marketing collaborator for dermatology products. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. In addition, in September 2003 we received clearance from the FDA to market the BLU-U® without Levulan® for the treatment of moderate inflammatory acne vulgaris.

In September 2002, DUSA reacquired all marketing and product rights from Schering AG when the parties terminated their marketing, development and supply agreement. Consequently, We commenced marketing our approved products directly in January 2003, and is wholly responsible for all regulatory, sales, marketing, customer service, and other related product activities which has resulted in significant marketing and sales expenses, including the costs associated with the launching of our initial sales force and other related marketing activities.

On March 2, 2004, we concluded a private placement of 2.25 million shares of our common stock. The purchase price was \$11.00 per share. We also granted the investors a right to purchase up to an aggregate of 337,500 additional shares of common stock at \$11.00 per share issuable upon exercise of additional investment rights which expire on April 14, 2004. We are filing this prospectus, at our expense, as required by the securities purchase agreement with the selling shareholders. We will not receive any proceeds from the resale of the common stock by the selling shareholders.

Our principal executive offices are located at 25 Upton Drive, Wilmington, Massachusetts, 01887 and our telephone number is (978) 657-7500.

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 our approved products, the Levulan® Kerastick® with the BLU-U® brand light source for the treatment of AKs of the face or scalp, and the BLU-U® without Levulan® for the treatment of moderate inflammatory acne.

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 our approved products, revenues from product sales will be lower than anticipated and our financial condition may be adversely affected. As of September 1, 2002, DUSA and our former marketing partner for dermatology products terminated the parties' marketing, development and supply agreement. As a result of this termination, DUSA is solely responsible for marketing its approved dermatology products in the United States and the rest of the world. We will be doing so without the experience of having marketed pharmaceutical products in the past. In October 2003, DUSA began hiring a small direct sales force and has engaged a small number of independent sales representatives to market our products. Acquiring and retaining marketing and sales force capabilities involves significant expense, and current sales levels are not offsetting the expenses related to these efforts. We may need to hire additional sales people to penetrate the market. If our sales and marketing efforts fail, then sales of the Kerastick® and the BLU-U® will be adversely affected.

If we cannot improve physician reimbursement and/or convince more private insurance carriers to adequately reimburse physicians for our therapy, sales of our Levulan® Kerastick® for AKs product may suffer.

Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our Levulan® Kerastick® for AKs 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, adoption of our therapy and sales of our products could be negatively impacted. As of January 1, 2004, a new national reimbursement code for Medicare and other third-party payors for the BLU-U® PDT application procedure and for the costs of the Levulan® Kerastick® became effective. Doctors can also bill for any applicable visit fees. However, some physicians have suggested that even the new reimbursement levels still do not fully reflect the required efforts to routinely execute our PDT therapy in their practices.

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® and the BLU-U®, any supply or manufacturing problems could negatively impact our sales.

If we experience problems producing Kerastick® units in our new facility, or either of our contract suppliers fail to supply DUSA's requirements of Levulan® or the BLU-U®, our business, financial condition and results of operations would suffer. We are not currently approved to manufacture the BLU-U® on our own and have not ordered any new BLU-U® units since 2001. In addition, while we have received FDA approval to manufacture the Kerastick® in our own manufacturing facility, we have not yet produced commercial quantities of Kerastick® units in the facility on a regular basis.

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Manufacturers and their subcontractors often encounter difficulties when commercial quantities of products are manufactured for the first time, or re-starting production after a long lay-off, 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 commence, re-start and 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 failure to comply with ongoing governmental regulations in the United States and elsewhere will limit our ability to market our products.

Both the manufacture and marketing of our products, the Levulan® Kerastick® with the BLU-U® for AKs and the BLU-U® without Levulan® to treat moderate inflammatory acne 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 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, DUSA 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,
- refuse to approve pending applications or supplements to approved applications filed by us,
- refuse to permit exports of our products from the United States,
- require us to recall products,
- require us to notify physicians of labeling changes and/or product related problems,
- impose restrictions on our operations, and/or
- criminally prosecute us.

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

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

Manufacturing facilities are subject to ongoing periodic inspection by the FDA, including unannounced inspections. We cannot guarantee that our third-party supply sources, or our own new Kerastick® facility, will continue to meet all applicable FDA regulations in the future. If we, or

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any of our manufacturers, 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 an adverse effect on our financial condition and operations.

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 DUSA's 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, DUSA might be required to seek additional funding. There is no guarantee that adequate funding sources could be found to continue the development of all our potential products. DUSA might be required to commit substantially greater capital than we have to research and development of such products and we may not have sufficient funds to complete all or any of our development programs.

We have significant losses and anticipate continued losses for the foreseeable future.

We have a history of operating losses. We expect to have continued losses through at least 2004 as we attempt to increase sales of our approved products in the marketplace and continue research and development of potential new products. As of December 31, 2003, our accumulated deficit was \$58,909,781. Although sales of the Kerastick® have increased with the addition of our sales force and our ongoing medical education activities, we cannot predict whether any of our products will achieve significant market acceptance or generate sufficient revenues to enable us to become profitable.

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 product patent protection for our Levulan® brand of the compound ALA. Our basic patents are for methods of detecting and treating various diseased tissues using ALA (or related compounds called precursors), in combination with light. We own or exclusively license patents and patent applications related to the following:

- methods of using ALA and its unique physical forms in combination with light, and
- compositions and apparatus for those methods, and
- unique physical forms of ALA.

We have limited 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 counter-parts in only four foreign countries. 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.

Our patent protection in Australia may be diminished or lost entirely. In 2002, we received notice of a lawsuit filed in Australia by PhotoCure ASA alleging that Australian Patent No. 624985, which is one of the patents licensed by PARTEQ Research & Development Innovations, the technology transfer arm of Queen's University at Kingston, Ontario, to us, relating to our ALA technology, is invalid. As a consequence of this action, Queen's University assigned the Australian patent to DUSA so that we can participate directly in the litigation. We have filed a response to the allegations of invalidity in court and have also filed a counter suit alleging that PhotoCure's activities in Australia infringe our patent. We cannot predict the outcome of PhotoCure's action alleging invalidity. Australia is a significant pharmaceutical market for AK therapies, and loss of this patent could negatively impact us in at least two ways. First, if we are able to enter the Australia market, the lack of a patent would probably retard or diminish our market share. Second, third-parties might not be interested in licensing the product in Australia without patent protection which would limit potential revenues from this market.

Some of the indications for which we are developing 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 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.

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.

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-party competitors may infringe one or more of our patents, and we could be required to spend significant resources to enforce our patent rights. Also, if we were to sue a third-party for infringement of our patents in the United States, that third-party could challenge the validity of our patent(s). We cannot guarantee that a third-party will not claim, with or without merit, that we have infringed their patent(s) or misappropriated their proprietary material. Defending this type of legal action involves 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 United States Patent and Trademark Office to determine the priority of invention. A third-party could also request the declaration of a patent interference between one of our issued U.S. 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.

We have only two therapies that have received regulatory approval or clearance and we cannot predict whether we will ever develop or commercialize any other products.

Except for the Levulan® Kerastick® with the BLU-U® to treat AKs, and the use of the BLU-U® alone to treat moderate inflammatory acne, all of our potential products are in early stages of development and may never result in any commercially successful products.

We do not know if any of our products will ever be commercially successful. Currently, we are developing a single drug compound, ALA, under the trademark Levulan®, with light for a number of different medical conditions using photodynamic therapy, or PDT. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products. Except for DUSA's two approved therapies, all of our other potential products are at an early stage of development and subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

- delays in product development, clinical testing or manufacturing,
- unplanned expenditures in product development, clinical testing or manufacturing,
- failure in clinical trials or failure to receive regulatory approvals,
- emergence of superior or equivalent products,
- inability to market products due to third-party proprietary rights, and
- failure to achieve market acceptance.

We cannot predict how long the development for our early stage products will take or whether they will be medically effective. We cannot be sure that a successful market will ever develop for our drug technology.

We must receive separate approval for each of our potential products before we can sell them commercially in the United States or abroad.

All of our potential Levulan® products will require the approval of the FDA before they can be marketed in the United States. If we fail to obtain the required approvals for these products our revenues will be limited. Before an application to the FDA seeking approval to market a new drug, called an NDA, can be filed, a product must undergo, among other things, extensive animal testing and human clinical trials. The process of obtaining FDA approvals can be lengthy, costly, and time-consuming. Following the acceptance of an NDA, the time required for regulatory approval can vary and is usually 1 to 3 years or more. The FDA may require additional animal studies and/or human clinical trials before granting approval. Our Levulan® PDT products are based on 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. 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.

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.

Since our sales goals for our products have not been met, and may not be met in the future, we may need substantial additional funds to fully develop, manufacture, market and sell our other potential products. In addition to the funds we recently received in connection with a private placement in February 2004, we may obtain funds through other public or private financings, including equity financing, and/or through collaborative arrangements. We cannot predict whether any financing will be available on acceptable terms.

Dependent on the extent of available funding, we may continue to delay, reduce in scope or eliminate some of our research and development programs as we did in 2003. We may also choose to license rights to third parties to commercialize products or technologies that we would otherwise have attempted to develop and commercialize on our own which could reduce our potential revenues.

Because of the nature of our business, the loss of key members of our management team could delay achievement of our goals.

We are a small company with only 51 employees. 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. 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.

Risks Related to our Industry

Product liability and other claims against us may reduce demand for our products or result in damages.

We have had a lawsuit filed against us based on a product liability claim which, regardless of merit, could result in a damage award for which we may not have adequate insurance coverage.

The development, manufacture and sale of medical products exposes us to product liability claims related to the use or misuse of our products. Product liability claims can be expensive to defend and may result in significant judgments against us. On January 29, 2004, we were served with a complaint filed in the State of Michigan Circuit Court for the County of Oakland. The case has been removed to the U.S. District Court, Eastern District of Michigan, Southern Division. The complaint alleges unspecified damages suffered by the plaintiff arising from recurrence of epileptic or similar seizures following exposure to the BLU-U®. We are unable to predict the outcome of this litigation. Although we currently maintain product liability insurance for coverage of our products in amounts we believe to be commercially reasonable we cannot be certain that the coverage amounts are adequate. A successful claim in excess of our insurance coverage could materially harm our business, financial condition and results of operations. Additionally, we cannot guarantee that continued product liability insurance coverage will be available in the future at acceptable costs. If the cost is too high, we may have to self-insure.

Our business involves environmental risks and we may incur significant costs complying with environmental laws and regulations.

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

We may not be able to compete against traditional treatment methods or keep up with rapid changes in the biotechnology and pharmaceutical industries that could make some or all of our products non-competitive or obsolete.

Competing products and technologies based on traditional treatment methods may make some or all of our programs or potential products noncompetitive or obsolete.

Well-known pharmaceutical, biotechnology and chemical companies are marketing well-established therapies for the treatment of many of the same conditions we are seeking to treat including AKs, acne, photodamaged skin and Barrett's esophagus. Doctors may prefer to use familiar methods, rather than trying our products. Reimbursement issues may 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.

Our PDT / PD competitors in the biotechnology and pharmaceutical industries may have better products, manufacturing capabilities or marketing expertise.

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

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 has also filed for regulatory approvals in the United States, and has received a notice of approvability from the FDA for its AK product. If PhotoCure receives FDA product approval in the United States and successfully enters the United States marketplace, its product will represent direct competition for our products.

Axcan Pharma Inc. has announced that it 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, which we are also pursuing.

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

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

Risks Related to Our Stock

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 March 1, 2004 there were outstanding options and warrants to purchase 2,709,825 shares of common stock, with exercise prices ranging from U.S. \$1.60 to \$31.00 per share, and ranging from CDN \$4.69 to CDN \$10.875 per share, respectively. In addition, DUSA granted investors of a private placement rights to purchase up to an aggregate of an additional 337,500 shares of common stock at \$11.00 per share. These additional investment rights expire April 14, 2004, or 30 trading days from the closing of the private placement, which occurred on March 2, 2004. If the holders exercise a significant number of these securities at any one time, the market price of the common stock could fall, and the value of the common stock held by other shareholders would be diluted. The holders of the options, warrants and rights 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 biotechnology stock could result in the sudden change 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, 2003 to March 10, 2004, the price of our stock has ranged from a low of \$1.40 to a high of \$14.87. Factors that contributed to the volatility of our stock during the last 12 months included:

- levels of product sales,
- general market conditions,
- increased marketing activities,
- changes in third-party payor reimbursement for our therapy, and
- failure to close a strategic partnership for Barrett's esophagus.

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

If our market capitalization falls back to a level significantly below our cash value, we could be subject to a tender offer that does not reflect the potential value of our business and could minimize the return to our shareholders on their investments.

The price of our common stock has been negatively impacted by disappointing product sales, the termination of our dermatology marketing, development and supply agreement in late 2002, general market conditions, and the limited acceptance of the value of our therapy. Based on this, our share price traded at a level below our cash value during much of 2003. If our share price again falls below our cash value, there may be a risk of companies offering to acquire us at reduced values which do not reflect the business potential of our assets.

Effecting a change of control of DUSA would be difficult, which may discourage offers for shares of our common stock.

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

may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future.

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

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

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

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares of common stock by the selling shareholders. We will receive the exercise price for the shares of common stock that underlie the additional investment rights if those securities are converted with cash payments into shares by their holders. Potential proceeds to DUSA if all holders of additional investment rights convert their securities into shares of common stock total \$3,712,500. We expect to allocate the net proceeds that we received as a result of the private placement to the selling shareholders together with any proceeds received upon the exercise of additional investment rights as follows:

- approximately 10% to 20% will be used to expand our sales force;
- approximately 20% to 30% will be used to fund our research and development programs; and
- the remainder will be used for other general corporate purposes.

We may also use a portion of the net proceeds to acquire or invest in businesses, technologies or products that are complementary to our business. We currently have no commitments or agreements with respect to any acquisitions. The information above represents our best estimate of our use of the net proceeds of this offering based upon the current state of our business operations, our current business plan and strategy and current economic and industry conditions. Actual allocation of the net proceeds may differ from the estimates set forth above.

DILUTION

Our net tangible book value at December 31, 2003 was approximately \$40 million, or \$2.88 per share. Net tangible book value per share is determined by dividing our tangible net worth (total tangible assets less total liabilities) by the number of shares of common stock outstanding. After giving effect to the private placement of 2.25 million shares concluded on March 2, 2004 at the offering price of \$11.00 per share (less placement agent fees and commissions and estimated offering expenses), our net tangible book value at December 31, 2003 would have been approximately \$65 million, or \$3.99 per share. This represents an immediate increase in net tangible book value of \$1.11 per share to existing shareholders and an immediate dilution in net tangible book value of \$7.01 per share to new investors purchasing shares at the offering price. The following table illustrates this per10.0pt;">2,210,269

	342,880
Liberty Media Corp. - Entertainment, Series A*	5,520,368
	748,160
Time Warner Inc.	7,548,934
	511,700

Warner Music Group Corp.

2,118,438

Total Media

17,398,009

TOTAL CONSUMER DISCRETIONARY

20,252,895

CONSUMER STAPLES 4.3%

Food Products 1.4%

235,600

Kraft Foods Inc., Class A Shares

6,865,384

Household Products 2.9%

124,800

Kimberly-Clark Corp.

7,648,992

98,800

Procter & Gamble Co.

6,376,552

Total Household Products

14,025,544

TOTAL CONSUMER STAPLES

20,890,928

ENERGY 8.2%

Energy Equipment & Services 2.5%

44,710

Diamond Offshore Drilling Inc.

3,970,248

206,920

Halliburton Co.

4,094,947

	137,340
National-Oilwell Varco Inc.*	
	4,105,092
<i>Total Energy Equipment & Services</i>	
	12,170,287
Oil, Gas & Consumable Fuels 5.7%	
	499,741
Crosstex Energy Inc.	
	5,102,356
	41,095
Devon Energy Corp.	

	3,322,942
	950,610
El Paso Corp.	
	9,220,917
	177,530
Total SA, ADR	
	9,842,263
<i>Total Oil, Gas & Consumable Fuels</i>	
	27,488,478
TOTAL ENERGY	
	39,658,765
FINANCIALS 4.9%	

Capital Markets 2.6%

	321,700
Charles Schwab Corp.	
	6,150,904
	307,220
Invesco Ltd.	
	4,580,650
	333,237
Och-Ziff Capital Management Group	
	1,549,552

Total Capital Markets

12,281,106

See Notes to Financial Statements.

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Schedule of investments *continued*

October 31, 2008

LMP CAPITAL AND INCOME FUND INC.

SHARES	SECURITY	VALUE
	Commercial Banks 0.4%	
54,400	Wells Fargo & Co.	\$ 1,852,320
	Diversified Financial Services 1.9%	
225,300	JPMorgan Chase & Co.	9,293,625
	TOTAL FINANCIALS	23,427,051
HEALTH CARE 7.1%		
	Health Care Equipment & Supplies 1.2%	
142,020	Medtronic Inc.	5,727,667
	Health Care Providers & Services 1.0%	
209,000	UnitedHealth Group Inc.	4,959,570
	Health Care Technology 1.4%	
824,980	HLTH Corp.*	6,839,084
	Pharmaceuticals 3.5%	
78,200	Johnson & Johnson	4,796,788
135,200	Novartis AG, ADR	6,893,848
158,500	Wyeth	5,100,530
	<i>Total Pharmaceuticals</i>	<i>16,791,166</i>
	TOTAL HEALTH CARE	34,317,487
INDUSTRIALS 12.7%		
	Aerospace & Defense 3.2%	
74,020	L-3 Communications Holdings Inc.	6,008,203
86,790	TransDigm Group Inc.*	2,615,851
124,800	United Technologies Corp.	6,859,008
	<i>Total Aerospace & Defense</i>	<i>15,483,062</i>
	Air Freight & Logistics 0.5%	
68,170	Expeditors International of Washington Inc.	2,225,750
	Building Products 1.7%	
737,600	Assa Abloy AB	8,269,746
	Commercial Services & Supplies 2.4%	
548,680	Covanta Holding Corp.*	11,829,541
	Industrial Conglomerates 3.0%	
519,470	General Electric Co.	10,134,860
247,030	McDermott International Inc.*	4,231,624
	<i>Total Industrial Conglomerates</i>	<i>14,366,484</i>
	Machinery 1.2%	
175,700	Dover Corp.	5,581,989
	Road & Rail 0.7%	
76,220	CSX Corp.	3,484,778
	TOTAL INDUSTRIALS	61,241,350

See Notes to Financial Statements.

LMP CAPITAL AND INCOME FUND INC.

SHARES	SECURITY	VALUE
INFORMATION TECHNOLOGY 3.3%		
220,900	Communications Equipment 1.3%	
76,810	Nokia Oyj, ADR	\$ 3,353,262
	QUALCOMM Inc.	2,938,750
	<i>Total Communications Equipment</i>	6,292,012
326,420	Computers & Peripherals 0.8%	
	EMC Corp.*	3,845,228
	Software 1.2%	
98,600	Autodesk Inc.*	2,101,166
196,300	Oracle Corp.*	