

SCOLR Pharma, Inc.  
Form S-3/A  
April 08, 2005  
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As filed with the Securities and Exchange Commission on April 8, 2005

Registration No. 333-123316

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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**AMENDMENT NO. 1**

**TO**

**FORM S-3**

**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

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**SCOLR Pharma, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State of Incorporation)

**91-1689591**  
(I.R.S. Employer Identification No.)

**3625 132nd Avenue SE**

**Bellevue, Washington 98006**

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(425) 373-0171

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**Daniel O. Wilds, President & Chief Executive Officer**

*Copies to:*

**SCOLR Pharma, Inc.**

**W. Michael Hutchings, Esq.**

**3625 132nd Avenue SE, Suite 300**

**DLA Piper Rudnick Gray Cary US LLP**

**Bellevue, Washington 98006**

**701 Fifth Avenue, Suite 7000**

**(425) 373-0171**

**Seattle, WA 98104-7044**

(Name, address, including zip code, and telephone number,

**(206) 839-4800**

including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public: From time to time as described in the prospectus.**

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, check the following box and list the Securities Act registration statement number of 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 registrations 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. "

**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 this registration statement shall become effective on such date as the Securities and Exchange 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. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission becomes 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.**

**SUBJECT TO COMPLETION, DATED APRIL 8, 2005**

PROSPECTUS

## **SCOLR Pharma, Inc.**

### **3,825,000 SHARES OF COMMON STOCK**

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The selling stockholders of SCOLR Pharma, Inc. listed on page 10, may offer and resell up to 3,825,000 shares of our common stock under this prospectus, each for their own accounts, as follows:

Up to 3,750,000 shares of our common stock which we issued in a private placement on February 8, 2005; and

Up to 75,000 shares of our common stock which we will issue upon exercise of warrants we issued in a private placement on February 8, 2005.

The number of shares the selling stockholders may sell includes shares of common stock that are currently issued and outstanding as well as shares of common stock that they may receive if they exercise their warrants. The selling stockholders have the right to determine both the number of shares they will offer and the time or times when they will offer shares. They may sell the shares at the market price at the time of sale or at such other prices as they may negotiate. We cannot assure you that the selling stockholders will sell all or a portion of the common stock offered under this prospectus.

We will not receive any of the proceeds from the sale of the common stock by the selling stockholders. However, we will receive up to \$375,000 in proceeds from the exercise of warrants if the warrants are exercised for cash.

Our common stock is traded on the American Stock Exchange under the symbol **DDD**. On April 7, 2005, the last reported sale price of our common stock on the American Stock Exchange was \$3.90 per share.

Our principal executive offices are located at 3625 132nd Avenue SE, Suite 300, Bellevue, Washington 98006. The telephone number of our principal executive offices is (425) 373-0171.

**Investing in our common stock is highly speculative and involves a high degree of risk. You should consider carefully the risks and uncertainties in the section entitled Risk Factors beginning on page 3 of the prospectus and in the documents we file with the Securities and Exchange Commission that are incorporated by reference in this prospectus before making a decision to purchase our stock.**

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

The date of this prospectus is \_\_\_\_\_, 2005.

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You should rely only on the information contained or incorporated in this prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated in this prospectus or to make representations not contained in this prospectus. This prospectus is neither an offer to sell nor a solicitation of an offer to buy any securities other than those registered by this prospectus, nor is it an offer to sell or a solicitation of an offer to buy securities in jurisdictions where an offer or solicitation would be unlawful. The information contained or incorporated in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

In this prospectus and in documents incorporated in this prospectus, references to the Company, SCOLR, we, us and our refer to SCOLR Pharma, Inc., a Delaware corporation.

Controlled Delivery Technology is a registered trademark of SCOLR Pharma, Inc. Other trademarks referred to in this prospectus belong to their respective owners.

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**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and other reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document that we file at the SEC's public reference facilities at 450 Fifth Street, NW, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the public reference rooms. Our SEC filings are also available to the public free of charge at the SEC's web site at <http://www.sec.gov> and at our website at <http://www.scolr.com>.

This prospectus is a part of the registration statement on Form S-3 that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules and regulations of the SEC. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus. You should refer to the registration statement for additional information about us and the common stock being offered in this prospectus. Statements that we make in this prospectus relating to any documents filed as an exhibit to the registration statement or any document incorporated by reference into the registration statement may not be complete and you should review the referenced document itself for a complete understanding of its terms.

**INCORPORATION OF DOCUMENTS BY REFERENCE**

The SEC allows us to incorporate by reference the information we have filed with them, which means that we can disclose information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus except for any information superseded by information contained directly in this prospectus. You should review that information to understand the nature of any investment by you in our common stock. Information we file with the SEC in the future will update and supersede the information in this prospectus. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, after the date of the initial registration statement and prior to effectiveness of the registration statement:

our annual report on Form 10-KSB for the fiscal year ended December 31, 2004;

our current reports on Form 8-K filed with or furnished to the SEC on January 11, 2005, January 25, 2005, February 11, 2005, and March 22, 2005; and

the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on February 3, 2004, including any amendments or reports filed for the purpose of updating this information.

If you would like a copy of any of these documents, at no cost, please write or call us at:

**SCOLR Pharma, Inc.**

**3625 132nd Avenue SE, Suite 300**

**Bellevue, Washington 98006**

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**Attention: Director of Finance**

**Telephone: (425) 373-0171**

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**THE COMPANY**

We are a specialty pharmaceutical company leveraging our formulation experience and knowledge with our proprietary and patented Controlled Delivery Technology (CDT<sup>®</sup>) platform to develop novel pharmaceutical, over-the-counter and nutritional products. Our CDT platform is currently based on three patented drug delivery technologies. Our CDT platform includes intellectual property from two U.S. patents licensed exclusively to us by Temple University, and a third U.S. patent assigned to us by Dr. Reza Fassihi, a Professor of Biopharmaceutics and Industrial Pharmacy at the Temple University School of Pharmacy. We have collaborated with Dr. Fassihi over the last five years to develop prototype prescription and OTC drug formulations, and a number of currently marketed dietary supplements that use the delivery system concepts embodied in the three CDT patents.

Our proprietary CDT system can be used in solid oral dosage formulations, the preferred route for drug administration, to yield tablets or capsules that release their active agents predictably and programmably over a specified timeframe of up to 24 hours. We believe we can apply our technology to create significant enhancements to a large universe of existing oral pharmaceutical, OTC and nutritional products. CDT-based controlled release dry blend and direct compression tablet and capsule formulations contain readily available and generally regarded as safe (GRAS) excipients, e.g., non-active ingredients such as combinations of hydrophilic polymers and poly-ionics or electrolytes. These excipients are used to control the release rate of the active drug component of the CDT tablet or capsule formulation resulting in predictable delivery profiles. These include attaining near linear sustained release profiles with zero-order kinetics required for reproducible, cost effective, and optimized *in vivo* delivery of drugs for up to 24 hours. In addition, our proprietary amino-acid technology can be incorporated in immediate and sustained release solid oral formulations to increase the solubility characteristics of previously non-soluble and sparingly soluble drugs without employing costly micro-milling, nano-particulate, or coated particle technologies.

Our principal executive offices are located at 3625 132nd Avenue SE, Suite 300, Bellevue, Washington 98006. Our telephone number is (425) 373-0171.

***Private Placement of Common Stock***

On February 8, 2005, we raised approximately \$15 million through a private placement of our common stock. We sold a total of 3,750,000 shares of our common stock to a group of accredited investors at a price of \$4.00 per share. The placement agent for the financing, Taglich Brothers, Inc., received warrants to purchase up to 75,000 shares of our common stock at an exercise price of \$5.00 per share exercisable for five years. Two members of our board of directors, Michael N. Taglich and Robert C. Schroeder, are affiliates of Taglich Brothers, Inc.

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**RISK FACTORS**

This prospectus includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this prospectus, the words anticipate, believe, estimate, may, intend and expect and similar expressions identify certain of such forward-looking statements. Although we believe that our plans, intentions and expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. Actual results, performance or achievements could differ materially from historical results or those contemplated, expressed or implied by the forward-looking statements contained in this prospectus. Important factors that could cause actual results to differ materially from our forward-looking statements are set forth in this prospectus, including under this heading Risk Factors and others detailed from time to time in our periodic reports filed with the SEC. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a results of new information, future events or otherwise.

**The shares of common stock offered by this prospectus involve a high degree of risk. You should only acquire shares of our common stock if you can afford to lose your entire investment. You should carefully consider the following risk factors, as well as all of the other information set forth in this prospectus, before making a decision to purchase shares of our common stock.**

**We have incurred substantial operating losses in recent years and we expect to continue to incur substantial losses in the future, which may negatively impact our ability to run our business.**

We have incurred net losses since 2000, including net losses of \$4.9 million in 2004, \$8.7 million in 2003 and \$2.7 million in 2002. We have continued to incur losses after December 31, 2004. We have accumulated net losses of approximately \$26.6 million from our inception through December 31, 2004, and we expect to continue to incur significant operating losses in the future.

We plan to continue the costly process of simultaneously conducting clinical trials and preclinical research for multiple product candidates. Our product development program may not lead to commercial products, either because our product candidates fail to be effective, are not attractive to the market, or because we lack the necessary financial or other resources or relationships to pursue our programs through commercialization. Our net losses are likely to increase significantly as we continue preclinical research and clinical trials, apply for regulatory approvals, develop our product candidates, expand our operations and develop the infrastructure to support commercialization of our potential products.

We have funded our operations primarily through the issuance of equity securities to investors and may not be able to generate positive cash flow in the future. If we are unable to generate sufficient cash flow from operations, we will need to seek additional funds through the issuance of equity securities or other sources of financing. If we are unable to obtain necessary additional financing, our ability to run our business will be adversely affected and we may be required to reduce the scope of our cease our operations.

**We do not have sufficient cash to fund the development of our drug delivery operations. If we are unable to obtain additional equity or debt financing in the future, we will be required to reduce the scope of our business or cease our operations.**

With the \$15 million we raised in our recently completed private placement of common stock, we believe that our cash on hand, including our cash equivalents, will be sufficient to fund our drug delivery business at planned levels through early 2006. We will need to raise additional capital to fund operations, conduct clinical trials, continue research and development projects and commercialize our product candidates. The timing and amount of our need for additional financing will depend on a number of factors, including:

the structure and timing of collaborations with strategic partners and licensees;

our timetable and costs for the development of marketing operations and other activities related to the commercialization of our product candidates;

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the progress of our research and development programs and expansion of such programs;

the emergence of competing technologies and other adverse market developments; and

the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

Additional equity or debt financing may not be available to us on acceptable terms, or at all. If we raise additional capital by issuing equity securities, substantial dilution to our existing stockholders may result which could decrease the market price of our common stock due to the sale of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales, or the perception of possible sales, could also impair our ability to raise capital in the future. In addition, the terms of any equity financing may adversely affect the rights of our existing stockholders. If we raise additional funds through strategic alliance and licensing arrangements, we may be required to relinquish rights to certain of our technologies or product candidates, or to grant licenses on terms that are unfavorable to us, which could substantially reduce the value of our business.

If we are unable to obtain sufficient additional financing, we would be unable to meet our obligations and we would be required to delay, reduce or eliminate some or all of our business operations, including the pursuit of licensing, strategic alliances and development of drug delivery programs.

**If our clinical trials are not successful or take longer to complete than we expect, we may not be able to develop and commercialize our products.**

In order to obtain regulatory approvals for the commercial sale of potential products utilizing our CDT platform, we or our collaborators will be required to complete clinical trials in humans to demonstrate the safety and efficacy, or in certain cases, the bioequivalence, of the products. However, we or our collaborators may not be able to commence or complete these clinical trials in any specified time period, or at all, either because the appropriate regulatory agency objects or for other reasons, including:

unexpected delays in the initiation of clinical sites;

slower than projected enrollment of eligible patients;

competition with other ongoing clinical trials for clinical investigators or eligible patients;

scheduling conflicts with participating clinicians;

limits on manufacturing capacity; and

the failure of our products to meet required standards.

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We also rely on academic institutions and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated scheduled or consistent with a clinical trial protocol.

Even if we complete a clinical trial of one of our potential products, the clinical trial may not indicate that our product is safe or effective to the extent required by the FDA or other regulatory agency to approve the product. If clinical trials do not show any potential product to be safe or efficacious, or if we are required to conduct additional clinical trials or other testing of our products in development beyond those that we currently contemplate, we may be delayed in obtaining, or may not obtain, marketing approval for our products. Our product development costs may also increase if we experience delays in testing or approvals, which could allow our competitors to bring products to market before we do and would impair our ability to commercialize our products.

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### **We may not obtain regulatory approval for our products, which would materially impair our ability to generate revenue.**

Each OTC or pharmaceutical product developed by us will require a separate costly and time consuming regulatory approval before we or our collaborators can manufacture and sell it in the United States or internationally. The regulatory process to obtain market approval for a new drug takes many years and requires the expenditure of substantial resources. We have had only limited experience in preparing applications and obtaining regulatory approvals and primarily rely on third party contractors. As a result, we have less control over the timing and other aspects of the regulatory process than if we had our own expertise in this area. Third parties may not perform their responsibilities on our anticipated schedule or consistent with our priorities.

We may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical data to demonstrate compliance with, or upon the failure of the product to meet the FDA's requirements for safety, efficacy, quality and/or bioequivalence; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a marketing application, in the form of an NDA or an abbreviated new drug application, or ANDA, the FDA may deny the application, may require additional testing or data and/or may require post marketing testing and surveillance to monitor the safety or efficacy of a product. In addition, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of products incorporating our controlled release technology.

Certain products incorporating our technology will require the filing of an NDA. A full NDA must include complete reports of preclinical, clinical and other studies to prove adequately that the product is safe and effective, which involves among other things, full clinical testing, and as a result requires the expenditure of substantial resources. In certain cases involving controlled release versions of FDA-approved immediate release products, we may be able to rely on existing publicly available safety and efficacy data to support an NDA for controlled release products under Section 505(b)(2) of the FDCA when such data exists for an approved immediate release or controlled release version of the same active chemical ingredient. We can provide no assurance, however, that the FDA will accept a section 505(b)(2) NDA, or that we will be able to obtain publicly available data that is useful. The section 505(b)(2) NDA process is a highly uncertain avenue to approval because the FDA's policies on section 505(b)(2) have not yet been fully developed. There can be no assurance that the FDA will approve an application submitted under section 505(b)(2) in a timely manner or at all. Our inability to rely on the 505(b)(2) process would increase the cost and extend the time frame for FDA approvals.

### **We face intense competition in the drug delivery business, and our failure to compete effectively would decrease our ability to generate meaningful revenues from our products.**

The drug delivery business is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. We are subject to competition from numerous other entities that currently operate or intend to operate in the industry. These include companies that are engaged in the development of controlled-release drug delivery technologies and products as well as other manufacturers that may decide to undertake in-house development of these products. Some of our direct competitors in the drug delivery industry include Alza, Andrx Corporation, Biovail, Labopharm, Penwest and SkyePharma.

Many of our competitors have more extensive experience than we have in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. Many competitors also have competing products that have already received regulatory approval or are in late-stage development, and may have collaborative arrangements in our target markets with leading companies and research institutions.

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Our competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than we are able to develop, commercialize or obtain. As a result, our competitors may commercialize products more rapidly or effectively than we do, which would adversely affect

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our competitive position, the likelihood that our products will achieve market acceptance and our ability to generate meaningful revenues from our products.

**If we fail to comply with extensive government regulations covering the manufacture, distribution and labeling of our products, we may have to withdraw our products from the market, close our facilities or cease our operations.**

Our products, potential products and manufacturing and research activities are subject to varying degrees of regulation by a number of government authorities in the United States (including the Drug Enforcement Agency, Food and Drug Administration, Federal Trade Commission and Environmental Protection Agency) and in other countries. For example, our activities, including preclinical studies, clinical trials, and manufacturing, distribution and labeling are subject to extensive regulation by the FDA and comparable authorities outside the United States. Also, our statements and our customers' statements regarding dietary supplement products are subject to regulation by the FTC. The FTC enforces laws prohibiting unfair or deceptive trade practices, including false or misleading advertising. In recent years the FTC has brought a number of actions challenging claims by nutraceutical companies.

Each OTC or pharmaceutical product developed by us will require a separate costly and time consuming regulatory approval before we or our collaborators can manufacture and sell it in the United States or internationally. Even if regulatory approval is received, there may be limits imposed by regulators on a product's use or it may face subsequent regulatory difficulties. Approved products are subject to continuous review and the facilities that manufacture them are subject to periodic inspections. Furthermore, regulatory agencies may require additional and expensive post-approval studies. If previously unknown problems with a product candidate surface or the manufacturing or laboratory facility is deemed non-compliant with applicable regulatory requirements, an agency may impose restrictions on that product or on us, including requiring us to withdraw the product from the market, close the facility, and/or pay substantial fines.

We also may incur significant costs in complying with environmental laws and regulations. We are subject to federal, state, local and other laws and regulations governing the use, manufacture, storage, handling, and disposal of materials and certain waste products. The risk of accidental contamination or injury from these materials cannot be completely eliminated. If an accident occurs, we could be held liable for any damages that result and these damages could exceed our resources.

**If we cannot establish collaborative arrangements with leading individuals, companies and research institutions, we may have to discontinue the development and commercialization of our products.**

We have limited experience in conducting full scale clinical trials, preparing and submitting regulatory applications or manufacturing and selling pharmaceutical products. In addition, we do not have sufficient resources to fund the development, regulatory approval and commercialization of our products. We expect to seek collaborative arrangements and alliances with corporate and academic partners, licensors and licensees to assist with funding research and development, to conduct clinical testing, and to provide manufacturing, marketing, and commercialization of our product candidates. We may rely on collaborative arrangements to obtain the regulatory approvals for our products.

For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also enter into collaboration agreements with them on terms that are favorable to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements.



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Factors that may affect the success of our collaborations include the following:

our collaborators may have insufficient economic motivation to continue their funding, research, development and commercialization activities;

our collaborators may discontinue funding any particular program, which could delay or halt the development or commercialization of any product candidates arising out of the program;

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our collaborators may choose to pursue alternative technologies or products, either on their own or in collaboration with others, including our competitors;

our collaborators may lack sufficient financial, technical or other capabilities to develop these product candidates;

we may underestimate the length of time that it takes for our collaborators to achieve various clinical development and regulatory approval milestones; and

our collaborators may be unable to successfully address any regulatory or technical challenges they may encounter.

If we cannot establish collaborative relationships, we will be required to find alternative sources of funding and to develop our own capabilities to manufacture, market and sell our products. If we were not successful in finding funding and developing these capabilities we would have to terminate the development and commercialization of our products.

### **We have no manufacturing capabilities and will be dependent on third party manufacturers.**

We do not have commercial scale facilities to manufacture any products we may develop in accordance with requirements prescribed by the FDA. Accordingly, we have to rely on third party manufacturers of the products we are evaluating in clinical trials. There can be no assurance that any third parties upon which we rely for our products in clinical development will perform and any failures by third parties may delay development of or the submission of products for regulatory approval, impair our collaborators' ability to commercialize products as planned and deliver products on a timely basis, require us or our collaborators to cease distribution or recall some or all batches of our products or otherwise impair our competitive position, which could have a material adverse effect on our business, financial condition and results of operations.

### **If we fail to protect and maintain the proprietary nature of our intellectual property, our business, financial condition and ability to compete would suffer.**

We principally rely on patent, trademark, copyright, trade secret and contract law to establish and protect our proprietary rights. We own or have exclusive rights to several U.S. patents and patent applications and we expect to apply for additional U.S. and foreign patents in the future. The patent positions of pharmaceutical, nutraceutical, and bio-pharmaceutical firms, including ours, are uncertain and involve complex legal and factual questions for which important legal issues are largely unresolved. The coverage claimed in our patent applications can be significantly reduced before a patent is issued, and the claims allowed on any patents or trademarks we hold may not be broad enough to protect our technology. In addition, our patents or trademarks may be challenged, invalidated or circumvented, or the patents of others may impede our collaborators' ability to commercialize the technology covered by our owned or licensed patents. Moreover, any current or future issued or licensed patents, or trademarks, or existing or future trade secrets or know-how, may not afford sufficient protection against competitors with similar technologies or processes, and the possibility exists that certain of our already issued patents or trademarks may infringe upon third party patents or trademarks or be designed around by others. In addition, there is a risk that others may independently develop proprietary technologies and processes that are the same as, or substantially equivalent or superior to ours, or become available in the market at a lower price. There is a risk that we have infringed or in the future will infringe patents or trademarks owned by others, that we will need to acquire licenses under patents or trademarks belonging to others for technology potentially useful or necessary to us, and that licenses will not be available to us on acceptable terms, if at all. We cannot assure you that:

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our patents or any future patents will prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents;

any of our future processes or products will be patentable;

any pending or additional patents will be issued in any or all appropriate jurisdictions;

our processes or products will not infringe upon the patents of third parties; or

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we will have the resources to defend against charges of patent infringement by third parties or to protect our own patent rights against infringement by third parties.

We may have to litigate to enforce our patents or trademarks or to determine the scope and validity of other parties' proprietary rights. Litigation could be very costly and divert management's attention. An adverse outcome in any litigation could adversely affect our financial results and stock price.

We also rely on trade secrets and proprietary know-how, which we seek to protect by confidentiality agreements with our employees, consultants, advisors, and collaborators. There is a risk that these agreements may be breached, and that the remedies available to us may not be adequate. In addition, our trade secrets and proprietary know-how may otherwise become known to or be independently discovered by others.

### **Significant expenses in applying for patent protection and prosecuting our patent applications will increase our need for capital and could harm our business and financial condition.**

We intend to continue our substantial efforts in applying for patent protection and prosecuting pending and future patent applications both in the United States and internationally. These efforts have historically required the expenditure of considerable time and money, and we expect that they will continue to require significant expenditures. If future changes in United States or foreign patent laws complicate or hinder our efforts to obtain patent protection, the costs associated with patent prosecution may increase significantly.

### **If we fail to attract and retain key executive and technical personnel we could experience a negative impact on our ability to develop and commercialize our products and our business will suffer.**

The success of our operations will depend to a great extent on the collective experience, abilities and continued service of relatively few individuals. We are dependent upon the continued availability of the services of our employees, many of whom are individually key to our future success. For example, if we lose the services of our President and CEO, Daniel O. Wilds, or our Vice President and Chief Technical Officer, Stephen J. Turner, we could experience a negative impact on our ability to develop and commercialize our CDT technology, our financial results and our stock price. We also rely on members of our scientific staff for product research and development. The loss of the services of key members of this staff could substantially impair our ongoing research and development and our ability to obtain additional financing.

In addition, we are dependent upon the continued availability of Dr. Reza Fassihi, with whom we have a consulting agreement. The agreement expires December 31, 2006, but may be terminated by either of party on 30-days' notice. If our relationship with Dr. Fassihi is terminated, we could experience a negative impact on our ability to develop and commercialize our CDT technology.

Our success also significantly depends upon our ability to attract and retain highly qualified personnel. We face intense competition for personnel in the drug delivery industry. To compete for personnel we may need to pay higher salaries and provide other incentives than those paid and provided by more established entities. Our limited financial resources may hinder our ability to provide such salaries and incentives. Our personnel may voluntarily terminate their relationship with us at any time, and the process of locating additional personnel with the combination of skills and attributes required to carry out our strategy could be lengthy, costly and disruptive. If we lose the services of key personnel, or fail to replace the services of key personnel who depart, we could experience a severe negative impact on our financial results and stock price.

**Future laws or regulations may hinder or prohibit the production or sale of our products.**

We may be subject to additional laws or regulations in the future, such as those administered by the FDA or other federal, state or foreign regulatory authorities. Laws or regulations that we consider favorable, such as the DSHEA, may be repealed. Current laws or regulations may be interpreted more stringently. We are unable to predict the nature of such future laws, regulations or interpretations, nor can we predict what effect they may have on our business. Possible effects or requirements could include the following:

The reformulation of certain products to meet new standards;

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The recall or discontinuance of certain products unable to be reformulated;

Imposition of additional record keeping requirements;

Expanded documentation of the properties of certain products; or

Expanded or different labeling, or scientific substantiation.

Any such requirement could have a material adverse effect on our results of operations and financial condition.

**If we fail to adequately manage the size of our business, it could have a severe negative impact on our financial results or stock price.**

Our management believes that, to be successful, we must appropriately manage the size of our business. We have added numerous personnel and have added several new research and development projects. We anticipate that we will experience additional growth in connection with the development, manufacture and commercialization of our products. If we experience rapid growth of our operations, we will be required to implement operational, financial and information procedures and controls that are efficient and appropriate for the size and scope of our operations. The management skills and systems currently in place may not be adequate and we may not be able to manage any significant growth effectively. Our failure to effectively manage our existing operations or our growth could have a material adverse effect on our financial performance or stock price.

**A significant number of shares of our common stock are or will be eligible for sale in the open market, which could drive down the market price for our common stock and make it difficult for us to raise capital.**

As of March 18, 2005, 34,513,386 shares of our common stock were outstanding, and there were approximately 5,838,379 million shares of our common stock issuable upon exercise or conversion of outstanding options and warrants. Of these shares, this prospectus covers the resale of up to 3,750,000 shares of our outstanding common stock and up to 75,000 shares of common stock issuable upon exercise or conversion of warrants. Sales of a large number of shares by the selling stockholders could materially decrease the market price of our common stock and make it more difficult to raise additional capital through the sale of equity securities.

Our stockholders may experience substantial dilution if we raise additional funds through the sale of equity securities. The issuance of a large number of additional shares of our common stock upon the exercise or conversion of outstanding options or warrants or in an equity financing transaction could cause a decline in the market price of our common stock due to the sale of a large number of shares of our common stock in the market, of the perception that these sales could occur.

The risk of dilution and the resulting downward pressure on our stock price could also encourage investors to engage in short sales of our common stock. By increasing the number of shares offered for sale, material amounts of short selling could further contribute to progressive price declines in our common stock.

**Certain provisions in our charter documents and otherwise may discourage third parties from attempting to acquire control of our company, which may have an adverse effect on the price of our stock.**

Our board of directors has the authority, without obtaining stockholder approval, to issue up to 5,000,000 shares of preferred stock and to fix the rights, preferences, privileges and restrictions of such shares without any further vote or action by our stockholders. Our certificate of incorporation and bylaws also provide for a classified board and special advance notice provisions for proposed business at annual meetings. In addition, Delaware and Washington law contain certain provisions that may have the effect of delaying, deferring or preventing a hostile takeover of our company. Further, we have a stockholder rights plan that is designed to cause substantial dilution to a person or group that attempts to acquire our company without approval of our board of directors, and thereby make a hostile takeover attempt prohibitively expensive for a potential acquirer. These provisions, among others, may have the effect of making it more difficult for a third party to acquire, or discouraging a third party from attempting to acquire, control of our company, even if stockholders may consider such a change in control to be in their best interests, which may cause the price of our common stock to suffer.

**Table of Contents****SELLING STOCKHOLDERS**

We are registering a total of 3,825,000 shares of our common stock on behalf of the selling stockholders. The following table sets forth the number of shares beneficially owned by each of the selling stockholders. Except as otherwise indicated, none of the selling stockholders has held a position or office or had a material relationship with us within the past three years other than as a result of the ownership of our common stock or other securities of ours or as a result of being a service provider to us. The shares offered by this prospectus may be offered from time to time by the selling stockholders named below.

Beneficial ownership is determined in accordance with rules promulgated by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. This table is based upon information supplied to us by the selling stockholders and information filed with the SEC. Except as otherwise indicated, we believe that each selling stockholder has sole voting and investment power with respect to all shares of the common stock shown as beneficially owned by it. The percent of beneficial ownership for the selling stockholders is based on 34,513,386 shares of our common stock outstanding as of March 18, 2005.

We may amend or supplement this prospectus from time to time in the future to update or change this list and shares which may be resold.

<u>Selling Stockholder</u>	<u>Number of Shares Beneficially Owned</u>	<u>Number of Shares Registered for Sale Hereby</u>	<u>Number of Shares to be Owned after Completion of the Offering (1)</u>	<u>Percent of Outstanding Shares to be Owned after Completion of the Offering (1)</u>
Joseph P. Allen	12,500	2,500	10,000	*
Robert W. Allen	467,619	100,000	367,619	1.07%
Applebaum Family LTD Partnership (2)	26,785	12,500	14,285	*
E H Arnold	346,666	80,000	266,666	*
Gary P. Arnold	238,095	50,000	188,095	*
Atlas Equity I, LTD (3)	905,228	350,000	555,228	1.61%
Tom H. Barrett	20,000	20,000		*
Thomas J. Bean	25,000	8,000	17,000	*
Keith Becker	30,000	20,000	10,000	*
Raymond M. Beebe and Joan P. Beebe	39,047	20,000	19,047	*
Ronald A. Bero	46,547	12,500	34,047	*
John R. Bertsch (4)	202,382	50,000	152,382	*
Monica L. Bertsch	12,000	5,000	7,000	*
Eileen Y. Bertsch Trust (5)	7,500	2,500	5,000	*
Francis Bissaillon IRA (6)	29,047	10,000	19,047	*
Mordecai Bluth	12,000	5,000	7,000	*
Steven A. Boggs	40,000	10,000	30,000	*
Jeremy David Bond	35,523	6,000	29,523	*
Charles S. Brand	63,089	20,000	43,089	*
Baldev S. Brar and Gurmukh K. Brar	9,523	5,000	4,523	*
Sandra L. Brecher	27,000	25,000	2,000	*
Edward Brody	2,500	2,500		*
Richard Buchakjian	32,047	10,000	22,047	*
Kyle G. Buchakjian	5,500	2,500	3,000	*
Peter Carroll and Maureen Carroll	14,523	5,000	9,523	*
Joseph D. Chamberlain	25,000	25,000		*



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Joseph O. Chabot and Debora Chabot	5,000	5,000		*
Richard C. Clayton	199,500	50,000	149,500	*
Kenneth W. Cleveland	55,900	5,000	50,900	*

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<u>Selling Stockholder</u>	<u>Number of Shares Beneficially Owned</u>	<u>Number of Shares Registered for Sale Hereby</u>	<u>Number of Shares to be Owned after Completion of the Offering (1)</u>	<u>Percent of Outstanding Shares to be Owned after Completion of the Offering (1)</u>
Stephen Cohen	15,500	10,000	5,500	*
Edward J. Cook and Eleanor A. Cook	40,595	2,500	38,095	*
John Crabtree and Teresa Crabtree	15,000	5,000	10,000	*
John W. Crow	39,047	20,000	19,047	*
Ralph J. Cuomo and Leslie L. Cuomo	5,000	5,000		*
Robert L. DeBruyn Trust UAD 10/5/94 (7)	24,523	10,000	14,523	*
Tracey H. DeBruyn Trust UAD 10/5/94 (8)	15,000	10,000	5,000	*
Guertino De Luca and Francis De Luca	65,119	12,500	52,619	*
Steven J. Dennis	15,000	5,000	10,000	*
SDS Capital Group SPC, Ltd. (9)	62,500	62,500		*
Michael P. Duffy and Ellen L. Duffy	39,047	20,000	19,047	*
Richard Duke	60,000	10,000	50,000	*
Frank M. Durrance	25,000	25,000		*
Robert J. Edmonson	30,000	10,000	20,000	*
John M. Ehlen	10,000	10,000		*
Embry Family Living Trust (10)	25,000	25,000		*
Albert C. Esposito and Brooke Crowley Esposito	30,000	15,000	15,000	*
Albert Esposito Sr. and Margaret Esposito	19,047	15,000	4,057	*
Robert L. Falk	14,523	5,000	9,523	*
Harry M. Farnham III	15,000	15,000		*
Lawrence D. Feldhacker	24,523	10,000	14,523	*
Kenneth J. Feroldi and Nancy J. Feroldi	36,250	15,000	21,250	*
Arthur H. Finnel	46,000	20,000	26,000	*
Robert Louis Fisher and Carroll Fisher	29,047	10,000	19,047	*
Dennis Fortin (11)	213,095	25,000	188,095	*
Michael J. Fourticq, Sr.	62,619	15,000	47,619	*
James R. Foutch	72,619	25,000	47,619	*
Carolyn L. Foutch	12,500	12,500		*
Stephen Friedland and Linda Friedland	24,047	5,000	19,047	*
Douglas A. Friedrich and Melanie Friedrich	35,000	10,000	25,000	*
Shadow Capitol LLC (12)	228,572	25,000	203,572	*
Robert P. Giesen	20,000	6,000	14,000	*
Harold L. Gilbert and Sara V. Gilbert	30,000	20,000	10,000	*
Jeffrey H. Golden	17,023	7,500	9,523	*
The Ingrates Restated Profit Sharing Retirement Plan (13)	5,000	5,000		*
Arnold Granet	10,000	2,500	7,500	*
Gary L. Gray	3,000	3,000		*
Meadowbrook Opportunity Fund LLC (14)	210,000	60,000	150,000	*
Woodrow W. Gunter II	60,000	20,000	40,000	*
Terry E. Hagen and Dawn R. Hagen	10,000	5,000	5,000	*
Michael P. Hagerty	60,000	10,000	50,000	*
Thomas Heirigs and Sheryl Heirigs (15)	19,047	10,000	9,047	*
SEP FBO Ronald C. Hintz Pershing LLC as Custodian (16)	60,000	25,000	35,000	*
Jeffrey G. Hipp and Mary Ann Hipp	24,047	5,000	19,047	*
Glenn R. Hubbard	100,119	32,500	67,619	*

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Stephen P. Hughes	14,523	5,000	9,523	*
Iroquois Capital LP (17)	71,750	71,750		*
Scott J. Isaac	30,950	10,000	20,950	*
KueKenhof Equity Fund, L.P. (18)	50,000	50,000		*
Ronald Johnson	29,047	5,000	24,047	*
Joe Don Jones	15,523	3,000	12,523	*
Leo Jones	78,119	20,500	57,619	*
John P. Junge	20,000	10,000	10,000	*
Howard A. Kalka (19)	125,000	25,000	100,000	*
Lawrence Kane	12,023	2,500	9,523	*
Larry S. Kaplan and Marla B. Kaplan	18,000	5,000	13,000	*
Steven D. Kasle and Mercy Kasle	20,000	8,000	12,000	*
Robert Koski	10,000	10,000		*
Richard A. Kraemer Trust UAD 12/23/96 (20)	30,000	10,000	20,000	*
Mark C. Ladendorf and Debra Ladendorf	11,250	6,250	5,000	*
A.F. Lehmkuhl	35,809	7,000	28,809	*
The Shirley J. Lewis Rev Trust UA DTD 6/26/01 (21)	43,809	20,000	23,809	*
Andrew K. Light	36,523	20,000	16,523	*
Akros Capital Fund, L.P. (22)	8,000	8,000		*
Marvin J. Loutsenhizer	2,500	2,500		*
IRA FBO Samuel E. Leonard Pershing LLC as Custodian Roth Account (23)	8,000	8,000		*
Roger W. Lunstra	48,809	25,000	23,809	*
Robert W. Main	10,000	5,000	5,000	*
William H. Mallender	9,500	4,500	5,000	*
Gary L. Manka	6,500	2,500	4,000	*
Donald McCulloch and Jacqueline McCulloch	29,523	4,000	25,523	*
Thomas C. Mina	3,500	2,500	1,000	*
Roger J. Minch	4,000	4,000		*
Donald V. Moline	5,000	5,000		*
Thomas J. Murphy	37,500	37,500		*
Joseph Martha	5,000	5,000		*
Richard V. Nuttal	3,000	3,000		*
Ashok Kumar Narang	43,809	10,000	33,809	*
Rosalie A. Naser, Revocable Living Trust 11/3/99 (24)	14,000	5,000	9,000	*
Bruce Newell	20,000	10,000	10,000	*
Atalanta Selective Fund #6 (25)	84,000	35,000	49,000	*
Highland Avenue Partners LLC (26)	36,000	15,000	21,000	*
Jeffrey Hugh Newman	6,250	6,250		*
P. Kenneth Nitz (27)	20,715	10,000	10,715	*
Sandra P. Nitz (28)	20,715	10,000	10,715	*
Keith A. Palmer and Theresa R. Palmer	10,000	8,000	2,000	*
John L. Palazzola and Maria Palazzola	92,619	25,000	67,619	*
Walter T. Parkes	20,000	10,000	10,000	*
Robert G. Paul	44,047	5,000	39,047	*

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<u>Selling Stockholder</u>	<u>Number of Shares Beneficially Owned</u>	<u>Number of Shares Registered for Sale Hereby</u>	<u>Number of Shares to be Owned after Completion of the Offering (1)</u>	<u>Percent of Outstanding Shares to be Owned after Completion of the Offering (1)</u>
Wulf Paulick and Renate Paulick	49,047	10,000	39,047	*
Donald Paxton	25,000	5,000	20,000	*
Sara Bower Penn Living Trust DTD 4/30/02 (29)	130,238	35,000	95,238	*
Norper Investments (30)	43,809	20,000	23,809	*
Carl A. Quimby and Evelyn B. Quimby	10,000	5,000	5,000	*
David A. Random	10,000	10,000		*
Mark Ravich	60,120	12,500	47,620	*
Arthur J. Rechten	5,000	3,500	1,500	*
Joseph F. Regan	19,523	10,000	9,523	*
John J. Resich Jr. Retirement Trust (31)	29,047	10,000	19,047	*
J. Michael Reisert Inc. (32)	10,000	6,250	3,750	*
David Frank Rios and Margaret Jo Rios Trust DTD 6/22/99 (33)	97,619	50,000	47,619	*
Allen R. Rowland	75,000	25,000	50,000	*
James M. Rubens	17,000	7,000	10,000	*
Rx Healthcare Overseas Fund (34)	449,400	449,400		*
Rx Healthcare Partners I LP (34)	16,400	16,400		*
RX Healthcare Partners II LP (34)	284,200	284,200		*
Starr F. Schlobohm Revocable Trust (35)	59,523	10,000	49,523	*
Scot Holding Inc. (36)	15,000	15,000		*
Jeffrey L. Sadar and Barbara A. Sadar	31,000	5,000	26,000	*
Dolphin Offshore Partners, L.P. (37)	788,000	150,000	638,000	1.85%
Eric W. Sanderson	10,000	10,000		*
Special Trust for Nina B. Sando UA 3/20/87 (38)	30,000	5,000	25,000	*
Glenn Schabel	24,500	12,500	12,000	*
Andrew M. Schatz and Barbara F. Wolf	35,000	10,000	25,000	*
Ben Sevack	10,000	5,000	5,000	*
RFS Trust U/A/D 12/30/96 (39)	20,000	10,000	10,000	*
Mark B. Seiger	12,500	12,500		*
Valdemar A. Skov	7,500	2,500	5,000	*
Howard Smith	20,000	5,000	15,000	*
W.C. Smith Jr	27,500	2,500	25,000	*
Rodney G. Snow and Barbara M. Snow	15,000	5,000	10,000	*
Maurice Solomon	31,547	12,500	19,047	*
Spahr-Derebery Family Trust UA/D 10/11/90 (40)	39,047	10,000	29,047	*
Michael D. Stedem	38,571	10,000	28,571	*
William C. Steele	56,509	12,500	44,009	*
Arthur D. Sterling	97,619	50,000	47,619	*
James L. Tadych	31,547	12,500	19,017	*
Eugene R. Thomas and Betty Jane Thomas	12,500	2,500	10,000	*
Susan Thorstenn and Magnus Thorstenn	37,500	37,500		*
Pension Inc. Trustee FBO Thuemling Industrial Products Inc. Profit Sharing Plan (41)	29,047	10,000	19,047	*
Gladys M. Unverferth	35,000	25,000	10,000	*
Robert D. Van Roijen Jr. Trust UA DTD 12/14/82 (42)	60,000	50,000	50,000	*
Patience Partners LP (43)	12,000	10,000	2,000	*

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<u>Selling Stockholder</u>	<u>Number of Shares Beneficially Owned</u>	<u>Number of Shares Registered for Sale Hereby</u>	<u>Number of Shares to be Owned after Completion of the Offering (1)</u>	<u>Percent of Outstanding Shares to be Owned after Completion of the Offering (1)</u>
The Thomas J Waggoner Marital Trust (44)	41,071	12,500	28,571	*
William E. Ward	10,200	4,000	6,200	*
D & M Partnership (45)	24,285	10,000	14,285	*
John R. Wiencek	11,000	5,500	5,500	*
Northridge Partners (46)	25,000	25,000		*
James Wilen	25,000	25,000		*
Tad Wilson	33,809	10,000	23,809	*
Paul R. Winter	50,285	36,000	14,285	*
John R. Worthington Trust UA 3/28/00 (47)	48,095	10,000	38,095	*
Taglich Brothers, Inc. (48)	7,000	7,000		*
Douglas E. Hailey (49)	92,755	8,750	83,909	*
Robert C. Schroeder (50)	168,207	8,750	159,457	*
Russell J. Bernier (51)	60,500	16,500	44,000	*
Michael Brunone (52)	39,987	10,000	29,987	*
Vincent Palmieri (53)	8,000	5,000	3,000	*
Richard C. Oh (54)	9,187	5,000	4,187	*
Michael N. Taglich (55)	641,226	7,000	634,226	1.84%
Robert F. Taglich (56)	418,297	7,000	411,297	1.19%

\* Less than one percent.

- (1) We do not know when or in what amounts the selling stockholders will offer shares for sale, if at all. The selling stockholders may sell any or all of the shares included in and offered by this prospectus. Because the selling stockholder may offer all or some of the shares pursuant to this offering, we cannot estimate the number of shares that will be held by the selling stockholders after completion of the offering. However, for purposes of this table, we have assumed that after completion of the offering, none of the shares included in and covered by this prospectus will be held by the selling stockholder.
- (2) Irving Applebaum has voting and dispositive control over the shares held by Applebaum Family LTD Partnership.
- (3) Jacob Gottlieb and Dmitry Balyasny have voting and dispositive control over the shares held by Atlas Equity I, LTD.
- (4) Includes 32,144 shares of common stock issuable upon exercise of a warrant.
- (5) Eileen Y. Bertsch has voting and dispositive control over the shares held by Eileen Y. Bertsch Trust.
- (6) Includes 19,047 shares of common stock held by the selling stockholder's spouse, Barbara Bissaillon, as to which the selling stockholder disclaims beneficial ownership.
- (7) Robert L. DeBruyn has voting and dispositive power over the shares held by Robert L. DeBruyn Trust UAD 10/5/94.
- (8) Tracey H. DeBruyn has voting and dispositive power over the shares held by Tracey H. DeBruyn Trust UAD 10/5/94.
- (9) Steven Derby has voting and dispositive power over the shares held by SDS Capital Group SPC, Ltd.
- (10) Lloyd B. Embry and Kay T. Embry have voting and dispositive power over the shares held by the Embry Family Living Trust.
- (11) Includes 21,429 shares of common stock issuable upon exercise of a warrant.
- (12) Includes 32,144 shares of common stock issuable upon the exercise of a warrant. B. Kent Gallinghouse has voting and dispositive power over the shares held by Shadow Capital LLC.
- (13) Jay Goldman has voting and dispositive power over the shares held by The Ingrates Restated Profit Sharing Retirement Plan.
- (14) Michael Ragins and Evan Greenberg have voting and dispositive power over the shares held by Meadowbrook Opportunity Fund LLC.

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- (15) Thomas A. Heirigs identified himself as an affiliate of Taglich Brothers, Inc., a registered broker-dealer. Dr. Heirigs acquired the shares in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.
- (16) Ronald C. Hintz has voting and dispositive power over the shares held by SEP FBO Ronald C. Hintz Pershing LLC as Custodian.
- (17) Joshua Silverman has voting and dispositive power of the shares held by Iroquois Capital LP.
- (18) Michael C. James has voting and dispositive power over the shares held by KueKenhof Equity Fund, L.P.
- (19) Includes 21,429 shares of common stock issuable upon exercise of a warrant.
- (20) Richard A. Kraemer has voting and dispositive control over the shares held by Richard A. Kraemer Trust UAD 12/23/96.
- (21) Shirley J. Lewis and Guy W. Lewis have voting and dispositive power over the shares held by The Shirley J. Lewis Rev Trust UA DTD 6/26/01.
- (22) Brady T. Lipp has voting and dispositive control over the shares held by Akros Capital Fund, L.P. Akros Capital Fund, L.P. is an affiliate of Jesup & Lamont, a registered broker-dealer. Akros Capital Fund, L.P. acquired the shares in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.
- (23) Samuel E. Leonard has voting and dispositive power over the shares held by IRA FBO Samuel E. Leonard Pershing LLC as Custodian Roth Account.
- (24) Rosalie A. Naser has voting and dispositive control over the shares held by Rosalie A. Naser, Revocable Living Trust 11/3/99.
- (25) L. Mark Newman has voting and dispositive control over the shares held by Atalanta Selective Fund #6.
- (26) L. Mark Newman has voting and dispositive control over the shares held by Highland Avenue Partners LLC.
- (27) Includes 10,715 shares of common stock issuable upon exercise of a warrant.
- (28) Includes 10,715 shares of common stock issuable upon exercise of a warrant.
- (29) Sara J. Penn has voting and dispositive control over the shares held by Sara Bower Penn Living Trust DTD 4/30/02.
- (30) Norman Perry has voting and dispositive control over the shares held by Norper Investments.
- (31) John J. Resich, Jr. has voting and dispositive control over the shares held by John J. Resich Jr. Retirement Trust.
- (32) J. Michael Reisert has voting and dispositive control over the shares held by J. Michael Reisert Inc.
- (33) David Frank Rios and Margaret Jo Rios have voting and dispositive control over the shares held by David Frank Rios and Margaret Jo Rios Trust DTD 6/22/99.
- (34) Teena Lerner has voting and dispositive power over the shares held by Rx Healthcare Partners I LP, Rx Healthcare Partners II LP, and Rx Healthcare Overseas Fund.
- (35) Starr F. Schlobohm has voting and dispositive power over the shares held by Starr F. Schlobohm Revocable Trust.
- (36) Thomas A. Prendergast has voting and dispositive control over the shares held by Scot Holding Inc.
- (37) Includes 25,000 shares of common stock issuable upon exercise of a warrant. Peter E. Salas has voting and dispositive control over the shares held by Dolphin Offshore Partners, L.P.
- (38) Nina B. Sando and John W. McNeil have voting and dispositive control over the shares held by Special Trust for Nina B. Sando UA 3/20/87.
- (39) Richard F. Sherman has voting and dispositive power over the shares held by RFS Trust U/A/D 12/30/96.
- (40) Gregory E. Spahr and M. Jennifer Derebery have voting and dispositive control over the shares held by Spahr-Derebery Family Trust UA/D 10/11/90.
- (41) Terry Thuemling has voting and dispositive power over the shares held by Pension Inc. Trustee FBO Thuemling Industrial Products Inc. Profit Sharing Plan.
- (42) Robert D. Van Roijen, Jr. has voting and dispositive power over the shares held by Robert D. Van Roijen Jr. Trust UA DTD 12/14/82.
- (43) Robert D. Van Roijen, Jr. has voting and dispositive power over the shares held by Patience Partners LP.
- (44) Patsy Ann Waggoner has voting and dispositive power over the shares held by The Thomas J Waggoner Marital Trust.

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- (45) Dean Weinberg and Michael Weinberg have voting and dispositive control over the shares held by D & M Partnership. Dean Weinberg identified himself as an affiliate of JPMorgan Chase & Co., a registered broker-dealer. Mr. Weinberg acquired the shares in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.
- (46) James Wilen has voting and dispositive control over the shares held by Northridge Partners.
- (47) John R. Worthington has voting and dispositive control over the shares held by John R. Worthington Trust UA 3/28/00.
- (48) Consists of warrants to purchase an aggregate of 7,000 shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Michael Taglich and Robert Schroeder are members of the board of directors of SCOLR Pharma and are also affiliates of Taglich Brothers, Inc. Mr. Taglich and Richard C. Oh have voting and dispositive power over the shares held by Taglich Brothers, Inc.
- (49) Consists of 92,755 shares of common stock issuable upon exercise of warrants. Mr. Hailey, an employee of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.
- (50) Consists of 111,957 shares of common stock issuable upon exercise of warrants and 56,250 shares of common stock issuable upon exercise of stock options. Mr. Schroeder, an affiliate of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Mr. Schroeder is currently a member of the board of directors of SCOLR Pharma but he will not stand for re election at our 2005 annual meeting of stockholders.
- (51) Includes 16,500 shares of common stock issuable upon exercise of warrants. Mr. Bernier, an employee of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.
- (52) Consists of 39,987 shares of common stock issuable upon exercise of warrants. Mr. Brunone, an employee of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.
- (53) Consists of 8,000 shares of common stock issuable upon exercise of warrants. Mr. Palmieri, an employee of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.

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- (54) Consists of 9,187 shares of common stock issuable upon exercise of warrants. Mr. Oh, an employee of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.
- (55) Includes 162,788 shares of common stock issuable upon exercise of warrants and 68,950 shares of common stock issuable upon exercise of stock options. Michael N. Taglich, an employee of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Mr. Taglich is a member of the board of directors of SCOLR Pharma.
- (56) Includes 159,780 shares of common stock issuable upon exercise of warrants. Robert F. Taglich, an employee of Taglich Brothers, Inc., received these warrants to purchase shares of our common stock from Taglich Brothers, Inc. in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares. Taglich Brothers, Inc. is a registered broker-dealer. Taglich Brothers, Inc. acquired these securities as compensation for its services as placement agent in the ordinary course of business and, at the time of acquisition, did not have any plans or proposals, directly or with another person, to distribute the shares.



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**PLAN OF DISTRIBUTION**

We are registering 3,825,000 shares of our common stock on behalf of the selling stockholders. As used in this prospectus, selling stockholders includes the selling stockholders (including certain current and former service providers who hold warrants to purchase shares of our common stock) named in the table below and pledgees, donees, transferees or other successors-in-interest selling shares received from a named selling stockholder as a gift, partnership distribution or other non-sale-related transfer after the date of this prospectus. The selling stockholders may sell the shares from time to time and may also decide not to sell all the shares they are allowed to sell under this prospectus. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The sales may be made on one or more exchanges or in the over-the-counter market or otherwise and in one or more transactions. The shares may be sold by one or more of the following methods:

a block trade in which the broker-dealer so engaged will attempt to sell shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

on the American Stock Exchange or on such other markets on which our common stock may from time to time be trading;

in privately-negotiated transactions;

through the writing of options on the shares of common stock, short sales or any combination the two; or

any combination of the foregoing, or any other available means allowable under law.

The selling stockholders may sell at market prices at the time of sale, at prices related to the market price or at negotiated prices. It is possible that the selling stockholders will attempt to sell shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the then current market price. The selling stockholders may also resell all or a portion of their shares in open market transactions in reliance upon available exemptions under the Securities Act, such as Rule 144, provided they meet the requirements of these exemptions. Some or all of the shares of common stock issuable upon exercise of warrants may not be issued to, or sold by, the selling stockholders.

Alternatively, the selling stockholders may from time to time offer shares through brokers, dealers or agents. Brokers, dealers, agents or underwriters participating in transactions may receive compensation in the form of discounts, concessions or commissions from the selling stockholders (and, if it acts as agent for the purchaser of the shares, from that purchaser). The discounts, concessions or commissions might be in excess of those customary in the type of transaction involved.

The shares may be sold by selling stockholders only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states the shares may not be sold unless the shares have been registered or qualified for sale in that state or an exemption from registration or qualification is available and is complied with.

We have agreed to pay the costs and expenses of registering the shares under the Securities Act, including registration and filing fees, printing expenses, administrative expenses, legal fees and accounting fees. If the shares are sold through underwriters or broker-dealers, the selling

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stockholders will be responsible for underwriting discounts, underwriting commissions and agent commissions.

We have agreed to indemnify certain of the selling stockholders against liabilities they may incur because of an untrue or alleged untrue statement of a material fact contained in this prospectus or the omission or alleged omission to state in the prospectus a material fact required to be contained in the prospectus, or necessary to make the statements in this prospectus not misleading. However, we shall not be required to indemnify the selling stockholders for liabilities that we incur based on our reliance on written information that the selling

## **Table of Contents**

stockholders have furnished to us expressly for use in this prospectus. Likewise, certain of the selling stockholders have agreed to indemnify us against liabilities that we incur as a result of any statement or omission made in this prospectus based on written information that the selling stockholders have provided to us expressly for use in this prospectus. No selling stockholder, however, will be liable to us for amounts in excess of the net proceeds that such selling stockholder receives from the sale of its shares pursuant to this prospectus.

The selling stockholders and any brokers, dealers or agents, upon effecting the sale of any of the shares of common stock, may be deemed to be underwriters as that term is defined under the Securities Act or the Exchange Act. In addition, the selling stockholders and any other persons participating in the sale or distribution of the shares of common stock will be subject to applicable provisions of the Exchange Act. These provisions may limit the timing of purchases and sales of any of common stock by the selling stockholders or any other such person. The foregoing may affect the marketability of the shares of our common stock. Any profits on the sale of the common stock by the selling stockholders and any discounts, commissions or concessions received by any such broker-dealers or agents might be deemed to be underwriting discounts and commissions under the Securities Act. The Exchange Act rules include, without limitation, Regulation M, which may limit the timing of purchases and sales of any of the common stock by the selling stockholders and any other such person. In addition, Regulation M may restrict the ability of any person engaged in the distribution of the common stock to engage in market-making activities with respect to our common stock for a period of up to five business days prior to the commencement of distribution. This may affect the marketability of the common stock and the ability of any person or entity to engage in market-making activities with respect to the common stock. Because selling stockholders may be deemed to be underwriters within the meaning of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act.

We have agreed to keep the registration statement, of which this prospectus constitutes a part, effective until the earliest of (i) the date when the selling stockholders have resold all of the shares, (ii) the date on which the selling stockholders may sell all of the shares pursuant to Rule 144(k) of the Securities Act, or (iii) February 8, 2008.

We may suspend the use of this prospectus if we learn of any event that causes this prospectus to include an untrue statement of material fact or omit to state a material fact required to be stated in the prospectus or necessary to make the statements in the prospectus not misleading in light of the circumstances then existing. If this type of event occurs, a prospectus supplement or post-effective amendment, if required, will be distributed to the selling stockholders.

## **USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of the shares by any of the selling stockholders, but we will receive up to \$375,000 in proceeds from the exercise of the warrants, if exercised for cash. We will use the proceeds received from the exercise of the warrants, if any, for research and development in our drug delivery business, working capital and general corporate purposes.

## **LEGAL MATTERS**

DLA Piper Rudnick Gray Cary US LLP, will issue a legal opinion as to the validity of the issuance of the shares of common stock offered under this prospectus.

## **EXPERTS**

The financial statements and schedules incorporated by reference in this prospectus and elsewhere in the registration statement have been audited by Grant Thornton LLP, independent registered public accountants, as indicated in their report with respect thereto, and are included herein in reliance upon the authority of said firm as experts in auditing and accounting.

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We have not authorized any person to make a statement that differs from what is in this prospectus. If any person does make a statement that differs from what is in this prospectus, you should not rely on it. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state in which the offer or sale is not permitted. The information in this prospectus is complete and accurate as of its date, but the information may change after that date.

**SCOLR Pharma, Inc.**

**3,825,000 Shares of Common Stock**

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**Prospectus**

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April , 2005

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**Table of Contents****PART II****INFORMATION NOT REQUIRED IN THE PROSPECTUS****ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

The following table sets forth our estimated costs and expenses in connection with the sale and distribution of the securities being registered, other than underwriting commissions and discounts, if any. All of the amounts shown are estimates except the Securities and Exchange Commission registration fees.

	<b>To be Paid by the Registrant</b>
	<u>                    </u>
SEC registration fee	\$ 2,143
AMEX registration fee	\$ 45,000
Legal fees and expenses	\$ 30,000
Accounting fees and expenses	\$ 3,000
Transfer agent's fees	\$ 2,000
Miscellaneous fees and expenses	\$ 10,000
	<u>                    </u>
<b>Total</b>	<b>\$ 92,143</b>

**ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

Our certificate of incorporation provides that our directors shall not be personally liable for breach of her or his fiduciary duty unless the breach involves: (i) the director's duty of loyalty to us or our stockholders; (ii) acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; (iii) acts or omissions in respect of certain unlawful dividend payments or stock redemptions or repurchases; or (iv) any transaction from which such director derives improper personal benefit.

The effect of this provision is to eliminate our rights and the rights of our stockholders through stockholders' derivative suits on our behalf, to recover monetary damages against a director for breach of her or his fiduciary duty of care as a director including breaches resulting from negligent or grossly negligent behavior except in the situations described in clauses (i) through (iv) above. The limitations summarized above, however, do not affect our or our stockholders' ability to seek non-monetary remedies, such as an injunction or rescission, against a director for breach of her or his fiduciary duty.

Our bylaws require us to indemnify and hold harmless certain persons from personal liability incurred as a result of their position with us or certain other entities. This provision extends to our current and former directors and officers and persons serving other entities on our behalf. The provision requires us to indemnify such persons to the full extent authorized by the Delaware General Corporation Law (the "General Corporation Law").

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Section 145 of the General Corporation Law generally permits a company to indemnify an officer or director who was or is a party or is threatened to be made a party to any proceeding because of his or her position with the company. However, such indemnification is permitted only if the officer or director acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of such company and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

We maintain a directors and officers liability insurance policy covering certain liabilities that may be incurred by our directors and officers in connection with the performance of their duties. The entire premium for such insurance is paid by us.

See also the undertakings set out in response to Item 17 herein.

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**Table of Contents****ITEM 16. EXHIBITS**

The following exhibits are filed with this registration statement.

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
4.1	Certificate of Incorporation of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	8/13/2004
4.2	Certificate of designation of Series A Junior Participating Preferred Stock		8-K	1.1	000-24693	11/6/2002
4.3	Rights Agreement, dated as of November 1, 2002, by and between SCOLR, Inc. and OTR, Inc.		8-K	1.1	000-24693	11/6/2002
4.4	Bylaws of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	5/17/2004
4.5	Form of Common Stock Purchase Warrant		8-K	4.1	001-31982	2/11/2005
4.6	Common Stock Purchase Agreement, dated as of February 8, 2005, by and between SCOLR Pharma, Inc. and the Purchasers listed therein		8-K	10.1	001-31982	2/11/2005
4.7	Registration Rights Agreement, dated as of February 8, 2005, by and among SCOLR Pharma, Inc. and the Purchasers listed therein		8-K	10.2	001-31982	2/11/2005
5.1	Opinion of DLA Piper Rudnick Gray Cary US LLP	X				
23.1	Consent of Grant Thornton LLP	X				
23.2	Consent of DLA Piper Rudnick Gray Cary US LLP (included in Exhibit 5.1)	X				
24.1	Power of Attorney (previously filed)					

**ITEM 17. UNDERTAKINGS**

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the Securities Act);

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be



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reflected in the form of prospectus filed with the Securities and Exchange Commission (the Commission ) pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

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(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however*, that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is included in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ), that are incorporated by reference in this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein and the offering of such securities at the time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification by the Registrant for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the referenced in Item 15 of this registration statement, or otherwise, the Registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.



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/s/ MICHAEL N. TAGLICH\*

Director

April 8, 2005

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**Michael N. Taglich**

\*By:

/s/ DANIEL O. WILDS  
**Daniel O. Wilds**

**Attorney-in-Fact**

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**Table of Contents****INDEX TO EXHIBITS**

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