

SCOLR INC  
Form S-3  
March 26, 2004

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As filed with the Securities and Exchange Commission on March 26, 2004

Registration No.

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**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**Form S-3**

**REGISTRATION STATEMENT**

**UNDER  
THE SECURITIES ACT OF 1933**

**SCOLR, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State of Incorporation)*

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

**3625 - 132nd Avenue Southeast**

**Bellevue, Washington 98006  
(425) 373-0171**

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

**Daniel O. Wilds, President & Chief Executive Officer  
SCOLR, Inc.  
3625 - 132nd Avenue Southeast  
Bellevue, Washington 98006  
(425) 373-0171**

*(Name, address, including zip code, and telephone  
number, including area code,  
of agent for service)*

*Copies to:*  
**Alan M. Mitchel, Esq.  
Gray Cary Ware & Freidenrich LLP  
701 Fifth Avenue, Suite 7000  
Seattle, WA 98104-7044  
(206) 839-4880**

**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.

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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.

### CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value \$0.001 per share	4,308,388(1)	\$3.38(2)	\$14,562,351(2)	\$1,846(2)

- (1) Includes 1,046,733 shares of common stock issuable upon exercise of outstanding warrants as described in the prospectus. This registration statement also includes an indeterminate number of shares of common stock which may be issued pursuant to the antidilution provisions of warrants held by selling stockholders.
- (2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c). Represents the average of the high and low sales prices of our common stock for March 22, 2004 as reported on the American Stock Exchange.

**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 incomplete and may be changed. The selling stockholders 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.

**SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2004**

**PROSPECTUS**

# **SCOLR, Inc.**

## **4,308,388 Shares of Common Stock**

This prospectus relates to 4,308,388 shares of our common stock that may be sold by the selling stockholders named in the prospectus. 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 \$4,972,171 in proceeds from the exercise of warrants prior to the sale of the underlying shares by the selling stockholders.

Our common stock is traded on the American Stock Exchange under the symbol DDD. On March 24, 2004, the last reported sale price of our common stock on the American Stock Exchange was \$3.40 per share.

Our principal executive offices are located at 3625 - 132nd Avenue Southeast, 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. See Risk Factors beginning on page 9.**

**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 \_\_\_\_\_, 2004.

You should rely only on the information contained or incorporated in this prospectus. We and the selling stockholders have not authorized anyone to provide you with information different from that contained or incorporated in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. 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, Inc.

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SCOLR, Inc. s executive offices are located at 3625 - 132nd Avenue SE, Bellevue, Washington 98006. Our telephone number is (425) 373-0171 and our Internet address is [www.scolr.com](http://www.scolr.com). The information on our Internet website is not incorporated by reference in this prospectus.

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**SUMMARY**

Because this is a summary, it does not contain all the information about us that may be important to you. You should read the more detailed information set forth in other sections of this prospectus, as well as the information, financial statements and related notes that are incorporated by reference in this prospectus. You should also carefully consider the factors described under "Risk Factors" beginning at page 5.

**Strategy and Recent Developments**

We are a drug delivery company that develops and formulates over-the-counter products, prescription drugs and nutraceutical products that use our patented Controlled Delivery Technology (CDT®).

Over the last few years, we have engaged in the drug delivery business as well as a probiotics business in which we formulated and manufactured nutraceutical-based health and dietary supplements for both the animal and human nutrition markets. Since 2001, we have taken steps to transform our business from a nutraceutical company specializing in probiotic formulations to a company concentrating primarily on developing and commercializing drug delivery technology. The purpose of this transition was to allow us to take advantage of the perceived long-term growth potential and prospects associated with our CDT technology. The transition to a focused drug delivery business culminated with the sale of our probiotics business, effective as of December 31, 2003.

Since 2002 we have achieved critical milestones and invested significant resources in our CDT technology (including \$2,048,155 during 2002 and \$2,176,018 during 2003), bringing us closer to our goal of becoming a focused drug delivery company. Most notably:

We successfully conducted proof-of-concept experiments that established the viability of our patented drug delivery concept.

In October 2002, we completed an in-vivo/in-vitro correlation, our first human clinical trial, establishing that results achieved in the test tube were achievable in human patients.

In November 2002, we presented the results of our clinical trial to the pharmaceutical industry at the annual meeting of the American Association of Pharmaceutical Scientists (AAPS).

In collaboration with the inventor, we developed technology embodied in the first CDT patent owned exclusively by us. Designed as a simpler solution to certain difficult formulation issues, this technology extends our capabilities to include poorly soluble drugs which are difficult and costly to formulate and produce with currently available manufacturing techniques and processes.

We changed our name to SCOLR, Inc. SCOLR is an acronym for our lead technology: Self Correcting Oral Linear Release systems.

Archer-Daniels-Midland introduced NovaSoy® Daily Dose™, the first ADM product to include our CDT technology, to the European markets in October 2002. This once-a-day supplement provides delivery of natural based soy isoflavones (a phytoestrogen) throughout the day. NovaSoy Daily Dose generated revenue of \$195,788 in 2003.

During the first quarter of 2003, our first commercial CDT product, Once Daily Glucosamine & Chondroitin, was introduced to the U.S. nutraceutical industry. Our CDT Glucosamine & Chondroitin product is currently available nationwide in more than 8,000 retail outlets, including Wal Mart (under the Spring Valley label), Trader Joe's (under the Trader Darwin's label), and Rite Aid stores. In addition, GNC introduced its first two products which include our CDT technology in early 2004.

We realized our first CDT royalty revenues of \$582,953 in 2003. We expect these revenues to increase in 2004.

In June 2003, we completed a \$5.3 million financing of convertible notes. The notes were converted into 5,047,559 shares of common stock effective December 15, 2003.

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In August 2003, we entered into an evaluation agreement for drug delivery systems with a Fortune 100 technology based company. Pursuant to this agreement we will work together to identify potential opportunities where our technology might complement our client's offerings and potentially accelerate introduction of our CDT platform into the pharmaceutical market.

In November 2003, we received payment and a letter of acceptance for completion of a feasibility study for the first molecule identified under the evaluation agreement with the Fortune 100 client. We are currently negotiating the second stage of development, under which we would work to advance the commercialization of the molecule utilizing our CDT platform. We have also held discussions with this client to initiate work on several other candidate compounds.

Primarily as a result of our presentation and introductions at the AAPS meeting in November 2003, we have completed follow-up meetings with several of the largest multinational pharmaceutical companies. Our goal is to secure licensing agreements and/or strategic alliances with corporate partners to develop new and innovative CDT products for the marketplace.

We completed the sale of our probiotics development and manufacturing assets as of December 31, 2003.

In January 2004, we commenced an internal development program targeting select major existing drugs for reformulation using our CDT platform. We commenced an in vivo animal study for the first candidate drug in February of 2004.

In February 2004, we completed a private placement of 3,206,538 shares of our common stock at a price of \$3.25 per share and gross proceeds of approximately \$10.4 million. The purchasers also received five year warrants to purchase 801,636 shares of common stock at an exercise price of \$4.75 per share.

**Business**

Our business is centered around the development and licensing of our Controlled Delivery Technology. Our CDT system currently consists of three patented drug delivery platforms for prescription drugs, over-the-counter (OTC) products, and nutraceuticals. The basis of these platforms is technology embodied in two issued U.S. patents licensed exclusively to us by Temple University, and a third issued U.S. patent assigned to us by Dr. Reza Fassihi.

Dr. Fassihi is 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 drugs, OTC products and dietary supplements that use the delivery system concepts embodied in the three CDT patents. Dr. Fassihi was appointed to our board of directors in November 2003.

The CDT system is used in solid oral dosage forms, the preferred route for drug administration. This technology is designed to produce 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 existing pharmaceutical, OTC and nutraceutical products.

For many reasons, pharmaceutical companies increasingly prefer controlled release rather than immediate release of the active agent in their drugs. We believe the advantages of controlled drug delivery typically include improved patient compliance, product differentiation, greater efficacy, and an improved safety profile.

Our proprietary CDT technology improves upon conventional multiple daily dose immediate release forms of existing products by providing the therapeutic benefits of controlled release drug delivery. In addition, we believe our technology can provide enhanced dosage formats for existing medications that provide superior patient convenience and product differentiation.

A technology such as CDT may also allow pharmaceutical companies to reformulate existing drugs, thereby improving product release profiles and defending important revenue streams, particularly for existing blockbuster drugs nearing patent expiration.

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We believe our CDT drug delivery technology enjoys many competitive advantages when compared to other controlled delivery methodologies. Our CDT technology is a robust and simple technology that allows for low cost manufacturing (using conventional blending and compression equipment in a two-step process). It can deliver comparatively high therapeutic payloads of active ingredient. It is also highly programmable to deliver active therapeutic agents over a wide range of release profiles and timeframes.

A critical part of our strategy is to enter into various collaborative arrangements and alliances with corporate partners, licensors and licensees to provide funding for the research, development, clinical testing, manufacturing, marketing and commercialization of our product candidates. In March 2002, we entered a global strategic alliance with Archer-Daniels-Midland Company for the development of certain CDT-based dietary supplement and nutraceutical products. In August 2003, we entered into an evaluation agreement for drug delivery systems with a Fortune 100 technology based company. Pursuant to this agreement we are working together to identify potential opportunities where our technology might complement our client's offering and potentially accelerating introduction of our CDT platform into the pharmaceutical market.

Following the recent successful completion of our CDT proof-of-concept human clinical trial, we have received expressions of interest from several of the largest pharmaceutical companies. Virtually all of these potential licensing partners currently have prescription drug franchises for which they are seeking technological enhancements (such as CDT) to extend the life of those franchises in the face of core patent expirations over the next 5-10 years. In our active pursuit of collaborations with these pharmaceutical companies, we are seeking upfront licensing fees, royalty payments, and milestone payments for the use of our CDT technology.

Our drug delivery business has begun generating revenue from CDT-based sales to the dietary supplement markets. These sales are being generated through existing relationships with retailers such as Wal-Mart, Rite-Aid, Trader Joe's and the General Nutrition Center. We expect to realize increased royalty income from the initial CDT dietary supplement and OTC formulations in 2004. We do not expect royalty income from CDT prescription drugs earlier than 2007.

### **Recent Transactions    Common Stock Financing**

In February 2004, we completed a \$10.4 million financing of our common stock. The financing included the sale of 3,206,538 shares of our common stock at a purchase price of \$3.25 per share, along with the issuance of five-year warrants to purchase up to an aggregate of 801,636 shares of our common stock. The warrants have an exercise price of \$4.75 per share. The transaction provided us with approximately \$9.4 million in net proceeds. We will receive up to an additional \$4,972,171 in proceeds from the exercise of warrants. The issued shares of common stock and the shares of common stock issuable upon exercise of the warrants are included in this prospectus.

In consideration of certain placement services, we paid a cash fee of approximately \$729,487 and issued warrants to purchase up to 224,458 shares of common stock at an exercise price of \$4.75 per share. In addition, we issued (i) 32,000 shares of common stock and a warrant to purchase 15,000 shares of common stock to an unaffiliated thirty party as a finder's fee, and (ii) 23,077 shares of common stock and warrants to purchase 5,679 shares of common stock to Rostrevor Partners in partial payment of its advisory fee in connection with the sale of our probiotics division. The issued shares of common stock and the shares of common stock issuable upon exercise of the warrants are included in this prospectus.

### **The Offering**

This prospectus relates to the resale of an aggregate of 4,308,388 shares of common stock, which were issued, or are issuable, by us as follows:

3,261,615 shares of outstanding common stock.

1,046,773 shares of common stock issuable upon exercise of warrants exercisable at \$4.75 per share.



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As of March 24, 2004, we had 50,000,000 shares of our common stock authorized. Of this number, 30,089,296 shares were issued and outstanding, and an additional 1,046,773 shares were issuable upon exercise of the warrants included in this prospectus.

The number of shares offered by this prospectus represents approximately 14% of the total common stock outstanding as of March 25, 2004, assuming full exercise of the warrants. The number of shares ultimately offered for sale by the selling stockholders is dependent upon the number of warrants exercised, and whether the selling stockholders decide to sell their shares.

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**RISK FACTORS**

**The shares of common stock offered by this prospectus are highly speculative and 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 and expect to continue to incur substantial losses.**

We had a net loss of \$8,742,536 and \$2,661,152 for the years ended December 31, 2003 and December 31, 2002, respectively;

We used cash from operations of \$2,830,620 and \$960,207 in 2003 and 2002, respectively;

We had an accumulated deficit of \$21,676,704 at December 31, 2003;

We expect to incur capital expenditures of \$750,000 (including equipment and patent and trademark expenses) during 2004; and

We expect to continue to incur significant operating losses as a result of research and development expenses associated with our drug delivery business.

**We will require additional financing to develop our drug delivery operations.**

With the proceeds of our recently completed \$10.4 million common stock financing, we anticipate that we will be able to fund our drug delivery business at planned levels and have the resources to seek collaborative research projects through 2005. Our ability to develop the drug delivery business will depend upon many factors, including:

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

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

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

To some extent, the timing and amount of our research and development spending is discretionary and subject to the availability of appropriate opportunities and funding.

Our anticipated cash expenditures and need for capital also assume that our revenues are not adversely affected by the other factors set forth in this Risk Factors section.

**If we are unable to obtain additional financing, we will have to curtail our business operations and research and development programs and alter our business model.**

Our long term financing needs depend largely on our ability to enter into alliances and collaborations that will help finance our drug delivery business. We will be required to fund research and development costs to create an effective in-house drug delivery development unit. Additionally, we will need to fund the significant costs associated with the research and development and commercialization of a drug delivery product. If we are unable to find a partner to share or subsidize these costs for a given product, we will need to raise substantial additional financing to fund these efforts on our own.

Additional financing may be unavailable to us on acceptable terms. If adequate funds are unavailable, we may be unable to meet our obligations. Our inability to raise additional capital would require us to delay, reduce or eliminate some of our business operations, including the pursuit of licensing, strategic alliances and development of our drug delivery business.

If we raise additional capital by issuing equity securities, further dilution to our stockholders will result. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. If we raise additional funds through strategic alliance and licensing arrangements, we may be required to relinquish



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rights to certain of our technologies or product candidates, or to grant licenses on terms that are unfavorable to us. Either of these results could reduce our value.

### **Our strategy to focus on our drug delivery business is very risky and may result in the loss of your investment.**

While we believe our CDT business has good prospects for growth, it is essentially a startup, high-risk business that is not expected to produce any substantial revenue or profits for some time, if ever. Developing drug delivery systems and drugs using our CDT technology is extremely expensive, and taking a single product to market takes years to complete. We may not be able to achieve profitability in a timely manner, or at all.

### **We face intense competition in the drug delivery business, and our failure to compete effectively could severely limit our growth and potential.**

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. Such entities 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, Biovail, Labopharm, Penwest and Skyepharma. We recently learned that another manufacturer has introduced a controlled release version of glucosamine chondroitin which may compete with the product we sell to Walmart and Trader Joe's, among others.

### **If we are unsuccessful in entering beneficial collaborations or maintaining existing collaborations we will require substantial additional capital and we will be unable to execute our business plan.**

A critical part of our strategy is to enter into various collaborative arrangements and alliances with corporate and academic partners, licensors and licensees to provide funding for the research, development, clinical testing, manufacturing, marketing, and commercialization of our product candidates. Collaborations are essential as we require more financial and other resources for our drug delivery business. Currently all revenues from our drug delivery operations are the result of licensing agreements or similar collaborations.

Our success depends on our ability to develop new collaborator relationships and maintain our existing collaborations. If we cannot maintain our existing collaborations or establish new collaborations, we would be required to terminate the development of products or find alternative sources of funding. Moreover, we have no experience in conducting full scale clinical trials, preparing and submitting regulatory applications or manufacturing and selling pharmaceutical 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 attractive 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.

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 particular programs, which could delay or halt the development or commercialization of any product candidates arising out of such programs;

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;

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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.

We are highly dependent on our collaboration and consulting arrangements with Dr. Fassihi. We have a consulting agreement with Dr. Fassihi that expires in December 2006 but may be terminated by either party on 30-days notice. Our agreement with ADM terminates upon the expiration of the licensed patents. However, the agreement is subject to termination on short notice under certain circumstances if we breach the agreement or upon a bankruptcy event. We also work with a subsidiary of Royal Numico N.V. in connection with the manufacture and distribution of glucosamine and chondroitin to Walmart, Trader Joe's and Rite Aid. We are currently finalizing a written agreement with Royal Numico. If any of our existing collaborative arrangements are terminated, we may not be able to find new collaborative partners to replace them, and we may not be able to execute our business plan.

**Any failure to obtain and protect our intellectual property could adversely affect our business.**

Patent and trade secret protection is important to our business and our success will depend in part on our ability to obtain patents, maintain trade secret protection and operate without infringing on the rights of others. We own or have exclusive rights to several U.S. patents and patent applications. 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. Furthermore, our patent applications may not result in the issuance of patents. In addition, patents of others may impede our collaborators' ability to commercialize the technology covered by our owned or licensed patents. The cost of obtaining and protecting patents is substantial and could increase materially if we are involved in patent litigation. This potential cost could include the loss of revenue resulting from enjoining our manufacture and sale of existing or potential products. The issuance of a patent is inconclusive as to its validity or as to the enforceable scope of the claims of the patent. We cannot assure you that:

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

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.

Our business and financial results could be materially harmed if we fail to avoid infringement of the patent or proprietary rights of others or to protect our patent rights.

Part of our intellectual property is in the form of trade secrets and know-how and may not be protected by patents. We cannot assure you that we will be able to protect these rights. We require employees, consultants, advisors, and collaborators to enter into confidentiality agreements. However, these agreements may not provide meaningful protection for our trade secrets, know-how, or other proprietary information if any unauthorized use or disclosure occurs.

**Significant expenses in applying for patent protection and prosecuting our patent applications will increase our need for capital.**

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

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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 cannot retain key personnel, then our business will suffer.**

As a small company, the success of our operations will depend to a great extent on the collective experience, abilities and continued service of relatively few individuals. In particular, our success largely depends on our President and CEO, Daniel Wilds (who joined us in August 2003), our Vice President and Chief Technical Officer, Stephen Turner, and our CDT Consultant, Dr. Reza Fassihi. The loss of Mr. Wilds, Dr. Fassihi or Mr. Turner could adversely impact our ability to develop and commercialize our CDT technology. In addition, we depend on the continued availability of our Chairman, David T. Howard, who previously served as President and CEO. We do not have an employment agreement with Mr. Wilds. Our consulting agreement with Dr. Fassihi expires December 31, 2006 but may be terminated by either of us on 30-days notice. Our employment agreement with Mr. Turner has no set term and may be terminated by Mr. Turner on 30 days notice. 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, also, our ability to obtain additional financing. We do not carry life insurance on any of our employees. We are not aware of any key employees planning to leave or retire from the Company.

**If we cannot attract and retain the necessary personnel, our business will not be successful.**

Our success 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.

**If any of our products is deemed unsafe, our business could be materially harmed.**

With respect to the registration, approval, and commercialization of our CDT drug delivery technology, all analytic work completed to-date has involved in-vitro scientific studies and one proof-of-concept human clinical trial. Additional human clinical bioavailability and bioequivalence trials must be conducted to validate the asset value and commercial advantages associated with our CDT patents. Until such clinical trials are performed, we cannot assure you that the patented CDT technologies possess the necessary correlation between the available in-vitro analytic work and their performance in human subjects to become commercially viable technologies and products that are attractive to major pharmaceutical and OTC companies.

**Unfavorable publicity could materially hurt our business and the value of your investment.**

We believe that the nutritional supplement, OTC, and pharmaceutical markets are affected by national media attention regarding the consumption of dietary supplements, OTC products and prescription drugs. There can be no assurance that future scientific research or publicity will be favorable to these industries or any particular product, or consistent with earlier research or publicity. Future reports of research that are perceived less favorably or that question such earlier research could have a material adverse effect on us. Because of our dependence upon consumer perceptions, adverse publicity associated with illness or other adverse effects resulting from the consumption of our products or any similar products distributed by other companies could have a material adverse impact on us. Such adverse publicity could arise even if the adverse effects associated with such products resulted from failure to consume such products as directed. In addition, we may be unable to counter the effects of negative publicity concerning the efficacy of our products.

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### **Government regulators and regulations could adversely affect our ability to operate and grow.**

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 DEA, FDA, FTC and EPA) and in other countries.

The FDA regulates, to varying degrees and in different ways, dietary supplements and pharmaceutical products, including their manufacture, testing, exportation, labeling, and in some cases, advertising. We anticipate that any FDA testing and approvals of our products would be initiated as part of future collaborations with strategic partners.

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. Our bioequivalence, bioavailability, or clinical studies and other data may not result in FDA approval to market our new products. 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.

Many of our nutraceutical products, including our glucosamine & chondroitin and Novasoy Daily Dose products, are regulated under DSHEA (Dietary Supplement Health Education Act) regulations and contain ingredients that are Generally Regarded As Safe (G.R.A.S.) by the FDA and, therefore, do not currently require extended approvals. Recent legislation has resulted in a regulatory environment which sets what we consider to be reasonable limitations and guidelines on health claims and labeling for natural products and dietary supplements under the DSHEA. We may, however, be wrong in our belief that the current and foreseeable governmental regulation of dietary supplements, probiotics and animal nutrition products will have a minimal impact on our nutraceutical business.

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.

### **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

The recall or discontinuance of certain products unable to be reformulated

Imposition of additional record keeping requirements

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Expanded documentation of the properties of certain products

Expanded or different labeling, or scientific substantiation

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

**We will be adversely affected unless we properly manage our growth.**

We are in the process of significantly increasing spending on our drug delivery business. As part of this increased spending, we are adding numerous personnel, and several new research and development projects. Our rapid growth may strain our management team, production facilities, administrative capabilities, and other resources. In addition, we may be unable to effectively allocate our existing and future resources between our drug delivery and other businesses while maintaining focus on our core competencies. We cannot assure you that we will succeed in effectively managing our existing operations or our growth, which could adversely affect our financial performance.

**Unfavorable economic conditions could hinder the growth of our drug delivery business.**

Our success depends substantially on how our potential collaborators decide to spend their money. Potential collaborators for our drug delivery business may be hesitant to spend the funds necessary for new collaborations in an uncertain environment. The continuing war on terrorism, new terrorist attacks, actual or threatened, and related political events, are examples of events that may adversely impact the U.S. and international economic environment and our business.

**Our share price has fluctuated significantly and may be very volatile in the future.**

For the 52-week period ended March 24, 2004, the sale price of our common stock has ranged between a low of \$0.85 and a high of \$3.97.

In the future, our share price could be affected by a number of factors, including without limitation:

fluctuations in our operating results

changes in expectations as to our financial performance

increased competition

dilution from additional financings

In addition, the stock market, in general, has experienced volatility that often has been unrelated to the operating performance of particular companies. These broad market and industry fluctuations may adversely affect the trading price of our common stock regardless of our actual operating performance.

**Sales of our common stock by selling stockholders could have an adverse effect on the market price of our common stock.**

All of the outstanding shares of common stock included in this prospectus were sold in private placement transactions within the past year. Because these transactions were not registered under the Securities Act, these shares are considered restricted for purposes of said Act. Because the issuance of the warrants was also not registered, the shares issuable upon warrant exercise will also be deemed restricted upon issuance. Because these securities have been held less than one year, these securities and the underlying shares are not eligible for public resale under Rule 144 promulgated under the Securities Act. By including the shares in this prospectus, we are significantly enhancing these stockholders ability to sell the outstanding shares and shares underlying the warrants. This prospectus covers the sale of up to 4,308,388 shares. The average daily trading volume of our common stock during the three-month period ended February 27, 2004 was approximately 101,000 shares. 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.



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Our stockholders may experience further dilution if we raise additional funds through the sale of equity securities. The risk of dilution may cause our stockholders to sell their shares, which may cause a decline in the price of our common stock.

The risk of dilution and the resulting downward pressure on our stock price could encourage investors to engage in short sales of our common stock. Our stockholders may also engage in short sales or other hedging transactions to limit their exposure to downward movement in our stock price. 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.

### **The value of your investment may be reduced by our nonpayment of dividends.**

We have never paid any cash dividends on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on the common stock by us will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant.

### **Provisions in our charter documents could prevent or frustrate any attempts to replace our current management by stockholders.**

Our certificate of incorporation and bylaws contain provisions, such as undesignated preferred stock and prohibitions on cumulative voting in the election of directors, which could make it more difficult for a third party to acquire us without the consent of our board of directors. Our certificate of incorporation contains provisions having anti-takeover effects, including the authorization of our board of directors to issue up to 50,000,000 shares of common stock and up to 5,000,000 shares of preferred stock with such voting powers, designations, preferences and relative participating, optional or other special rights, and qualifications, or prescriptions as may be prescribed by the board of directors. The issuance of such common stock or preferred stock may be used by the board of directors to impede a party seeking to acquire control of us. Also, our bylaws provide for a staggered board. The staggered board protects directors of the classes not being elected in a proxy contest for control of the board and dilutes the ability of stockholders to influence corporate governance policies. These provisions may have the effect of preventing or hindering any attempts by our stockholders to replace our current management, even if such removal would be beneficial to stockholders generally.

### **Our stockholder rights plan may delay or prevent beneficial takeover bids by third parties, which could decrease the value of your investment.**

Our board of directors adopted a stockholders rights plan or poison pill in November 2002. The stockholders rights plan is intended to protect stockholders' interests in the event we are confronted with coercive or unfair takeover practices. The poison pill is triggered ten days after any person has become the beneficial owner of 15% or more of our outstanding stock. An acquirer who triggers the rights faces significant dilution of its interest in us. The stockholders rights plan may also impede a party seeking to acquire control of us. These provisions apply even if the offer may be considered beneficial by some stockholders. The anti-takeover provisions of our stockholder rights plan may entrench management and may delay or prevent beneficial takeover bids by third parties, which could decrease the value of your investment.

## **FORWARD LOOKING STATEMENTS**

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include statements regarding, among other things, (a) our expectations about product development activities, (b) our growth strategies, (c) anticipated trends in our industry, (d) our future financing plans, and (e) our anticipated needs for working capital. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words *may*, *will*, *should*, *expect*, *anticipate*, *estimate*, *intend*, or *project* or the negative of these words or other variations on these words or comparable terminology.

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Forward-looking statements may be found under Management's Discussion and Analysis or Plan of Operation and Description of Business in our Form 10-KSB for the year ended December 31, 2003 as well as in this prospectus generally.

Forward-looking statements may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. Actual events or results may differ as a result of various factors, including, without limitation, the risks outlined under Risk Factors beginning on page 8 and matters described in this prospectus generally. Because of these risks and uncertainties, the events anticipated in the forward-looking statements may not occur.

**USE OF PROCEEDS FROM EXERCISE OF WARRANTS**

We will not receive any proceeds from the sale of the shares pursuant to this prospectus.

We will receive up to \$4,972,171 in proceeds from the exercise of the warrants prior to the sale of the underlying shares by the selling stockholders pursuant to this prospectus. We intend to use such proceeds, if any, for research and development in our drug delivery business, working capital and general corporate purposes. The amount we receive depends on the number of warrants exercised.

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

The table below sets forth information concerning the resale by the selling stockholders of our common stock. Because the selling stockholders may sell all, a portion or none of their shares, no estimate can be made of the aggregate number of shares that may actually be sold by any selling stockholder or that may be subsequently owned by any selling stockholder.

The following table sets forth, to our knowledge, the following information with respect to each selling stockholder: the stockholder's name, the number of shares of common stock beneficially owned, the number of shares of common stock that may be sold in this offering, and the number of shares of common stock such stockholder will own after the offering, assuming he or she sells all of the shares offered.

<b>Stockholder's Name</b>	<b>Shares Owned Before Offering(1)</b>	<b>Shares Included in Prospectus(1)</b>	<b>% of Common Stock After Offering(1)*</b>	<b>Shares Owned After Offering(1)</b>
Alexandra Global Master Fund Ltd.(2)	0	387,500		0
Atlas Equity I, Ltd.(3)	0	384,616		0
Brunone, Michael R.	20,987	9,000		20,987
Cranshire Capital, L.P.(4)	0	192,308		0
Elliott Associates, L.P.(5)	0	76,923		0
Elliott International, L.P.(6)	0	115,385		0
Hailey, Douglas	75,159	8,846		75,159
Melo, Antonio	10,000	2,000		10,000
Oh, Richard C.	1,187	3,000		1,187
Omicron Master Trust(7)	0	288,461		0
Palmieri, Vincent	0	3,000		0
Portside Growth and Opportunity Fund(8)	0	192,308		0
RHP Master Fund, Ltd.(9)	0	96,154		0
Rodman & Renshaw, LLC(10)	0	170,612		0
Rostrevor Partners(11)	0	28,756		0
Schroeder, Robert	93,207	10,000		93,207
SF Capital Partners(12)	0	288,460		0
Spectra Capital Management, LLC(13)	0	96,154		0
SRG Capital, LLC(14)	0	115,385		0
Stetson, David L.	48,833	47,000		48,833
Tag/ Kent Partners(15)	0	50,000		0
Taglich, Michael N.(15)	411,737	71,039	1.4%	411,737
Taglich, Robert F.	319,637	21,000	1.1%	319,637
Topaz Partners(16)	0	769,231		0
Volman, Slava	26,950	43,750		26,950
Dolphin Offshore Partners, L.P.(17)	500,000	125,000	1.7%	500,000
Interdynamic Fund Biomed Tech(18)	0	30,000		0
J. Michael Reisert Inc.(19)	0	12,500		0
Meadowbrook Opportunity Fund LLC(20)	0	125,000		0
Merlin Biomed II, L.P.(18)	0	47,500		0
Merlin Biomed International, Ltd.(18)	0	67,500		0
Merlin Biomed Longterm Appreciation Fund, L.P.(18)	0	105,000		0

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Stockholder's Name	Shares Owned Before Offering(1)	Shares Included in Prospectus(1)	% of Common Stock After Offering(1)*	Shares Owned After Offering(1)
Merlin Biomed Offshore Master Fund L.P.(18)	0	270,000		0
Merlin Biomed, L.P.(18)	0	105,000		0

## Notes

\* Unless otherwise listed, less than 1%.

- (1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any shares as to which the selling stockholder has sole or shared voting power or investment power and also any shares that the selling stockholder has the right to acquire within 60 days. The actual number of shares of common stock issuable upon the exercise of the warrants and upon the conversion of the notes is subject to adjustment depending on the occurrence of various events, and could materially depart from the number estimated in the table.
- (2) Alexandra Investment Management, LLC, a Delaware limited liability company ( Alexandra ), serves as investment adviser to Alexandra Global Master Fund Ltd., a British Virgin Islands company ( Master Fund ). By reason of such relationship, Alexandra may be deemed to share dispositive power over the shares of common stock stated as beneficially owned by Master Fund. Alexandra disclaims beneficial ownership of such shares of common stock. Messrs. Mikhail A. Filimonov ( Filimonov ) and Dimitri Sogoloff ( Sogoloff ) are managing members of Alexandra. By reason of such relationships, Filimonov and Sogoloff may be deemed to share dispositive power over the shares of common stock stated as beneficially owned by Master Fund. Filimonov and Sogoloff disclaim beneficial ownership of such shares of common stock.
- (3) Dmitry Balyasny, Managing Member of Balyasny Asset Management, L.P., Manager. Jacob Gottlieb also has voting and investment powers over the securities held of record.
- (4) Mitchell Kopin, President of Downview Capital Inc., the General Partner of Cranshire Capital, L.P. has sole voting and investment power.
- (5) The general partners of Elliott Associates, L.P. are Paul E. Singer and two entities controlled by him. Elliott Associates, L.P. and Elliott International, L.P. are under common control, and may be deemed to be a group.
- (6) The general partner and investment manager of Elliott International, L.P. are controlled by Paul E. Singer. Elliott Associates, L.P. and Elliott International, L.P. are under common control, and may be deemed to be a group.
- (7) Omicron Capital, L.P., a Delaware limited partnership ( Omicron Capital ), serves as investment manager to Omicron Master Trust, a trust formed under the laws of Bermuda ( Omicron ), Omicron Capital, Inc., a Delaware corporation ( OCI ), serves as general partner of Omicron Capital, and Winchester Global Trust Company Limited ( Winchester ) serves as the trustee of Omicron. By reason of such relationships, Omicron Capital and OCI may be deemed to share dispositive power over the shares of our common stock owned by Omicron, and Winchester may be deemed to share voting and dispositive power over the shares of our common stock owned by Omicron. Omicron Capital, OCI and Winchester disclaim beneficial ownership of such shares of our common stock. Omicron Capital has delegated authority from the board of directors of Winchester regarding the portfolio management decisions with respect to the shares of common stock owned by Omicron and, as of April 21, 2003, Mr. Olivier H. Morali and Mr. Bruce T. Bernstein, officers of OCI, have delegated authority from the board of directors of OCI regarding the portfolio management decisions of Omicron Capital with respect to the shares of common stock owned by Omicron. By reason of such delegated authority, Messrs. Morali and Bernstein may be deemed to share dispositive power over the shares of our common stock owned by Omicron. Messrs. Morali and Bernstein disclaim beneficial ownership of such shares of our common stock and neither of such persons has any legal right to maintain such delegated authority.

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No other person has sole or shared voting or dispositive power with respect to the shares of our common stock being offered by Omicron, as those terms are used for purposes under Regulation 13D-G of the Securities Exchange Act of 1934, as amended. Omicron and Winchester are not affiliates of one another, as that term is used for purposes of the Securities Exchange Act of 1934, as amended, or of any other person named in this prospectus as a selling stockholder. No person or group (as that term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, or the SEC's Regulation 13D-G) controls Omicron and Winchester.

- (8) The Investment Advisor to Portside Growth and Opportunity Fund is Ramius Capital Group, LLC. The Managing Member of Ramius Capital Group, LLC is C4S & Co., the Managing Members of which are Peter Cohen, Morgan Stark, Thomas Strauss and Jeffrey Solomon. As such, Messrs. Cohen, Stark, Strauss and Solomon may be deemed beneficial owners of the shares. Messrs. Cohen, Stark, Strauss and Solomon therefore disclaim beneficial ownership of such shares.
- (9) RHP Master Fund, Ltd. is a party to an investment management agreement with Rock Hill Investment Management, L.P., a limited partnership of which the general partner is RHP General Partner, LLC. Pursuant to such agreement, Rock Hill Investment Management directs the voting and disposition of shares owned by RHP Master Fund. Messrs. Wayne Bloch, Gary Kaminsky and Peter Lockhart own all of the interests in RHP General Partner. The aforementioned entities and individuals disclaim beneficial ownership of the Company's Common Stock owned by the RHP Master Fund.
- (10) Rodman & Renshaw served as a placement agent in the February 2004 financing.
- (11) Jonathan G. Morgan is the Managing Director and has voting and investment powers over the securities held of record.
- (12) Michael A. Roth and Brian J. Stark are the founding members and direct the management of Staro Asset Management, L.L.C., a Wisconsin limited liability company ( Staro ) which acts as investment manager and has sole power to direct the management of SF Capital Partners Ltd. Through Staro, Messrs. Roth and Stark possess sole voting and dispositive power over all of the shares owned by SF Capital Partners Ltd.
- (13) Gregory I. Porges holds voting and investment power over the securities held of record.
- (14) Edwin Mecabe jointly with Tai May Lee hold voting and investment power over the securities held of record.
- (15) Michael Taglich is the General Partner of Tag/ Kent Partners and is the brother of Robert F. Taglich. Ownership reported for Mr. Taglich includes securities owned by Tag/ Kent but does not include securities owned by Robert F. Taglich. However, Michael Taglich disclaims beneficial ownership of the common stock owned by Tag/ Kent Partners.
- (16) Herbert J. Marks and David Muschel hold voting and investment power over the securities held of record.
- (17) Peter E. Salas holds voting and investment power over the securities held of record.
- (18) Stuart T. Weisbrod holds voting and investment power over the securities held of record.
- (19) J. Michael Reisert holds voting and investment power over the securities held of record.
- (20) Evan Greenberg holds voting and investment power over the securities held of record.

Other than the persons listed below, the selling stockholders have not held any positions or offices or had material relationships with us or any of our affiliates within the past three years other than as a result of the ownership of our common stock. We may amend or supplement this prospectus, from time to time to update the disclosure.

The following persons have held positions or offices or had material relationships with us or our affiliates within the past three years:

Name	Relationship
Schroeder, Robert	Director and placement agent affiliate
Taglich, Michael	Director and placement agent affiliate



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Name	Relationship
Taglich, Robert	Placement agent affiliate
Rodman & Renshaw, LLC	Placement agent
Brunone, Michael	Placement agent affiliate
Palmieri, Vincent	Placement agent affiliate
Oh, Richard	Placement agent affiliate
Hailey, Douglas	Placement agent affiliate
Melo, Antonio	Placement agent affiliate
Rostrevor Partners	Financial advisor

In connection with the issuance of convertible notes in June 2003, we agreed to use our best efforts for three years to nominate and secure the election of a designee of Taglich Brothers to serve as a director on our board of directors, or at Taglich Brothers' discretion, permit a designee to attend board meetings as a non-voting observer. Mr. Michael Taglich is currently serving as the director designated by Taglich Brothers.

**PLAN OF DISTRIBUTION**

The selling stockholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

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

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. Each selling stockholder does not expect these commissions and discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions

they assume. The selling stockholders may



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also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities.

The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling stockholders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each selling stockholder has advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume limitations by reason of Rule 144(e) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to the prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

## **Expenses of the Distribution**

We will bear all of the costs and expenses of registering under the Securities Act the sale of shares of common stock offered by this prospectus. Commissions and discounts, if any, attributable to the sales of the common stock will be borne by the selling stockholders.

## **State Securities Laws**

To comply with the securities laws of various states, if applicable, sales of the common stock made in those states can only be made through registered or licensed brokers or dealers. In addition, some states do not allow the securities to be sold unless they have been registered or qualified for sale in the applicable state or an

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exemption from the registration or qualification requirement is available and is complied with by us and the selling stockholders. We will obtain such registrations or qualifications as are reasonably requested by the selling stockholders.

**LEGAL MATTERS**

The validity of the issuance of the common stock offered hereby will be passed upon for us by Gray Cary Ware & Freidenrich LLP, Seattle, Washington, as our counsel in connection with this offering.

**EXPERTS**

The financial statements incorporated in this prospectus by reference to our Annual Report on Form 10-KSB as of December 31, 2003 and for the year then ended, have been included herein in reliance on the report of Grant Thornton LLP, independent public accountants, given on the authority of that firm as experts in auditing and accounting.

**INCORPORATION OF DOCUMENTS BY REFERENCE**

The SEC allows us to incorporate by reference the information we file with them. This means that we can disclose information to you by referring you to those documents. The documents that have been incorporated by reference are an important part of the prospectus, and you should review that information to understand the nature of any investment by you in our common stock. Information contained in this prospectus and information we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information

The following documents filed by us with the SEC are incorporated herein by reference:

our annual report on Form 10-KSB for the fiscal year ended December 31, 2003;

our current reports on Form 8-K dated January 23, 2004, February 11, 2004, February 18, 2004, and February 26, 2004; 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.

In addition, we are incorporating by reference all future filings we make with the SEC, under Sections 13(a), 13(c), 14 or 15(d) of the Securities and Exchange Act of 1934, prior to the sale of all the shares covered by this prospectus.

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

**SCOLR, Inc.**

**3625 - 132nd Avenue Southeast  
Bellevue, Washington 98006  
Attention: Director of Finance  
Telephone: (425) 373-0171**

You should only rely upon the information included in or incorporated by reference into this prospectus or in any prospectus supplement that is delivered to you. We have not authorized anyone to provide you with additional or different information.

The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted.

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**WHERE YOU CAN FIND MORE INFORMATION**

We file reports and other information with the U.S. Securities and Exchange Commission, including annual reports on Form 10-K or 10-KSB and quarterly reports on Form 10-Q or 10-QSB. You may read and copy any document that we file at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about its Public Reference Room. Our SEC filings are also available to you free of charge at the SEC's web site at <http://www.sec.gov>.

This prospectus is a part of the registration statement that we filed on Form S-3 with the SEC. The registration statement contains more information about us and our common stock than this prospectus, including exhibits and schedules. 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.

**DISCLOSURE OF COMMISSION POSITION ON**

**INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

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.

Section 145 of the Delaware 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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act of 1933 and is therefore unenforceable.

**Table of Contents****PART II TO FORM S-3****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 offering other than commissions and discounts, if any. We will bear all of the costs set forth in the table.

Item	Company Expense
SEC registration fee	\$ 1,846
Printing and engraving expenses	\$ 15,000
Legal fees and expenses	\$50,000
Accounting fees and expenses	\$ 15,000
Miscellaneous	\$ 15,000
Total	\$96,846

**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.

Section 145 of the Delaware 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.

**Item 16. Exhibits**

Exhibit Number	Notes	Description
2.1	(14)	Asset Purchase Agreement by and between SCOLR, Inc. and Nutraceutix, Inc., dated as of December 31, 2003

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4.1	(5)	SCOLR, Inc. Certificate of Incorporation, as amended
4.2	(12)	Certificate of Designation of Series A Junior Participating Preferred Stock of SCOLR, Inc.

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<b>Exhibit Number</b>	<b>Notes</b>	<b>Description</b>
4.3	(4)	SCOLR, Inc. Bylaws, as amended
5.1	*	Consent and Opinion of Gray Cary Ware & Freidenrich LLP
10.1	(9)	Form of Note Purchase Agreement, Subordinated Note and Warrant dated as of April 30, 2003
10.2	(15)	Form of 6.0% Convertible Note dated June 25, 2003
10.3	(15)	Form of Common Stock Purchase Warrant dated June 25, 2003
10.4	(15)	Convertible Note Purchase Agreement dated June 25, 2003
10.5	(19)	Securities Purchase Agreement dated February 24, 2004
10.6	(19)	Registration Rights Agreement dated February 24, 2004
10.7	(19)	Form of Common Stock Purchase Warrant dated February 24, 2004
10.8	(6)	Promissory Note to Clyde Berg in the principal amount of \$1 million together with related Security Agreement and Warrant Agreement dated September 30, 2002
10.9	(1)	Company 1995 Stock Option Plan, together with amendment No. 1 thereto
10.10	(10)	Amendment No. 2 to Company 1995 Stock Option Plan
10.11	(15)	Form of Incentive Stock Option Agreement
10.12	(15)	Form of Nonqualified Stock Option Agreement
10.13	(7)	Exclusive Patent License Agreement dated March 8, 2002, by and between Archer-Daniels-Midland Company and the Company
10.14	(15)	Research and Transfer Agreement dated September 11, 1998, by and among Temple University, Dr. Reza Fassihi, and the Company
10.15	(15)	License Agreement dated December 22, 1998, as amended, by and between Temple University and the Company
10.16	(15)	License Agreement dated September 6, 2000, by and between Temple University and the Company
10.17	(15)	Master Research and Development Agreement dated May 1, 2001, by and between Temple University and the Company
10.18	(15)	Consulting Agreement dated December 22, 2000, by and between Dr. Reza Fassihi and the Company
10.19	(15)	Intellectual Property Assignment and Assumption Agreement dated May 24, 2001, by and between Dr. Reza Fassihi and the Company
10.20	(15)	License Agreement dated September 1, 2001, by and between Temple University and the Company
10.21	(15)	Intellectual Property Assignment and Assumption Agreement dated August 1, 2002, by and between Dr. Reza Fassihi and the Company
10.22	(15)	Additional Services Agreement dated August 7, 2002, by and between Dr. Reza Fassihi and the Company
10.23	(14)	License, Manufacture, and Distribution Agreement by and between SCOLR, Inc. and Nutraceutix, Inc., dated as of December 31, 2003
10.24	(15)	Building Lease 3625 132nd Avenue SE, Bellevue, WA, dated April 15, 2003
10.25	(11)	Separation Agreement dated January 15, 2001, by and between William D. St. John and the Company
10.26	(15)	Employment Agreement dated July 2, 2003, by and between Stephen Turner and the Company
10.27	(15)	Separation Agreement dated August 7, 2003, by and between David T. Howard and the Company
10.28	(15)	Advisory Agreement dated August 7, 2003, by and between David T. Howard and the Company

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Exhibit Number	Notes	Description
10.29	(18)	Amendment to Advisory Agreement dated December 30, 2003, by and between David T. Howard and the Company
10.30	(14)	Separation Agreement dated December 31, 2003, by and between Steven H. Moger and the Company
10.31	(6)	Loan and Security Agreement dated April 30, 2002, by and between Access Business Finance LLC and the Company
10.32	(8)	Second Amendment of Loan and Security Agreement dated May 1, 2003, by and between Access Business Finance LLC and the Company
10.33	(20)	Letter Agreement between the Company, Michael N. Taglich and Tag/Kent Partners
23.1	*	Consent of Grant Thornton LLP, Independent Certified Public Accountants
23.2	*	Consent of Gray Cary Ware & Freidenrich LLP (included in Exhibit 5.1)
24.1	*	Power of Attorney of Randall L-W. Caudill
24.2	*	Power of Attorney of Reza Fassihi
24.3	*	Power of Attorney of David T. Howard
24.4	*	Power of Attorney of Herbert L. Lucas
24.5	*	Power of Attorney of Robert C. Schroeder
24.6	*	Power of Attorney of Michael N. Taglich

**Notes**

Portions of such exhibit have been omitted pursuant to a request for confidential treatment filed with the SEC.

\* Included herewith.

- (1) Incorporated by reference to the Company's registration statement on Form 10-SB (File No. 000-24693), filed with the SEC on July 27, 1998.
- (2) Incorporated by reference to Amendment No. 1 to the Company's registration statement on Form 10-SB (File No. 000-24693), filed with the SEC on March 25, 1999.
- (3) Incorporated by reference to the Company's Form 10-KSB for the fiscal year ended December 31, 1999.
- (4) Incorporated by reference to the Company's Form 10-KSB for the fiscal year ended December 31, 2001.
- (5) Incorporated by reference to the Company's Form 10-QSB for the quarterly period ending June 30, 2002.
- (6) Incorporated by reference to the Company's Form 10-QSB for the quarterly period ending September 30, 2002.
- (7) Incorporated by reference to the Company's Form 10-KSB for the fiscal year ended December 31, 2002.
- (8) Incorporated by reference to the Company's Form 10-QSB for the quarterly period ending March 31, 2003.
- (9) Incorporated by reference to the Company's current report on Form 8-K, filed with the SEC on May 5, 2003.
- (10) Incorporated by reference to the Company's registration statement on Form S-8 (File No. 333-40290), filed with the SEC on June 28, 2000.
- (11) Incorporated by reference to the Company's current report on Form 8-K, filed with the SEC on April 6, 2001.
- (12) Incorporated by reference to the Company's current report on Form 8-K, filed with the SEC on November 6, 2002.

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(13) Incorporated by reference to the Company's Form 10-QSB/ A for the quarterly period ending June 30, 2003.

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- (14) Incorporated by reference to the Company's current report on Form 8-K, filed with the SEC on January 23, 2003.
- (15) Incorporated by reference to the Company's registration statement on Form S-2, File No. 333-107906, filed with the SEC on August 13, 2003.
- (16) Incorporated by reference to Amendment No. 1 to the Company's registration statement on Form S-2 (File No. 333-107906), filed with the SEC on October 3, 2003.
- (17) Incorporated by reference to Amendment No. 2 to the Company's registration statement on Form S-2 (File No. 333-107906), filed with the SEC on October 30, 2003.
- (18) Incorporated by reference to Post-Effective Amendment No. 1 to the Company's S-2 registration statement on Form S-3 (File No. 333-107906), filed with the SEC on January 29, 2004.
- (19) Incorporated by reference to the Company's current report on Form 8-K, filed with the SEC on February 26, 2004.
- (20) Incorporated by reference to the Company's Form 10-KSB for the fiscal year ended December 31, 2003

**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;

(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 reflected in the form of prospectus filed with the SEC 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;

(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, that are incorporated by reference in this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, 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 Securities 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.

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Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the indemnification provisions described herein, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange 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, 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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Daniel O. Wilds  
Attorney-in-fact

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