SCOLR INC
Form 424B3
November 14, 2003

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Filed pursuant to Rule 424(b)(3)
Registration File No. 333-107906

PROSPECTUS

SCOLR, INC.

9,450,660 SHARES OF COMMON STOCK

This prospectus relates to 9,450,660 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 $1,209,249 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 Over the Counter Bulletin Board under the symbol SCLL. On October 27, 2003, the last reported sale price of our common stock on the Over the Counter Bulletin Board was $2.21 per share.

Our principal executive offices are located at 8340 154th Avenue NE, Redmond, Washington 98052-3864. The telephone number of our principal executive offices is (425) 883-9518.

Investing in our common stock 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 November 14, 2003.

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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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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 9.

Businesses

We have two revenue generating centers:

Our probiotics business formulates and manufactures nutraceutical-based health and dietary supplements for both the animal and human nutrition markets.

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

Strategy and Recent Developments

Over the last two years, we have taken steps to transform our business from a nutraceutical company specializing in probiotic formulations to a company focused primarily on developing and commercializing drug delivery technology. The purpose of this transition is to allow us to take advantage of the long-term growth potential and prospects associated with our CDT technology.

During the last year we achieved critical milestones and invested significant resources in our CDT technology (including $2,048,000 during 2002 and $1,051,000 during the first six months of 2003), bringing us closer to our goal of becoming a more 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 AAPS Meeting (American Association of Pharmaceutical Scientists).

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 corporate identity through a name change to SCOLR, Inc. SCOLR is an acronym for our lead technology: Self Correcting Oral Linear Release systems.

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We continue to operate our probiotics business with a view toward selling it or entering alliances to provide us with capital that will allow us to focus more of our attention and resources on our drug delivery business.

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 a delivery of natural based soy isoflavones (a phytoestrogen) throughout the day. NovaSoy Daily Dose have generated revenue of $185,058 through June 30, 2003.

During the first quarter of 2003, our first two commercial CDT products, Novasoy Daily Dose and Once Daily Glucosamine & Chondroitin, were introduced to the U.S. nutraceutical industry. Our CDT Glucosamine & Chondroitin product is currently available nationwide in more than 7,000 retail outlets, including Wal Mart (under the Spring Valley label), Trader Joe s (under the Trader Darwin s label), and Rite Aid stores.

We realized our first CDT royalty revenues of approximately $108,000 and $319,000 during the first quarter and first six months of 2003, respectively. We expect these revenues will accelerate later this year and in 2004.

Between April 30 and May 6, 2003, we completed a $550,000 subordinated note financing (which was subsequently repaid with proceeds from our June 25, 2003 financing).

On June 25, 2003, we completed a $5.0 million financing of our 6.0% Convertible Notes Due June 25, 2006.

Primarily as a result of our presentation and introductions at the AAPS meeting in November, we have completed follow-up meetings with several of the top 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.

Probiotics

Our probiotics unit is a supplier of ingredients to retailers and manufacturers in the U.S. nutraceutical market for probiotics supplements. Nutraceuticals are biologically active materials, either derived from plant, microbial, or animal sources or by synthesis. Nutraceuticals are formulated to provide specific health benefits for humans and productivity benefits in animals.

We intend to continue to pursue opportunities to sell or enter into alliances for the probiotics operations in an effort to reduce indebtedness and obtain additional funding for the drug delivery business. In addition, the near-term revenues derived from applying CDT to nutraceutical markets will be used to support development of the drug delivery business.

Drug Delivery

Our drug delivery unit 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.

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.

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. We are seeking other relationships that are similar to the ADM alliance.

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

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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, and Trader Joe s. We expect to realize increased royalty income from the initial CDT dietary supplement and OTC formulations in 2003. We do not expect royalty income from CDT prescription drugs earlier than 2006.

Recent Financing Transactions

The following is a summary of two financing transactions that occurred during the second quarter of 2003.

Subordinated Note Financing

Between April 30 and May 6, 2003, we issued $550,000 in non-interest bearing subordinated notes. Purchasers of the notes received three-year warrants to purchase up to an aggregate of 235,722 shares of our common stock exercisable at $1.11 per share, subject to certain anti-dilution adjustments. The notes and warrants were issued in a private placement relying on the registration exemption provided by Rule 506 under the Securities Act of 1933. The transaction provided us with approximately $505,000 in net proceeds.

In consideration of certain placement services, we paid a cash fee and issued additional warrants to purchase up to 20,357 shares at $1.11 per share. The subordinated notes were paid and cancelled on or about June 25, 2003, using a portion of the proceeds of the convertible note financing described below.

All of the warrants include registration rights requiring us to file a registration statement with the Securities and Exchange Commission (SEC), registering for resale the shares of common stock issuable upon exercise of the warrants. These shares are included in this prospectus.

Convertible Note Financing

On June 25, 2003, we completed a $5.0 million financing of 6.0% Convertible Notes Due June 25, 2006. The notes were issued in a private placement relying on the registration exemption provided by Rule 506 under the Securities Act of 1933. The transaction provided us with approximately $4.7 million in net proceeds.

Interest on the notes is payable quarterly. The principal balance is convertible into shares of our common stock at a conversion price equal to $1.05 per share, subject to certain anti-dilution adjustments. Such adjustments are required following:

the issuance, sale or distribution of shares of common stock at a price less than $1.05 per share; and

the issuance of options, warrants or other rights to purchase common stock that are exercisable at, convertible into or exchangeable for common stock at a price less than $1.05 per share.

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Despite the foregoing, such anti-dilution adjustments are not triggered by:

(1) the grant or exercise of options to employees or directors pursuant to stock purchase plans;

(2) shares or options issued in connection with an acquisition of another entity or in connection with a licensing transaction;

(3) the exercise of any options, warrants or other rights to purchase common stock that were outstanding as of April 30, 2003; or

(4) the issuance, sale or distribution by the Company of up to 750,000 shares of common stock regardless of the price.

We have the right to force conversion of all the notes into shares of our common stock at any time, provided our common stock trades at $2.10 or higher for 20 trading days within a 30-consecutive day trading period.

The notes and warrants include registration rights requiring us to file a registration statement with the SEC registering for resale the shares of common stock issuable upon conversion of the notes or exercise of the warrants. The registration statement is to be filed no later than 60 days after the final closing date (June 25, 2003) with an effective date no later than 150 days after the final closing date. In the event the registration statement is not effective within 150 days after June 25, 2003, the conversion price for the notes will be reduced by the percentage resulting from multiplying 2% by the number of thirty (30) day periods beyond the 150-day period.

The shares issuable upon exercise of the warrants and conversion of the notes are included in this prospectus.

In consideration of certain placement services, we paid a cash fee of approximately $200,000, issued $300,000 of notes and issued warrants to purchase up to 476,191 shares at an exercise price of $1.155 per share.

The Offering

This prospectus relates to the resale of an aggregate of 9,450,660 shares of common stock, which were issued, or are issuable, by us as follows:

2,920,831 shares of outstanding common stock.

750,000 shares of common stock issuable upon exercise of warrants exercisable at $0.50 per share.

256,079 shares of common stock issuable upon exercise of warrants exercisable at $1.11 per share.

476,191 shares of common stock issuable upon exercise of warrants exercisable at $1.155 per share.

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5,047,559 shares of common stock issuable upon conversion of notes.

Of the 2,920,831 shares of outstanding common stock included in this registration statement 821,330 shares are being registered pursuant to registration rights granted to the holders. The remaining 2,099,501 shares of outstanding stock are included in this registration statement to reduce administrative costs associated with the resale of such securities.

As of August 7, 2003, we had 50,000,000 shares of our common stock authorized. Of this number, 21,349,107 shares were issued and outstanding, and an additional 6,529,829 shares were issuable upon exercise or conversion of the warrants and notes included in this prospectus.

The number of shares offered by this prospectus represents approximately 34.5% of the total common stock outstanding as of August 7, 2003, assuming full exercise or conversion of the warrants and notes. The number of shares ultimately offered for sale by the selling stockholders is dependent upon the number of warrants and notes exercised or converted, 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 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.

As a result of our significant operating losses and lack of capital resources, our independent auditor has raised substantial doubt about our ability to continue as a going concern

The consolidated financial statements in our Form 10-KSB for the year ended December 31, 2002 were prepared on the assumption that we will continue as a going concern. As part of its report, our independent auditor raised substantial doubt about our ability to continue as a going concern based on factors such as:

We used cash from operations of $960,207 and had a net loss of $2,557,328 for the year ended December 31, 2002;

We used cash from operations of $1,379,583 and had a net loss of $899,200 for the six months of 2003;

We had an accumulated deficit of $13,833,367 at June 30, 2003;

We expect to incur capital expenditures of $850,000 (including equipment and patent and trademark expenses) between June 30, 2003 and September 30, 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.

If we cannot obtain additional financing we will be unable to develop our drug delivery operations

With the proceeds of our recently completed $5.0 million convertible note 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 the third quarter of 2004. We currently anticipate negative cash flow of approximately $166,000 per month. 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;

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

continuation of our probiotics operations and royalties from our CDT products.

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 the probiotics operations are self funding, that no sale proceeds are available to support our drug delivery operations and that our revenues are not adversely affected by the other factors set forth in this Risk Factors section.

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

We will require substantial additional financing to implement our CDT technology business plan. 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.

While our probiotics business is currently cash flow positive and expected to remain so, these revenues are insufficient to offset the spending levels required for our drug delivery business. During 2002 we raised approximately $1,580,000 through the private placement of common stock. In September 2002, we obtained a $1,000,000 loan from Mr. Clyde Berg, a stockholder, and granted Mr. Berg warrants to purchase 750,000 shares of our common stock for $0.50 per share. The resale of the shares which may be issued upon exercise of these warrants is included as part of this registration statement.

In the second quarter of 2003, we issued $5,850,000 in notes through two financing transactions, of which $5,300,000 remains outstanding. We recorded a discount on the $5,300,000 of convertible notes of $3,600,000 which is being recognized as interest expense over the earlier of the term of the notes (3 years) or upon the conversion of the notes into common stock. As a result, we will record significant interest costs (which far exceed the actual cash expense) which will decrease earnings and impair our ability to raise additional capital. The sale of equity securities could also cause dilution due to antidilution provisions in our convertible notes. The convertible notes provide that the conversion price (currently $1.05) will be reduced if we sell additional stock at less than $1.05 per share. Accordingly, any such sale would result in additional dilution to our stockholders.

Holders of the convertible notes have the ability to accelerate the maturity of their notes after a change of control which is deemed to have occurred if:

any person becomes the owner of 50% or more of the combined voting power of the company;

the company merges with another entity in a transaction in which the owners of our securities own less than 50% of the voting power of the surviving entity; or

we sell, lease or otherwise dispose of all or substantially all of our assets.

A sale of the Company s probiotics operation will not be deemed a change of control under the notes.

We continue to attempt to sell or enter joint venture or partnership arrangements for our probiotics business. However, the proceeds of any such sale, partnership or joint venture must be used to repay outstanding indebtedness and will not be sufficient to provide significant funding for our drug delivery operations.

Additional financing may be unavailable to us on acceptable terms. In particular, we are limited in our ability to borrow additional funds because we have granted security interests in our assets to our existing lenders. 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 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 need to continue to seek financing distracts management from focusing on our day-to-day operations and long-term strategies.

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. As discussed throughout this Risk Factors section, developing drug delivery systems and drugs using our CDT technology is extremely expensive, and taking a single product to market takes years to complete.

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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 BestSweets has introduced a controlled release version of glucosamine chondroitin which may be competitive with the product we sell to Walmart and Trader Joe s, among others.

If we are not successful in entering beneficial 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 any particular program, which could delay or halt the development or commercialization of any product candidates arising out of the program;
- 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.

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 glucosomine and chondroitin to Walmart, Trader Joe s and Rite Aid. We are currently finalizing a written agreement with Royal Numico. We believe we are current with respect to our obligations under existing agreements.

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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 six U.S. and two foreign patents (which expire between 2012 and 2023), and 10 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 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.

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If we cannot retain key personnel, then our business will suffer

As a small company, with, as of September 1, 2003, approximately 30 employees and consultants, 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 of Operations and CFO, Steve Moger, our Director of Product Development, Steve 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. The loss of Mr. Moger would severely impact our probiotics operations. 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 employment agreements with Messrs. Wilds or Moger. Our consulting agreement with Dr. Fassihi expires December 31, 2006 but may be terminated by either of us 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, then our drug delivery business will not be successful

The future success of our drug delivery business 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

Although many of the ingredients of our dietary supplement and probiotics products are vitamins, minerals, herbs, and other substances for which there is a long history of human consumption, some of our products contain innovative ingredients. While we believe all of our products to be safe when taken as directed, there is little long-term experience with human consumption of certain of these innovative product ingredients in a concentrated form. Accordingly, no assurance can be given that our products, even when used as directed, will have the effects intended. Although we test the formulation and production of our products to ensure that they are safe when consumed, as directed, we have not sponsored clinical trials on the long-term effect of human consumption.

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

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directed. In addition, we may be unable to counter the effects of negative publicity concerning the efficacy of our products.

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 & chondroiton 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

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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

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.

Our probiotics business has lost a significant customer and may lose additional business

In 2002, we received approximately 60% of our total revenues from four customers: Rexall Sundown (23%), Supplement Sciences (20%), NBTY (10%) and Trader Joe s (8%). Since then, our relationship with NBTY has ended and Rexall Sundown was subsequently acquired by NBTY on July 25, 2003. While we have not received any indication of a change in our relationship with Rexall Sundown, NBTY is known to reduce purchases from outside vendors. Accordingly, this acquisition could have an adverse effect on our sales. In addition, we recently learned that Supplemental Sciences will discontinue substantially all of its business with us. The loss of Supplemental Sciences as a major customer, together with any reduction of sales to Rexall Sundown will significantly reduce revenues from our probiotics operations.

We are dependent on a small number of suppliers for probiotic raw materials

Certain raw materials necessary to make our probiotics products are produced by a limited number of suppliers. There can be no assurance that suppliers will continue to provide the raw materials needed by us in the quantities requested or at a price we are willing to pay. Because we do not control the actual production of these raw materials, we are also subject to delays caused by interruption in production of materials based on conditions not wholly within our control. Our inability to obtain adequate supplies of raw materials for our products at favorable prices, or at all, as a result of any of the foregoing factors or otherwise, could adversely affect our ability to produce products and generate revenues.

Our drug delivery business will be adversely affected unless we properly manage its 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, a new cGLP laboratory facility, 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

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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 sales of our products and the growth of our drug delivery business

Our success depends substantially on how our customers and potential collaborators decide to spend their money. Sales of our probiotics products have historically been negatively impacted during uncertain economic times. For example, the economic downturn and other disruptions and uncertainties resulting from the terrorist attacks on September 11, 2001 had a significant adverse impact on our probiotics business. Furthermore, 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.

The liquidity of our common stock and our ability to raise additional capital is limited because our stock is listed on the OTC Bulletin Board

Trading in our common stock is conducted in the over-the-counter market on the electronic bulletin board. As a consequence:

- the liquidity of our common stock is impaired, not only in the number of securities which can be bought and sold but also by delays in the timing of transactions
- additional requirements may be imposed by brokers under penny stock rules"
- coverage of our company by security analysts and the news media is decreased
- ultimately, our common stock is less attractive to potential investors and other sources of financing, and as a currency to attract personnel or pay for acquisitions by us

Accordingly, purchasers of our common stock may have difficulty in reselling their shares on the OTC bulletin board.

Because our common stock is subject to penny stock rules, it may be more difficult to liquidate your investment

Our common shares are subject to rules promulgated by the Securities and Exchange Commission relating to penny stocks, which apply to companies whose shares are not traded on a national stock exchange or on the NASDAQ system, trade at less than $5.00 per share, or who do not meet certain other financial requirements specified by the SEC. These rules require brokers who sell penny stocks to certain persons to complete certain documentation, make suitability inquiries of investors, and provide investors with certain information concerning the risks of trading in such penny stocks. These rules may discourage or restrict the ability of brokers to sell our common shares and may affect the secondary market for our common shares. These rules could also impair our ability to raise funds in the future.

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

Since January 1, 2002, the sale price of our common stock on the OTC Bulletin Board has ranged between a low bid of $0.52 and a high ask of $2.60.

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

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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

The warrants and notes for which the underlying shares are 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 securities and the underlying shares are considered restricted for purposes of said Act. Furthermore, 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 underlying shares in this prospectus, we are significantly enhancing these stockholders ability to sell these shares. This prospectus covers the sale of up to 9,450,660 shares. The average weekly trading volume of our common stock during the four weeks ended on September 26, 2003 was 41,531 shares. Sales of such 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 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. The Company s Certificate of Incorporation contains provisions having anti-takeover effects, including the authorization of the 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 the Company. 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 values of your investment

The 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 the Company. The stockholders rights plan may also impede a party seeking to acquire control of the Company. 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, b intend, or project or the negative of these words or other variations on these words or comparable terminology.

Forward-looking statements may be found under Management s Discussion and Analysis or Plan of Operation and Description of Business in the Form 10-KSB that accompanies this prospectus 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 9 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.

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We will receive up to $1,209,249 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 working capital and general corporate purposes. The amount we receive depends on the number of warrants exercised and the use of cashless exercise provisions by the warrant holders. Cashless exercise provisions allow a holder to forego a number of shares otherwise issuable upon exercise of a warrant in lieu of paying some or all of the warrant s cash exercise price.

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.

For each selling stockholder, the table below sets forth the name, 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 each selling stockholder will own after the offering, assuming they sell all of the shares offered.

Stockholder (2)	Shares owned before offering (1)	Shares included in prospectus (1)	Shares owned after offering (1)	% of common stock after offering (1)*
2002 Kaplan Family Trust (Kalman Kaplan)	47,143	47,143	0	
Alden, Eric	39,523	22,023	17,500	
Allen, Robert W. and Susan M	347,699	167,619	180,080	
Alvin R. Bonnette Revocable Trust U/A DTD 1/31/85 (Alvin R. Bonnette)	47,619	47,619	0	
Applebaum Family Limited Partnership (Irving Applebaum)	14,285	14,285	0	
Arnold, E. H	266,666	266,666	0	
Arnold, Gary P. and Patricia A	188,095	188,095	0	
Baroni, Philip	19,047	19,047	0	
Beebe, Raymond M	19,047	19,047	0	
Berg, Clyde	1,667,777	1,147,777	520,000	1.87 %
Berglas, Linda M	12,500	12,500	0	
Bero, Ronald A	19,047	19,047	0	
Bertsch, John	157,382	127,382	30,000	
Bibicoff, Allison	161,309	161,309	0	
Bibicoff, Harvey	1,047,952	880,952	167,000	
Bibicoff, Hillary	125,000	125,000	0	
Bissaillon, Francis P	19,047	19,047	0	
Bond, Jeremy	9,523	9,523	0	
Botwinick, Herbert	12,500	12,500	0	
Botwinick, Steven	12,500	12,500	0	
Brand, Charles	23,809	23,809	0	
Brar, Baldev S. and Gurmukh K	9,523	9,523	0	
Brody, Edward L	28,571	28,571	0	
Brunone, Michael	26,187	26,187	0	
Buchakjian, Richard	19,047	19,047	0	
Butter, Gerald A	17,233	1,333	15,900	
Carroll, Peter G	9,523	9,523	0	
Chamberlain, Joseph D	19,047	19,047	0	
Clayton, Richard	47,619	47,619	0	
Cleveland, Kenneth W	23,809	23,809	0	
Clifford, John C	47,619	47,619	0	
Cook, Edward	38,095	38,095		