

SCOLR INC
Form 10KSB
March 24, 2004

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

o ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

o TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission file number 000-24693

Scolr, Inc.

(Name of small business issuer in its charter)

Delaware
(State of Incorporation)

91-1689591
(IRS Employer Identification No.)

3625 132nd Avenue S.E.
Bellevue, WA
(Address of principal executive offices)

98006
(Zip Code)

Issuer's telephone number:

(425) 373-0171

Securities registered under Section 12(b) of the Exchange Act:

| Title of Class | Name of Each Exchange on Which Registered |
|---|--|
| Common stock, \$.001 par value (Including Associated Preferred Stock Purchase Rights) | American Stock Exchange |

Securities registered under Section 12(g) of the Exchange Act:

None

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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Check if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB.

The issuer's revenues for the fiscal year ended December 31, 2003 were \$6,594,073

The aggregate market value of the voting common stock held by non-affiliates computed by reference to the price at which the stock was last sold, as reported on the American Stock Exchange, as of March 17, 2004 was approximately \$89,039,894.

As of March 17, 2004, there were 29,894,296 shares outstanding of the issuer's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant has incorporated by reference into Part III of this Form 10-KSB portions of its Proxy Statement for the 2004 Annual Meeting of Shareholders.

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SCOLR, Inc.

FORM 10-KSB

CAUTIONARY STATEMENT PURSUANT TO THE

PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Except for the historical information, the matters discussed in this Form 10-KSB contain 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. These 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, believe, intend, or project or the negative of these variations on these words or comparable terminology. Readers should carefully review the risk factors described in this document and in other documents we file from time to time with The Securities and Exchange Commission, including the Quarterly Reports on Form 10-QSB to be filed later in the fiscal year, that attempt to advise you of the risks and factors that may affect our future results.

Item 1. Description of Business
Overview

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 the animal and human nutrition markets. Since 2001, we have transformed our business from a nutraceutical company specializing in probiotic formulations to a company concentrating 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 was completed with the sale of our probiotics business, effective as of December 31, 2003. See Sale of Probiotics Division below.

We were incorporated on October 12, 1994 in Delaware under the name Caddy Systems, Inc. From April 1995 to July 2002, we operated under the name Nutraceutix, Inc. In July 2002, we changed our name to SCOLR, Inc. SCOLR is an acronym for our lead technology: Self Correcting Oral Linear Release Systems. Our website is www.scolr.com. Information contained on our website is not part of, and is not incorporated into, this annual report. Our filings with the SEC are available without charge on our website as soon as reasonably practicable after filing.

Drug Delivery Business

Our business is centered around the development and licensing of our Controlled Delivery Technology. Our CDT platform currently consists of three patented drug delivery technologies for prescription drugs, over-the-counter (OTC) products, and nutraceuticals. The basis of these technologies is 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 has been a consultant to the Company since 2000 and was appointed to our board of directors in November 2003.

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The CDT platform 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 platform enjoys many competitive advantages when compared to other controlled delivery methodologies. Our CDT technology is robust and simple allowing for low cost manufacturing (using conventional blending and compression equipment in a two- or three-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.

Corporate Strategy

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 (ADM) 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 be useful in complementing our client's offerings and potentially accelerating introduction of our CDT platform to the pharmaceutical market.

Following the successful completion of our CDT proof-of-concept human clinical trial in late 2002, 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 Corporation (GNC). We expect to realize increased royalty income from our CDT dietary supplements in 2004. We do not expect royalty income from CDT prescription drugs earlier than 2007.

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.

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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 AAPS meeting (American Association of Pharmaceutical Scientists).

In collaboration with Dr. Fassihi, 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 CDT based products 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 our 6.0% Convertible Notes Due June 25, 2006. The notes were converted into 5,047,559 shares of common stock effective December 15, 2003.

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 work together to identify potential opportunities where our technology might be useful in complementing our client's offerings and potentially accelerating introduction of our CDT platform to 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 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.

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 a select group of significant, existing drugs for reformulation using our CDT platform. We commenced an in vivo animal study for the first drug candidate in February 2004.

In late February 2004, we completed a private placement of 3,206,538 shares of common stock for \$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.

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Drug Delivery Technology

In December 1998, we obtained the exclusive rights to a patent pending for technology pertaining to the controlled delivery of dietary supplement capsules and tablets from Temple University. We trademarked this technology as CDT Controlled Delivery Technology. We consider the technology to be distinctive in its ability to program in-vitro release patterns for each health supplement contained in a single tablet or capsule. We believe our technology provides a relatively low cost of manufacture as compared to immediate release formulations of the same active ingredient. We believe that the wide applicability of its technology among the available range of vitamin and herbal products suitable for once or twice daily dosing or pulsed release provides a unique commercial opportunity in the \$19 billion U.S. dietary supplement and nutraceutical market.

Controlled delivery technologies are widely employed within the OTC and pharmaceutical industries, while they are relatively rare within the dietary supplement industry. In the pharmaceutical industry, sustained-release technologies have been shown to optimize the therapeutic effectiveness, enhance the compliance to the dosing schedule, and reduce the frequency and severity of side effects of a single Active Pharmaceutical Ingredient (API). We believe that this unique technology will offer similar benefits within the health and dietary supplement industry.

Our Controlled Delivery Technology was developed at Temple University, School of Pharmacy for the chronic administration of calcium channel blockers such as nifedipine, diltiazem, and verapamil which are prescribed for the long-term management of chronic angina pectoris and benign essential hypertension. The physicochemical properties and intrinsic pharmacological characteristics of these drugs, such as high or low solubility, limited absorption, or pre-systemic metabolism, necessitated the development of a highly controllable drug delivery system to provide continuous active ingredient release with zero-order kinetics typified by precise and reproducible performance. The first generation of this technology is based on swellable hydrophilic matrices, which allow for the controlled diffusion of dietary supplements from the matrix through the tablets progressive swelling and erosion. The CDT tablets or capsules employ combinations of hydrophilic polymers and poly-ionics or electrolytes specific to each health supplement or OTC product and the desired release profile. Depending upon the matrix composition, the selection and ratio of polymers, ionic substrates, or electrolytes various release patterns and rates can be achieved.

One of the most difficult challenges for a controlled delivery technology is to produce a continuous release formulation with near linear, zero-order kinetics of a highly soluble API for periods up to 24 hours. Linear, zero-order kinetics means that a precise quantity of API is released during each unit of time over the entire course of the release pattern until 100% of the API is released. There are no bursts or lag phases in the release pattern. After obtaining the exclusive license for the technology from Temple University, the Company, in collaboration with Temple University, specifically developed continuous, zero-order kinetics tablets of Vitamin C. Vitamin C was considered to be a technological challenge due to its high water solubility and its high permeability. Following the Vitamin C project, the Company and Temple University developed individual, controlled-release, linear, zero-order kinetics tablets of glucosamine, Calcium D-glucarate, several sports nutrition prohormones, and diet formulations. The Company believes that both the dietary supplement and nutraceutical industries offer many opportunities to apply this technology.

In 1999, we licensed the right from Temple University to apply the CDT Patent No. 1 technology to OTC products. We have not yet manufactured OTC products using the technology contained in the CDT Patent No. 1. In September 2001, we acquired the exclusive license for the rights to CDT Patent No. 1 in prescription drugs. On January 8, 2002, CDT Patent No. 1 was issued by the United States Patent and Trademark Office (USPTO) as US Patent 6,337,091.

In September 2000, the Company acquired the worldwide rights to Patent No. 6,090,411 (CDT Patent No. 2) for application in dietary and health supplements, OTC products and prescription drugs. This technology (issued on July 18, 2000) provides for the controlled and programmable release of the API with zero-order kinetics through the dry blending and direct compression of a salt, a polymer, and the API. We believe the CDT Patent No. 2 technology possesses several critical and unique advantages over comparable

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sustained-release technologies currently employed by the drug delivery industry in manufacturing extended or sustained-release products:

The technology does not involve a granulation step at manufacturing; thereby, shortening process times and eliminating potentially toxic solvents from the manufacturing process. Processes are faster and easily validated.

The technology involves the development of the desired release pattern through the dry blending of a selected salt and polymer in various ratios in order to create a dry matrix. The resulting matrix is directly compressible on all currently available tableting equipment routinely used in the pharmaceutical industry.

The technology and its applicability to dietary supplements, OTC products or prescription pharmaceuticals are extremely rugged and flexible; the in-vitro dissolution results are not affected by drug solubility, pH, tablet size or configuration, tablet hardness, or friability.

The technology has a remaining patent life of 18 years.

The technology is a 2 step process involving GRAS (Generally Regarded as Safe) excipients in novel quantities and using standard pharmaceutical processing equipment and technology; thereby, enabling the manufacturer of CDT products to produce controlled release products at approximately the same costs as immediate release formulations of the same API.

We believe that the technology embodied in the CDT Patent No. 2 demonstrates significant advantages over current sustained-release technologies that involve multiple polymer systems, coated beads or coated tablets. Our technology is easily manufactured on conventional pharmaceutical equipment with fewer processing steps. Furthermore, it is applicable to a wider range of APIs, dietary supplements and OTC products than other technologies. We believe that the CDT Patent No. 2 will provide for more rapid product formulation and development leading to faster submissions to the regulatory authorities, faster time to market, and less expensive manufacturing.

On February 12, 2003, The USPTO issued US Patent 6,517,868 (CDT Patent No. 3) for an amino acid CDT drug delivery platform for pharmaceutically active compounds. The amino acid CDT platform is one of three patents for modified oral dosage release systems currently in pre-commercialization development by the Company. Designed as a simpler solution to certain difficult formulation issues, the amino acid platform extends our capability to include poorly soluble drugs which are difficult and costly to formulate and produce with currently available manufacturing techniques and processes. Although this is our third CDT patent, it is the first CDT patent owned exclusively by us. In collaboration with Dr. Fassihi, SCOLR has, over the last three years, developed prototype prescription drugs, OTC products and dietary supplements which employ the novel delivery system concepts embodied in all three CDT patents.

The issuance of CDT Patent No. 3 is significant because it demonstrates our transition from a licensee of technology to our development as an innovator in drug delivery. This new CDT amino acid technology broadens the field of potential prescription drug candidates for our CDT platform to include drugs with solubility issues where developing controlled release formulations is currently both difficult and costly. The new CDT amino acid patent, in conjunction with the CDT salt patent and CDT dual polymer patent combine to create a range of modified oral drug delivery systems which address the most challenging hurdles of oral drug delivery, including zero order kinetics, poorly soluble active ingredients and ingredients difficult to tablet. The CDT technology has been shown to accomplish this at reasonable cost and time savings to the manufacturer.

We have taken advantage of the faster time-to-market in the dietary supplement industry. Several nutraceutical products employing CDT technology were introduced in early 2003. The first commercial introduction of an OTC product utilizing CDT is expected in 2005 and CDT based prescription drugs are planned for not earlier than 2007.

The oral controlled release market for OTC products and prescription drugs has been estimated at \$19.9 billion in 2000 with a forecast of approximately \$40.0 billion in the United States in 2010 (Data

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Monitor) and has been reported to be growing at twice the annualized rate of the pharmaceutical market; in general. A total of 42 out of 52 blockbuster drugs (\$82 billion combined worldwide sales) will face patent expiration by the year 2007. The Company believes that the drug delivery industry will continue to show strong growth in the future as many multi-national pharmaceutical companies seek new drug delivery technologies to evergreen their existing pharmaceutical franchises through new drug introductions involving older molecules incorporating new patented drug delivery technology. Since revenues from a drug can drop by up to 70% when its patent expires, any method of adding new life to an existing product will protect brand sales. Incorporation of new, patented drug delivery technology is one such proven strategy.

Competition

Our business is highly competitive and is affected by new technologies, government regulations, availability of financing and other factors. In the drug delivery field, examples of our major competitors include Alza Corporation, Biovail, Inc., Penwest, Skyepharma PLC, Elan, Andrx, Inc., Impax Laboratories, Inc., Labopharm, and KV Pharmaceuticals, Inc. The successful development and commercialization of major controlled delivery prescription drugs can take five to seven years and millions of dollars of research and clinical trials. These major competitors are better funded and equipped to fully realize the potential from new and unique patented drug delivery systems and are in possession of significantly stronger financial and research and development resources. See Item 6. Management's Discussion and Analysis or Plan of Operation Risk Factors.

Research and Development

In 2000, we reorganized our research and development capabilities and structure in order to focus on exploitation of the newly acquired CDT Patent No. 2 and the opportunities presented in the OTC and prescription drug markets for drug delivery. In 2003 and 2002, we spent \$403,186 (approximately 6% of revenues) and \$540,826 (approximately 8% of revenues), respectively, on product research and development. We will have to increase our research and development expenditures to take advantage of opportunities in the pharmaceutical and OTC markets for our technology. As part of our strategy, we seek to supplement our research and development efforts by entering into research and development agreements, joint venture, and other collaborative arrangements with other companies.

Our business includes the development of products requested by private label customers and/or new product concepts that can be licensed to customers. We also seek and review new nutraceutical materials and drug delivery technologies developed at universities or by independent researchers with the view to acquiring the intellectual property. We then conduct applied research on the intellectual property to develop a commercial product or application which can be licensed to co-developers or commercial partners.

Intellectual Property

Following the sale of our probiotics division, the Company had four federal trademark registrations and 16 trademark applications pending with the USPTO. Our policy is to pursue registrations for all of the trademarks associated with its key products and technologies. A list of our registered and pending trademarks is as follows: CDT, SCOLR, and SCORx.

Our success will depend in part on our ability to obtain and maintain patent protection for our technologies and to preserve our trade secrets. No assurance can be given that our issued patents will not be challenged or circumvented by competitors. With respect to already issued patents, there can be no assurance that any patents issued to us will not be challenged, invalidated, circumvented or that the patents will provide us proprietary protection or a commercial advantage.

We are obligated to pay an annual license maintenance fee, share in some up-front payments from customers and pay royalties based on product sales with respect to the CDT patents licensed by Temple University or assigned to us by Dr. Fassihi. In addition, we are obligated to pay Dr. Fassihi an annual license maintenance fee, share in up-front payments from customers and pay royalties based on product sales with respect to CDT Patent No. 3.

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Probiotics Business

Sale of Probiotics Division

On January 15, 2004, we completed the sale of our probiotics development and manufacturing division to Nutraceutix, Inc., a Washington corporation, pursuant to an Asset Purchase Agreement dated as of December 31, 2003. The new Nutraceutix entity was formed and is owned by Steven H. Moger, the Company's former Vice President of Operations, Chief Financial Officer and General Manager of the probiotics division. Mr. Moger resigned his positions with the Company in connection with the sale.

The assets sold comprise substantially all of the assets and properties used in connection with our probiotics division, including equipment, inventory and intellectual property rights. The division engaged in the business of formulating and manufacturing probiotics-based health and dietary supplements for the animal and human nutrition markets. The Company also granted Buyer the right to manufacture and sell certain products utilizing SCOLR's patented CDT technology pursuant to a License, Manufacture, and Distribution Agreement also dated as of December 31, 2003.

We received \$722,756 in cash at closing and the Asset Purchase Agreement provides for deferred payments of at least \$2 million. The deferred payments are tied to the Buyer's achievement of certain sales levels and royalties. The consideration for the sale was determined pursuant to arm's-length negotiations after extensive negotiations with a number of third parties (including industry buyers) and took into account various factors concerning the valuation of the probiotics business, including valuations of comparable companies, the operating results, financial condition and prospects of the division and the opinion of the financial advisor retained by the Board of Directors. See Note B to the Company's Financial Statements for additional information concerning the asset sale and the deferred payments to the Company.

In connection with the sale we repaid indebtedness of approximately \$1,098,500, which debt had been secured by the assets of the probiotics division.

Manufacturing

During 2003 and prior years the Company operated manufacturing facilities in Redmond, Washington and Lafayette Colorado. Both of these facilities and related manufacturing operations were included in the sale of the probiotic assets. In the future, we will employ contract manufacturers, including Nutricia and Nutraceutix, to manufacture certain of our private label products.

The probiotics unit manufactured private label health supplements incorporating our patented and proprietary technologies or the probiotics produced in the Redmond, Washington fermentation facilities. Finished goods production took place at its encapsulating, tableting, bottling, and labeling facility in Lafayette, Colorado. In addition to its own products, we manufactured microbial products for several agriculture companies on a private label and OEM basis at its fermentation plant located in Redmond, Washington. These products included microbial inoculum, feed and food additives and microbial-based dietary supplements.

Sources and Availability of Raw Materials and Principal Suppliers

Our technology allows for the use of conventional, readily available Generally Regarded As Safe (GRAS) excipients. A wide variety of materials can be used for formulation development and are available from a large number of manufacturers and distributors. The materials used in controlled delivery formulation are generally available.

Dependence on Significant Customers

In 2003, the Company received approximately 54% of its total revenues from three customers: Rexall Sundown (21%), Trader Joe's (21%), and Supplement Sciences (12%). There will be no continuing revenues from these customers or other probiotics customers as a result of the sale of the probiotic business. However, the Company will receive royalties on the sale of products to Trader Joe's and other customers for certain

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CDT products which were previously manufactured by the probiotics unit. Royalty revenues in 2003 were primarily attributable to our relationship with Nutricia and sales of Glucosamine & Chondroitin.

Government Regulation

The Company must receive separate regulatory approval for each of our product candidates before the Company or its collaborators can sell them in the United States or internationally. The manufacture and sale of OTC and prescription drugs in the U.S. and internationally is governed by a variety of statutes, regulations and policies which require; among other things:

1. approval of manufacturing facilities and practices;
2. controlled research and testing of products;
3. review and approval of submissions containing manufacturing, preclinical, and clinical data in order to obtain marketing approval based on establishing the safety and efficacy of the product for each use sought, including adherence to Good Manufacturing Practices during production and storage; and
4. control of marketing activities, including advertising and labeling.

The products currently under development will require significant development, preclinical and clinical testing and investment of significant funds prior to their commercialization. The process of obtaining such approvals is likely to take many years and require the expenditure of substantial resources, and there can be no assurance that the development and clinical trials performed by the Company or our collaborators will be successful. See Item 6. Management's Discussion and Analysis or Plan of Operation Liquidity and Capital Resources and Risk Factors.

Compliance with Environment Laws

The Company may incur significant costs in complying with environmental laws and regulations. The Company is 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. In the event of an accident, we could be held liable for any damages that result and any such liability could exceed our resources. There can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws and regulations in the future, or that our operations, business, or assets will not be materially adversely affected by current or future environmental laws or regulations.

Employees

As of December 31, 2003 and prior to the sale of the probiotics business the Company employed 37 full time employees. Subsequent to the sale, the Company retained 10 employees consisting of three executives, one sales and marketing personnel, four research and development personnel, and two quality assurance personnel. None of the Company's employees are represented by labor unions. The Company believes its relationship with employees is good.

Item 2. Description of Property

The Company's corporate headquarters, including administrative offices and research and development facilities are located approximately fifteen miles east of Seattle at 3625 132nd Avenue SE, Bellevue Washington 98006. The property, consisting of 10,510 square feet, is leased for a term of sixty (60) months at an average annual rent of \$112,639, with a lease termination date of September 30, 2008.

Item 3. Legal Proceedings

Except as described below, the Company is not a party to any material litigation. The Company is involved in a dispute concerning rights purportedly granted to Bionutrics, Inc. pursuant to a letter of intent dated December 9, 2002. The Company has been advised that a complaint has been filed by Bionutrics in

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Maricopa County, Arizona seeking specific performance, a declaratory judgment and claiming breach of contract, tortious interference with business expectancy and seeking injunctive relief. However, the complaint has not been served. We intend to vigorously defend the case if the complaint is served.

Item 4. Submission of Matters to a Vote of Securities Holders

No matters were submitted to our shareholders during the quarter ended December 31, 2003.

Item 5. Market For Common Equity and Related Stockholder Matters

Our Common Stock was traded in the over-the-counter bulletin board (Symbol: SCLL) until February 5, 2004. Commencing on February 6, 2004, the common stock has been traded on the American Stock Exchange (Symbol: DDD). The following table sets forth the range of high and low bid prices for the Company's Common Stock on a quarterly basis for the past two full years, and reflects inter-dealer prices, without retail mark-up, mark-down, or commission and may not necessarily represent actual transactions.

COMMON STOCK

| Period | Fiscal Year 2003 | High Bid | Low Bid |
|----------------|-------------------------|-----------------|----------------|
| First Quarter | | 1.00 | .95 |
| Second Quarter | | 1.80 | 1.67 |
| Third Quarter | | 2.25 | 2.18 |
| Fourth Quarter | | 2.15 | 2.03 |

| Period | Fiscal Year 2002 | High Bid | Low Bid |
|----------------|-------------------------|-----------------|----------------|
| First Quarter | | 1.55 | 0.52 |
| Second Quarter | | 1.60 | 0.90 |
| Third Quarter | | 1.18 | 0.77 |
| Fourth Quarter | | 1.28 | 0.72 |

As of March 17, 2004, we had 1,428 shareholders of record. We have not paid or declared any dividends upon its Common Stock since inception and do not contemplate or anticipate paying any dividends upon the Common Stock in the foreseeable future.

Recent Sales of Unregistered Securities

We issued 3,206,538 shares of its common stock and warrants (Warrants) to purchase 801,636 shares of common stock to pursuant to a Securities Purchase Agreement dated February 24, 2004. The common stock was sold at \$3.25 per share for gross proceeds of approximately \$10.4 million. The Warrants are exercisable until February 23, 2009 at \$4.75 per share, subject to customary anti-dilution provisions. After a period of 12 months following the effective date of a registration covering the resale of shares issued upon exercise of the Warrants, we have the right to call the Warrants for cancellation if the volume weighted average price of the common stock is above \$8.00 for 20 consecutive trading days.

Rodman & Renshaw acted as the lead placement agent for the transaction and Taglich Brothers, Inc. assisted in the financing. The placement agents received a cash commission of \$729,487 and Warrants to purchase 224,458 shares, of which Taglich Brothers received \$174,965 and Warrants to purchase 12,408 shares. Michael N. Taglich and Robert C. Schroeder, directors of the Company, are affiliates of Taglich Brothers. In addition, Mr. Taglich (and a partnership of which Mr. Taglich is a general partner) purchased 49,631 shares of common stock and Warrants to purchase 12,408 shares as part of the private placement. However, Mr. Taglich's agreement with the Company was amended to increase the purchase price applicable to the 49,631 shares purchased by him to \$3.63 per share.

The Company also issued (i) 32,000 shares of common stock and a Warrant to purchase 15,000 shares to an unaffiliated third party as a finder's fee, and (ii) 23,077 shares of common stock and Warrants to purchase

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5,679 shares to Rostrevor Partners in partial payment of its advisory fee in connection with the sale of the Company's probiotics division.

The common stock and Warrants were issued to accredited investors and such sales were exempt from registration under the Securities Act of 1933, as amended, pursuant to Rule 506 of Regulation D and Section 4(2) of such Act. In connection with the offering, the Company agreed to register the resale of the common stock and shares to be issued upon exercise of the Warrants with the Securities and Exchange Commission. The Company is subject to certain penalties if the registration statement is not filed within 30 days of the closing, or if the registration statement is not declared effective by the Securities and Exchange Commission within 120 days of such closing.

Item 6. *Management's Discussion and Analysis or Plan of Operation*
Introduction and Overview

We have historically generated substantially all of our revenues through our probiotics unit which was sold as of December 31, 2003. Accordingly, except for the deferred purchase price and royalties relating to the CDT technology, we will no longer receive revenues from the probiotics division. Our drug delivery business has begun generating revenue from CDT-based sales in the dietary supplement markets. We expect to realize increased royalty income from our initial CDT dietary supplement and OTC formations in 2004. However, we will continue to incur substantial operating losses for the foreseeable future as we develop our technology, expand our operations and develop systems that support commercialization of our CDT platform. Our strategy includes a significant commitment to research and development activities in connection with the growth of our drug delivery platform. Our results of operations going forward will be dependent on our ability to commercialize our technology and generate royalties, development fees, milestone and similar payments.

In recent years, we have generated substantially all of our working capital through the sale of securities. In June 2003, we completed a \$5.3 million financing of 6.0% convertible notes due June 25, 2006. These notes were converted into 5,047,559 shares of common stock effective December 15, 2003. In February 2004, we completed a private placement of 3,206,538 shares of common stock for \$3.25 per share together with five-year warrants to purchase 801,636 shares of common stock at \$4.75 per share for gross proceeds of \$10.4 million.

Results of Operations

Net Revenues

Net revenues increased 1% percent or \$79,830 to \$6,594,073 for the year ended December 31, 2003 from net revenues of \$6,514,243 for the year ended December 31, 2002. An analysis of our revenue-generating centers is outlined below:

Revenue Generating Centers

During 2002 and 2003 we operated the two primary revenue-generating centers described below.

1. *Manufacturing Center (Probiotics business)* consisting of (A) dietary supplement manufacturing operations, including the manufacture of dietary supplement products, on an OEM or private label basis, and (B) fermentation operations involving the sale of viable (live) freeze dried microorganisms on a private label and OEM basis. Both of these sub-centers were included in the sale of the probiotics development and manufacturing operations effective December 31, 2003.

2. *Licensing Fees, Research & Development Contracts and Royalties Center (Drug delivery business)* We generate licensing fees, research and development contracts and royalties for the formulation

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of Controlled Delivery Technology prescription drugs, OTC products, and dietary supplements. Licensing agreements and research and development contracts are expected to include royalty revenues that would be recognized in future years. Royalties for dietary supplements are expected to increase this year and beyond as CDT Glucosamine & Chondroitin and other CDT products are sold to Wal-Mart, Rite-Aid, Trader Joes, GNC and other retail outlets. In addition, we expect to receive royalties for sales of certain CDT products previously manufactured by our probiotics division.

Manufacturing Revenues

Manufacturing revenues decreased 8% or \$487,131 to \$5,972,120 for the year ended December 31, 2003 from revenues of \$6,459,251 for the year ended December 31, 2002.

Dietary supplement manufacturing revenues increased 17% or \$546,721 to \$3,852,697 for the year ended December 31, 2003 from revenues of \$3,305,976 for the year ended December 31, 2002. The increase in dietary supplement manufacturing revenues during the year ended December 31, 2003 is primarily attributable to sales of CDT Glucosamine & Chondroitin products introduced during the first quarter of 2003. Sales of CDT Glucosamine & Chondroitin were \$859,876 for the year.

Fermentation revenues decreased 33% or \$1,033,852 to \$2,119,423 for the year ended December 31, 2003 from revenues of \$3,153,275 for the year ended December 31, 2002. The decline is mainly attributable to the loss of substantially all sales to one major customer and a decrease in sales to another significant customer. We will not receive manufacturing revenues due to the sale of the probiotics development and manufacturing operations effective December 31, 2003.

Licensing Fees, Research and Development Contracts and Royalties

Licensing fees and research and development contract revenues for 2003 were \$39,000 as compared to \$54,000 for 2002. Royalty revenues for 2003 were \$582,953 compared to \$992 for 2002. This increase in royalty revenues was the result of the introduction of CDT Glucosamine & Chondroitin products and sales of Novasoy products which incorporate our CDT technology during 2003. We anticipate future growth in revenues derived from drug delivery technology licensing fees and research and development contracts.

Gross Profit

Gross profit increased 46% or \$639,760 to \$2,017,394 in 2003 compared to \$1,377,634 in 2002. Gross profit as a percentage of sales was 31% in 2003 and 21% in 2002. The decrease in manufacturing revenues had a negative effect on gross profit and gross profit as a percentage of sales but was more than offset by lower manufacturing costs associated with the downsizing of the fermentation facility in April 2003 and increased royalty revenues from CDT technology licenses.

Selling and Marketing Expenses

Selling and marketing expenses increased 29% or \$106,992 to \$479,714 in 2003 from \$372,722 in 2002. The increase in selling and marketing expenses for the year is largely attributable to \$93,000 in consulting fees paid for evaluation and analysis of potential alliances and development agreements with pharmaceutical companies. We anticipate significant additional marketing expenses as we increase our business development efforts to support our drug delivery business.

Research and Development Expenses

Research and development expenses decreased 25% or \$137,640 to \$403,186 in 2003 from \$540,826 in 2002. The higher level of research and development expenses during 2002 was due to the costs associated with our first human clinical trial conducted as an in vitro/in vivo proof of concept study to support its patented CDT drug delivery system. We expect to incur capital expenditures of \$750,000 (including equipment and patent and trademark expenses) during 2004. In addition, we expect research and development expenses to

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increase significantly as we expand our research and development activities to support our drug delivery business.

General and Administrative Expenses

General and administrative expenses increased 53% or \$1,460,026 to \$4,193,294 in 2003 compared to \$2,733,268 in 2002. The increase for 2003 is primarily attributable to a \$896,955 non-cash expense for accelerated vesting of stock options for employees terminated in connection with the sale of the probiotics division. In addition, we incurred increased legal fees relating to financing activities, compliance with new regulatory requirements (including Sarbanes-Oxley), expansion of the management team to include Daniel O. Wilds as President and Chief Executive Officer, consulting fees to our Chairman, David T. Howard, and additional rent for leased facilities. Also, in conjunction with a separation agreement with our former Chief Scientific Officer and our Vice President of Administration, Secretary and Treasurer dated March 31, 2001, we recorded severance costs of \$157,448 for the year ended December 31, 2003 and \$159,152 for the year ended December 31, 2002. These expenses have been reclassified from Other Expense to General and Administration expense as previously reported. We expect general and administrative expenses to decline in 2004 as significant expenses during 2003 will be nonrecurring.

Operating Profit/ Loss

Operating loss for the year ended December 31, 2003 was \$3,058,800 as compared to an operating loss of \$2,269,182 for the year ended December 31, 2002.

Interest Expense

Interest expense increased \$5,369,459 to \$5,698,382 for the year ended December 31, 2003 compared to \$328,923 for the year ended December 31, 2002. The interest was comprised of non-cash interest of \$5,302,460 and cash interest of \$395,922. The non-cash amount is attributable to the accounting treatment for the convertible notes issued in June 2003, including the amortization of debt discount and associated debt issue costs, and expense associated with the issuance of a warrant as part of the \$1 million loan entered into with a shareholder in 2002. See Notes K and U to Notes to Financial Statements. The cash portion of the interest expense is due to interest paid on outstanding indebtedness, including the convertible notes, the \$1 million shareholder loan, the line of credit, and notes and leases for capital equipment.

Other Income/Expense

Other income was \$14,645 for the year ended December 31, 2003 compared to other expense of \$63,047 for the year ended December 31, 2002.

Net Earnings (Loss)

The net loss for the year ended December 31, 2003 was \$8,742,537 compared to a net loss of \$2,661,152 for the year ended December 31, 2002. The substantial increase in net loss was primarily the result of the increased interest expense.

Restatement of Financial Information

During the year ended December 31, 2003, the Company determined that certain costs that were incurred during 2002 and deferred as a prepaid expense at December 31, 2002, should have been expensed in the year ended December 31, 2002. These costs totaled approximately \$104,000 and were incurred in conjunction with the anticipated sale of its probiotics business. These costs have been recorded as a prior period adjustment in the period ended December 31, 2003.

During the year ended December 31, 2003, the Company determined that severance costs related to the separation agreement with its former Chief Scientific Officer and its former Vice President of Administration that were classified as Other expense, should have been classified as General and Administrative expense

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on the Statement of Operations. These costs totaling \$157,448 and \$159,152 for the years ended December 31, 2003 and 2002, respectively have been reported in General and Administration expense.

The following is a summary of the effects of such restatement on the Company's financial statements as of December 31, 2002 and for the year then ended:

| | <u>As Originally Reported</u> | <u>As Restated</u> |
|------------------------------------|-----------------------------------|--------------------|
| Balance Sheet: | | |
| Current assets | \$ 1,645,766 | \$ 1,541,942 |
| Total assets | 4,013,837 | 3,910,013 |
| Accumulated deficit | (12,830,343) | (12,934,167) |
| Stockholders' equity | 1,231,907 | 1,128,083 |
| Statement of Operations: | | |
| General and Administrative expense | \$ 2,470,292 | \$ 2,733,268 |
| Operating profit (loss) | \$ (2,006,206) | \$ (2,269,182) |
| Other expense (severance costs) | \$ (159,152) | \$ (0) |
| Net earnings (loss) | \$ (2,557,328) | \$ (2,661,152) |
| Net loss per share | \$ (0.13) | \$ (0.13) |

Liquidity and Capital Resources

As of December 31, 2003, the Company had working capital of \$817,107 as compared to negative working capital of \$145,692 at December 31, 2002. The change in working capital reflects the issuance of \$5.3 million of convertible notes in June 2003 for net proceeds of approximately \$4.7 million and is offset by the net loss for the year ended December 31, 2003. In February 2004, we completed the sale of 3,206,538 shares of common stock and 801,636 warrants for net proceeds of approximately \$9.4 million. We believe that we have sufficient resources to fund our drug delivery business at planned levels and to seek collaborative development projects over the next two years.

In connection with the sale of our probiotics unit, we repaid our \$800,000 line of credit (of which \$155,488 was outstanding on December 31, 2003) together with the \$1 million loan from a shareholder.

We will require substantial additional financing to implement our business plan to develop our drug delivery business. Our long term financing needs depend largely on our ability to enter into alliances and collaborations that will help finance the 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. We anticipate that we will need to raise additional financing to fund these efforts. See **Risk Factors** for more information regarding our financing requirements and the related risks and uncertainties.

As of December 31, 2003, we had accounts receivable of \$716,676 (less \$0 for doubtful accounts), as compared to \$486,417 as of December 31, 2002 (less \$12,524 for doubtful accounts), a net change of \$230,259. The increase in accounts receivable is mainly attributable to the accrual of royalty revenue from the sales of CDT products. These royalties are due 30 days after quarter end.

Table of Contents**Contractual Obligations**

As of December 31, 2003, our commitments to make future payments under long term contractual obligations were as follows (in thousands):

| Contractual Obligations | Payments Due by Period | | | |
|-------------------------|------------------------|---------------------|-------------------|-------------------|
| | Total | Less than 1 Year | 1 to 3 Years | 4 to 5 Years |
| Operating Leases | \$ 591,665 | \$ 8,008 | \$ 472,233 | \$ 111,424 |
| Capital Lease | 121,367 | 65,896 | 55,471 | |
| Total | \$ 713,032 | \$ 73,904 | \$ 527,704 | \$ 111,424 |

New Accounting Pronouncements

In May 2003, Financial Accounting Standards Board (FASB) issued Statement 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. Statement 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. Statement 150 is effective for all financial instruments entered into or modified after May 31, 2003. The Company adopted Statement 150 on June 1, 2003. The adoption of Statement 150 did not have any effect on the Company's financial position, results of operations, or cash flows.

The FASB has published a revision to Interpretation 46 (46R) to clarify some of the provisions of FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, and to exempt certain entities from its requirements. The additional guidance is being issued in response to input received from constituents regarding certain issues arising in implementing Interpretation 46.

Under the new guidance, special effective date provisions apply to enterprises that have fully or partially applied Interpretation 46 prior to issuance of this revised Interpretation. Otherwise, application of Interpretation 46R (or Interpretation 46) is required in financial statements of public entities that have interests in structures that are commonly referred to as special-purpose entities for periods ending after December 15, 2003. Application by public entities, other than small business issuers, for all other types of variable interest entities is required in financial statements for periods ending after March 15, 2004. Application by small business issuers to variable interest entities other than special-purpose entities and by nonpublic entities to all types of variable interest entities is required at various dates in 2004 and 2005. In some instances, enterprises have the option of applying or continuing to apply Interpretation 46 for a short period of time before applying this revised Interpretation. We believe that adoption of Interpretation 46 will have no effect on our financial statements.

Risk Factors

The following is a description of some of the risks and uncertainties that may cause our actual results of operation to differ materially from those currently expected or desired.

We have incurred substantial operating losses and expect to continue to incur substantial losses.

We had a net loss of \$8,742,537 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;

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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 operations.

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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 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 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. 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.

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, KV Pharmaceuticals, Labopharm, Penwest and Skyepharma.

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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 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. 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 Nutricia, a subsidiary of General Nutrition Corporation, in connection with the manufacture and distribution of glucosamine & chondroitin to Walmart and Rite Aid. We are currently finalizing a written agreement with Nutricia. We believe we are current with respect to our obligations under existing agreements.

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

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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.

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. We also rely on members of our scientific staff for product research and development. Our employment agreement with Mr. Turner has no set term and may be terminated by Mr. Turner on 30 days' notice. 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

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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.

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

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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

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 February 27, 2004, the sale price of our common stock has ranged between a low of \$0.82 and a high of \$3.97.

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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.

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.

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Item 7. *Financial Statements*

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REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors and Stockholders

SCOLR, Inc.

We have audited the accompanying balance sheets of SCOLR, Inc. (a Delaware Corporation) as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above, present fairly, in all material respects, the financial position of SCOLR, Inc. as of December 31, 2003 and 2002, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note V of Notes to the Financial Statements, the 2002 financial statements have been restated.

/s/ GRANT THORNTON LLP

Seattle, Washington
February 20, 2004, except for notes C and W, as to
which the date is February 24, 2004

Table of Contents**SCOLR, INC.****BALANCE SHEETS**

| | December 31, | |
|---|---------------------|-------------------------------|
| | 2003 | 2002 (As Restated) |
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash | \$ 1,282,656 | \$ 257,382 |
| Accounts receivable, less allowance for doubtful accounts of \$0 and \$12,524, respectively | 716,676 | 486,417 |
| Current portion of notes receivable | 961,854 | 166,154 |
| Inventories | | 493,541 |
| Prepaid expenses | 227,363 | 138,448 |
| | <hr/> | <hr/> |
| Total current assets | 3,188,549 | 1,541,942 |
| PROPERTY AND EQUIPMENT net | 299,371 | 1,494,315 |
| OTHER ASSETS | | |
| Intangible assets net | 359,409 | 818,371 |
| Noncurrent portion of notes receivable | 1,660,615 | 55,385 |
| | <hr/> | <hr/> |
| | \$ 5,507,944 | \$ 3,910,013 |
| | <hr/> | <hr/> |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| CURRENT LIABILITIES | | |
| Line of credit | \$ 155,488 | \$ 296,387 |
| Current maturities of long-term obligations | | 168,870 |
| Current maturities of capital lease obligations | 52,801 | 215,347 |
| Stockholder loan payable, less discount on debt of \$10,677 | 989,323 | |
| Accounts payable trade | 544,246 | 782,385 |
| Accrued liabilities | 529,584 | 124,645 |
| Deferred revenue | 100,000 | 100,000 |
| | <hr/> | <hr/> |
| Total current liabilities | 2,371,442 | 1,007,030 |
| LONG-TERM OBLIGATIONS, less current maturities | | 56,650 |
| CAPITAL LEASE OBLIGATIONS, less current maturities | 50,979 | 327,273 |
| SHAREHOLDER LOAN PAYABLE, less discount on debt of \$289,627 | | 710,373 |
| COMMITMENTS AND CONTINGENCIES (Note L) | | |
| STOCKHOLDERS EQUITY | | |
| Preferred stock, authorized 5,000,000 shares, \$.01 par value, none issued or outstanding | | |
| Common stock, authorized 50,000,000 shares, \$.001 par value, 26,462,646 and 21,198,947 issued and outstanding as of December 31, 2003 and 2002, respectively | 26,463 | 21,199 |
| Additional contributed capital | 24,735,764 | 14,041,051 |
| Accumulated deficit | (21,676,704) | (12,934,167) |
| | <hr/> | <hr/> |
| Total stockholders equity | 3,085,523 | 1,128,083 |
| | <hr/> | <hr/> |
| | \$ 5,507,944 | \$ 3,910,013 |
| | <hr/> | <hr/> |

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The accompanying notes are an integral part of these financial statements.

Table of Contents**SCOLR, INC.****STATEMENTS OF OPERATIONS**

| | Years Ended December 31, | |
|---------------------------------------|---------------------------------|-------------------------------|
| | 2003 | 2002 (As Restated) |
| Net revenues | \$ 6,594,073 | \$ 6,514,243 |
| Cost of revenues | 4,576,679 | 5,136,609 |
| | <u>2,017,394</u> | <u>1,377,634</u> |
| Gross profit | | |
| Operating expenses | | |
| Marketing and selling | 479,714 | 372,722 |
| Research and development | 403,186 | 540,826 |
| General and administrative | 4,193,294 | 2,733,268 |
| | <u>5,076,194</u> | <u>3,646,816</u> |
| Operating loss | (3,058,800) | (2,269,182) |
| Other income (expense) | | |
| Interest expense | (5,698,382) | (328,923) |
| Other | 14,645 | (63,047) |
| | <u>(5,683,737)</u> | <u>(391,970)</u> |
| NET LOSS | \$ (8,742,537) | \$ (2,661,152) |
| Net loss per share, basic and diluted | \$ (0.41) | \$ (0.13) |

The accompanying notes are an integral part of these financial statements.

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SCOLR, INC.

STATEMENT OF STOCKHOLDERS EQUITY

Years Ended December 31, 2003 and 2002 (As Restated)

| | Common Stock | | Additional Contributed Capital | Accumulated Other Comprehensive Income | Stock Subscription | Subscription Receivable | Accumulated Deficit | Total |
|---|--------------|-----------|--------------------------------------|---|-----------------------|----------------------------|------------------------|--------------|
| | Shares | Amount | | | | | | |
| Balance at January 1, 2002 | 18,008,289 | \$ 18,008 | \$ 11,871,184 | \$ (35,982) | \$ 120,000 | \$ (120,000) | \$ (10,273,015) | \$ 1,580,195 |
| Issuance of common stock for cash, net of fees of \$4,963 | 2,890,658 | 2,891 | 1,574,040 | | | | | 1,576,931 |
| Impairment of available for sale security | | | | 35,982 | | | | 35,982 |
| Fair value of warrants issued with debt | | | 331,002 | | | | | 331,002 |
| Fair value of warrants issued for services | | | 145,125 | | | | | 145,125 |
| Issuance of common stock for stock subscription and note receivable exchanged for services | 300,000 | 300 | 119,700 | | (120,000) | 120,000 | | 120,000 |
| Net loss for the year | | | | | | | (2,661,152) | (2,661,152) |
| Balance at December 31, 2002 | 21,198,947 | 21,199 | 14,041,051 | | | | (12,934,167) | 1,128,083 |
| Issuance of common stock for cash | 216,140 | 216 | 145,747 | | | | | 145,963 |
| Fair value of stock options and warrants issued for services | | | 43,400 | | | | | 43,400 |
| Fair value of warrants issued with debt and beneficial conversion feature | | | 4,313,659 | | | | | 4,313,659 |
| Conversion of debt to common stock | 5,047,559 | 5,048 | 5,294,952 | | | | | 5,300,000 |
| Additional compensation due to accelerated vesting of employee stock options | | | 896,955 | | | | | 896,955 |
| Net loss for the year | | | | | | | (8,742,537) | (8,742,537) |
| Balance at December 31, 2003 | 26,462,646 | \$ 26,463 | \$ 24,735,764 | \$ | \$ | \$ | \$ (21,676,704) | \$ 3,085,523 |

The accompanying notes are an integral part of this financial statement.

Table of Contents**SCOLR, INC.****STATEMENTS OF CASH FLOWS**

| | December 31, | |
|--|--------------------|-----------------------|
| | 2003 | 2002 (As Restated) |
| Cash flows from operating activities: | | |
| Net loss | \$(8,742,537) | \$(2,661,152) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 490,684 | 489,300 |
| Loss on the sale of equipment | | 38,045 |
| Amortization of discount on debt | 4,006,899 | 41,375 |
| Loss on sale of intangible assets | 15,930 | |
| Amortization of debt issuance costs | 1,295,563 | |
| Warrants, stock options, and common stock issued for services | 43,400 | 265,125 |
| Impairment of available-for-sale security | | 35,982 |
| Expense for accelerated vesting of employee stock options | 896,955 | |
| Loss on sale of operations | 98,891 | |
| Changes in assets and liabilities | | |
| Accounts receivable | (230,259) | 488,423 |
| Notes receivable | 166,154 | 184,490 |
| Inventories | (563,611) | 251,557 |
| Prepaid expenses | (144,945) | 25,508 |
| Accounts payable | (256,001) | 54,268 |
| Accrued liabilities and deferred revenue | 92,257 | (173,128) |
| Net cash used in operating activities | <u>(2,830,620)</u> | <u>(960,207)</u> |
| Cash flows from investing activities: | | |
| Proceeds from sale of intangible assets | 130,000 | |
| Purchase of equipment and furniture | (246,988) | (44,170) |
| Proceeds from sale of equipment | | 49,504 |
| Patent and technology rights expenditures | (211,216) | (154,140) |
| Net cash used in investing activities | <u>(328,204)</u> | <u>(148,806)</u> |
| Cash flows from financing activities: | | |
| Payments on long-term obligations and capital lease obligations | (453,389) | (606,663) |
| Payments on bridge note payable | (550,000) | |
| Proceeds from shareholder note payable & long-term obligations | 42,276 | 1,124,940 |
| Proceeds from convertible note payable, net of issuance costs | 4,634,897 | |
| Proceeds from bridge note payable, net of issuance costs | 505,250 | |
| Net payments on line of credit | (140,899) | (821,895) |
| Net proceeds from issuance of common stock, net of costs | 145,963 | 1,576,931 |
| Net cash provided by financing activities | <u>4,184,098</u> | <u>1,273,313</u> |
| Net increase in cash | 1,025,274 | 164,300 |
| Cash at beginning of period | 257,382 | 93,082 |

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| | | |
|---|--------------|------------|
| Cash at end of period | \$ 1,282,656 | \$ 257,382 |
| Cash paid during the year for: | | |
| Interest | \$ 395,922 | 287,548 |
| Noncash investing and financing activities: | | |
| Purchase of equipment under capital lease obligations | \$ | \$ 130,567 |
| Issuance of warrants for debt issuance costs | \$ 585,710 | \$ 331,002 |
| Issuance of common stock for stock subscription | \$ | \$ 120,000 |
| Conversion of debt into common stock | \$ 5,300,000 | \$ |
| Fair value of assets sold with probiotics unit | \$ 2,588,678 | \$ |
| Net liabilities assumed from sale of probiotics unit | \$ 253,247 | \$ |

The accompanying notes are an integral part of these financial statements.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS****December 31, 2003 and 2002****Note A Summary of Significant Accounting Policies**

SCOLR, Inc. (the Company) is a drug delivery company that develops and formulates pharmaceutical, over-the-counter, and nutritional products. SCOLR is currently active in the controlled delivery technologies business and was active in 2003 and prior years in the nutraceutical industry, including dietary supplements, probiotics, and specialty food ingredients. The Company uses its patented CDT™ controlled delivery technologies to develop products and license technology to pharmaceutical and nutritional product companies. Until 2003, the Company also manufactured and packaged probiotics, developed proprietary nutritional product formulations, and offered specialty nutraceutical ingredients, including several that utilize CDT™ technologies. Effective December 31, 2003, the Company sold its probiotics development and manufacturing unit. The Company's customers are located throughout the United States.

A summary of the Company's significant accounting policies consistently applied in the preparation of the accompanying financial statements follows.

1. Accounts Receivable

The majority of the Company's account receivable are due from companies in the human and agricultural nutraceutical industries. Credit is extended based on evaluation of a customer's financial condition and generally, collateral is not required. Accounts receivable are due within 30 days and are stated at amounts due from customers net of an allowance for doubtful accounts if considered necessary. Accounts outstanding longer than the contractual payment terms are considered past due. The Company determines its allowance by considering a number of factors, including the length of time trade accounts receivable are past due, the company's previous loss history, the customer's current ability to pay its obligation to the Company, and the condition of the general economy and the industry as a whole. The Company writes off accounts receivable when they become uncollectible, and payments subsequently received on such accounts are credited to the allowance for doubtful accounts.

2. Inventories

Inventories are stated at the lower of cost or market; cost is determined using the first-in, first-out method. The Company establishes an allowance for potentially obsolete and slow moving items.

3. Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided for in amounts sufficient to relate the cost of depreciable assets to operations over their estimated service lives. Leasehold improvements are amortized over the lives of the respective leases or the service lives of the improvements, whichever is shorter. Leased property under capital leases is amortized over the service lives of the assets as the leases substantially transfer ownership and have bargain purchase options. The straight-line method of depreciation is followed for substantially all assets for financial reporting purposes. The estimated useful lives in determining depreciation and amortization are as follows:

| | |
|--|------------|
| Furniture and fixtures | 3-5 years |
| Machinery and equipment | 3-10 years |
| Leasehold improvements | 3 years |
| Machinery and equipment under capital leases | 3-10 years |

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SCOLR, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

4. Intangible Assets

Intangible assets include capitalized technical and product rights, patents and trademarks. Technical and product rights and patents and trademarks are stated at cost and amortized to operations over their estimated useful lives or statutory lives, whichever is shorter. The weighted average remaining amortization period of patents and trademarks at December 31, 2003 was 9.05 years. The Company evaluates its technical and product rights and patents and trademarks annually to determine potential impairment by examining the carrying amount of the assets to determine if the carrying amount is recoverable, and by comparing the carrying amount to the asset's fair value.

5. Revenue Recognition

The Company generates revenue from technology licenses, collaborative research and development arrangements, and cost reimbursement contracts. Revenue under technology licenses and collaborative agreements typically consists of nonrefundable and/or guaranteed technology license fees, technology access fees, and various milestone and future product royalty payments.

Revenues from license fees, option fees and up-front payments, which are received in connection with other rights or services that represent continuing obligations of the Company, are recognized systematically over the period that the fees or payments are earned. Revenues from milestone payments representing completion of separate and substantive earnings processes are recognized when the milestone is achieved and amounts are due and payable.

Revenues from royalties are received from related and third parties for sales of products that include technology developed or licensed by the Company. Revenues are recognized when due and amounts are considered collectible.

Revenue from the sale of nutraceutical products is recognized upon shipment to the customer.

6. Research and Development Costs

All expenditures for research and development are expensed in the period they are incurred.

7. Earnings (Loss) Per Share

Basic earnings (loss) per share are based on the weighted average number of shares outstanding during the year and income available to common shareholders. Earnings (loss) per share assuming dilution are based on the assumption that outstanding stock options and warrants were exercised. The weighted average shares for computing basic earnings (loss) per shares were 21,518,982 and 20,124,161 for the years ended December 31, 2003 and 2002, respectively. At December 31, 2003 there were 4,201,607 shares of potentially issuable common stock. Because of the net loss for the year ended December 31, 2003, potentially issuable common stock was not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive.

8. Stock-Based Compensation

The Company has a stock based employee compensation plan, which is described more fully in Note R. The Company applies APB Opinion 25, Accounting for Stock Issued to Employees, and related Interpretations in accounting for its plan. Because the exercise price of the Company's common stock equals the market price of the underlying stock on the date of the grant, no corresponding compensation expense has been recognized. However, in 2003, in conjunction with the sale of the probiotics development and manufacturing unit, the Company recognized expense of \$896,955 as the result of accelerated vesting of 672,035 shares of employee stock options.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company has adopted the disclosure only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123). If the Company had elected to recognize compensation expense based upon the fair value at the grant date for awards under these plans consistent with the methodology prescribed by SFAS 123, the Company's net loss would change to the pro forma amounts indicated below.

The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS 123 using the assumption described in Note R to its stock-based awards.

| | 2003 | (As Restated) 2002 |
|---|---------------|-----------------------|
| Net loss | | |
| As reported | \$(8,742,537) | \$(2,661,152) |
| Total stock-based compensation expense determined under fair-value-based method | (877,643) | (127,091) |
| Stock-based compensation expense included in reported net loss | 896,955 | |
| Pro forma net loss | \$(8,723,225) | \$(2,788,243) |
| Net loss per share | | |
| As reported | \$ (0.41) | \$ (0.13) |
| Pro forma | \$ (0.41) | \$ (0.14) |

9. Use of Estimates

In preparing the Company's financial statements in accordance with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

10. Reclassifications

Certain reclassifications have been made to the 2002 financial statements to conform to the 2003 presentation.

11. New Accounting Pronouncements

In May 2003, Financial Accounting Standards Board (FASB) issued Statement 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. Statement 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. Statement 150 is effective for all financial instruments entered into or modified after May 31, 2003. The Company adopted Statement 150 on June 1, 2003. The adoption of Statement 150 did not have any effect on the Company's financial position, results of operations, or cash flows.

The FASB has published a revision to Interpretation 46 (46R) to clarify some of the provisions of FASB Interpretation No. 46, Consolidation of Variable Interest Entities, and to exempt certain entities from its requirements. The additional guidance is being issued in response to input received from constituents regarding certain issues arising in implementing Interpretation 46. Under the new guidance, special effective date provisions apply to enterprises that have fully or partially applied Interpretation 46 prior to issuance of this revised Interpretation. Otherwise, application of Interpretation 46R (or Interpretation 46) is required in financial statements of public entities that have interests in structures that are commonly referred to as special-purpose entities for periods ending after December 15, 2003. Application by public entities,

other than

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

small business issuers, for all other types of variable interest entities is required in financial statements for periods ending after March 15, 2004. Application by small business issuers to variable interest entities other than special-purpose entities and by nonpublic entities to all types of variable interest entities is required at various dates in 2004 and 2005. In some instances, enterprises have the option of applying or continuing to apply Interpretation 46 for a short period of time before applying this revised Interpretation. The Company believes that adoption of Interpretation 46 will have no effect on its financial statements.

Note B Sale of Operations

The Company's operations are comprised of a single reportable segment. The financial information used by the Company's Chief Operating decision maker is only provided for this single reportable segment.

Effective December 31, 2003, the Company sold its probiotics development and manufacturing unit and assets to Steven H. Moger, the Company's former Vice President of Operations, Chief Financial Officer, and General Manager. Mr. Moger has resigned his position as an officer of the Company in connection with the sale. The purchase price was \$2.72 million, which included payment for certain inventories and tangible assets, as well as all intellectual property related to the Company's probiotics development and manufacturing unit. In addition, Mr. Moger assumed certain lease obligations. The Company received \$722,756 cash at closing, with the remaining \$2 million subject to the buyer's achievement of certain sales levels and royalties. Certain other indemnification obligations relating to title to the assets sold, compliance with laws, and certain matters relating to taxes continue until the expiration of the statute of limitations applicable to claims with respect to such matters. As of the December 31, 2003 transaction date, the carrying amount of assets and liabilities included in the sale transaction were as follows:

| | |
|-------------------------------|-------------------|
| Assets | |
| Inventories | \$1,055,133 |
| Prepaid expense | 56,030 |
| Property and Equipment | 1,133,967 |
| Technical and Property Rights | 114,975 |
| Patents and Trademarks | 228,573 |
| | <u>2,588,678</u> |
| Liabilities | |
| Note Payable | \$ 51,127 |
| Lease Obligations | 202,120 |
| | <u>\$ 253,247</u> |

The purchase price includes the initial payment of \$722,756 and the Deferred Purchase Price of \$2 million. The Deferred Purchase Price is comprised of the following: (1) Percentage of Buyers Total Covered Sales of 0%-10% per year as defined in the agreement, and (2) Royalty fee equal to 10% of the Controlled Delivery Technology sales. There are also minimum payments that must be made each year regardless of the sales levels or royalty amounts calculated. Payments of the Deferred Purchase Price shall be made quarterly. Such payments shall be made for a period equal to the longer of (a) four years, or (b) until the combined total of payments of the Deferred Purchase Price and Royalty payments equals \$2 million. The Company has calculated the Present value of the \$2 million based on estimated projected payments and using a rate equal to the Federal Treasury's five-year treasury bill rate of 3.27% at December 31, 2003. Since the Deferred Purchase Price is known and is a minimum amount and the only contingency is the amount to be paid per year, the \$1,844,328 present value amount is included in the total purchase price in determining the gain or loss on the sale of assets.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The loss resulting from the Company's sale of its probiotics development and manufacturing unit is summarized as follows:

| | |
|----------------------------------|------------|
| Cash received at closing | \$ 722,756 |
| Discounted note receivable | 1,844,328 |
| Liabilities assumed by purchaser | 253,247 |
| | <hr/> |
| Total proceeds | 2,820,331 |
| Carrying value of assets sold | 2,588,678 |
| Transaction expenses | 330,544 |
| | <hr/> |
| Loss on sale | \$ 98,891 |
| | <hr/> |

Note C Management Plans

The Company incurred a net loss of \$8.7 million for the year ended December 31, 2003 and used cash from operation of \$2.8 million. The Company has \$1.3 million in cash at December 31, 2003. Effective December 31, 2003, the Company sold its probiotics development and manufacturing operations, which was the Company's primary revenue generating unit. In 2004, the Company will devote its efforts to the development and marketing of its Drug Delivery operations. Accordingly, revenues are expected to be substantially less in 2004 and the Company's Drug Delivery operations are expected to consume substantial amounts of cash. Additionally, the Company's negative cash flow from operations is expected to continue and possibly accelerate, in the foreseeable future. The development of the Company's technology and potential products will continue to require substantial funds.

In February 2004, the Company raised approximately \$10.4 million through the sale of 3,206,538 shares of common stock. The Company also expects to increase revenues related to its Drug Delivery business in 2004 and in the future. Due to this and other factors, the Company believes it will continue as a going concern through 2004 and beyond.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate the continuation of the Company as a going concern. The financial statements do not include any adjustments to reflect the possible effects on the recoverability and classification of assets and liabilities that may result from the outcome of this uncertainty.

Note D Accounts Receivable

Accounts receivable consist of the following at December 31:

| | <u>2003</u> | <u>2002</u> |
|---|-------------|-------------|
| Trade receivables | \$ 589,001 | \$ 498,941 |
| Royalty receivable | 127,675 | |
| Less allowance for doubtful receivables | | (12,524) |
| | <hr/> | <hr/> |
| Net receivables | \$ 716,676 | \$ 486,417 |
| | <hr/> | <hr/> |

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Changes in the Company's allowance for doubtful accounts are as follows at December 31:

| | <u>2003</u> | <u>2002</u> |
|-------------------------------------|-------------|-----------------|
| Beginning Balance | \$ 12,524 | \$ |
| Write-off of uncollectible accounts | (12,524) | |
| Bad debt expense | 5,000 | 18,051 |
| Accounts written-off | (5,000) | (5,527) |
| Ending Balance | <u>\$</u> | <u>\$12,524</u> |

Note E Notes Receivable

Notes receivable consist of the following at December 31:

| | <u>2003</u> | <u>2002</u> |
|---|--------------------|------------------|
| Note receivable for D-Glucarate agreement; with monthly payments of \$13,846 through April 2004 | \$ 55,385 | \$221,539 |
| Note receivable from sale of probiotics unit; payments per agreement (see Note B) | 1,844,328 | |
| Note receivable from sale of probiotics unit; payment due on closing | 722,756 | |
| | <u>2,622,469</u> | <u>221,539</u> |
| Less current portion | 961,854 | 166,154 |
| | <u>\$1,660,615</u> | <u>\$ 55,385</u> |

Aggregate maturities of notes receivable are as follows:

| <u>Year Ending December 31,</u> | |
|---------------------------------|--------------------|
| 2004 | \$ 961,854 |
| 2005 | 458,515 |
| 2006 | 571,120 |
| 2007 | 510,845 |
| 2008 | 120,135 |
| Total | <u>\$2,622,469</u> |

The note receivable from the sale of the probiotics unit is based on an estimate of the estimated quarterly payments to be received discounted using to the five year United States Treasury bill rate of 3.27% on December 31, 2003.

Note F Inventories

While inventories have historically been a material component of the Company's financial statements, there were no remaining inventories at the end of 2003 because all inventories were sold with the sale of the probiotics development and manufacturing unit on December 31, 2003.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Inventories consist of the following at December 31:

| | <u>2003</u> | <u>2002</u> |
|---|-------------|-------------|
| Raw materials | \$ | \$270,165 |
| Work in progress | | 206,386 |
| Finished goods | | 52,467 |
| | — | — |
| | | 529,018 |
| Less allowance for obsolete and slow moving items | | 35,477 |
| | — | — |
| | \$ | \$493,541 |
| | — | — |

Note G Property and Equipment

Property and equipment consist of the following at December 31:

| | <u>2003</u> | <u>2002</u> |
|---|-------------|-------------|
| Furniture and fixtures | \$ 29,511 | \$ 70,129 |
| Machinery and equipment | 207,117 | 2,104,984 |
| Leasehold improvements | | 71,962 |
| Machinery and equipment under capital leases | 239,790 | 966,278 |
| | — | — |
| | 476,418 | 3,213,353 |
| Less accumulated depreciation and amortization | 28,262 | 1,437,172 |
| Less accumulated amortization of machinery and equipment under capital leases | 148,785 | 281,866 |
| | — | — |
| | \$299,371 | \$1,494,315 |
| | — | — |

Note H Intangible Assets

Intangible assets consist of the following at December 31:

| | <u>2003</u> | <u>2002</u> |
|-------------------------------|-------------|-------------|
| Technical and product rights | \$ | \$2,237,444 |
| Patents and trademarks | 497,346 | 899,527 |
| | — | — |
| | 497,346 | 3,136,971 |
| Less accumulated amortization | 137,937 | 2,318,600 |
| | — | — |
| | \$359,409 | \$ 818,371 |

For the years ended December 31, 2003 and 2002, amortization expense totaled \$182,719 and \$189,450, respectively.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The following is a schedule by years of future amortization expense based on existing intangible assets as of December 31, 2003.

| <u>Year Ending December 31,</u> | |
|---------------------------------|------------|
| 2004 | \$ 62,568 |
| 2005 | 58,735 |
| 2006 | 47,651 |
| 2007 | 42,235 |
| 2008 | 38,234 |
| | <hr/> |
| Total | \$ 249,423 |
| | <hr/> |

Note I Line of Credit

On April 30, 2003, the Company renewed its secured line of credit agreement for a term of one year with a borrowing base equal to the lesser of 90% of eligible trade receivables or \$800,000, bearing interest at the rate of prime plus 8% (12% at December 31, 2003). The line of credit is collateralized by accounts receivable, inventories and equipment and expires on April 30, 2004. The last advance on the line was in December 2003 in anticipation of the sale of the probiotics unit. The line was subsequently paid off in January 2004.

Note J Long-Term Obligations

The Company had no remaining notes payable at the end of 2003 as all notes were either paid off during 2003 or assumed by the purchaser upon the sale of the probiotics development and manufacturing unit on December 31, 2003.

Long-term obligations consist of the following at December 31:

| | <u>2003</u> | <u>2002</u> |
|---|-------------|-------------|
| Notes payable for equipment; with monthly installments totaling \$13,801, including 16.4% interest; collateralized by production equipment; due in 2003 | \$ | \$ 96,707 |
| Notes payable to third party for leasehold improvement advance, payable in 34 monthly installments of \$3,695 including 15.5% interest | | 75,856 |
| Note payable to a third party for payment of legal settlement; payable in 36 monthly installments of \$5,000 beginning April 3, 2000; no stated interest rate | | 10,000 |
| Note payable to a third party; with monthly installments of \$1,643, including interest at 12.7%; collateralized by equipment | | 26,800 |
| Other notes payable | | 16,157 |
| | <hr/> | <hr/> |
| | | 225,520 |
| Less current maturities | | 168,870 |
| | <hr/> | <hr/> |
| | \$ | \$ 56,650 |
| | <hr/> | <hr/> |

Note K Shareholder Loan Payable and Warrant Issuance

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On September 30, 2002, the Company received a \$1,000,000 secured loan from an existing shareholder. The loan is due on September 30, 2004 and bears interest at a rate of 8% which is due monthly beginning November 1, 2002. The loan is secured by substantially all of the assets of the Company. In conjunction with the loan, the Company granted warrants to purchase 750,000 shares of common stock at \$0.50 per share

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

exercisable for ten years. The loan was discounted for the relative fair value of the warrants totaling approximately \$331,000, which is being recognized as interest expense over the loan term. The fair value of warrants was determined using the Black-Scholes option-pricing model with the following assumptions: volatility of 79%, risk-free interest rate of 3%, expected life of ten years and 0% dividend yield. At December 31, 2003, the balance of the loan was \$989,323, net of a discount of \$10,677. The expected life of the loan was shortened and the amortization of the discount accelerated due to the subsequent payment in full of the note upon the closing of the sale of the probiotics unit in January 2004. Interest expense recognized from the amortization of the discount during the year ended December 31, 2003 totaled \$278,950.

Note L Lease Obligations

The Company conducts a substantial portion of its operations utilizing leased manufacturing and office facilities, expiring through 2007. Some of the operating leases provide that the Company pays taxes, maintenance, insurance and other occupancy expenses applicable to leased premises. The Company also leases machinery and equipment under capital leases expiring through 2006.

The following is a schedule by years of future minimum lease payments together with the present value of the minimum payments under capital and operating leases as of December 31, 2003:

| <u>Year Ending December 31,</u> | <u>Capital Leases</u> | <u>Operating Leases</u> |
|---|---------------------------|-----------------------------|
| 2004 | \$ 65,896 | \$ 8,008 |
| 2005 | 52,247 | 147,704 |
| 2006 | 3,224 | 160,896 |
| 2007 | | 163,633 |
| 2008 | | 111,424 |
| | <u>121,367</u> | <u>\$591,665</u> |
| Future minimum lease payments | | |
| | 17,587 | |
| Less amount representing interest | | |
| Present value of minimum lease payments | <u>\$103,780</u> | |
| Current maturities | \$ 52,801 | |
| Long-term maturities | 50,979 | |
| | <u>\$103,780</u> | |

Rent expense for leased facilities and equipment was \$777,770 and \$708,284 for the years ended December 31, 2003 and 2002, respectively.

Note M Income Taxes

The Company accounts for income taxes using the liability method as prescribed by Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The income tax provision reconciled to the tax computed at the statutory federal rate was approximately as follows at December 31:

| | <u>2003</u> | <u>2002</u> |
|--|---------------|-------------|
| Tax benefit at statutory rate | \$(2,972,500) | \$(869,500) |
| Permanent differences | 1,237,800 | 2,400 |
| Expiration of net operating losses and credits | 157,500 | 400,500 |
| Increase (decrease) in valuation allowance | 1,577,200 | 466,600 |
| | <u>\$</u> | <u>\$</u> |

Deferred tax assets and liabilities consist of the approximately following at December 31:

| | <u>2003</u> | <u>2002</u> |
|--|--------------|--------------|
| Current asset, net | | |
| Inventory and accounts receivable reserves | \$ | \$ 16,300 |
| Other accrued liabilities | 20,200 | 41,200 |
| Warrants issued for services and interest | 383,200 | 63,400 |
| Less valuation allowance | (403,400) | (120,900) |
| | <u>\$</u> | <u>\$</u> |
| Non-current asset, net | | |
| Net operating loss carry forwards | \$ 3,242,000 | \$ 2,052,600 |
| Depreciation and amortization | (136,500) | (244,400) |
| Other tax credits | | 2,600 |
| Less valuation allowance | (3,105,500) | (1,810,800) |
| | <u>\$</u> | <u>\$</u> |

The Company has established a valuation allowance of \$3,508,900 and \$1,931,700 as of December 31, 2003 and 2002, respectively, due to the uncertainty of future utilization of net operating loss carryforwards and realization of other deferred tax assets.

At December 31, 2003, an operating loss carryforward of approximately \$9,535,000 expiring through 2023 is available to offset future taxable income. Net operating loss carryforwards of approximately \$456,000 and \$1,077,000 expired during 2003 and 2002, respectively. Tax credits of approximately \$2,600 and \$34,200 expired during 2002 and 2003, respectively. If ownership changes should occur, there may be certain limitations on the use of these carryforwards, as defined by Internal Revenue Code Section 382.

Note N Separation Agreement

The Company entered into a separation agreement with its former Chief Scientific Officer and a separation agreement with its former Vice President of Administration, Secretary and Treasurer, both of which became fully binding on the parties on March 31, 2001 and effective as of January 15, 2001. At December 31, 2003 and 2002, the Company recorded severance costs totaling \$157,448 and \$159,152, respectively. These costs have been reclassified from Other Expense, as previously reported, to General and Administrative expense.

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Under this agreement the Company is to pay the former Chief Scientific Officer \$12,500 a month through January 15, 2004. If this individual earns an income during the three-year period from January 15, 2001 through January 15, 2004, then the amounts earned will offset payments due him. For the first twelve

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SCOLR, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

months of the agreement, no amounts offset the monthly payments. Beginning with the period ended January 15, 2002 and for each twelve-month period thereafter, the former Chief Scientific Officer is to provide the Company with an accounting of income earned during the preceding twelve months. The amount earned will then be used to offset future payments. As future payments are contingent upon the earnings of this individual, no liability is established for the preceding twelve months. At December 31, 2003, the Company has accrued severance payments totaling approximately \$90,000 that may be used to offset amounts earned by the Chief Scientific Officer.

Note O Sale of Product Line and Related Intangible Assets

In February 2003, the Company sold its feed additive product line for \$230,000, net of certain royalties, to a third party for \$130,000 cash payment and an executed purchase order of inventory for the remaining \$100,000. The assets sold included inventories of \$2,019 and related intellectual property of \$122,311 resulting in a net gain of \$5,670.

Note P Technical Rights, Patent License and Royalty Agreements

The Company has agreements with Temple University (Temple) providing it with exclusive worldwide rights for its Controlled Delivery technology, with the right to sublicense. Under the terms of the agreements with Temple, the Company is required to make minimum annual royalty payments totaling \$55,000.

Under a technical and product rights agreement (the Feed Additives Agreement) with a limited partnership, which has now been dissolved, the Company had full and exclusive rights, title and interest to use and market certain feed additive products developed under the agreement. Also under the Feed Additives Agreement, the Company was required to make royalty payments to the former partners of the limited partnership on sales of feed additives until December 31, 2010. During 2003 and 2002, royalty expense for feed additives amounted to \$4,772 and \$64,929, respectively. In February 2003, the Company sold its feed additive product line to a third party for \$230,000. The assets included inventories and intellectual property of the feed additive product line. Upon closing of the sale, the Company was relieved of all future royalty payments.

On March 25, 2002, the Company entered into an Exclusive Patent License Agreement with Archer-Daniels-Midland Company (ADM). Under the terms of the agreement, the Company will grant ADM an exclusive license to manufacture, use, sell and offer to sell products covered by certain patents owned by the Company. ADM will pay the Company a running royalty on a quarterly basis. During the year ended December 31, 2003 and 2002, the Company recorded royalty revenue of \$61,567 and contract revenue of \$54,000 relating to this agreement, respectively.

Note Q Retirement Plan

The Company has a defined contribution 401(k) retirement plan (the Plan) which covers all employees. The Company will match 25% of employee contributions, up to 8% of employee contributions. The Company contributed \$15,594 and \$21,740 to the Plan for the years ended December 31, 2003 and 2002, respectively.

Note R Stock Options

Under the terms of the Company's 1995 Stock Option Plan, officers, directors, employees and others related to the Company may be granted incentive stock options or nonqualified stock options to purchase up to an authorized 4,000,000 shares of common stock. The options are generally granted at exercise prices equal to the market value of the Company's common stock on the date of the grant. The options generally vest over three years and expire ten years from date of grant.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The fair value of option grants is estimated using the Black-Scholes option-pricing model with the following assumptions for the years ended December 31:

| | <u>2003</u> | <u>2002</u> |
|-------------------------|-------------|-------------|
| Expected volatility | 73% - 78% | 83% |
| Expected dividend yield | 0% | 0% |
| Risk-free interest rate | 3.5% - 4.5% | 3% |
| Expected life | 10.0 years | 10.0 years |

A summary of the Company's stock option plan's activity is as follows:

| | <u>2003</u> | | <u>2002</u> | |
|--|------------------|--|------------------|--|
| | <u>Shares</u> | <u>Weighted Average Exercise Price</u> | <u>Shares</u> | <u>Weighted Average Exercise Price</u> |
| Outstanding at beginning of year | 2,507,675 | \$.68 | 3,490,583 | \$.67 |
| Granted | 739,399 | 1.65 | 246,802 | 1.06 |
| Exercised | (216,139) | .67 | (307,328) | .43 |
| Forfeited | (528,598) | .74 | (922,382) | .85 |
| | <u>2,502,337</u> | <u>\$.95</u> | <u>2,507,675</u> | <u>\$.68</u> |
| Options exercisable at end of year | <u>1,911,789</u> | <u>\$.80</u> | <u>1,552,050</u> | <u>\$.65</u> |
| Weighted-average fair value of options granted during the year | | <u>\$ 1.34</u> | | <u>\$.88</u> |

The following is a summary of stock options outstanding at December 31, 2003:

| | <u>Options Outstanding</u> | | |
|-----------------------|-------------------------------|--|--|
| <u>Exercise Price</u> | <u>Number Outstanding</u> | <u>Weighted-Average Remaining Contractual Life (years)</u> | <u>Number of Options Exercisable</u> |
| \$0.25 - \$0.90 | 1,626,042 | 5.868 | 1,486,612 |
| \$1.00 - \$1.20 | 466,896 | 8.639 | 270,632 |
| \$1.97 - \$2.28 | 409,399 | 9.669 | 154,545 |
| | <u>2,502,337</u> | | <u>1,911,789</u> |

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At December 31, 2003, the Company accelerated the vesting of 672,035 common stock shares of outstanding stock options for the employees terminated as result of the sale of the probiotics unit. In addition, the options that normally would have terminated three months after cessation of employment were extended to terminate at December 31, 2004. As a result, the Company has recognized \$896,955 of compensation expense according to APB Opinion 25 for the year ending December 31, 2003.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****Note S Warrants**

The Company has the following warrants outstanding to purchase common stock at December 31, 2003:

| | |
|--|-----------|
| Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.50, expiring September 2012 | 750,000 |
| Warrants issued in conjunction with services received whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.50, expiring December 2007 | 82,000 |
| Warrants issued in conjunction with services received whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.81, expiring December 2007 | 85,000 |
| Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$1.11, expiring April 2006 | 256,079 |
| Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$1.155, expiring June 2008 | 476,191 |
| Warrants issued in conjunction with services received whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$1.00, expiring March 2008 | 50,000 |
| | <hr/> |
| | 1,699,270 |
| | <hr/> |

Note T Major Customers and Concentration of Credit Risk

In 2003, the Company had sales to three customers, which accounted for approximately 21%, 21%, and 12% of net revenues. In 2002, the Company had sales to three customers, which accounted for 23%, 20%, and 10% of net revenues. All of these sales are related to the probiotics manufacturing unit sold in 2003.

The Company maintains its cash balances in two financial institutions, which at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk on cash.

Note U Financing Events***Convertible Notes Payable***

On June 25, 2003, the Company completed a private placement and issued \$5.3 million of Convertible Notes due June 25, 2006. The transaction provided the Company with approximately \$4.7 million in net proceeds. Interest accrues on the notes at 6% and is payable quarterly. Of the \$5.3 million of notes issued, \$75,000 was issued to Herbert L. Lucas, a director of the Company. The principal balance of the notes was convertible into shares of the Company's common stock at a conversion price equal to \$1.05 per share, subject to certain anti-dilution adjustments. The Company exercised its right to force conversion of all the notes into shares of the Company's common stock effective December 15, 2003, because the common stock had traded at \$2.10 or higher for 20 trading days within a 30-consecutive day trading period, as allowed under the agreement.

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In accordance with EITF 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, and EITF 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, an embedded beneficial conversion feature should be recognized and measured by allocating a portion of the proceeds of the note equal to the intrinsic value of that feature to additional paid-in

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SCOLR, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

capital. That amount should be calculated at the commitment date as the difference between the conversion price and the fair value of the common stock into which the note is convertible, multiplied by the number of shares into which the note is convertible (intrinsic value). The fair value of the Company's common stock on June 25, 2003 was \$1.77, resulting in a beneficial conversion feature of \$0.72 per share. As a result, the Company recorded a discount on the note for the beneficial conversion feature of approximately \$3.6 million, 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 the Company's common stock. As a result of the conversion of the notes into common stock, the Company recognized the entire amount of the discount as interest expense for the year ended December 31, 2003.

In consideration of certain placement services, the Company paid Taglich Brothers, Inc. a cash fee of approximately \$200,000, issued \$300,000 of convertible notes and issued warrants to purchase up to 476,191 shares at \$1.155 per share. Michael N. Taglich, an affiliate of Taglich Brothers, Inc. became a director of the Company on August 17, 2003. The fair value of the warrants was determined using the Black-Scholes option pricing model using the following assumptions: volatility of 72%, term of five years, risk-free interest rate of 3.36% and 0% dividend yield. The fair value of the warrants totaled approximately \$586,000. The total debt issuance costs of \$1,250,813 were being amortized as interest expense over the earlier of the term of the notes (3 years) or upon conversion of the notes into the Company's common stock. As a result of the conversion of the notes into common stock, the Company recognized interest expense of \$1.3 million for the year ended December 31, 2003.

The notes and warrants included registration rights which required the Company to file a registration statement with the Securities and Exchange Commission (SEC) registering, for resale, the shares of common stock issuable upon conversion of the notes or exercise of the warrants. The registration statement was 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. The Company filed the registration statement on August 13, 2003, and it was declared effective by the SEC on November 6, 2003.

Short-Term Notes Financing

Between April 30, 2003 and May 6, 2003 the Company issued \$550,000 of subordinated notes to a group of accredited investors, including Herbert L. Lucas, a director of the Company, who purchased \$75,000 of such subordinated notes. The transaction provided the Company with approximately \$505,000 in net proceeds. In conjunction with the sale of these notes the Company granted warrants to purchase 235,722 shares of the Company's common stock (including 32,144 warrants granted to Mr. Lucas) at \$1.11 per share exercisable for three years. The notes were unsecured and did not accrue interest. The notes were paid in full on June 25, 2003 with the proceeds received from the Convertible Note financing discussed above.

The loan was discounted for the relative fair value of the warrants totaling approximately \$94,000, which was recognized as interest expense upon payment of the loan. The fair value of warrants was determined using the Black-Scholes option-pricing model with the following assumptions: volatility of 72%, risk-free interest rate of 2.25%, expected life of three years and 0% dividend yield.

For placement services associated with the financing, the Company paid Taglich Brothers, Inc. a fee of \$23,750 and issued warrants to purchase up to 20,357 shares of the Company's common stock at \$1.11 per share exercisable for three years. The fair value of the warrants was valued using the Black-Scholes option-pricing model with the same assumptions as the bridge notes discussed above. The total debt issuance costs of approximately \$44,750 were recognized as interest expense upon the payment of the notes.

The warrants include registration rights requiring the Company to register the underlying shares of common stock with the SEC. The underlying shares were registered by the Company via the registration statement discussed above that was declared effective by the SEC on November 6, 2003.

Table of Contents**SCOLR, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****Note V Restatement of Financial Information**

During the year ended December 31, 2003, the Company determined that certain costs that were incurred during 2002 and deferred as a prepaid expense at December 31, 2002, should have been expensed in the year ended December 31, 2002. These costs totaled approximately \$104,000 and were incurred in conjunction with the anticipated sale of its Probiotics unit. The financial statements as of and for the year ended December 31, 2002 have been restated to correct the accounting for these costs.

Also during the year ended December 31, 2003, the Company determined that severance costs related to the separation agreement discussed in Note N that were classified as Other expense, should have been classified as General and Administrative expense on the Statement of Operations. These costs totaling \$157,448 and \$159,152 for the years ended December 31, 2003 and 2002, respectively, have been reclassified in General and Administration expense in the accompanying Statements of Operations.

The following is a summary of the effects of such restatement on the Company's financial statements as of December 31, 2002 and for the year then ended:

| | <u>As Originally Reported</u> | <u>As Restated</u> |
|------------------------------------|-----------------------------------|--------------------|
| Balance Sheet: | | |
| Current assets | \$ 1,645,766 | \$ 1,541,942 |
| Total assets | 4,013,837 | 3,910,013 |
| Accumulated deficit | (12,830,343) | (12,934,167) |
| Stockholders' equity | 1,231,907 | 1,128,083 |
| Statement of Operations: | | |
| General and administrative expense | \$ 2,470,292 | \$ 2,733,268 |
| Operating profit (loss) | \$ (2,006,206) | \$ (2,269,182) |
| Other expense (severance costs) | \$ (159,152) | \$ |
| Net earnings (loss) | \$ (2,557,328) | \$ (2,661,152) |
| Net loss per share | \$ (0.13) | \$ (0.13) |

Note W Subsequent Event

The Company issued 3,206,538 shares of its common stock and warrants (Warrants) to purchase 801,636 shares of common pursuant to a Securities Purchase Agreement dated February 24, 2004. The common stock was sold at \$3.25 per share for gross proceeds of approximately \$10.4 million. The Warrants are exercisable until February 23, 2009 at \$4.75 per share, subject to customary anti-dilution provisions. After a period of 12 months following the effective date of a registration covering the resale of shares issued upon exercise of the Warrants, the Company has the right to call the Warrants for cancellation if the volume weighted average price of the common stock is above \$8.00 for 20 consecutive trading days.

Rodman & Renshaw acted as the lead placement agent for the transaction and Taglich Brothers, Inc. assisted in the financing. The placement agents received a cash commission of \$729,487 and Warrants to purchase 224,458 shares, of which Taglich Brothers received \$174,965 and Warrants to purchase 12,408 shares. Michael N. Taglich and Robert C. Schroeder, directors of the Company, are affiliates of Taglich Brothers. In addition, Mr. Taglich (and a partnership of which Mr. Taglich is a general partner) purchased 49,631 shares of common stock and Warrants to purchase 12,408 shares as part of the private placement. However, Mr. Taglich's agreement with the Company was amended to increase the purchase price applicable to the 49,631 shares purchased by him to \$3.63 per share.

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SCOLR, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The Company also issued (i) 32,000 shares of common stock and a Warrant to purchase 15,000 shares to an unaffiliated third party as a finder's fee, and (ii) 23,077 shares of common stock and Warrants to purchase 5,679 shares to Rostrevor Partners in partial payment of its advisory fee in connection with the sale of the Company's probiotics unit.

The common stock and Warrants were issued to accredited investors and such sales were exempt from registration under the Securities Act of 1933, as amended, pursuant to Rule 506 of Regulation D and Section 4(2) of such Act. In connection with the offering, the Company agreed to register the resale of the common stock and shares to be issued upon exercise of the Warrants with the Securities and Exchange Commission. The Company is subject to certain penalties if the registration statement is not filed within 30 days of the closing, or if the registration statement is not declared effective by the Securities and Exchange Commission within 120 days of such closing.

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Item 8. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosures*

None.

Item 8A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Principal Financial Officer have reviewed and evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act), as of December 31, 2003. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures are adequate and effective for the purposes set forth in the definition of disclosure controls and procedures in Exchange Act Rule 15d-15(e).

Changes in Internal Controls

There has been no change in our internal controls over financial reporting that occurred during our last fiscal year that has materially affected or is reasonably likely to materially affect our internal controls over financial reporting.

Item 9. *Directors and Executive Officers of the Registrant*

We will file a definitive proxy statement (Proxy Statement) relating to our 2004 Annual Meeting of Shareholders within 120 days after the end of the fiscal year covered by this Report. The information required by this item is incorporated by reference to the Proxy Statement under the headings Directors and Executive Officers and Section 16(a) Beneficial Ownership Reporting Compliance.

Item 10. *Executive Compensation*

The information required by this item is incorporated by reference to the Proxy Statement under the heading Executive Compensation and Director Compensation.

Item 11. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required by this item is incorporated by reference to the Proxy Statement under the heading Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .

Item 12. *Certain Relationships and Related Transactions*

The information required by this item is incorporated by reference to the Proxy Statement under the heading Certain Relationships and Related Transactions.

Table of Contents**Item 13. Exhibits and Reports on Form 8-K****(a) Exhibits**

The following exhibits are filed herewith and this list is intended to constitute the exhibit index:

| Exhibit Number | Notes | Description |
|-------------------|-------|--|
| 2.1 | (14) | Asset Purchase Agreement by and between SCOLR, Inc. and Nutraceutix, Inc., dated as of December 31, 2003 |
| 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. |
| 4.3 | (4) | SCOLR, Inc. Bylaws, as amended |
| 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 |

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| Exhibit Number | Notes | Description |
|-------------------|-------|--|
| 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 |
| 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 | * | Letter Agreement between the Company, Michael N. Taglich and Tag Kent Partners dated March 2, 2004 |
| 23.1 | * | Consent of Grant Thornton LLP, Independent Certified Public Accountants |
| 31.1 | * | Certification of Daniel O. Wilds pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | * | Certification of Gail Vitulli pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | * | Certification of Daniel O. Wilds pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2 | * | Certification of Gail Vitulli pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

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.

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

(b) Reports on Form 8-K

A form 8-K was filed on November 12, 2003, under Item 9, relating to (i) the appointment of Dr. Reza Fassihi and Robert C. Schroeder to its Board of directors, (ii) the effectiveness of its Registration Statement on Form S-2, and (iii) the conversion of \$5.3 million of convertible notes into common stock.

Item 14. *Principal Accountant Fees and Services*

The information required by this item is incorporated by reference to the Proxy Statement under the heading *Principal Accountant Fees and Services*.

