SCOLR Pharma, Inc.
Form 10KSB
March 31, 2005
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

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

For the fiscal year ended December 31, 2004

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

For the transition period from _____ to _____.

Commission file number 001-31982

SCOLR Pharma, Inc.

(Name of small business issuer in its charter)

Delaware	**91-1689591**
(State of Incorporation)	**(IRS Employer Identification No.)**
3625 132nd Avenue S.E. Ste. 300 Bellevue, WA	**98006**
(Address of principal executive offices)	**(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 x No ¨

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, 2004 were $441,993.

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 18, 2005 was approximately $134,898,380.

As of March 18, 2005, there were 34,513,386 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 2005 Annual Meeting of Shareholders.

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SCOLR Pharma, Inc.

FORM 10-KSB

CAUTIONARY STATEMENT PURSUANT TO THE

PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

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

Item 1. Description of Business

Overview

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

We have applied our CDT platform to a number of nutritional products already on the market, including products sold to Wal-Mart, Rite Aid, General Nutrition Company (GNC), and Trader Joe s. In November 2004, we successfully completed preliminary human trial work for an OTC 12 hour extended release formulation of ibuprofen. We expect to commence additional U.S. human clinical work to support future regulatory approval during the second or third quarter of 2005. There are currently no extended release formulations of ibuprofen approved for use in North America. We also initiated human testing of CDT-based 12 hour extended release formulation of pseudoephedrine for the OTC market during the first quarter of 2005. The results from the initial segment of this testing were favorable. We plan to begin a human clinical evaluation of a CDT-based immediate release raloxifene formulation in the second quarter of 2005. Raloxifene is used to prevent and treat osteoporosis. We are currently evaluating additional drugs as potential CDT development candidates for expanding our growing portfolio of CDT applications.

Our proprietary CDT system can be used in solid oral dosage formulations, the preferred route for drug administration, to yield tablets or capsules that release their active agents predictably and programmably over a specified timeframe of up to 24 hours. We believe we can apply our technology to create significant delivery enhancements to a large universe of existing oral pharmaceutical, OTC, and nutritional products.

CDT-based controlled release dry blend and direct compression tablet and capsule formulations contain readily available and generally regarded as safe (GRAS) excipients, e.g., non-active ingredients such as combinations of hydrophilic polymers and poly-ionics or electrolytes. These excipients are used to control the release rate of the active drug component of the CDT tablet in order to provide predictable delivery profiles. These include attaining near linear sustained release profiles with zero-order kinetics required for reproducible, cost effective, and optimized *in-vivo*

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delivery of drugs for up to 24 hours. In addition, our proprietary amino-acid technology can be incorporated in immediate and sustained release solid oral formulations to increase the solubility characteristics of previously non-soluble and sparingly soluble drugs without employing costly micro-milling, nano-particulate, or coated particle technologies.

Prior to January 1, 2004, we manufactured nutraceutical-based health and dietary supplements for the animal and human nutrition markets. Our 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. and to SCOLR Pharma, Inc. in July 2004. 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.

Corporate Strategy

Our strategy is to develop pharmaceutical, OTC, and nutraceutical products utilizing our innovative oral drug delivery technologies. Our CDT platform is used in solid oral dosage forms. 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 the delivery of existing pharmaceutical, OTC, and nutraceutical products. Our proprietary drug delivery technologies are applicable to a wide range of drugs with different physical and chemical properties including water soluble and insoluble drugs as well as high dose and low dose drugs. Using these technologies, we can formulate drugs with precise release profiles. In selecting product candidates for development, we focus on the applicability of our platform to a particular compound, benefits to patients, as well as market size, patent protection, and other factors.

Our CDT platform is designed to reduce the frequency of drug administration, improve the effectiveness of the drug treatment, ensure greater patient compliance with a treatment program, and reduce side effects or increase drug safety by releasing drug dosages at specific times and in specific locations in the body. Oral administration is the preferred route of drug delivery, owing to its convenience and ease of use. Many orally-administered immediate release drug products deliver the majority of their drug components within one to three hours, requiring administration every four to six hours. Accordingly, patient non-compliance can be a significant problem for many immediate release drug products. Oral controlled-release technology circumvents the need for multiple dosing by extending the release of the active drug so that the drug maintains its therapeutic usefulness over a longer period of time. In addition, lowering the peak levels of drugs in the blood may reduce adverse side effects associated with certain drugs.

Controlled release drug delivery technologies can also provide effective product life cycle management tools. A technology such as CDT may allow pharmaceutical companies to reformulate existing drugs and initiate additional patent protection, thereby improving product release profiles and defending important revenue streams, particularly for existing blockbuster drugs nearing patent expiration. For example, as a product nears the end of its patent life, conversion to controlled-release dosing or a different route of administration could provide an extension to the patent or marketing exclusivity period. Many pharmaceutical and specialty pharmaceutical companies have successfully utilized controlled-release technology to develop product line extensions. We are engaged in preliminary discussions with a number of pharmaceutical companies regarding development of products incorporating our CDT platform. Potential licensing partners may 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 or are interested in potentially more cost-effective methodologies to enhance their competitive position.

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An important part of our strategy is to seek collaborations and strategic partnerships to develop or market some of our products. In particular, we are seeking 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. We are in discussions with various parties about potential collaborations. Although we may establish limited manufacturing or sales and marketing capabilities within the next few years, we also expect to seek to enter collaborations for the manufacturing, the selling, and the marketing of our potential products. Based on our evaluation of the terms and conditions of potential collaborations, we may seek to maintain control over product development to be better able to control the development timelines of our product candidates and retain more of their economic value.

Product Development

Our CDT technology has been used to develop several dietary supplement products that are currently being manufactured and distributed by third parties. We currently receive royalties and other payments from the sale of various formulations that incorporate our CDT technology, including combinations of glucosamine and chrondroitin, soy isoflavones, niacin, and other dietary products. These sales are being generated through relationships with retailers such as Wal-Mart, Rite-Aid, Trader Joe s, and GNC or by sales through Nutraceutix, our former probiotics division. Our CDT Glucosamine and 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.

We have also applied our CDT platform to a portfolio of more than twenty potential pharmaceutical targets on a preclinical demonstration basis. These target candidates include existing analgesic, cardiovascular, diabetes, nausea, and pulmonary products. During 2004, we commenced an internal development program targeting a select group of significant, existing drugs for reformulation in an effort to demonstrate the applicability and viability of our CDT platform. These include extended release formulations of ibuprofen, pseudoephedrine, raloxifene, tramadol, and niacin. We are currently evaluating additional drugs as potential CDT development candidates for expanding our growing portfolio of CDT applications.

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Following is a summary table of our lead products:

Lead Products	Application	Potential Advantages	Status	Current Market Estimate[1]
CDT 12 hr Ibuprofen	OTC Analgesic	First Extended Release OTC Ibuprofen 1 tablet vs. 3 every 12 hrs. Lower Cost Patent Protected	Human Pilot Study Positive NDA Trials start, Q-2, 05	$ 1 billion (U.S.)
CDT 12 hr Pseudoephedrine	OTC Decongestant	1/3rd size of existing OTC Product(s) Lower Cost Patent Protected	ANDA Trials started, Q-1,05 Initial results positive	$ 1 billion (U.S.)
CDT IR Raloxifene	Rx Osteoporosis	Less Drug for similar results[2] Simplified Manufacturing Lower Cost Patent Protected	Animal Study Positive Human Pilot Studies start, Q-2, 2005	$ 1 billion (Global)
CDT 12 hr Niacin	Rx Cardiac	Simplified Manufacturing Lower Cost Patent Protected	Human Pilot Study Positive Seeking Collaborator	$ 0.5 billion (Global)
CDT 12/24 hr Tramadol	Rx Analgesic	Multiple formats for flexible dosing	Preclinical Completed Seeking	$ 1 billion (Global)

Simplified Collaborator

Manufacturing

Lower Cost

Patent Protected

(1) Current market estimates based on market data sources including IMS, Data Monitor and public company disclosures by industry participants.

(2) Based on 2004 initial animal study.

Development Status of Lead Products

Ibuprofen We have developed an extended release formulation of ibuprofen based on our CDT platform. We obtained positive results from the initial human study completed in October 2004. This study involved ten subjects in a five-way crossover comparing the ibuprofen blood plasma levels of two CDT based formulations of 12-hour ibuprofen with currently marketed OTC Motrin® and prescription immediate release ibuprofen tablets. The resulting human plasma data provided clinical evidence that CDT ibuprofen performed as expected and consistent with laboratory data. Our formulation successfully prolonged the blood levels of ibuprofen over a 12-hour period. These interim results supported the advancement of a final formulation and additional human clinical work. We expect to generate additional clinical data to support preparation of a New Drug Application (NDA) filing later in 2005. In preparation for our additional clinical evaluation and to support our future NDA, we entered into an agreement with Cardinal Health, Inc. for the manufacture of the extended release 12-hour ibuprofen tablets to be used in our human clinical

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evaluation and the production of our cGMP clinical and product registration batches. There are currently no extended release formulations of Ibuprofen approved for use in North America. Based on industry sources, we estimate that North American sales of ibuprofen are more than $1 billion per year.

Pseudoephedrine We initiated human testing of our 12-hour CDT-based pseudoephedrine tablets in late February 2005 and the results from the initial segment of this testing were positive. These studies are intended to support an anticipated Abbreviated New Drug Application (ANDA) submission to the U.S. Food and Drug Administration (FDA) later in 2005. We believe our formulation will offer attractive tablet size and cost advantages when compared to similar tablets already on the market. In preparation for our additional clinical evaluation and to support our future ANDA, we have an agreement with UPM Pharmaceuticals for the manufacture of the extended release 12-hour pseudoephedrine tablets to be used in our clinical evaluations and UPM is responsible for manufacturing the cGMP clinical and U.S. product registration batches. Based on industry sources, we estimate that North America sales of products containing pseudoephedrine are more than $1 billion per year.

Raloxifene We plan to initiate human clinical evaluation of a CDT-based immediate release raloxifene formulation in the second quarter of 2005. Raloxifene is used to prevent and treat osteoporosis. This clinical study plan follows positive results from a recent animal study evaluating the amino acid technology s potential to improve drug permeability. Additional studies will be designed to provide further insight into the capabilities of the amino acid patent and our ability to enhance bioavailability as well as to support development of a raloxifene product. In preparation for our human clinical evaluation and to support our future regulatory filings, we entered into an agreement with UPM for the cGMP manufacturing of our immediate release raloxifene tablets. In 2003, Eli Lilly reported $922 million in global Evista® sales. Evista is Eli Lilly s immediate release raloxifene product for osteoporosis utilizing a different solubilization technology.

Tramadol and Niacin We have developed several extended release formulations for tramadol and niacin. Niacin is used in the OTC nutritional market as a dietary supplement and the pharmaceutical market at higher doses to lower cholesterol and triglycerides. Tramadol is a centrally acting synthetic analgesic currently available as Ultram® in an immediate release formulation. We have developed three controlled release formulations of tramadol for near-zero order release. In October 2002, we completed a human clinical trial of pharmaceutical niacin. Our results demonstrated a strong correlation between our laboratory and human results. The results of this study were presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS) in November, 2002 and were the subject of a peer reviewed article in a scientific journal. We have deferred additional development activities for formulations of niacin and tramadol pending identification of interested potential partners.

Our CDT Platform

For many reasons, pharmaceutical companies increasingly prefer controlled release rather than immediate release of the active agent in their drug products. The advantages of controlled drug delivery typically include improved patient compliance, product differentiation, greater efficacy, and an improved safety profile. An important characteristic of our proprietary CDT technology allows us to improve upon conventional multiple daily dose immediate release forms of existing products by providing the therapeutic benefits of extended 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. Our CDT platform represents a robust and simple approach to drug tablet and capsule formulation that allows for low cost manufacturing (using conventional blending and compression equipment in a two-three step process). It can deliver comparatively high payloads of an active ingredient while being programmable to deliver active therapeutic agents over a wide range of release profiles and timeframes.

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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 active ingredients from the matrix through the tablets progressive swelling and erosion. The CDT tablets or capsules employ combinations of conventional tableting materials selected specifically for the active ingredient(s) and the desired release profile. Various release patterns and rates can be achieved depending upon the matrix composition, the selection and ratio of polymers, ionic substrates, and excipients.

In December 1998, we obtained the exclusive rights to a patent pending (CDT Patent No. 1 or the dual polymer patent) 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. This technology provides us with the ability to program *in-vitro* release patterns for each health supplement contained in a single tablet or capsule. In 1999, we licensed the right from Temple University to apply the dual polymer technology to OTC products. In September 2001, we acquired the exclusive license for the rights to CDT Patent No. 1 for 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.

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 active pharmaceutical ingredient (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, in collaboration with Temple University, we successfully developed continuous, zero-order kinetics tablets of Vitamin C. Prior to our success, Vitamin C formulation work was considered to be a technological challenge due to its high water solubility and its high permeability. Following the Vitamin C project, we worked with Temple University to develop controlled-release, linear, zero-order kinetics tablets of glucosamine, Calcium D-glucarate, several sports nutrition prohormones, and diet formulations.

In September 2000, we acquired the worldwide rights to Patent No. 6,090,411 (CDT Patent No. 2 or the electrolyte or salt patent) from Temple University for application in dietary and health supplements, OTC products, and prescription drugs. This technology patent (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 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. Consequently, processes are faster and easily validated.

- The technology yields 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 currently available tableting equipment routinely used in the pharmaceutical industry.

- The technology is applicable to dietary supplements, OTC products or prescription pharmaceuticals providing formulators with a flexible approach; resulting in extremely rugged tablets. The in-vitro dissolution results of these tablets are not affected by drug solubility, pH, tablet size or configuration, tablet hardness, or friability.

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The technology has a remaining patent life through 2018.

The technology allows the formulator to use GRAS excipients in novel quantities to be manufactured using standard pharmaceutical processing equipment and technology. This enables the manufacturer of CDT products to produce controlled release products at approximately the same costs as immediate release formulations of the same API.

On February 12, 2003, the USPTO issued US Patent 6,517,868 (CDT Patent No. 3 or Amino Acid Patent) for the use of amino acids as a drug delivery technology for pharmaceutically active compounds. Designed as a simpler solution to certain difficult formulation issues, the amino acid technology extends our capability to include poorly soluble drugs which are difficult and costly to formulate and produce with currently available manufacturing techniques and processes. Dr. Fassihi assigned this patent to us in August 2002.

The issuance of CDT Patent No. 3 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 dual polymer patent, combine to create a range of modified oral drug delivery systems which we believe address the most challenging hurdles of oral drug delivery, including zero order kinetics, poorly soluble active ingredients and ingredients, difficult to tablet.

In 2004, we reported positive results from a new animal study evaluating our patented amino acid technology s potential to improve drug permeability. These results showed a significant increase in the total bioavailability and absorption rates with our novel formulations of the poorly-permeable compound atenolol. Atenolol, a calcium channel blocker used as a cardiac medication, is often employed as a control in drug formulation permeability evaluations. The listed reference drug, Tenormin® is marketed by Astra Zeneca. Significant additional animal and human testing will be required prior to commercializing drug formulations utilizing this technology.

In July 2004, we filed an application with the USPTO on an Asymmetrical Multiple Layered Tablet for Controlled Release. The technology in the asymmetrical patent application was designed to work with single or multiple ingredients and/or drugs, allowing those ingredients/drugs to be programmed for release at pre-selected rates and/or at pre-selected regions within the body. This patent would become the fourth in our suite of CDT technologies, further expanding the platform by facilitating an emerging trend in the pharmaceutical industry combination therapy. We believe that this newest technology, when added to our low cost, simple-to-manufacture CDT platform, has the potential to substantially broaden our reach by expanding and enhancing our ability to work with combination or cocktail therapies.

The oral controlled release market for OTC products and prescription drugs has been estimated at $31.9 billion in 2003 with a forecast of approximately $46.4 billion in the United States in 2008 (Data Monitor) and has been reported to be growing at twice the annualized rate of the pharmaceutical market; in general. We believe 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 , extend the life of, their existing pharmaceutical franchises through new drug introductions involving older molecules incorporating new patented drug delivery technology.

Research and Development

In 2004 and 2003, we spent $2,603,361 and $403,186 respectively, on product research and development. We plan 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.

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Intellectual Property

We have four federal trademark registrations. Our policy is to pursue registrations for all of the trademarks associated with our key products and technologies. A list of our registered trademarks is as follows: CDT, CDT logo and design, SCOLR, and SCORx.

We filed an application with the USPTO on an Asymmetrical Multiple Layered Tablet for Controlled Release. The technology in the asymmetrical patent application was designed to work with single or multiple ingredients and/or drugs, allowing those ingredients/drugs to be programmed for release at pre-selected rates and/or at pre-selected regions within the body. This patent would become the fourth in our suite of CDT technologies, further expanding the platform by facilitating an emerging trend in the pharmaceutical industry combination therapy.

In October 2004 we filed a provisional patent with the USPTO for a CDT extended release dosage form of ibuprofen. We also filed a provisional patent utilizing our amino acid technology for the first time in a product specific application, which encompasses a method for the improved oral delivery and bioavailability of raloxifene. In November 2004, we filed a provisional patent application with the USPTO utilizing our patented amino acid technology for an extended release form of ondansetron. Ondansetron is the active pharmaceutical ingredient used in the prescription drug Zofran® to treat chemotherapy-induced nausea. The development of an extended release form of ondansetron is the second application of our amino acid technology and is designed to safely improve solubility and the availability of insoluble and poorly soluble compounds. In December 2004, we filed a provisional patent application with the USPTO utilizing our amino acid technology for a method to improve the oral delivery and bioavailability of rosiglitazone. Rosiglitazone is the active pharmaceutical ingredient used in the prescription drugs Avandia® and Avandamet®.

Our success will depend in part on our ability to obtain and maintain patent protection for our technologies, preserve our trade secrets and operate without infringing the proprietary rights of others. The issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. 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. Furthermore, there is no assurance that any of our future processes or products will be patentable, our processed or products will not infringe upon the patents of third parties.

We are obligated to pay annual license maintenance fees, share in some up-front payments from customers, and pay royalties based on product sales with respect to the CDT patents licensed from Temple University or assigned to us by Dr. Fassihi.

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, 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 generally 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.

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. The new Nutraceutix entity was formed and is owned by Steven H.

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Moger, our former vice president of operations, chief financial officer and general manager of the probiotics division. The buyer, Mr. Moger, resigned his positions with us in connection with the sale.

The assets sold comprised 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. We also granted Nutraceutix the right to manufacture and sell certain products utilizing our patented CDT technology.

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 our board of directors.

Manufacturing

We do not have commercial scale manufacturing facilities. Accordingly, we have to rely on third party manufacturers of the products we are evaluating in clinical trials. We currently have agreements with Cardinal Health, Inc. and UPM Pharmaceuticals, Inc. for the manufacture of our CDT ibuprofen, pseudoephedrine, and raloxifene. We also work with Nutra and Nutraceutix regarding the manufacturing of dietary supplements containing our CDT technology.

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 widely available. The active chemical raw materials essential to our business are generally readily available from multiple sources in the U.S. and throughout the world. Certain raw materials used in the manufacture of our products are, however, available from limited sources and, in some cases a single source. Any curtailment in the availability of such raw materials could result in production or other delays and, in the case of products for which only one raw material supplier exists or has been approved by the FDA, could result in material loss of sales with consequent adverse effects on our business and results of operations. Also, because raw material sources for pharmaceutical products must generally be identified and approved by regulatory authorities, changes in raw material suppliers may result in production delays, higher raw material costs and loss of sales and customers. We obtain a portion of our raw materials from foreign suppliers, and our arrangements with such suppliers are subject to, among other risks, FDA approval, governmental clearances, export duties, political instability, and restrictions on the transfers of funds.

Government Regulation

Government authorities in the United States and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing of drug products. We must receive separate regulatory approval for each of our product candidates before we or our collaborators can sell them in the United States or internationally. In the U.S., the FDA regulates drug products

under the Food, Drug and Cosmetic Act (FDCA), and implements regulations and other laws. Before any of our drug products may be marketed in the U.S., each product must be approved by the FDA. The approval process requires substantial time, effort and financial resources, and there can be no assurances that any approval will be granted on a timely basis, or at all. There are several kinds of New Drug Applications (NDA) that may be

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submitted to the FDA to obtain approval of our new drugs, including full new drug applications; section 505(b)(2) NDAs; or Abbreviated New Drug Applications (ANDA). A full NDA is an NDA in which the information required for approval, including investigation of safety and effectiveness, comes from studies conducted by or for the sponsor or for which the sponsor has obtained a right of reference. A section 505(b)(2) NDA is an NDA in which at least some of the information required for approval comes from studies not conducted by or for the sponsor and for which the sponsor has obtained a right of reference. An ANDA generally utilizes existing data for proof of safety and effectiveness if the new drug subject to the ANDA can be show to be bioequivalent to a drug which the FDA has previously approved.

Our 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.

Employees

As of December 31, 2004, we employed 13 full time employees, consisting of three executives, one sales and marketing personnel, seven research and development personnel, and two quality assurance personnel. None of our employees is represented by labor unions. We believe our relationship with employees is good.

Item 2. Description of Property

Our corporate headquarters, including administrative offices and research and development facilities are located approximately 15 miles east of Seattle, Washington 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 $112,369, with a lease termination date of September 30, 2008.

Executive Officers of the Registrant

Our executive officers are generally elected annually at the meeting of our board of directors held in conjunction with the annual meeting of stockholders. The following are our current executive officers and their ages as of March 18, 2004:

Name	Age	Office	Position Since
Daniel O. Wilds	56	President and Chief Executive Officer	2003
Gail T. Vitulli	49	Director of Finance, Principal Financial Officer	2004
Stephen J. Turner	34	Vice President, Chief Technical Officer	2003
Alan M. Mitchel	48	Senior Vice President of Business and Legal Affairs	2005

The following sets forth the business experience, principal occupations and employment of each of our current executive officers who are not members of the board of directors.

Stephen J. Turner has worked for SCOLR Pharma since the fall of 1999 and primarily has been responsible for the commercialization and application of the CDT, controlled delivery technology platform. In the winter of 2003, Mr. Turner was promoted to our vice president and chief technical officer In addition to Mr. Turner s involvement in our growth and application of our technology platform, he is named on one recently issued patent, contributed to numerous additional patent filings, has several industry related publications, and has presented his research findings at numerous academic seminars and symposia. Mr. Turner is an active member in scientific organizations including AAPS (American Association of Pharmaceutical Scientists) and the Controlled Release Society. Mr. Turner holds a BS in biology with a minor in geochemistry from Western Washington University.

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Gail T. Vitulli has worked for SCOLR Pharma since 1999 as controller, and has been responsible for all aspects of our financial reporting. In January 2004, Ms Vitulli became our director of finance, principal financial officer. Ms. Vitulli has over twenty years progressive experience in accounting in both public and private industries. She has played a significant role in the development of several start-up companies and has headed large systems implementations. She holds a BA in business administration with a major in accounting from Seattle University.

Alan M. Mitchel has worked for SCOLR Pharma since January 2005 as senior vice president of business and legal affairs and chief legal officer. For more than five years prior to joining us, Mr. Mitchel practiced corporate law with private law firms in Seattle and Miami. Mr. Mitchel received an LLB from Duke University School of Law.

Item 3. Legal Proceedings

We are not a party to any material litigation.

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

No matters were submitted to our stockholders during the quarter ended December 31, 2004.

Item 5. Market For Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities

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

COMMON STOCK

	High	Low
2003		
First Quarter	1.00	.95
Second Quarter	1.80	1.67
Third Quarter	2.25	2.18
Fourth Quarter	2.15	2.03
2004		
First Quarter	3.97	2.10
Second Quarter	3.75	1.71
Third Quarter	3.00	1.64

Fourth Quarter	5.62	2.15

As of March 18, 2005, we had 1,461 stockholders of record. We have not paid or declared any dividends upon our common stock since inception and do not contemplate or anticipate paying any dividends upon the common stock in the foreseeable future.

Item 6. Management s Discussion and Analysis or Plan of Operation

We are a specialty pharmaceutical company that develops and formulates over-the-counter products, prescription drugs, and dietary supplement products that use our patented CDT technology. Prior to January 1,

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2004, we 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. We completed our transition to a focused specialty pharmaceutical business with the sale of our probiotics division effective as of December 31, 2003 for $722,756 in cash and deferred payments of at least $2 million (over the greater of four years or until we receive $2 million). The deferred payments are tied to the buyer s achievement of certain sales levels and royalties. As a result of the sale of this division as of December 31, 2003, our financial results for 2004 do not include operations of the probiotics division except for payments of the deferred purchase price and royalties relating to our CDT technology.

Prior to the sale of our probiotics unit, we generated substantially all of our revenues through the probiotics unit. Our drug delivery business generates royalty revenue from CDT-based sales in the dietary supplement markets. However, our net losses are likely to increase significantly as we continue preclinical research and clinical trials, apply for regulatory approvals, develop our product candidates, expand our operations and develop the infrastructure to support commercialization of our potential products. 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 products and technology and generate royalties, development fees, milestone and similar payments.

We have generated substantially all of our working capital though the sale of securities. On February 8, 2005, we raised approximately $15 million through a private placement of 3,750,000 shares of our common stock. In February 2004, we completed a private placement of 3,206,538 shares of common stock and warrants to purchase 801,636 shares of common stock for gross proceeds of approximately $10.4 million.

Results of Operations

Net Revenues

Net revenues decreased 93% percent or $6,152,080 to $441,993 for the year ended December 31, 2004 from net revenues of $6,594,073 for the year ended December 31, 2003. In 2004, we received royalty income for sales of products incorporating the CDT technology from Nutra and Archer-Daniels-Midland, which accounted for 84% and 16%, respectively, of our net revenues for the year. Revenues for the year ended December 31, 2003 included $5,972,120 in manufacturing revenues related to the probiotics business sold December 31, 2003. Other revenues for 2003 of $621,953 consisted of $582,953 revenues from royalties and $39,000 for research and development contract fees.

Royalty Revenues

Revenues from royalties decreased 24% for 2004 to $441,993 as compared to $582,953 in 2003. Royalty revenues for 2004 did not include an additional $249,598 royalties due for sales in 2004 reported by the buyer of the probiotics division. These additional royalties are derived primarily from CDT-based dietary supplement products being sold by the purchaser of our probiotics division and are applied to the note receivable from that sale. Payment of these royalties is received in the quarter subsequent to the quarter in which sales of covered products occurs and applied to the note upon receipt.

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The following table summarizes our revenues and other royalties which are not included in revenue for the last two fiscal years:

	For the year ended December 31,	
	2004	**2003**
Royalties Revenue	$ 441,993	$ 582,953
Research and Development Contract Revenue		39,000
Net revenues-Probiotics		5,972,120
Total Net Revenues as reported	$ 441,993	$ 6,594,073
Royalty payments received in subsequent quarter applied to Note Receivable	$ 249,598	
Total Royalties	$ 691,591	$ 582,953

Our drug delivery technology is generating royalty revenue from CDT-based product sales to the dietary supplement markets. These revenues are being generated through existing relationships with retailers such as Wal-Mart, Rite-Aid, Trader Joe s, and GNC.

As a result of the sale of the probiotics division, we did not receive any revenues from the sale of manufactured probiotic products reported in 2004 compared with $5,972,120 for 2003.

Licensing Fees, Research and Development Contracts

There were no revenues from licensing fees and research and development contract work for 2004 as compared to $39,000 for 2003.

Cost of Revenues

As a result of the sale of the probiotics business at December 31, 2003, there are no costs of revenues from the sale of manufactured probiotic products in 2004 compared to $4,576,679 for 2003.

Gross Profit

Gross profit decreased 78% or $1,575,401 to $441,993 in 2004 compared to $2,017,394 in 2003. Gross profit as a percentage of sales was 100% in 2004 (as we had no costs of goods sold during this period) and 31% in 2003. Gross profit in 2003 primarily consisted of manufacturing revenues and related cost of revenues associated with our former probiotics business whereas gross profit in 2004 only consisted of royalty revenues.

Selling and Marketing Expenses

Selling and marketing expenses represented approximately 4% of our operating expenses for 2004. Reduced selling and marketing expense in 2004 is primarily attributable to a decrease in personnel in connection with the sale of the probiotics operations. As a result, selling and marketing expenses decreased $263,963, to $215,751, for 2004 from $479,714 for 2003. Additional expenses are planned as we increase our selling and marketing efforts to support the commercialization of our drug delivery technology.

Research and Development Expenses

Research and development expenses represented approximately 47% of our operating expenses for 2004. Research and development expenses increased $2,200,175 to $2,603,361 for the year ended December 31, 2004 from $403,186 for the year ended December 31, 2003. The higher level of research and development expenses during 2004 is consistent with our transition to developing and commercializing our CDT drug delivery

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technology. These costs consisted of clinical work, regulatory, personnel, equipment, and outside consulting support. We expect research and development expenses to increase during 2005 as we continue to develop our technology, expand our operations, and develop systems that support commercialization of our CDT platform.

General and Administrative Expenses

General and administrative expenses represented approximately 49% of our operating expenses for 2004. General and administrative expenses decreased $1,500,140 to $2,693,154 for the year ended December 31, 2004 compared with $4,193,294 for the year ended December 31, 2003. Although there were substantial decreases in administrative costs over the same period in 2003 due to the sale of the probiotics business, we incurred offsetting expenses in 2004 relating to increased legal costs and services associated with our financing activities, compliance with new regulatory requirements, and establishing the infrastructure needed to support our increased research and development activities.

Other Income/Expense

Interest expense decreased $5,662,064 to $36,318 for 2004 compared with $5,698,382 for 2003. Interest expense for the year ended December 31, 2003 included non-cash interest of $5,302,460 related to convertible notes issued and converted in 2003. In addition, certain leases and obligations were transferred to the buyer of the probiotics business. The reduction in interest expense in 2004 was the result of repayment of our outstanding indebtedness in conjunction with the sale of the probiotics business.

Interest income increased $45,874 to $57,463 in 2004 from $11,589 for 2003. This increase is due to imputed interest income realized on the discount of the net present value for the note receivable due from the buyer of the probiotics business.

Other income increased $133,257 to $136,313 for 2004 compared to $3,056 for 2003. This increase was primarily due to the recognition in June 2004 of $100,000 of deferred revenue previously received as a non-refundable development fee.

Capital Expenditures

During 2004, we invested approximately $634,000 in capital equipment and leasehold improvements to build our infrastructure, and expand our formulation capability, and substantially increase our capacity to conduct laboratory based dissolution testing. We plan to invest approximately $350,000 in additional capital equipment during 2005.

Operating Profit/Loss

Operating loss for the year ended December 31, 2004 was $5,070,273 as compared to an operating loss of $3,058,800 for the year ended December 31, 2003.

Net Earnings (Loss)

The net loss for the year ended December 31, 2004 was $4,912,815 compared to a net loss of $8,742,537 for the year ended December 31, 2003. The higher net loss in 2003 was primarily the result of the operations and sale of the probiotics business in 2003 and our transition to a drug delivery business. Our net losses are likely to increase significantly as we continue preclinical research and clinical trials, apply for regulatory approvals, develop our product candidates, expand our operations, and develop the infrastructure to support commercialization of our potential products.

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Liquidity and Capital Resources

As of December 31, 2004, we had working capital of $6,318,119, as compared to negative working capital of $817,107 at December 31, 2003. The change in working capital reflects our February 2004 private placement for gross proceeds of approximately $10.4 million as well as the funding of our operations during the year. With the $15 million we raised in our February 2005 private placement of common stock, we believe that our cash on hand, including our cash equivalents, will be sufficient to fund our drug delivery business at planned levels through early 2006.

Net cash used in operating activities for 2004 was approximately $4.0 million. Expenditures during this period were a result of research and development expenses, clinical trial costs, contract manufacturing costs, general and administrative expenses in support of our operations and marketing expenses. We expect our operating losses and negative cash flow to increase as we continue preclinical research and clinical trials, apply for regulatory approvals, develop our product candidates, expand our operations and develop the infrastructure to support commercialization of our products.

We plan to continue the costly process of simultaneously conducting clinical trials and preclinical research for multiple product candidates. We will need to raise additional capital to fund operations, conduct clinical trials, continue research and development projects, and commercialize our products. We have funded our operations primarily through the issuance of equity securities and anticipate we will need to seek additional funds through the issuance of equity securities or other sources of financing. If we are unable to obtain necessary additional financing, our ability to run our business will be adversely affected and we may be required to reduce the scope of or discontinue operations.

As of December 31, 2004, we had accounts receivable of $92,772 (net of $42,644 for doubtful accounts), as compared to $716,676 as of December 31, 2003 (net of $0 for doubtful accounts), a net change of $623,904. The decrease in accounts receivable was primarily attributable to the reduction of accounts receivable related to the sale of the probiotic business.

Contractual Obligations

As of December 31, 2004, our commitments to make future payments under long term contractual obligations were as follows (in thousands):

	Payments Due by Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1 to 3 Years**	**4 to 5 Years**
Operating Leases	$ 628,043	$ 156,751	$ 462,532	$ 8,760
Capital Lease	55,471	52,247	3,224	
Total	$ 683,514	$ 208,998	$ 465,756	$ 8,760

We have certain material agreements with our manufacturing and testing vendors related to our ongoing clinical trial work associated with our development programs. Contract amounts are paid based on materials-used and on a work-performed basis. Generally, we have the right to terminate these agreements upon 30 days notice and would be responsible for services and materials and related costs incurred prior to termination.

New Accounting Pronouncements

In December 2004, Financial Accounting Standards Board (FASB) issued Statement 123(R) Share-Based Payment (revised 2004), which requires companies to recognize in the income statement the fair value of all employee share based payments, including grants of employee stock options as well as compensatory employee stock purchase plans, for interim periods beginning after June 15, 2005 and will become effective for us for the

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quarter ending September 30, 2005. Accordingly, SFAS 123(R) eliminates the ability to account for share based compensation using APB 25, and the pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. See Stock-Based Compensation above for the pro forma net loss and net loss per share amounts, for the years ended 2004, 2003 and 2002, as if we had used a fair-value-based method similar to the methods required under SFAS 123(R) to measure compensation expense for employee stock incentive awards. Although we have not yet determined whether the adoption of SFAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123 (see Note 8), we expect the adoption to have a material impact on the statements of operations for the six months ended December 31, 2005. This estimate is based on preliminary information and could materially change based on actual facts and circumstances arising during the six months ending December 31, 2005.

The FASB issued Statement 151 to clarify some of the provisions related to the accounting for abnormal amounts of idle facility expense, freight, handling costs and spoilage related to inventory. Paragraph 5 of ARB 43, Chapter 4, previously stated that ....under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and handling costs may be so abnormal as to require treatment as current charges This Statement requires that those items be recognized as current- period charges regardless of whether they meet the criterion of so abnormal. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities.

This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal years beginning after November 24, 2004. The provisions of this Statement should be applied prospectively. The adoption of Statement 151 will not have any effect on our financial position, results of operations, or cash flows.

FASB 153, Exchanges of Nonmonetary Assets amends FASB Statement No. 66, *Accounting for Sales of Real Estate,* amends guidance in APB Opinion No. 29, *Accounting for Nonmonetary Transactions,* is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. Opinion 29 provided an exception to the basic measurement principle (fair value) for exchanges of similar productive assets. That exception required that some nonmonetary exchanges, although commercially substantive, be recorded on a carryover basis. This Statement eliminates the exception to fair value for exchanges of similar productive assets and replaces it with a general exception for exchange transactions that do not have commercial substance that is, transactions that are not expected to result in significant changes in the cash flows of the reporting entity. By focusing the exception on exchanges that lack commercial substance, the Board believes this Statement produces financial reporting that more faithfully represents the economics of the transactions.

The provisions of this Statement are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges occurring in fiscal periods beginning after December 16, 2004. The provisions of this Statement should be applied prospectively. The adoption of Statement 153 will not have any material effect on our financial position, results of operations, or cash flows.

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Risk Factors

This annual report on Form 10-KSB contains forward looking statements that involve risks and uncertainties. Our business, operating results, financial performance, and share price may be materially adversely affected by a number of factors, including but not limited to the following risk factors, any one of which could cause actual results to vary materially from anticipated results or from those expressed in any forward-looking statements made by us in this annual report on Form 10-KSB or in other reports, press releases or other statements issued from time to time. Additional factors that may cause such a difference are set forth elsewhere in this annual report on Form 10-KSB.

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

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

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

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

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

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

- the structure and timing of collaborations with strategic partners and licensees;
- our timetable and costs for the development of marketing operations and other activities related to the commercialization of our product candidates;

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

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

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

Additional equity or debt financing may not be available to us on acceptable terms, or at all. If we raise additional capital by issuing equity securities, substantial dilution to our existing stockholders may result which

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could decrease the market price of our common stock due to the sale of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales, or the perception of possible sales, could also impair our ability to raise capital in the future. In addition, the terms of any equity financing may adversely affect the rights of our existing stockholders. If we raise additional funds through strategic alliance, and licensing arrangements, we may be required to relinquish rights to certain of our technologies or product candidates, or to grant licenses on terms that are unfavorable to us, which could substantially reduce the value of our business.

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

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

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

unexpected delays in the initiation of clinical sites;

slower than projected enrollment of eligible patients;

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

scheduling conflicts with participating clinicians;

limits on manufacturing capacity; and,

the failure of our products to meet required standards.

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

Even if we complete a clinical trial of one of our potential products, the clinical trial may not indicate that our product is safe or effective to the extent required by the FDA or other regulatory agency to approve the product. If clinical trials do not show any potential product to be safe or efficacious, or if we are required to conduct additional clinical trials or other testing of our products in development beyond those that we currently contemplate, we may be delayed in obtaining, or may not obtain, marketing approval for our products. Our product development costs

may also increase if we experience delays in testing or approvals, which could allow our competitors to bring products to market before we do and would impair our ability to commercialize our products.

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

Each OTC or pharmaceutical product developed by us will require a separate costly and time consuming regulatory approval before we or our collaborators can manufacture and sell it in the United States or internationally. The regulatory process to obtain market approval for a new drug takes many years and requires the expenditure of substantial resources. We have had only limited experience in preparing applications and

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obtaining regulatory approvals and primarily rely on third party contractors. As a result, we have less control over the timing and other aspects of the regulatory process than if we had our own expertise in this area. Third parties may not perform their responsibilities on our anticipated schedule or consistent with our priorities.

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

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

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

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

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

Our competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than we are able to develop, commercialize or obtain. As a result, our competitors may commercialize products more rapidly or effectively than we do, which would adversely affect our competitive position, the likelihood that our products will achieve market acceptance, and our ability to generate meaningful revenues from our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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;

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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.

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

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

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

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

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

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

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

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

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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 Dietary Supplement Health and Education Act, 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; or,

Expanded or different labeling, or scientific substantiation.

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

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

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

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

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

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

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

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

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

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Item 7. Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

SCOLR Pharma, Inc.

We have audited the accompanying balance sheets of SCOLR Pharma, Inc. (a Delaware Corporation) as of December 31, 2004 and 2003, 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 Pharma, Inc. as of December 31, 2004 and 2003, 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.

/s/ GRANT THORNTON LLP

Seattle, Washington

February 25, 2005

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SCOLR Pharma, Inc.

BALANCE SHEETS

	December 31,	
	2004	**2003**
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 6,758,860	$ 1,282,656
Accounts receivable, less allowance for doubtful accounts of $42,644 and $0 respectively	92,772	716,676
Current portion of notes receivable	430,951	961,854
Prepaid expenses	159,565	227,363
Total current assets	7,442,148	3,188,549
PROPERTY AND EQUIPMENT net	752,693	299,371
OTHER ASSETS		
Intangible assets net	487,938	359,409
Non-current portion of notes receivable	1,277,699	1,660,615
	$ 9,960,478	$ 5,507,944
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Line of credit	$	$ 155,488
Current maturities of capital lease obligations	47,841	52,801
Stockholder loan payable, less discount on debt of $10,677		989,323
Accounts payable trade	731,839	544,246
Accrued liabilities	344,349	529,584
Deferred revenue		100,000
Total current liabilities	1,124,029	2,371,442
CAPITAL LEASE OBLIGATIONS, less current maturities	3,137	50,979
Total liabilities	1,127,166	2,422,421
COMMITMENTS AND CONTINGENCIES (Note I, L, and M)		
STOCKHOLDERS EQUITY		
Preferred stock, authorized 5,000,000 shares, $.01 par value, none issued or outstanding		
Common stock, authorized 100,000,000 shares, $.001 par value, 30,690,886 and 26,462,646 issued and outstanding as of December 31, 2004 and 2003, respectively	30,691	26,463
Additional contributed capital	35,392,140	24,735,764
Accumulated deficit	(26,589,519)	(21,676,704)
Total stockholders equity	8,833,312	3,085,523
	$ 9,960,478	$ 5,507,944

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

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SCOLR Pharma, Inc.

STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2004	**2003**
Net revenues	$ 441,993	$ 6,594,073
Cost of revenues		4,576,679
Gross profit	441,993	2,017,394
Operating expenses		
Marketing and selling	215,751	479,714
Research and development	2,603,361	403,186
General and administrative	2,693,154	4,193,294
	5,512,266	5,076,194
Operating loss	(5,070,273)	(3,058,800)
Other income (expense)		
Interest expense	(36,318)	(5,698,382)
Interest income	57,463	11,589
Other	136,313	3,056
	157,458	(5,683,737)
NET LOSS	$ (4,912,815)	$ (8,742,537)
Net loss per share, basic and diluted	$ (0.16)	$ (0.41)

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

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SCOLR Pharma, Inc.

STATEMENT OF STOCKHOLDERS EQUITY

Years Ended December 31, 2004 and 2003

	Common Stock		Additional Contributed	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at January 1, 2003	21,198,947	$ 21,199	$ 14,041,051	$ (12,934,167)	$ 1,128,083
Issuance of common stock for cash	216,139	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	5,047,560	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
Issuance of common stock for cash	4,228,240	4,228	10,416,994		10,421,222
Fair value of warrants issued for cash			188,460		188,460
Fair value of stock options and warrants issued for services			50,922		50,922
Net loss for the year				(4,912,815)	(4,912,815)
Balance at December 31, 2004	30,690,886	$ 30,691	$ 35,392,140	$ (26,589,519)	$ 8,833,312

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

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SCOLR Pharma, Inc.

STATEMENTS OF CASH FLOWS

	December 31,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$ (4,912,815)	$ (8,742,537)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	256,824	490,684
Loss on the sale of equipment	444	
Amortization of discount on debt		4,006,899
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	50,922	43,400
Expense for accelerated vesting of employee stock options		896,955
Loss on sale of operations		98,891
Changes in assets and liabilities		
Accounts receivable	623,904	(230,259)
Notes receivable	55,385	166,154
Inventories		(563,611)
Prepaid expenses	67,798	(144,945)
Accounts payable	187,593	(256,001)
Accrued liabilities and deferred revenue	(285,235)	92,257
Net cash used in operating activities	(3,955,180)	(2,830,620)
Cash flows from investing activities:		
Payments on note receivable	858,434	
Proceeds from sale of intangible assets		130,000
Purchase of equipment and furniture	(633,844)	(246,988)
Patent and technology rights expenditures	(205,275)	(211,216)
Net cash used in investing activities	19,315	(328,204)
Cash flows from financing activities:		
Payments on long-term obligations and capital lease obligations	(52,802)	(453,389)
Payments on bridge note payable		(550,000)
Payments on shareholder loan	(989,323)	
Proceeds from shareholder note payable & long-term obligations		42,276
Proceeds from convertible note payable, net of issuance costs		4,634,897
Proceeds from bridge note payable, net of issuance costs		505,250
Payments on line of credit	(155,488)	(140,899)
Net proceeds from issuance of common stock and stock warrants, net of costs	10,609,682	145,963
Net cash provided by financing activities	9,412,069	4,184,098
Net increase in cash	5,476,204	1,025,274
Cash at beginning of period	1,282,656	257,382
Cash at end of period	$ 6,758,860	$ 1,282,656

Cash paid during the year for:		
Interest	$ 36,318	$ 395,922
Noncash investing and financing activities:		
Issuance of warrants for debt issuance costs	$	$ 585,710
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.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS

December 31, 2004 and 2003

Note A Summary of Significant Accounting Policies

SCOLR Pharma, Inc. is a drug delivery company that develops and formulates pharmaceutical, over-the-counter, and nutritional products. We use our patented CDT® Controlled Delivery Technologies to develop products and license technology to pharmaceutical and nutritional product companies. Prior to January 1, 2004, we also manufactured and packaged probiotic products, developed proprietary nutritional product formulations, and offered specialty nutraceutical ingredients, including several that utilize CDT technologies. 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. Our transition to a focused drug delivery business was completed with the sale of our probiotics business effective as of December 31, 2003.

We have incurred net losses since 2000. As of December 31, 2004, our accumulated deficit was $26,589,519. We expect our operating losses and negative cash flow to increase as we continue preclinical research and clinical trials, apply for regulatory approvals, develop our product candidates, expand our operations and develop the infrastructure to support commercialization of our products. Our business is subject to the risks and uncertainties associated with development of drug delivery systems and products. These risks include, but are not limited to, a history of net loses, technological changes, dependence on collaborations and key personnel, the successful commercialization of our product candidates, compliance with government regulations, patent infringement litigation and competition from current and potential competitors, (many of which have greater resources) dependence on third party manufacturers and a requirement for addition funding.

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

1. Accounts Receivable

In 2004, the majority of our accounts receivable were due from companies that provide royalty income from the use of our CDT technology. Payments are received on a quarterly basis, usually 45 days after the end of each quarter.

In 2003, most of our accounts receivable were related to the manufacturing of nutritional products in connection with the probiotics business.

We determine the allowance for doubtful accounts 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, and the condition of the general economy and

the industry as a whole. We write off accounts receivable when they become uncollectible, and payments subsequently received on such accounts are credited to the allowance for doubtful accounts.

2. 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.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

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
Software	3 years
Machinery and equipment	3-10 years
Leasehold improvements	3 years
Machinery and equipment under capital leases	3-10 years

3. 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, 2004 was 6.8 years. We evaluate our 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. No such impairment was recognized for the years end December 31, 2004 or 2003.

4. Revenue Recognition

We generate 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 us. Revenues are recognized when due and amounts are considered collectible.

5. Income Taxes

We account for income taxes under SFAS No. 109, Accounting for Income Taxes. Deferred tax assets and liabilities are provided for the temporary differences between the financial reporting basis and the tax basis of the Company s assets and liabilities and for net operating loss carryforwards and tax credit carryforwards. The deferred tax assets and liabilities, net operating loss carryforwards, and tax credit carryforwards are measured using enacted tax rates and laws that will apply when the assets and liabilities are expected to reverse. We provide a valuation allowance when necessary to reduce deferred tax assets to amounts expected to be realized.

6. Research and Development Costs

Research and development expenses include related salaries and benefits, clinical trial and related clinical trial manufacturing costs, contract and other outside service fees, and facility related costs. Research and development expenses consist of costs incurred for proprietary and collaboration research. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

research, clinical trial, and related clinical trial manufacturing costs, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

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. Diluted earnings (loss) per share include the effect of potential common stock, except when their effect is anti-dilutive. The weighted average shares for computing basic earnings (loss) per shares were 29,781,604 and 21,518,982 for the years ended December 31, 2004 and 2003, respectively. At December 31, 2004 there were 5,379,787 shares of potentially issuable common stock.

8. Stock-Based Compensation

We have an Equity Incentive Stock Option plan, which is described more fully in Note O. We apply APB Opinion 25, Accounting for Stock issued to Employees, and related interpretations in accounting for our plan.

Generally, the exercise price of our common stock equals the market price of the underlying stock on the date of the grant; therefore no corresponding compensation expense has been recognized. For these options we have adopted the disclosure only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123). However, with the adoption of the 2004 Equity Incentive Plan, non-employee directors may elect to receive the value of their quarterly retainer fee for services either in the form of cash or a stock-based director fee award, which will consist of either stock options or stock units. These awards are valued and expensed at the lower of the fair market value of the stock at the date of grant or the cash equivalent. In 2004, we recognized $15,000 expense related to these quarterly retainer fees in the form of stock option grants. Also, in 2003, in conjunction with the sale of the probiotics development and manufacturing unit, we recognized expense of $896,955 as the result of accelerated vesting of options to purchase 672,035 shares previously granted to employees under our 1995 Stock Option Plan.

If we had elected to recognize compensation expense based on the fair value at the grant date for all awards under these plans consistent with the methodology prescribed by SFAS 123, our 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 we had applied the fair value recognition provisions of SFAS 123 using the assumption described in Note O to its stock-based awards.

	2004	2003
Net loss		
As reported	$ (4,912,815)	$ (8,742,537)
Total stock-based compensation expense determined under fair-value-based method	(615,710)	(877,643)
Stock-based compensation expense included in reported net loss	15,000	896,955
Pro forma net loss	$ (5,513,525)	$ (8,723,225)
Net loss per share		
As reported	$ (0.16)	$ (0.41)
Pro forma	$ (0.19)	$ (0.41)

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

9. Use of Estimates

In preparing our 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 2003 financial statements to conform to the 2004 presentation.

11. New Accounting Pronouncements

In December 2004, Financial Accounting Standards Board (FASB) issued Statement 123(R) Share-Based Payment (revised 2004), which requires companies to recognize in the income statement the fair value of all employee share based payments, including grants of employee stock options as well as compensatory employee stock purchase plans, for interim periods beginning after June 15, 2005 and will becomes effective for us for the quarter ending September 30, 2005. Accordingly, SFAS 123(R) eliminates the ability to account for share based compensation using APB 25, and the pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. See Stock-Based Compensation above for the pro forma net loss and net loss per share amounts, for the years ended 2004, 2003 and 2002, as if we had used a fair-value-based method similar to the methods required under SFAS 123(R) to measure compensation expense for employee stock incentive awards. Although we have not yet determined whether the adoption of SFAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123 (see Note 8), we expect the adoption to have a material impact on the statements of operations for the six months ended December 31, 2005. This estimate is based on preliminary information and could materially change based on actual facts and circumstances arising during the six months ending December 31, 2005.

The FASB issued Statement 151 to clarify some of the provisions related to the accounting for abnormal amounts of idle facility expense, freight, handling costs and spoilage related to inventory. Paragraph 5 of ARB 43, Chapter 4, previously stated that under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and handling costs may be so abnormal as to require treatment as current charges This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities.

This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal years beginning after November 24, 2004. The provisions of this Statement should be applied prospectively. The adoption of Statement 151 will not have any effect on our financial position, results of operations, or cash flows.

FASB 153, Exchanges of Nonmonetary Assets amends FASB Statement No. 66, *Accounting for Sales of Real Estate,* amends guidance in APB Opinion No. 29, *Accounting for Nonmonetary Transactions,* is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

Opinion 29 provided an exception to the basic measurement principle (fair value) for exchanges of similar productive assets. That exception required that some nonmonetary exchanges, although commercially substantive, be recorded on a carryover basis. This Statement eliminates the exception to fair value for exchanges of similar productive assets and replaces it with a general exception for exchange transactions that do not have commercial substance that is, transactions that are not expected to result in significant changes in the cash flows of the reporting entity. By focusing the exception on exchanges that lack commercial substance, the Board believes this Statement produces financial reporting that more faithfully represents the economics of the transactions.

The provisions of this Statement are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. Earlier application is permitted for Nonmonetary asset exchanges occurring in fiscal periods beginning after December 16, 2004. The provisions of this Statement should be applied prospectively. The adoption of Statement 153 will not have any material effect on our financial position, results of operations, or cash flows.

Note B Management Plans

We incurred a net loss of $4.9 million for the year ended December 31, 2004, used cash from operations of approximately $4.0 million, and invested $839,119 in capital expenditures during the year. We had $6.8 million in cash at December 31, 2004. We plan to continue the costly process of simultaneously conducting clinical trials and preclinical research for multiple product candidates. Our net losses are likely to increase significantly as we continue preclinical research, apply for regulatory approvals, develop our product candidates, expand our operations, and develop the infrastructure to support commercialization of our potential products.

In February 2005, we raised approximately $15 million through the sale of 3,750,000 shares of common stock. We believe this financing will enable us to fund our drug delivery business at planned levels through early 2006. We will need to raise additional capital to fund operations, conduct clinical trials, continue research and development projects, and commercialization of our product candidates in the future.

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 SCOLR, Pharma, Inc. 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 C Accounts Receivable

Accounts receivable consist of the following at December 31:

	2004	2003
Trade receivables	$ 42,644	$ 589,001
Royalty and other receivable	92,772	127,675
Less allowance for doubtful receivables	(42,644)	
Net receivables	$ 92,772	$ 716,676

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

Changes in our allowance for doubtful accounts are as follows at December 31:

	2004	2003
Beginning Balance	$	$ 12,524
Bad debt expense	44,289	5,000
Write-off of uncollectible accounts	(1,645)	(17,524)
Ending Balance	$ 42,644	$

Note D Notes Receivable

Notes receivable consist of the following at December 31:

	2004	2003
Note receivable for D-Glucarate agreement; with monthly payments of $13,846 through April 2004	$	$ 55,385
Note receivable from sale of probiotics unit; payments per agreement	1,708,650	1,844,328
Note receivable from sale of probiotics unit; payment due on closing		722,756
	1,708,650	2,622,469
Less current portion	430,951	961,854
	$ 1,277,699	$ 1,660,615

Aggregate maturities of notes receivable are as follows:

Year Ending December 31,

2005	$ 430,951
2006	585,123
2007	556,928
2008	135,648
Total	$ 1,708,650

The note receivable from the sale of the probiotics unit is based on an estimate of the expected quarterly payments to be received and has an implied interest rate of 3.27%.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

Note E Property and Equipment

Property and equipment consist of the following at December 31:

	2004	2003
Furniture and fixtures	$ 40,862	$ 29,511
Software	33,851	
Machinery and equipment	779,129	207,117
Leasehold improvements	37,674	
Machinery and equipment under capital leases	217,680	239,790
	1,109,196	476,418
Less accumulated depreciation and amortization	178,738	28,262
Less accumulated amortization of machinery and equipment under capital leases	177,765	148,785
	$ 752,693	$ 299,371

Note F Intangible Assets

Intangible assets consist of the following at December 31:

	2004	2003
Patents and trademarks	$ 702,621	$ 497,346
Less accumulated amortization	214,683	137,937
	$ 487,938	$ 359,409

For the years ended December 31, 2004 and 2003, amortization expense totaled $76,746 and $182,719, respectively.

The following is a schedule by years of future amortization expense for each of the next five years based on existing intangible assets as of December 31, 2004.

Year Ending December 31,	
2005	$ 84,262
2006	73,179
2007	67,762
2008	63,762
2009	54,678
Total	$ 343,643

Note G Line of Credit

In 2003 we had a line of credit collateralized by accounts receivable, inventories, and equipment. The last advance on the line was in December 2003. The line of credit was repaid and closed in January 2004 in connection with the sale of the probiotics business.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

Note H Shareholder Loan Payable and Warrant Issuance

On September 30, 2002, we received a $1,000,000 secured loan from a shareholder. The loan provided for interest at a rate of 8% per annum payable monthly. The loan was also discounted for the relative fair value of warrants to purchase 750,000 shares granted in conjunction with the loan totaling approximately $331,000, which was recognized as interest expense over the loan term. In January 2004, in connection with the sale of the probiotics unit, the balance of the loan was paid in full and the unamortized amount of the discount was accelerated. Interest expense recognized from the amortization of the discount during the year ended December 31, 2004 totaled $10,677.

Note I Lease Obligations

We conduct a portion of our operations utilizing leased office facilities, and equipment with terms expiring through 2009. Some of the operating leases provide that we pay taxes, maintenance, insurance and other occupancy expenses applicable to leased premises. We also lease machinery and equipment under capital leases which expire 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, 2004:

Year Ending December 31,	Capital Leases	Operating Leases
2005	$ 52,247	$ 156,751
2006	3,224	169,865
2007		172,447
2008		120,220
2009		8,760
Future minimum lease payments	55,471	$ 628,043
Less amount representing interest	4,493	
Present value of minimum lease payments	$ 50,978	

Current maturities	$ 47,841
Long-term maturities	3,137
	$ 50,978

Rent expense for leased facilities and equipment was $209,746 and $777,770 for the years ended December 31, 2004 and 2003, respectively.

Note J Income Taxes

We account for income taxes using the liability method as prescribed by Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

The income tax provision reconciled to the tax computed at the U.S. federal rate of 34% was approximately as follows at December 31:

	2004	2003
Tax benefit at statutory rate	$ (1,670,357)	$ (2,972,462)
Permanent differences	(81,824)	1,237,859
Expiration of net operating losses and credits		157,604
Increase (decrease) in valuation allowance	1,752,181	1,576,999
	$	$

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

	2004	2003
Current asset, net		
Other current assets	$ 95,489	$ 20,181
Less valuation allowance	(95,489)	(20,181)
	$	$
Non-current asset, net		
Net operating loss carry forwards	$ 5,374,257	$ 3,241,958
Depreciation and amortization	11,830	(136,547)
Other non-current assets (liabilities)	146,994	383,131
Less valuation allowance	(5,533,081)	(3,488,542)
	$	$

We have established a valuation allowance of $5,628,570 and $3,508,723 as of December 31, 2004 and 2003, respectively, due to the uncertainty of future utilization of net operating loss carryforwards and realization of other deferred tax assets.

At December 31, 2004, an operating loss carryforward of approximately $15,806,638 expiring through 2024 is available to offset future taxable income. As of December 31, 2004, $1,081,375 of the net operating loss carryforward relates to tax benefits from stock option exercises. To the extent that net operating loss carryforwards, when realized, relate to these stock option deductions, the resulting benefit will be credited to stockholders equity. Net operating loss carryforwards of approximately $0 and $155,075 expired during 2004 and 2003, respectively. Tax credits of approximately $0 and $2,529 expired during 2004 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 L Technical Rights, Patent License and Royalty Agreements

We have agreements with Temple University (Temple) providing it with exclusive worldwide rights for our Controlled Delivery technology, with the right to sublicense. Under the terms of the agreements with Temple, we are required to make minimum annual royalty payments totaling $55,000.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

On August 1, 2002, we entered into an Intellectual Property Assignment and Assumption Agreement with Dr. Reza Fassihi, a current director of SCOLR Pharma. On June 10, 2004, we amended the agreement to provide for a $50,000 payment to Dr. Fassihi for his services to improve and enhance the value of the intellectual property and the filing of the patent application.

On March 25, 2002, we entered into an Exclusive Patent License Agreement with Archer-Daniels-Midland Company (ADM). Under the terms of the agreement, we granted ADM an exclusive license to manufacture, use, sell certain nutraceutical products, and offer to sell products covered by certain patents owned by us. ADM will pay us a running royalty on a quarterly basis. During the years ended December 31, 2004 and 2003, we recorded royalty revenue of $72,901 and $61,567, respectively.

Note M Future Commitments

We have certain material agreements with our manufacturing and testing vendors related to our ongoing clinical trial work associated with our drug delivery technology. Contract amounts are paid based on materials used and on a work performed basis. Generally, we have the right to terminate these agreements upon 30 days notice and would be responsible for services and materials and related costs incurred prior to termination.

Note N Retirement Plan

We have a defined contribution 401(k) retirement plan (the Plan) which covers all employees. We will match 25% of employee contributions, up to 8% of employee contributions. We contributed $7,597 and $15,594 to the Plan for the years ended December 31, 2004 and 2003, respectively.

Note O Stock Options

Under the terms of our 2004 Equity Incentive Stock Option Plan, our employees, consultants, officers and directors may be granted equity-based incentive awards in the form of stock options, stock appreciation rights, stock awards, and performance awards. Directors may receive director fee awards and outside directors will be entitled to automatic grants of stock options.

The options are generally granted at exercise prices equal to the market value of our common stock on the date of the grant. The options usually vest over three years and generally expire ten years from the date of grant.

The plan authorized the issuance of up to 2,000,000 shares of common stock, plus 350,104 shares which were previously reserved for issuance under our 1995 stock option plan but not subject to outstanding options, and 2,027,753 shares of common stock as of December 31, 2004 subject to outstanding options under the 1995 stock option plan, to the extent shares of common stock are not issued pursuant to such options.

If any award expires, lapses or otherwise terminates for any reason without having been exercised or settled in full, or if shares subject to forfeiture or repurchase are forfeited or repurchased by us, any such shares that are reacquired or subject to a terminated award will again become available for issuance under the plan. Appropriate adjustments will be made to the number of shares reserved under the plan, the share limits affecting incentive stock options, the grant limits and the terms of any outstanding awards in the event of any stock dividend, stock split, reverse stock split, recapitalization or similar change in our capital structure.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

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:

	2004	2003
Expected volatility	72% - 79%	73% - 78%
Expected dividend yield	0%	0%
Risk-free interest rate	3.4% - 4.8%	3.5% - 4.5%
Expected life	5.0-10.0 years	10.0 years

A summary of our stock option plan s activity is as follows:

	2004		2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	2,502,337	$ .95	2,507,675	$ 68
Granted	1,104,704	3.46	739,399	1.65
Exercised	(876,456)	.67	(216,139)	.67
Forfeited	(6,670)	.86	(528,598)	.74
Outstanding at end of year	2,723,915	$ 2.06	2,502,337	$ .95
Options exercisable at end of year	1,741,620	$ 1.26	1,911,789	$ .80
Weighted-average fair value of options granted during the year		$ 2.78		$ 1.34

The following is a summary of stock options outstanding at December 31, 2004:

	Options Outstanding		
Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life (years)	Number of Options Exercisable
$0.32 $1.20	1,254,504	5.739	1,150,837
$1.93 $2.28	594,411	7.410	551,200
$3.15 $4.98	875,000	9.310	39,583
	2,723,915		1,741,620

At December 31, 2004, we recognized $15,000 in expense related to stock options granted to non-employee directors who elected to receive the value of their quarterly retainer fee for services.

At December 31, 2003, we 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, we recognized $896,955 of compensation expense according to APB Opinion 25 for the year ending December 31, 2003.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

Note P Warrants

We have the following warrants outstanding to purchase common stock at December 31, 2004:

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	462,943
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
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 $4.75, expiring February 2009	245,137
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 $4.75, expiring February 2009	724,713
	2,655,872

Note Q Major Customers and Concentration of Credit Risk

In 2004, we received royalty income for sales of product related to the CDT technology from two customers, which accounted for 84% and 16% of net revenues. Accounts receivable balances at December 31, 2004 consisted of $84,286 and $8,095 and are payable within 45 days of the year-end. In addition, we received significant royalty payments from Nutraceutix, Inc. that were applied against the note receivable due. Had this amount been recognized as revenue for the 2004 sales, these three customers would account for 53%, 36% and 11% of net revenues.

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

We maintain our cash balances in two financial institutions, which at times, may exceed federally insured limits. We have not experienced any losses in such accounts and believe it is not exposed to any significant credit risk on cash.

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2004 and 2003

Note R Financing Events

On February 24, 2004, we entered into definitive agreements relating to the private placement of 3,206,538 shares of our common stock for $3.25 per share and gross proceeds of approximately $10.4 million. The purchasers received five year warrants to purchase 801,636 shares of common stock at an exercise price of $4.75 per share.

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, Inc. received $174,965 and warrants to purchase 53,846 shares. Michael N. Taglich and Robert Schroeder, directors of SCOLR Pharma, are affiliates of Taglich Brothers, Inc. In addition, Mr. Taglich purchased 49,631 shares of common stock and warrants to purchase 12,408 shares as part of the private placement. We also issued (i) 32,000 shares of our 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 its common stock and warrants to purchase 5,679 shares to Rostrevor Partners in partial payment of an advisory fee in connection with the sale of the our probiotics division.

Note S Subsequent Event

On February 8, 2005, we entered into a Common Stock Purchase Agreement and a Registration Rights Agreement for the private placement of 3,750,000 shares of our common stock for $4.00 per share to accredited investors. The sale of shares was for an aggregate purchase price of $15 million and resulted in net proceeds to us of approximately $14,100,000. Pursuant to the terms of the Registration Rights Agreement, we filed a registration statement with the Securities and Exchange Commission registering the resale of the shares issued in the private placement (including shares of common stock issuable upon exercise of warrants issued to the placement agent) and agreed to use our reasonable best efforts to have the registration statement declared effective as soon as practicable after the filing date, but in no event later than 120 days after the closing.

Taglich Brothers, Inc. acted as the placement agent for the transaction pursuant to a letter agreement dated as of February 8, 2005. In accordance with the letter agreement, the placement agent received a cash fee of $750,000 and warrants to purchase up to 75,000 shares of our common stock at an exercise price of $5.00 per share exercisable for five years. In addition, we agreed to reimburse the placement agent for its reasonable out-of-pocket expenses up to $30,000 incurred in connection with the private placement. Michael N. Taglich and Robert Schroeder are members of our board of directors and are also affiliates of Taglich Brothers, Inc.

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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

Under the supervision and with the participation of our management, including our chief executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our chief executive officer and the principal financial officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

Changes in Internal Control Over Financial Reporting

In connection with the sale of our probiotics division effective as of December 31, 2003, our chief financial officer resigned and his duties were assumed by our controller who now serves as our principal financial officer and director of finance. This resulted in limited segregation of duties regarding our accounting and financial reporting function. During the fourth quarter of 2004, we implemented a compliance program under which transactions are reviewed and tested to assure compliance with corporate policies. Such testing is performed by an individual independent of SCOLR Pharma who reports to our chief executive officer. Other than this change, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 8B. Other Information

None.

Item 9. Directors and Executive Officers of the Registrant

The information required by this item is incorporated by reference to the definitive proxy statement for our 2005 annual meeting of stockholders.

Item 10. Executive Compensation

The information required by this item is incorporated by reference to the definitive proxy statement for our 2005 annual meeting of stockholders.

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 definitive proxy statement for our 2005 annual meeting of stockholders.

Item 12. Certain Relationships and Related Transactions

The information required by this item is incorporated by reference to the definitive proxy statement for our 2005 annual meeting of stockholders.

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Item 13. Exhibits

The following exhibits are filed herewith:

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
2.1	Asset Purchase Agreement by and between SCOLR, Inc. and Nutraceutix, Inc. dated December 31, 2003		8-K	2.1	000-24693	1/23/2003
4.1	Certificate of Incorporation of SCOLR Pharma, Inc. as amended on July 31, 2004		10-QSB	3	001-31982	8/13/2004
4.2	Certificate of designation of Series A Junior Participating Preferred Stock		8-K	1.2	000-24693	11/6/2002
4.3	Bylaws of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	5/17/2004
4.4	Rights Agreement, dated as of November 1, 2002, by and between SCOLR, Inc. and OTR, Inc.		8-K	3	000-24693	11/6/2002
4.5	Form of Common Stock Purchase Warrant dated as of February 8, 2005		8-K	4.1	001-31982	2/11/2005
10.1	Form of Note Purchase Agreement, Subordinated Note and Warrant dated as of April 30, 2003		8-K	10	000-24693	5/5/2003
10.2	Form of Common Stock Purchase Warrant dated June 25, 2003		S-2	10.3	333-107906	8/13/2003
10.3	Registration Rights Agreement dated February 24, 2004		8-K	10.2	001-31982	2/26/2004
10.4	Form of Common Stock Purchase Warrant dated February 24, 2004		8-K	10.3	001-31982	2/26/2004
10.5	Promissory Note to Clyde Berg together with related Security Agreement and Warrant Agreement dated September 30, 2002		10-QSB	10.1	000-24693	11/14/2002
10.6	1995 Stock Option Plan, together with amendment No. 1 thereto*		10-SB	10.8	000-24693	7/27/1998
10.7	Amendment No. 2 to Company 1995 Stock Option Plan*		S-8	4.2	333-40290	6/28/2000
10.8	Form of Incentive Stock Agreement*		S-2	10.8	333-107906	8/13/2003
10.9	Form of Nonqualified Stock Option Agreement*		S-2	10.9	333-107906	8/13/2003
10.10	Exclusive Patent License Agreement dated March 8, 2002, between Archer-Daniels-Midland Company and the Company		10-KSB	10.15	001-31982	3/31/2003

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Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
10.11	Research and Transfer Agreement dated September 11, 1998, among Temple University, Dr. Reza Fassihi, and the Company		S-2	10.11	333-107906	8/13/2003
10.12	License agreement dated December 22, 1998, as amended, between Temple University and the Company		S-2	10.12	333-107906	8/13/2003
10.13	License Agreement dated September 6, 2000 between Temple University and the Company		S-2	10.13	333-107906	8/13/2003
10.14	Master Research and Development Agreement dated May 1, 2001, between Temple University and the Company		S-2	10.14	333-107906	8/13/2003
10.15	Consulting Agreement dated December 22, 2000, between Dr. Reza Fassihi and the Company*		S-2	10.15	333-107906	8/13/2003
10.16	Intellectual Property Assignment and Assumption Agreement dated May 24, 2001, between Dr. Reza Fassihi and the Company.		S-2	10.16	333-107906	8/13/2003
10.17	License Agreement dated September 1, 2001, between Temple University and the Company		S-2	10.17	333-107906	8/13/2003
10.18	Intellectual Property Assignment and Assumption Agreement dated August 1, 2002, between Dr. Reza Fassihi and the Company.		S-2	10.18	333-107906	8/13/2003
10.19	Additional Services Agreement dated August 7, 2002, between Dr. Reza Fassihi and the Company*		S-2	10.19	333-107906	8/13/2003
10.20	License, Manufacture, and Distribution Agreement between the Company and Nutraceutix, Inc., dated December 31, 2003		8-K	2.2	000-24693	1/23/2003
10.21	Building Lease 3625 132nd Avenue SE, Bellevue, WA, dated April 15, 2003		S-2	10.25	333-107906	8/13/2003
10.22	Employment Agreement dated July 2, 2003, between Stephen Turner and the Company*		S-2	10.27	333-107906	8/13/2003
10.23	Advisory Agreement dated August 7, 2003, between David T. Howard and the Company*		S-2	10.29	333-107906	8/13/2003

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Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
10.24	Amendment to Advisory Agreement dated December 30, 2003, between David T. Howard and the Company*		S-3	10.27	333-107906	1/29/2004
10.25	Letter Agreement between the Company, Michael N. Taglich and Tag/Kent Partners		10-QSB	10.33	001-31982	3/24/2004
10.26	2004 Equity Incentive Plan*		10-QSB	10	001-31982	8/12/2004
10.27	Form of Option Agreement under the 2004 Equity Incentive Plan*		10-QSB	10.2	001-31982	11/12/2004
10.28	Form of Outside Director Option Agreement for Annual grants to directors under the 2004 Equity Incentive Plan*		10-QSB	10.3	001-31982	11/12/2004
10.29	Form of Non Employee Director Option Agreement for stock based fee awards under the 2004 Equity Incentive Plan*		10-QSB	10.4	001-31982	11/12/2004
10.30	Amendment No. 1 to Intellectual Property Assignment and Assumption Agreement dated July 16, 2004 between Dr. Reza Fassihi and SCOLR Pharma, Inc.		10-QSB	10.1	001-31982	11/12/2004
10.31	Employment Agreement dated November 12, 2004 between SCOLR Pharma, Inc. and Daniel O. Wilds*		8-K	10.1	001-31982	11/17/2004
10.32	Employment Agreement dated January 10, 2005 between SCOLR Pharma, Inc. and Alan M. Mitchel*		8-K	10.1	001-31982	1/11/2005
10.33	Common Stock Purchase Agreement, dated as of February 8, 2005, between SCOLR Pharma, Inc. and the Purchasers listed in Exhibit A		8-K	10.1	001-31982	2/11/2005
10.34	Registration Rights Agreement, dated as of February 8, 2005, between SCOLR Pharma, Inc. and the Purchasers listed in Exhibit A		8-K	10.2	001-31982	2/11/2005
10.35	Letter Agreement, dated February 8, 2005 between SCOLR Pharma, Inc. and Taglich Brothers		8-K	10.3	001-31982	2/11/2005
23.1	Consent of Grant Thornton LLP	X				
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				

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Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				

Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the SEC. Portions of such exhibit have been omitted pursuant to a request for confidential treatment filed with the SEC.

* Management contract or compensatory plan or arrangement

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Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to the definitive proxy statement for our 2005 annual meeting of stockholders.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SCOLR, INC.

By: /s/ DANIEL O. WILDS
Daniel O. Wilds

Chief Executive Officer, President,

(Principal Executive Officer)

Date: March 29, 2005

Signature	Title	Date
/s/ RANDALL L-W. CAUDILL	Director	March 29, 2005
Randall L-W. Caudill		
/s/ REZA FASSIHI	Director	March 29, 2005
Reza Fassihi		
/s/ DAVID T. HOWARD	Chairman of the Board	March 29, 2005
David T. Howard		
/s/ HERBERT L. LUCAS	Director	March 29, 2005
Herbert L. Lucas		
	Director	March 29, 2005
Robert C. Schroeder		
/s/ MICHAEL N. TAGLICH	Director	March 29, 2005
Michael N. Taglich		
/s/ GAIL T. VITULLI	Director of Finance, Principal Financial Officer	March 29, 2005
Gail T. Vitulli		
/s/ DANIEL O. WILDS		March 29, 2005

Daniel O. Wilds	President, Chief Executive Officer (Principal Executive Officer) and Director	
/s/ Dr. Michael Sorell	Director	March 29, 2005
Dr. Michael Sorell		
/s/ Wayne L. Pines	Director	March 29, 2005
Wayne L. Pines		

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EXHIBIT INDEX

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
2.1	Asset Purchase Agreement by and between SCOLR, Inc. and Nutraceutix, Inc. dated December 31, 2003		8-K	2.1	000-24693	1/23/2003
4.1	Certificate of Incorporation of SCOLR Pharma, Inc. as amended on July 31, 2004		10-QSB	3	001-31982	8/13/2004
4.2	Certificate of designation of Series A Junior Participating Preferred Stock		8-K	1.2	000-24693	11/6/2002
4.3	Bylaws of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	5/17/2004
4.4	Rights Agreement, dated as of November 1, 2002, by and between SCOLR, Inc. and OTR, Inc.		8-K	3	000-24693	11/6/2002
4.5	Form of Common Stock Purchase Warrant dated as of February 8, 2005		8-K	4.1	001-31982	2/11/2005
10.1	Form of Note Purchase Agreement, Subordinated Note and Warrant dated as of April 30, 2003		8-K	10	000-24693	5/5/2003
10.2	Form of Common Stock Purchase Warrant dated June 25, 2003		S-2	10.3	333-107906	8/13/2003
10.3	Registration Rights Agreement dated February 24, 2004		8-K	10.2	001-31982	2/26/2004
10.4	Form of Common Stock Purchase Warrant dated February 24, 2004		8-K	10.3	001-31982	2/26/2004
10.5	Promissory Note to Clyde Berg together with related Security Agreement and Warrant Agreement dated September 30, 2002		10-QSB	10.1	000-24693	11/14/2002
10.6	1995 Stock Option Plan, together with amendment No. 1 thereto*		10-SB	10.8	000-24693	7/27/1998
10.7	Amendment No. 2 to Company 1995 Stock Option Plan*		S-8	4.2	333-40290	6/28/2000
10.8	Form of Incentive Stock Agreement*		S-2	10.8	333-107906	8/13/2003
10.9	Form of Nonqualified Stock Option Agreement*		S-2	10.9	333-107906	8/13/2003
10.10	Exclusive Patent License Agreement dated March 8, 2002, between Archer-Daniels-Midland Company and the Company		10-KSB	10.15	333-107906	3/31/03
10.11	Research and Transfer Agreement dated September 11, 1998, among Temple University, Dr. Reza Fassihi, and the Company		S-2	10.11	333-107906	8/13/2003

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Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
10.12	License agreement dated December 22, 1998, as amended, between Temple University and the Company		S-2	10.12	333-107906	8/13/2003
10.13	License Agreement dated September 6, 2000 between Temple University and the Company		S-2	10.13	333-107906	8/13/2003
10.14	Master Research and Development Agreement dated May 1, 2001, between Temple University and the Company		S-2	10.14	333-107906	8/13/2003
10.15	Consulting Agreement dated December 22, 2000, between Dr. Reza Fassihi and the Company*		S-2	10.15	333-107906	8/13/2003
10.16	Intellectual Property Assignment and Assumption Agreement dated May 24, 2001, between Dr. Reza Fassihi and the Company.		S-2	10.16	333-107906	8/13/2003
10.17	License Agreement dated September 1, 2001, between Temple University and the Company		S-2	10.17	333-107906	8/13/2003
10.18	Intellectual Property Assignment and Assumption Agreement dated August 1, 2002, between Dr. Reza Fassihi and the Company		S-2	10.18	333-107906	8/13/2003
10.19	Additional Services Agreement dated August 7, 2002, between Dr. Reza Fassihi and the Company*		S-2	10.19	333-107906	8/13/2003
10.20	License, Manufacture, and Distribution Agreement by and between the Company and Nutraceutix, Inc., dated December 31, 2003		8-K	2.2	000-24693	1/23/2003
10.21	Building Lease 3625 132nd Avenue SE, Bellevue, WA, dated April 15, 2003		S-2	10.25	333-107906	8/13/2003
10.22	Employment Agreement dated July 2, 2003, between Stephen Turner and the Company*		S-2	10.27	333-107906	8/13/2003
10.23	Advisory Agreement dated August 7, 2003, between David T. Howard and the Company		S-2	10.29	333-107906	8/13/2003
10.24	Amendment to Advisory Agreement dated December 30, 2003, between David T. Howard and the Company		S-3	10.27	333-107906	1/29/2004
10.25	Letter Agreement between the Company, Michael N. Taglich and Tag/Kent Partners		10-QSB	10.33	333-107906	3/24/2004
10.26	2004 Equity Incentive Plan*		10-QSB	10	001-31982	8/12/2004

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Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
10.27	Form of Option Agreement under the 2004 Equity Incentive Plan*		10-QSB	10.2	001-31982	11/12/2004
10.28	Form of Outside Director Option Agreement for Annual grants to directors under the 2004 Equity Incentive Plan*		10-QSB	10.3	001-31982	11/12/2004
10.29	Form of Non Employee Director Option Agreement for stock based fee awards under the 2004 Equity Incentive Plan*		10-QSB	10.4	001-31982	11/12/2004
10.30	Amendment No. 1 to Intellectual Property Assignment and Assumption Agreement dated July 16, 2004 between Dr. Reza Fassihi and SCOLR Pharma, Inc.		10-QSB	10.1	001-31982	11/12/2004
10.31	Employment Agreement dated November 12, 2004 between SCOLR Pharma, Inc. and Daniel O. Wilds*		8-K	10.1	001-31982	11/17/2004
10.32	Employment Agreement dated January 10, 2005 between SCOLR Pharma, Inc. and Alan M. Mitchel*		8-K	10.1	001-31982	1/11/2005
10.33	Common Stock Purchase Agreement, dated as of February 8, 2005, by and between SCOLR Pharma, Inc. and the Purchasers listed in Exhibit A		8-K	10.1	001-31982	2/11/2005
10.34	Registration Rights Agreement, dated as of February 8, 2005, by and between SCOLR Pharma, Inc. and the Purchasers listed in Exhibit A		8-K	10.2	001-31982	2/11/2005
10.35	Letter Agreement, dated February 8, 2005 between SCOLR Pharma, Inc. and Taglich Brothers		8-K	10.3	001-31982	2/11/2005
23.1	Consent of Grant Thornton LLP	X				
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				

Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the SEC. Portions of such exhibit have been omitted pursuant to a request for confidential treatment filed with the SEC.

* Management contract or compensatory plan or arrangement