

SCOLR Pharma, Inc.
Form S-3
October 27, 2005
Table of Contents

As filed with the Securities and Exchange Commission on October 27, 2005

Registration No. []

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

SCOLR Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

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

3625 132nd Avenue SE

Bellevue, Washington 98006

(425) 373-0171

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

Daniel O. Wilds

President and Chief Executive Officer

SCOLR Pharma, Inc.

3625 132nd Avenue SE, Suite 300

Bellevue, Washington 98006

(425) 373-0171

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

including area code, of agent for service)

Copies to:

W. Michael Hutchings

DLA Piper Rudnick Gray Cary US LLP

701 Fifth Avenue, Suite 7000

Seattle, WA 98104-7044

(206) 839-4800

Approximate date of commencement of proposed sale to the public:

From time to time as described in the prospectus.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. "

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of earlier effective registration statement for the same offering. "

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registrations statement number of the earlier effective registration statement for the same offering. "

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. "

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered(1)	Proposed Maximum Aggregate Offering Price (2)(3)	Amount of Registration Fee(3)
Common Stock, \$0.01 par value per share		
Warrants to Purchase Common Stock		
Total	\$ 40,000,000.00	\$ 4,708.00

- (1) Calculated pursuant to Rule 457(o) under the Securities Act. There is being registered hereunder an indeterminate number of shares of common stock and such indeterminate number of warrants to purchase shares of common stock of the registrant as may be sold from time to time by the registrant. Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock and such indeterminate number of warrants to purchase shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions. The aggregate offering price for all shares of common stock and/or warrants that the registrant may sell from time to time pursuant to this registration statement will not exceed \$40,000,000. The aggregate amount of the registrant's common stock and/or warrants registered hereunder that may be sold in at the market offerings for the account of the registrant is limited to that which is permissible under Rule 415(a)(4) under the Securities Act of 1933, as amended.
- (2) Estimated solely for the purposes of determining the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
- (3) Pursuant to General Instruction II(D) of Form S-3, the table does not specify by each class information as to the proposed maximum aggregate offering price. Any securities registered hereunder may be sold separately or with other securities registered hereunder.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. The registrant may not sell these securities until the registration statement filed with the Securities and Exchange Commission becomes effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 27, 2005

PROSPECTUS

SCOLR Pharma, Inc.

\$40,000,000

**COMMON STOCK
AND**

COMMON STOCK WARRANTS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using a shelf registration process. Under this process, we may offer from time to time in one or more offerings common stock and/or warrants to purchase common stock at an aggregate public offering price of up to \$40 million.

This prospectus provides you with a general description of the securities we may offer. Each time we offer securities, we will provide you with a prospectus supplement that describes the amount, price and terms of the securities we offer. The prospectus supplement also may add, update or change information contained in this prospectus. You should read carefully both this prospectus and any prospectus supplement, together with additional information described below under Information Incorporated by Reference.

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

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

We may sell the securities to or through underwriters, dealers or agents or directly to purchasers. We and our agents reserve the sole right to accept or reject in whole or in part any proposed purchase of securities. The prospectus supplement, which we will provide to you each time we offer securities, will set forth the names of any underwriters, dealers or agents involved in the sale of the securities, and any applicable fee, commission or discount arrangements with them. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution" in this prospectus. This prospectus may not be used to sell any of the common stock or warrants unless accompanied by a prospectus supplement.

Our common stock is traded on the American Stock Exchange under the symbol "DDD". On October 25, 2005, the last reported sale price of our common stock on the American Stock Exchange was \$4.55 per share.

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

Investing in our securities is highly speculative and involves a high degree of risk. You should consider carefully the risks and uncertainties in the section entitled "Risk Factors" beginning on page 2 of this prospectus and in the documents we file with the Securities and Exchange Commission that are incorporated by reference in this prospectus before making a decision to purchase our securities.

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

The date of this prospectus is _____, 2005.

Table of Contents

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

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

	Page
<u>The Company</u>	1
<u>Risk Factors</u>	2
<u>Plan of Distribution</u>	11
<u>Use of Proceeds</u>	12
<u>Where You can Find More Information</u>	13
<u>Incorporation of Documents by Reference</u>	13
<u>Legal Matters</u>	13
<u>Experts</u>	13

Table of Contents

THE COMPANY

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 four patented drug delivery technologies and includes intellectual property from two U.S. patents licensed exclusively to us by Temple University and two U.S. patents 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, and Trader Joes.

We are engaged in the development of CDT-based extended release formulations of ibuprofen, pseudoephedrine, a combination ibuprofen/pseudoephedrine and ondansetron, as well as an immediate release CDT formulation of raloxifene. Ibuprofen is an analgesic approved for treatment of pain and fever with no extended release formulation currently approved for use in North America. Pseudoephedrine is a decongestant that is widely used to relieve sinus pressure related to allergies and the common cold. Ondansetron HCl is the active ingredient in Zofran[®], GlaxoSmithKline's product for anti-nausea and vomiting associated with chemotherapy and radiation treatments for cancer. Raloxifene HCl is the active ingredient in Evista[®], Eli Lilly's product for osteoporosis which uses a different solubilization technology.

We expect to file an Abbreviated New Drug Application for CDT-based 12 hour extended release formulation of pseudoephedrine by December 2005. In addition, we are conducting human clinical testing of an extended release ibuprofen (OTC) and intend to submit a New Drug Application to the FDA in mid-2006. We also have achieved encouraging results from the first pilot bioavailability testing of our amino acid CDT-based raloxifene HCl tablets. CDT raloxifene uses technology from two of our issued patents which address insoluble and sparingly soluble active ingredients in oral drugs. We believe the trial data demonstrates that our patented amino acid CDT-based platform can be a viable alternative to currently utilized solubility and permeability-enhancing practices. We are continually 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 reproducible, cost effective, and optimized *in-vivo* delivery of drugs for up to 24 hours. In addition, our proprietary amino-acid technology can be incorporated in immediate and sustained release solid oral formulations to increase the solubility characteristics of previously non-soluble and sparingly soluble drugs without employing costly micro-milling, nano-particulate, liposomes, or coated particle technologies.

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

Table of Contents

RISK FACTORS

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

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

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 continued to incur losses after December 31, 2004, and for the three months and six months ended June 30, 2005, we had net losses of \$1.9 million and \$3.6 million, respectively. We have accumulated net losses of approximately \$30 million from our inception through June 30, 2005, 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, 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. We expect that we will need to seek additional funds through the issuance of equity securities or other sources of financing before the third quarter of 2006. 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 research and business activity or 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 private placement of common stock completed in February 2005, we believe that our cash on hand, including our cash equivalents, will be sufficient to fund our drug delivery business at planned levels through the third quarter of 2006. We will need to raise additional capital to fund operations, conduct clinical trials, continue research and development projects, and commercialize our

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

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;

Table of Contents

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 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.

Table of Contents

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 do not have experience in obtaining regulatory approvals. As a result, we believe we will rely primarily on third party contractors to obtain regulatory approval, which means we will 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.

If we fail to comply with all of the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 in a timely manner, our independent accounting firm could disclaim its opinion, or issue a qualified opinion, as it relates to the effectiveness of our internal controls which could cause an adverse reaction in the financial market and could make it difficult for us to raise capital.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission adopted rules requiring public companies to include a report of management on the company's internal control over financial reporting in their annual reports on Form 10-K. We were not subject to these requirements for the fiscal year ended December 31, 2004. We are currently performing a readiness assessment in preparation for our first Section 404 reporting requirement, which will be effective for fiscal year 2005. This report is required to contain an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent auditors must also attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting as well as the operating effectiveness of our internal controls. While we are expending significant resources in developing the necessary documentation and testing procedures required by Section 404, we may not be able to comply with all of the requirements imposed by Section 404 by the deadlines imposed under Section 404. If we fail to have an effectively designed and operating system of internal control, we will be unable to comply with the requirements of Section 404 in a timely manner. If we do not effectively complete our assessment or if our internal controls are not designed or operating effectively, our independent auditors may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal control or may issue a qualified opinion on the effectiveness of our internal controls. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements and could make it difficult for us to raise capital.

Table of Contents

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.

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.

Table of Contents

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;

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

Table of Contents

may not be broad enough to protect our technology. In addition, our patents or trademarks may be challenged, invalidated or circumvented, or the patents of others may impede our collaborators' ability to commercialize the technology covered by our owned or licensed patents. Moreover, any current or future issued or licensed patents, or trademarks, or existing or future trade secrets or know-how, may not afford sufficient protection against competitors with similar technologies or processes, and the possibility exists that certain of our already issued patents or trademarks may infringe upon third party patents or trademarks or be designed around by others. In addition, there is a risk that others may independently develop proprietary technologies and processes that are the same as, or substantially equivalent or superior to ours, or become available in the market at a lower price. There is a risk that we have infringed or in the future will infringe patents or trademarks owned by others, that we will need to acquire licenses under patents or trademarks belonging to others for technology potentially useful or necessary to us, and that licenses will not be available to us on acceptable terms, if at all. We cannot assure you that:

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

any of our future processes or products will be patentable;

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

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

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

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-

Table of Contents

days notice. If our relationship with Dr. Fassihi is terminated, we could experience a negative impact on our ability to develop and commercialize our CDT technology.

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

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

We may be subject to additional laws or regulations in the future, such as those administered by the FDA or other federal, state or foreign regulatory authorities. Laws or regulations that we consider favorable, such as the 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 October 26, 2005, 34,974,802 shares of our common stock were outstanding, and there were 5,507,531 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 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. We will need to seek additional funds through the issuance of equity securities or other sources of financing. The issuance of a large number of additional shares of our common stock upon the exercise of conversion

Table of Contents

of outstanding options or warrants or in an equity financing transaction could cause a decline in the market price of our common stock due to the sale of a large number of shares of our common stock in the market, of the perception that these sales could occur.

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

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

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we so indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below.

General

We may issue warrants for the purchase of our common stock in one or more series. We may issue warrants independently or together with common stock, and the warrants may be attached to or separate from such shares of common stock. We will evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We will describe in the applicable prospectus supplement the terms of the series of warrants, including, but not limited to:

the offering price and aggregate number of warrants offered;

the currency for which the warrants may be purchased;

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

the number of shares of common stock purchasable upon the exercise of one warrant and the price at which such shares of common stock may be purchased upon such exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

the terms of any rights to redeem or call the warrants;

Table of Contents

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreement and warrants may be modified;

federal income tax consequences of holding or exercising the warrants; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase shares of our common stock on the terms and conditions and at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. Seattle, Washington time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will terminate.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver upon exercise of the warrants.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at our corporate offices, we will issue and deliver the shares of common stock issuable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender shares of common stock as all or part of the exercise price for warrants.

Enforceability of Rights By Holders of Warrants

In the event we engage the services of a warrant agent, any such warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

Table of Contents

PLAN OF DISTRIBUTION

We may sell the securities being offered hereby at prices and under terms then prevailing, at prices related to the then current market price or in negotiated transactions from time to time in one or more of the following ways:

directly to one or more purchasers;

through one or more underwriters on a firm commitment or best-efforts basis;

through broker-dealers, who may act as agents or principals, including a block trade in which a broker or dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

through agents;

in privately negotiated transactions; or

in any combination of these methods of sale.

We will set forth in a prospectus supplement the terms of the offering of securities, including:

the name or names of any agents or underwriters, dealers or agents;

the number of shares and purchase price of the common stock being offered and the proceeds we will receive from the sale;

any underwriting discounts and commissions or agency fees and other items constituting underwriters' or agents' compensation;

any over-allotment options under which underwriters may purchase additional securities from us;

any discounts or concessions allowed or re-allowed or paid to dealers; and

any securities exchange on which the common stock or the warrants may be listed.

The distribution of securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices.

Agents

We may designate agents who agree to use their reasonable efforts to solicit purchases for the period of their appointment or to sell securities on a continuing basis. Agents may receive compensation in the form of commissions, discounts or concessions from us. Agents may also receive compensation from the purchasers of the securities for whom they sell as principals. Each particular agent will receive compensation in amounts negotiated in connection with the sale, which might be in excess of customary commissions. Agents and any other participating broker-dealers may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act in connection with sales of the shares. Accordingly, any commission, discount or concession received by them and any profit on the resale of the securities purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act. We have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. As of the date of this prospectus, there are no special selling arrangements between any broker-dealer or other person and us. No period of time has been fixed within which the securities will be offered or sold.

If required under applicable state securities laws, we will sell the securities only through registered or licensed brokers or dealers. In addition, in some states, we may not sell securities unless they have been registered or

Table of Contents

qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

Underwriters

If we use underwriters for a sale of securities, the underwriters will acquire the securities for their own account. The underwriters may resell the securities in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may change from time to time any initial public offering price and any discounts or concessions the underwriters allow or re-allow or pay to dealers. We may use underwriters with whom we have a material relationship. We will describe any such underwriter in the prospectus supplement naming the underwriter the nature of any such relationship.

Direct Sales

We may also sell the securities directly to one or more purchasers without using underwriters or agents. Underwriters, dealers and agents that participate in the distribution of the securities may be underwriters as defined in the Securities Act and any discounts or commissions they receive from us and any profit on their resale of the securities may be treated as underwriting discounts and commissions under the Securities Act. We will identify in the applicable prospectus supplement any underwriters, dealers or agents and will describe their compensation. We may have agreements with the underwriters, dealers and agents to indemnify them against specified civil liabilities, including liabilities under the Securities Act. Underwriters, dealers and agents may engage in transactions with or perform services for us in the ordinary course of their businesses.

Stabilization Activities

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of our securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the common stock originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of our common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. These transactions may be effected on the American Stock Exchange or otherwise.

Costs

We will bear all costs, expenses and fees in connection with the registration of the securities (including the shares of our common stock issuable upon exercise of the warrants), as well as the expense of all commissions and discounts, if any, attributable to sales of the securities by us.

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

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

USE OF PROCEEDS

Except as otherwise described in the applicable prospectus or post-effective amendment, the net proceeds from the sale of securities offered hereunder will be added to our general funds and used for research and development in our drug delivery business, working capital and general corporate purposes.

Table of Contents

WHERE YOU CAN FIND MORE INFORMATION

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

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

INCORPORATION OF DOCUMENTS BY REFERENCE

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

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

our quarterly reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005;

our current reports on Form 8-K filed with or furnished to the SEC on January 11, 2005, January 25, 2005, February 11, 2005, March 22, 2005, May 12, 2005, June 16, 2005, July 13, 2005, August 5, 2005, August 15, 2005, October 13, 2005, October 21, 2005; and

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

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

SCOLR Pharma, Inc.

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

3625 132nd Avenue SE, Suite 300

Bellevue, Washington 98006

Attention: Director of Finance

Telephone: (425) 373-0171

LEGAL MATTERS

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

EXPERTS

The financial statements incorporated by reference to our annual report on Form 10-KSB for the year ended December 31, 2004 in this prospectus and elsewhere in the registration statement have been audited by Grant Thornton LLP, independent registered public accountants, as indicated in their report with respect thereto, and are included herein in reliance upon the authority of said firm as experts in auditing and accounting.

Table of Contents

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

SCOLR Pharma, Inc.

\$40,000,000

**COMMON STOCK
AND**

COMMON STOCK WARRANTS

—————
Prospectus
—————

October , 2005

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

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

	To be Paid by the Registrant
SEC registration fee	\$ 4,708
AMEX registration fee	\$ 45,000
Legal fees and expenses	\$ 75,000
Accounting fees and expenses	\$ 50,000
Transfer agent's fees	\$ 5,000
Miscellaneous fees and expenses	\$ 15,000
Total	\$ 194,708

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

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

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

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

Section 145 of the General Corporation Law generally permits a company to indemnify an officer or director who was or is a party or is threatened to be made a party to any proceeding because of his or her position with the company. However, such indemnification is permitted only if the officer or director acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

such company and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

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

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

II-1

Table of Contents**ITEM 16. EXHIBITS**

The following exhibits are filed with this registration statement.

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
4.1	Certificate of Incorporation of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	8/13/2004
4.2	Certificate of designation of Series A Junior Participating Preferred Stock		8-K	1.1	000-24693	11/6/2002
4.3	Rights Agreement, dated as of November 1, 2002, by and between SCOLR, Inc. and OTR, Inc.		8-K	1.1	000-24693	11/6/2002
4.4	Bylaws of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	5/17/2004
4.5	Form of Common Stock Purchase Warrant		8-K	4.1	001-31982	2/11/2005
4.6	Common Stock Purchase Agreement, dated as of February 8, 2005, by and between SCOLR Pharma, Inc. and the Purchasers listed therein		8-K	10.1	001-31982	2/11/2005
4.7	Registration Rights Agreement, dated as of February 8, 2005, by and among SCOLR Pharma, Inc. and the Purchasers listed therein		8-K	10.2	001-31982	2/11/2005
4.8	Settlement Agreement and First Amendment to the License, Manufacture and Distribution Agreement, dated as of August 3, 2005, by and between Nutraceutix Inc. and SCOLR Pharma, Inc.		8-K	10.3	001-31982	8/05/2005
5.1	Opinion of DLA Piper Rudnick Gray Cary US LLP	X				
23.1	Consent of Grant Thornton LLP	X				
23.2	Consent of DLA Piper Rudnick Gray Cary US LLP (included in Exhibit 5.1)	X				

ITEM 17. UNDERTAKINGS

The undersigned Registrant hereby undertakes:

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

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

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the Commission) pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

Table of Contents

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

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

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

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

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

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

Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bellevue, State of Washington, on October 27, 2005.

SCOLR PHARMA, INC.

By: /s/ DANIEL O. WILDS
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Form S-3 Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u> /s/ Daniel O. Wilds</u> Daniel O. Wilds	President, Chief Executive Officer (Principal Executive Officer) and Director	October 27, 2005
<u> /s/ Michael N. Taglich</u> Michael N. Taglich	Chairman of the Board of Directors	October 27, 2005
<u> /s/ Randall L-W. Caudill</u> Randall L-W. Caudill	Director	October 27, 2005
<u> /s/ Reza Fassihi</u> Reza Fassihi	Director	October 27, 2005
<u> /s/ Herbert L. Lucas</u> Herbert L. Lucas	Director	October 27, 2005
<u> /s/ Hans Mueller</u> Hans Mueller	Director	October 27, 2005
<u> /s/ Wayne Pines</u> Wayne Pines	Director	October 27, 2005
<u> /s/ Michael Sorell</u> Michael Sorell	Director	October 27, 2005

Edgar Filing: SCOLR Pharma, Inc. - Form S-3

/s/ Gail T. Vitulli

Director of Finance (Principal Financial and
Accounting Officer)

October 27, 2005

Gail T. Vitulli

II-4

Table of Contents**INDEX TO EXHIBITS**

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
4.1	Certificate of Incorporation of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	8/13/2004
4.2	Certificate of designation of Series A Junior Participating Preferred Stock		8-K	1.1	000-24693	11/6/2002
4.3	Rights Agreement, dated as of November 1, 2002, by and between SCOLR, Inc. and OTR, Inc.		8-K	1.1	000-24693	11/6/2002
4.4	Bylaws of SCOLR Pharma, Inc. as amended		10-QSB	3	001-31982	5/17/2004
4.5	Form of Common Stock Purchase Warrant		8-K	4.1	001-31982	2/11/2005
4.6	Common Stock Purchase Agreement, dated as of February 8, 2005, by and between SCOLR Pharma, Inc. and the Purchasers listed therein		8-K	10.1	001-31982	2/11/2005
4.7	Registration Rights Agreement, dated as of February 8, 2005, by and among SCOLR Pharma, Inc. and the Purchasers listed therein		8-K	10.2	001-31982	2/11/2005
4.8	Settlement Agreement and First Amendment to the License, Manufacture and Distribution Agreement, dated as of August 3, 2005, by and between Nutraceutix Inc. and SCOLR Pharma, Inc.		8-K	10.3	001-31982	8/05/2005
5.1	Opinion of DLA Piper Rudnick Gray Cary US LLP	X				
23.1	Consent of Grant Thornton LLP	X				
23.2	Consent of DLA Piper Rudnick Gray Cary US LLP (included in Exhibit 5.1)	X				