SCOLR Pharma, Inc.
Form 10-Q
May 13, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended March 31, 2005

OR

¨ TRANSITION REPORT PURSUANT TO 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.

(Exact name of registrant as specified in its charter)

Delaware	**91-1689591**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3625 132nd Avenue S.E., Bellevue, Washington 98006

(Address of principal executive offices)

425-373-0171

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 ¨

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act):

Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Title	Shares outstanding as of May 12, 2005
Common Stock, par value $0.001	34,513,386

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

SCOLR Pharma, Inc.

BALANCE SHEETS

	March 31, 2005	December 31, 2004
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 18,898,832	$ 6,758,860
Accounts receivable, less allowance for doubtful accounts of $0 and $42,644 respectively	91,762	92,772
Current portion of note receivable	512,003	430,951
Prepaid expenses	203,239	159,565
Total current assets	19,705,836	7,442,148
PROPERTY AND EQUIPMENT net	744,092	752,693
OTHER ASSETS		
Intangible assets net	471,540	487,938
Noncurrent portion of note receivable	1,148,230	1,277,699
	$ 22,069,698	$ 9,960,478
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Current maturities of capital lease obligations	$ 36,387	$ 47,841
Accounts payable trade	397,079	731,839
Accrued liabilities	317,166	344,349
Total current liabilities	750,632	1,124,029
CAPITAL LEASE OBLIGATIONS, less current maturities		3,137
	750,632	1,127,166
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	34,513	30,691
Additional contributed capital	49,641,922	35,392,140
Accumulated deficit	(28,357,369)	(26,589,519)
Total stockholders equity	21,319,066	8,833,312
	$ 22,069,698	$ 9,960,478

The accompanying notes are an integral part of these financial statements

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SCOLR Pharma, Inc.

STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31,	
	2005	**2004**
Revenues	$ 87,458	$ 133,294
Operating expenses		
Marketing and selling	47,527	41,431
Research and development	1,215,480	369,997
General and administrative	688,940	632,067
	1,951,947	1,043,495
Operating loss	(1,864,489)	(910,201)
Other income (expense)		
Interest expense	(1,883)	(25,137)
Interest income	96,859	7,151
Other	1,663	13,584
	96,639	(4,402)
Net loss	$ (1,767,850)	$ (914,603)
Net loss per share, basic and diluted	$ (0.05)	$ (0.03)

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

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SCOLR Pharma, Inc.

STATEMENTS OF CASH FLOWS

Three Months ended March 31,

(Unaudited)

	2005	2004
Cash flows from operating activities:		
Net loss	$ (1,767,850)	$ (914,603)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	82,000	44,135
Loss on the sale of equipment		444
Stock options issued for services	15,000	21,071
Changes in assets and liabilities		
Accounts receivable	1,010	509,331
Note receivable		27,693
Prepaid expenses	(43,674)	56,144
Accounts payable	(334,760)	(211,927)
Accrued liabilities and deferred revenue	(12,183)	(307,952)
Net cash used in operating activities	(2,060,457)	(775,664)
Cash flows from investing activities:		
Payments on note receivable	48,417	722,756
Purchase of equipment and furniture	(51,650)	(178,766)
Patent and technology rights expenditures	(5,351)	(61,184)
Net cash provided by (used in) investing activities	(8,584)	482,806
Cash flows from financing activities:		
Payments on long-term obligations and capital lease obligations	(14,591)	(12,411)
Payments on shareholder loan		(989,323)
Net payments on line of credit		(155,488)
Proceeds from issuance of common stock, net of issuance costs	14,223,604	9,977,472
Net cash provided by financing activities	14,209,013	8,820,250
Net increase in cash and cash equivalents	12,139,972	8,527,392
Cash and cash equivalents at beginning of period	6,758,860	1,282,656
Cash and cash equivalents at end of period	$ 18,898,832	$ 9,810,048
Cash paid during the year for:		
Interest	$ 1,883	$ 25,137
Noncash investing and financing activities:		
Issuance of warrants at fair market value for debt issuance costs	$ 194,899	$

Stock options issued for accrued services	$ 15,000	$

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

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SCOLR Pharma, Inc.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 FINANCIAL STATEMENTS

The unaudited financial statements of SCOLR Pharma, Inc. have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial reporting and pursuant to the rules and regulations of the Securities and Exchange Commission. In the opinion of management, the financial information includes all adjustments that we consider necessary for a fair presentation of the financial position at such dates and the operations and cash flows for the periods then ended. The balance sheet at December 31, 2004, has been derived from the audited financials statements at that date. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to SEC rules and regulations on quarterly reporting. The results of operations for interim periods are not necessarily indicative of the results to be expected for the entire fiscal year ending December 31, 2005. The accompanying unaudited financial statements and related notes should be read in conjunction with the audited financial statements and the Form 10-KSB for our fiscal year ended December 31, 2004.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. Estimates are used for, but not limited to: depreciable lives of assets; and deferred tax valuation allowances. Future events and their effects cannot be determined with certainty. Accordingly, the accounting estimates require the exercise of judgment. The accounting estimates used in the preparation of the financial statements may change as new events occur, as more experience is acquired, as additional information is obtained and as our operating environment changes. Actual results could differ from those estimates.

NOTE 2 NEW ACCOUNTING PRONOUNCEMENT

In March 2005, Financial Accounting Standards Board (FASB) amended Statement 123(R) Share-Based Payment (issued 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. The original implementation date was for interim periods beginning after June 15, 2005, the revised date is for annual and interim periods beginning after December 15, 2005 and will become effective for us for the beginning on January 1, 2006. 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. 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 disclosure under SFAS 123 (see Note 5), we expect the adoption to have a material impact on the statements of operations for the three months ended March 31, 2006. The estimate is based on preliminary information and could materially change based on actual facts and circumstances arising during the three months ended March 31, 2006.

NOTE 3 FINANCING EVENTS

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).

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 valued at $194,899 using the Blade-Scholes option-pricing model, 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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NOTE 4 NOTE RECEIVABLE

In 2003, we sold our probiotics development and manufacturing business. We calculated the present value of the $2 million original deferred purchase price note based on estimated projected payments and using a rate equal to the Federal Treasury s five-year treasury bill rate of 3.27% at December 31, 2003. Payments are made quarterly, applied to the principal and interest on the note in the quarter they are received, calculated based on the agreement, and include royalty payments for sales of products using the CDT technology.

NOTE 5 STOCK OPTIONS

We have stock-based employee compensation plans and apply APB Opinion 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for our plans. 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). 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. We recognized $15,000 and $0 expense for the three months ended March 31, 2005 and 2004, respectively, related to these quarterly retainer fees in the form of stock option grants.

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 to its stock-based awards for the periods ended March 31:

	2005	2004
Net loss, as reported	$ (1,767,850)	$ (914,603)
Total stock-based compensation expense determined under fair-value-based method	(586,781)	(83,107)
Stock-based compensation expense included in reported net loss	15,000	
Pro forma net loss	$ (2,339,631)	$ (997,710)
Basic and diluted loss per share:		
As reported	$ (0.05)	$ (0.03)
Pro forma net loss per share	$ (0.07)	$ (0.04)

NOTE 6 EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is based on the weighted average number of shares outstanding during the quarter and income available to common shareholders. Diluted earnings (loss) per share includes the effect of potential common stock, except when their effect is anti-dilutive. The weighted average shares for computing basic earnings (loss) per share were 32,837,443 and 27,643,265 for the three months ended March 31, 2005 and 2004, respectively. At March 31, 2005, there were 5,855,451 shares of potentially issuable common stock.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the financial statements, including the notes thereto, appearing in Item 1 of Part 1 of this quarterly report and in our 2004 Annual Report on Form 10-KSB.

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 report. Important factors that could cause actual results to differ materially from our forward-looking statements are set forth in this report under the heading Risk Factors , and are detailed from time to time in our periodic reports filed with the SEC. We undertake no obligation to update any forward-looking statements, whether as a results of new information, future events or otherwise.

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. In November 2004, we successfully completed preliminary human trial work for an OTC 12 hour extended release formulation of ibuprofen. There are currently no extended release formulations of ibuprofen approved for use in North America. During the first quarter of 2005, we initiated human testing of CDT-based 12 hour extended release formulation of pseudoephedrine for the OTC market. We also expect to commence additional U.S. human clinical work to support future regulatory approval and plan to begin a human clinical evaluation of a CDT-based immediate release raloxifene formulation in the second quarter of 2005. The results from the initial segment of this testing were favorable. We are continually evaluating additional drugs as potential CDT development candidates for expanding our growing portfolio of CDT applications. Recently, we announced that we would be proceeding with the internal development of three additional drug targets. The targets include a 24-hour OTC pseudoephedrine (PSE) decongestant product, a 12-hour OTC combination ibuprofen/PSE cough/cold product, and an extended-release ondansetron anti-nausea product.

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* 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.

Our website is *www.scolr.com*. Information contained on our website is not part of, and is not incorporated into, this quarterly report. Our filings with the SEC are available without charge on our website.

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Critical Accounting Policies and Estimates

Since December 31, 2004, none of the critical accounting policies, or our application thereof, as more fully described in our Annual Report on Form 10-KSB for the year ended December 31, 2004, has significantly changed. However, as the nature and scope of our business operations mature, certain of our accounting policies and estimates may become more critical. You should understand that generally accepted accounting principles require management to make estimates and assumptions that affect the amounts of assets and liabilities of contingent assets and liabilities at the date of our financial statements, as well as the amounts of revenues and expenses during the periods covered by our financial statements. The actual amounts of these items could differ materially from these estimates. For example, we estimate the value of the note receivable from the sale of our probiotics unit based on an estimate of the expected quarterly payments to be received.

Results of Operations

Comparison of the Quarter Ended March 31, 2005 and 2004

Revenues

Revenues for the quarter ended March 31, 2005, and March 31, 2004, consisted of royalty income from sales of products incorporating our CDT technology. Revenues decreased 34% or $45,836, to $87,458 for the quarter ended March 31, 2005, from $133,294 for the quarter ended March 31, 2004. This decrease was primarily due to reduced sales by NUTRA as well as no royalties from Archer-Daniels-Midland during the quarter.

Revenues do not include royalty income from sales reported by the purchaser of our probiotics division. These additional royalties are derived primarily from CDT-based dietary supplement products being sold by the purchaser of this 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.

The following table summarizes our revenues and other royalties which are not included in revenue:

	For the three months ended March 31,	
	2005	**2004**
Royalties Revenues as reported	$ 87,458	$ 133,294
Royalty payments received in subsequent quarter applied to Note Receivable	105,952	66,186
Total Royalties	$ 193,410	$ 199,480

Operating Expenses

Selling and Marketing Expenses

Selling and marketing expenses increased 15% or $6,096, to $47,527 for the quarter ended March 31, 2005, compared to $41,431 for the quarter ended March 31, 2004. This increase is primarily due to increased expense for advertising and promotion and salary related expenses. Additional expenses are planned as we increase our selling and marketing efforts to support commercialization of our drug delivery technology.

Research and Development Expenses

Research and development expenses increased 229% or $845,483, to $1,215,480 for the quarter ended March 31, 2005, compared to $369,997 for the quarter ended March 31, 2004. During the first quarter of 2005, we spent approximately $640,000 for the development, testing, and manufacturing of our products for our current and planned clinical trials. We initiated human testing of a CDT-based 12 hour extended release formulation of pseudoephedrine for the OTC market during the first quarter of 2005 and incurred expenses in connection with other scheduled trials. In addition, we spent approximately $165,000 for supplies, including raw materials for our research and development activities. We also had increases in salaries and related expenses due to additional personnel to support expansion of our operations and to develop systems to support commercialization of our CDT platform. We expect research and development expenses to continue to increase as we initiate additional clinical trials and related development activities.

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General and Administrative Expenses

General and administrative expenses increased 9% or $56,873, to $688,940 for the quarter ended March 31, 2005 compared to $632,067 for the quarter ended March 31, 2004. Substantially all of this increase is attributable to additional personnel to support our financing activities, compliance with new regulatory requirements, and strengthening the infrastructure to support our increased research and development activities.

Operating Profit/Loss

Operating loss for the quarter ended March 31, 2005, was $1,864,489 as compared to an operating loss of $910,201 for the quarter ended March 31, 2004. Most of this increase is due to our increased research and development expenses .

Other Income/Expense

Other income was $96,639 for the quarter ended March 31, 2005, compared with other expense of ($4,402) for the quarter ended March 31, 2004. This increase was primarily due to interest of $68,351 received on our higher cash balances and non-cash interest income recognized from the note receivable from the purchaser of our probiotics division. Interest expense decreased $23,254 to 1,883 for the quarter ended March 31, 2005 from $25,137 for the quarter ending March 31, 2004 due to the payoff of a line of credit and shareholder loan in January 2004.

Net Earnings

The net loss for the quarter ended March 31, 2005, was $1,767,850 compared with a net loss of $914,603 for the quarter ended March 31, 2004. This is due to our increased operating expenses previously discussed.

Liquidity and Capital Resources

As of March 31, 2005, we had working capital of $18,955,204 as compared with working capital of $6,318,119 at December 31, 2004. The change in working capital reflects the sale of 3,750,000 shares of common stock for net proceeds of approximately $14.1 million during 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 early 2006.

Net cash used in operating activities for the first quarter of 2005 was approximately $1.8 million. Expenditures during this period were a result of research and development expenses, clinical trial costs, contract manufacturing costs, and 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.

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As of March 31, 2005, our commitments to make future payments under long term contractual obligations were as follows:

	Payments Due by Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1 to 3 Years**	**4 to 5 Years**
Operating Leases	$ 571,230	$ 169,451	$ 395,209	$ 6,570
Capital Lease	36,387	36,387		
Total	$ 607,617	$ 205,838	$ 395,209	$ 6,570

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.

Risk Factors

This quarterly report on Form 10-Q 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 quarterly report 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 quarterly report.

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 ended March 31, 2005, we had a net loss of $1.8 million. We have accumulated net losses of approximately $28.4 million from our inception through March 31, 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, 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.

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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 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

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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 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;

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.

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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;
- 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.

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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.

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.

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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 31, 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 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.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market rate risk for changes in interest rates relates primarily to money market funds included in our investment portfolio. Investments in fixed rate earning instruments carry a degree of interest rate risk as their fair market value may be adversely impacted due to a rise in interest rates. We do not use any hedging transactions or any financial instruments for trading purpose and we not a party to any leveraged derivatives

Item 4. 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 principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this quarterly report.

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PART II: OTHER INFORMATION

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On February 8, 2005, we issued 3,750,000 shares of our common stock in a private placement to accredited investors. In connection with this financing, we issued warrants to purchase up to 75,000 shares of our common stock to Taglich Brothers, Inc., the placement agent. We relied on Regulation D and Section 4(2) of the Securities Act of 1933 for an exemption from registration for this transaction. In April 2005, we registered on a Form S-3 registration statement the resale of the shares of common stock issued in the private placement and the shares of common stock issuable upon exercise of the warrants.

Item 6. Exhibits

The following exhibits are filed herewith:

			Incorporated by Reference			
Exhibit No.	**Description**	**Filed Herewith**	**Form**	**Exhibit No.**	**File No.**	**Filing Date**
10.1	Employment Agreement, dated January 10, 2005, between SCOLR Pharma, Inc. and Alan M. Mitchel*		8-K	10.1	001-31982	1/11/2005
10.2	Summary of SCOLR Pharma Non-employee Director Compensation*	X				
10.3	Common Stock Purchase Agreement, dated as of February 8, 2005, between SCOLR Pharma, Inc. and the Purchasers listed on Exhibit A		8-K	10.1	001-31982	2/11/2005
10.4	Registration Rights Agreement, dated as of February 8, 2005, between SCOLR Pharma, Inc. and the Purchasers listed on Exhibit A		8-K	10.2	001-31982	2/11/2005
10.5	Letter Agreement, dated February 8, 2005 between SCOLR Pharma, Inc. and Taglich Brothers		8-K	10.3	001-31982	2/11/2005
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 Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				

* Indicates management contract or compensatory plan or arrangement.

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SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SCOLR, INC.

Date: May 13, 2005

By: */s/ Daniel O. Wilds*
Daniel O. Wilds
Chief Executive Officer and President,
(Principal Executive Officer)

Date: May 13, 2005

By: */s/ Gail T. Vitulli*
Gail T. Vitulli
Director of Finance and Principal Financial Officer
(Principal Financial Officer)

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