SCOLR Pharma, Inc.
Form 10-Q
May 08, 2007
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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, 2007

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., Suite 400, 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 a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (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 1, 2007**
Common Stock, par value $0.001	38,125,146

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SCOLR Pharma, Inc.

FORM 10-Q

For the Three Months Ended March 31, 2007

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

SCOLR Pharma, Inc.

CONDENSED BALANCE SHEETS

	March 31,2007 (Unaudited)	December 31,2006
ASSETS		
Current Assets		
Cash and cash equivalents	$ 14,959,269	$ 15,217,946
Short-term investments	445,658	993,542
Accounts receivable, less allowance for doubtful accounts of $0 and $0	459,145	864,620
Interest and other receivables	7,017	15,576
Prepaid expenses	363,681	347,136
Total current assets	16,234,770	17,438,820
Property and Equipment net of accumulated depreciation of $928,822 and $854,420, respectively	931,193	730,512
Intangible assets net of accumulated amortization of $334,956 and $319,903, respectively	413,213	325,148
	$ 17,579,176	$ 18,494,480
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 202,622	$ 189,065
Accrued expenses	1,237,643	825,158
Deferred revenue		185,577
Current portion of term loan	74,653	
Total current liabilities	1,514,918	1,199,800
Long-term portion of term loan	171,847	
Fair value of warrants to purchase common stock		1,171,045
Total liabilities	1,686,765	2,370,845
Commitments and Contingencies (Note 10)		
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 38,125,146 and 38,048,146 issued and outstanding as of March 31, 2007 and December 31, 2006, respectively	38,125	38,048
Additional paid-in capital	64,964,566	63,139,210
Accumulated other comprehensive gain (loss)	(1)	55
Accumulated deficit (Note 12)	(49,110,279)	(47,053,678)
Total stockholders equity	15,892,411	16,123,635
	$ 17,579,176	$ 18,494,480

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

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SCOLR Pharma, Inc.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Revenues		
Licensing fees	$ 173,077	$ 19,231
Royalty income	325,620	73,615
Research and development income	621,222	
Total revenues	1,119,919	92,846
Operating expenses		
Marketing and selling	249,882	186,866
Research and development	1,795,874	1,333,293
General and administrative	1,176,498	1,787,309
Total operating expenses	3,222,254	3,307,468
Loss from operations	(2,102,335)	(3,214,622)
Other income (expense)		
Unrealized loss on fair value of warrants		(4,166)
Interest income	204,976	131,245
Interest expense	(161)	(159)
Other	2,941	
	207,756	126,920
NET LOSS	$ (1,894,579)	$ (3,087,702)
Net loss per share, basic and diluted	$ (0.05)	$ (0.09)
Shares used in computing basic and diluted net loss per share	38,084,501	35,187,799

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

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SCOLR Pharma, Inc.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Cash flows from operating activities:		
Net loss	$ (1,894,579)	$ (3,087,702)
Reconciliation of net loss to net cash used in operating activities		
Depreciation and amortization	92,262	87,055
Write-off of long term assets	6,571	
Loss on the disposal of equipment	5,700	
Unrealized loss on fair value of warrants		4,166
Share-based compensation for non-employee services	25,742	151,560
Share-based compensation for employee services	404,655	549,051
Increase (decrease) in cash resulting from changes in assets and liabilities		
Accounts receivable	414,034	91,666
Prepaid expenses and other current assets	(16,545)	(60,865)
Accounts payable and accrued expenses	426,042	179,259
Deferred revenue	(185,577)	(54,069)
Net cash used in operating activities	(721,695)	(2,139,879)
Cash flows from investing activities:		
Payments received on note receivable		505,927
Purchase of property and equipment	(282,496)	(34,558)
Patent and technology rights expenditures	(110,783)	(30,207)
Purchase of short-term investments	(438,111)	(395,110)
Maturities of short-term investments	985,939	1,491,584
Net cash provided by investing activities	154,549	1,537,636
Cash flows from financing activities:		
Net proceeds from term loan	246,500	
Payments on long-term obligations and capital lease obligations		(3,137)
Proceeds from exercise of options and warrants	61,969	413,634
Net cash provided by financing activities	308,469	410,497
Net decrease in cash	(258,677)	(191,746)
Cash at beginning of period	15,217,946	10,928,442
Cash at end of period	$ 14,959,269	$ 10,736,696
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$	$ 159
Supplemental schedule of non-cash financing information		
Unrealized loss on short-term investments	$ (56)	$ (183)
Reclassification of fair value of warrant liability to equity	$ 1,171,045	$ 85,200

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 normal and recurring adjustments that the Company considers necessary for a fair presentation of the financial position at such dates and the results of operations and cash flows for the periods then ended. In addition, with the adoption of a change in accounting, a $162,022 non-recurring adjustment to the beginning balance of accumulated deficit is included in the March 31, 2007, balance sheet. (See Note 12) The balance sheet at December 31, 2006, 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, 2007. The accompanying unaudited financial statements and related notes should be read in conjunction with the audited financial statements and the Form 10-K for the Company s fiscal year ended December 31, 2006.

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 those used in revenue recognition, the determination of the allowance for doubtful accounts, depreciable lives of assets, estimates and assumptions used in the determination of fair value of stock options and warrants, including share-based compensation expense, 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 the Company s operating environment changes. Actual results could differ from those estimates.

Note 2 New Accounting Pronouncement

In February 2007, the Financial Accounting Standards Board issued Statement 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). This Statement permits entities to elect to measure certain financial instruments and other items at fair value and report the change in fair value through earnings. The fair value option may be applied on an instrument by instrument basis, is irrevocable and is applied only to entire instruments. SFAS 159 contains additional financial statement presentation and disclosure requirements for those entities that elect to adopt the standard and is effective for fiscal years beginning after November 15, 2007. The Company does not anticipate any material impact on its financial condition or results of operations as a result of the adoption of SFAS 159.

Note 3 Technical Rights, Patent License and Royalty Agreements

On March 14, 2007, the Company received a notice of termination from Wyeth Consumer Healthcare with respect to the Company s development and license agreement with Wyeth. The Development and License Agreement, which was signed December 21, 2005, provided Wyeth with global rights to use the Company s technology for all products containing ibuprofen. The termination of the agreement was effective April 16, 2007.

During the three months ended March 31, 2007, the Company recognized research and development income of $500,000 related to a milestone payment from Wyeth and approximately $109,000 for reimbursement of research and development costs related to the agreement. The agreement with Wyeth provided for an upfront fee of $250,000 which was previously recorded as deferred revenue and was being amortized as licensing fee income over the development period. As a result of the termination of the agreement, during the three months ended March 31, 2007, the Company recognized the approximately $173,000 remaining balance of previously deferred licensing fee income.

As a result of the termination, the Company reacquired all rights to use its technology for products containing ibuprofen.

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Note 4 Accounts Receivable

At March 31, 2007, accounts receivable consisted of royalty receivables from CDT-based product sales. During the three months ended March 31, 2007, the Company received payment of approximately $454,000 from Wyeth Consumer Healthcare in settlement of the accounts receivable for reimbursement of research and development costs.

Note 5 Liquidity

The Company incurred a net loss of approximately $1.9 million for the three months ended March 31, 2007, and used cash from operations of approximately $721,695. Cash flows of $154,549 provided by investing activities during the three months ended March 31, 2007, primarily represent maturing short-term investments of approximately $986,000. This amount is offset by the use of investing cash flows for the purchase of research and development equipment and short-term investments. Cash flow from financing activities of $308,469 for the three months ended March 31, 2007, primarily reflects net proceeds from a $250,000 bank term loan agreement for the purchase of equipment to be used in the Company s research and development activities.

The Company had approximately $15.4 million in cash, cash equivalents and short-term investments at March 31, 2007. The Company has a history of recurring losses and plans to continue the process of simultaneously conducting clinical trials and preclinical development for multiple product candidates. The Company s net losses are likely to increase as it continues preclinical research, applies for regulatory approvals, develops its product candidates, expands its operations, and develops the infrastructure to support commercialization of its potential products. The Company believes that its cash, cash equivalents and short-term investments will be sufficient to fund its drug delivery business at planned levels through early 2008. Accordingly, the financial statements have been prepared on the basis of a going concern which contemplates realization of assets and satisfaction of liabilities in the normal course of business.

The Company plans to raise additional capital to fund operations, conduct clinical trials, and continue research and development projects and commercialization of its product candidates. The Company may raise additional capital through public or private equity financing, partnerships, debt financing, or other sources. In November 2005, the Securities and Exchange Commission declared effective the Company s registration statement that it filed using a shelf registration process. In addition to the registered direct offering completed on April 21, 2006, for approximately $11.9 million, the Company may offer from time-to-time, one or more additional offerings of common stock and/or warrants to purchase common stock under this shelf registration up to an aggregate public offering price of $40 million. As of March 31, 2007, approximately $28 million remains available for issuance under this shelf registration statement. Additional funds may not be available on favorable terms or at all. If adequate funds are not available, the Company may curtail operations significantly including the delay, modification or cancellation of research and development projects.

Note 6 Comprehensive Loss

The components of comprehensive loss for the three months ended March 31, 2007 and 2006, are as follows:

	Three months ended March 31,	
	2007	2006
Net loss	$ (1,894,579)	$ (3,087,702)
Other comprehensive loss for the period:		
Change in unrealized net loss on short-term investments	(56)	(183)
Comprehensive loss for the period	$ (1,894,635)	$ (3,087,885)

Accumulated other comprehensive loss of $(1) at March 31, 2007, equals the cumulative unrealized net gains and (losses) on short-term investments.

Note 7 Bank Term Loan

On March 26, 2007, the Company executed a $250,000 bank term loan agreement for the purchase of equipment to be used in its research and development activities. The stated interest rate and effective interest rate of the loan are 8.25% and 9.34%, respectively. The loan matures in February 2010. Principal and interest payments are to be made in 36 equal monthly payments of $7,877 each, with a final payment due on the date of maturity. The obligations under the loan are secured by the acquired equipment.

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Note 8 Income Taxes

In June 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies the accounting and disclosure for uncertainty in income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, measurement, classification, interest and penalties, accounting for interim periods, disclosure and transition, and clearly scopes income taxes out of Financial Accounting Standards Board Statement No. 5, *Accounting for Contingencies*. The Company adopted FIN 48 on January 1, 2007. The adoption of FIN 48 had no impact on the Company s financial statements.

Historically, the Company has not incurred any interest or penalties associated with tax matters and no interest or penalties were recognized during the three months ended March 31, 2007. However, the Company has adopted a policy whereby amounts related to interest and penalties associated with tax matters are classified as general and administrative expense when incurred.

The Company has incurred net operating losses. The Company continues to maintain a valuation allowance for the full amount of the net deferred tax asset balance associated with its net operating losses as sufficient uncertainty exists regarding its ability to realize such tax assets in the future. There were no unrecognized tax benefits as of January 1, or March 31, 2007. The Company expects the amount of the net deferred tax asset balance and full valuation allowance to increase in future periods as it incurs future net operating losses.

Tax years that remain open for examination include 2003, 2004, 2005, and 2006. In addition, tax years from 1992 to 2002 may be subject to examination in the event that the Company utilizes the NOL s from those years in its current or future year tax returns.

Note 9 Net Loss Per Share Applicable to Common Stockholders

Basic net loss per share represents loss available to common stockholders divided by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share include the effect of potential common stock, except when the effect is anti-dilutive. The weighted average shares for computing basic earnings (loss) per share, including those common shares subject to registration rights and potential liquidated damages classified on the balance sheet as temporary equity at March 31, 2006, were 38,084,501 for the three months ended March 31, 2007, and 35,187,799 for the three months ended March 31, 2006.

At March 31, 2007 and 2006, options and warrants to acquire 5,557,457 and 5,573,625 shares, respectively, of common stock, prior to the application of the treasury stock method, were not included in the computation of diluted net loss per share as the effect would have been anti-dilutive.

Note 10 Future Commitments

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

Note 11 Warrants

During the three months ended March 31, 2007, no warrants were issued or exercised. The Company had the following warrants to purchase common stock outstanding at March 31, 2007:

Issue Date	Issued Warrants	Exercise Price	Term	Outstanding Warrants	Expiration Date
September 30, 2002	750,000	$ 0.50	10 years	750,000	September 30, 2012
December 16, 2002	85,000	0.50	5 years	85,000	December 16, 2007
March 18, 2003	50,000	1.00	5 years	50,000	March 18, 2008
June 25, 2003	476,191	1.16	5 years	452,943	June 25, 2008
February 24, 2004	245,137	4.75	5 years	245,137	February 23, 2009
February 24, 2004	801,636	4.75	5 years	699,712	February 23, 2009
February 8, 2005	75,000	5.00	5 years	75,000	February 7, 2010

April 21, 2006	11,000	7.50	5 years	11,000	April 20, 2011
Total	2,493,964			2,368,792	

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Each warrant entitles the holder to purchase one share of common stock at the exercise price.

Note 12 Change in Accounting for Fair Value of Warrants to Purchase Common Stock

In December 2006, the Financial Accounting Standards Board, (FASB) issued FASB Staff Position EITF 00-19-2, *Accounting for Registration Payment Arrangements* (FSP EITF 00-19-2). FSP EITF 00-19-2 requires an issuer of financial instruments, such as debt, convertible debt, equity shares or warrants, to account for a contingent obligation to transfer consideration under a registration payment arrangement in accordance with FASB Statement 5, *Accounting for Contingencies*, and FASB Interpretation 14, *Reasonable Estimation of the Amount of a Loss*. FSP EITF 00-19-12 applies to registration payment arrangements regardless of whether they are issued as a separate agreement (such as a registration rights agreement or shareholders rights agreement) or are included as a provision of either the financial instruments or some other agreement. FSP EITF 00-19-12 also applies to an arrangement in which the issuer endeavors to obtain or maintain listing on a stock exchange. We adopted FSP EITF 00-19-2 effective January 1, 2007.

The Company has previously classified warrants issued as a part of its February 24, 2004, private placement as a liability because the Company granted registration rights which included the payment of liquidated damages under certain circumstances including in the event that the effective SEC registration statement registering the resale of shares of common stock issuable upon exercise of the warrants does not remain effective. The Company generally uses its best efforts and all commercially reasonable efforts to maintain effective registration statements. Accordingly, Company management believes that as of both the date of inception and the date of adopting this FSP, its obligation to transfer consideration under its registration payments arrangements is not probable. Further, the Company had determined that without regard to the registration payment arrangement, all warrants issued would have been classified as equity instruments in accordance with other applicable generally accepted accounting principles for all periods.

Prior to the adoption of this FSP, the Company accounted for the warrants and the registration payment arrangement as one instrument and classified the entire arrangement as a liability. Based on the guidance of the FSP, the Company reclassified the fair value of the warrant liability to stockholders equity on January 1, 2007. The amount reclassified of $1,171,045 was based on the fair value of the warrant liability at December 31, 2006. The fair value of the entire arrangement at inception was $1,527,245. The difference between the December 31, 2006, fair value of warrant liability and the fair value of the warrant liability at its inception was $356,202, however, $194,180 was previously reclassified to accumulated deficit when the warrants were exercised. The remaining $162,022 was presented as a cumulative effect adjustment to the opening balance of accumulated deficit.

The adoption of FSP EITF 00-19-02 had no effect on the Company s net loss. The following table presents the effect of the adoption of FSP EITF 00-19-02 on accumulated deficit:

Accumulated deficit at December 31, 2006 as previously reported	$ (47,053,678)
Change in accounting principle	(162,022)
Beginning accumulated deficit adjusted January 1, 2007	(47,215,700)
Add: Net loss for the three months ended March 31, 2007	(1,894,579)
Ending accumulated deficit at March 31, 2007	$ (49,110,279)

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 I of this quarterly report and in our 2006 annual report on Form 10-K.

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 stater 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 result, 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 in Item 1A of Part II, 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.

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Overview

We are a specialty pharmaceutical company that develops and formulates over-the-counter products, prescription drugs, and dietary supplement products that use our patented CDT technology. Our drug delivery business generates royalty revenue from CDT-based sales in the dietary supplement markets as well as licensing fees. Our net losses are likely to increase significantly as we continue preclinical research and clinical trials, apply for regulatory approvals, develop our product candidates, expand our operations and develop the infrastructure to support commercialization of our potential products. Our strategy includes a significant commitment to research and development activities in connection with the growth of our drug delivery platform. Our results of operations going forward will be dependent on our ability to commercialize our products and technology and generate royalties, licensing fees, development fees, milestone and similar payments.

Critical Accounting Policies and Estimates

Since December 31, 2006, none of our critical accounting policies, or our application thereof, as more fully described in our annual report on Form 10-K for the year ended December 31, 2006, 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 or 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.

New Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies the accounting and disclosure for uncertainty in income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, measurement, classification, interest and penalties, accounting for interim periods, disclosure and transition, and clearly scopes income taxes out of Financial Accounting Standards Board Statement No. 5, *Accounting for Contingencies.* FIN 48 is effective January 1, 2007, for calendar year-end companies. The adoption of FIN 48 did not have a material impact on our statement of operations or balance sheet

In February 2007, the Financial Accounting Standards Board issued Statement 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). This Statement permits entities to elect to measure certain financial instruments and other items at fair value and report the change in fair value through earnings. The fair value option may be applied on an instrument by instrument basis, is irrevocable and is applied only to entire instruments. SFAS 159 contains additional financial statement presentation and disclosure requirements for those entities that elect to adopt the standard and is effective for fiscal years beginning after November 15, 2007. The Company does not anticipate any material impact on its financial condition or results of operations as a result of the adoption of SFAS 159.

Change in Accounting for Fair Value of Warrants to Purchase Common Stock

We have previously classified warrants we issued as a part of our February 24, 2004, private placement as a liability because we agreed to pay liquidated damages to warrant holders in the event that the effective SEC registration statement registering the resale of shares of common stock issuable upon exercise of warrants does not remain effective. In December 2006, the FASB issued FASB Staff Position EITF 00-19-2, Accounting for Registration Payment Arrangements (FSP EITF 00-19-2), which provides guidance on the impact the registration rights have on the classification of the warrants. Based on the guidance of the FSP, we now evaluate separately the warrants and the registration rights obligations and we reclassified the fair value of the warrant liability to stockholders equity on January 1, 2007. The amount we reclassified was $1,171,045, which was based on the fair value of the warrant liability at December 31, 2006. The fair value of the entire arrangement at inception was $1,527,245. The difference between the fair value of warrant liability at inception and December 31, 2006, was $356,202, however, we previously reclassified $194,180 as a cumulative effect adjustment to the opening balance of accumulated deficit. The adoption of FSP EITF 00-19-02 had no effect on our net loss.

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Results of Operations

Comparison of the Three Months Ended March 31, 2007 and 2006

Revenues

Revenues consist of research and development income and licensing revenue related to our agreement with Wyeth Consumer Healthcare, which was terminated effective April 16, 2007. Revenues also consist of royalty income from sales of products incorporating our CDT technology.

Total revenues increased significantly to $1.1 million for the three months ended March 31, 2007, compared to $92,846 for the same period in 2006, primarily as a result of the recognition of approximately $609,000 of research and development income and approximately $173,000 of licensing fee income attributable to the terminated agreement with Wyeth. On March 14, 2007, we received a notice of termination from Wyeth Consumer Healthcare that the Development and Licensing Agreement to use our technology in products containing ibuprofen would be terminated (without cause) effective April 16, 2007. The research and development income recognized during the three months ended March 31, 2007, included a $500,000 milestone payment from Wyeth and a $109,000 reimbursement of research and development costs. The agreement with Wyeth, dated December 21, 2005, provided for an upfront fee of $250,000 which was recorded as deferred revenue and was being amortized as licensing fee income over the development period. As a result of the termination of the agreement, during the three months ended March 31, 2007, we recognized the remaining balance of previously deferred licensing fee income. We reacquired all rights to use our technology in products containing ibuprofen as a result of the termination of the agreement.

Our drug delivery technology generates royalty revenue from CDT-based product sales to the dietary supplement markets, including sales through retailers such as Wal-Mart, Kroger, CVS and Meijer. During the three months ended March 31, 2007, royalty income increased approximately $252,000 to $325,620 compared to $73,615 for the same period in 2006, primarily as a result of royalties generated through our alliance with Perrigo, under which we began receiving royalty payments in the second quarter of 2006. We receive payments based on a percentage of Perrigo s net profits derived from the sales of products under the agreement.

Operating Expenses

Marketing and Selling Expenses

Marketing and selling expenses increased 34%, or $63,016, to $249,882 for the three months ended March 31, 2007, compared to $186,866 for the same period in 2006, primarily due to increases of $18,940 in higher commission expense related to higher royalty income, $12,615 in salaries and related expenses, and $12,313 attributable to non-cash, share-based compensation.

Research and Development Expenses

Research and development expenses increased 35%, or $462,581, to approximately $1.8 million for the three months ended March 31, 2007, compared to approximately $1.3 million for the same period in 2006. This increase was primarily due to an increase of $252,063 for supplies and clinical trial expenses related to our development projects and an increase of $140,352 in salaries and related expenses. We expect research and development costs to increase during 2007 as we continue to advance our development efforts.

General and Administrative Expenses

General and administrative expenses decreased 34%, or $610,811, to $1.2 million for the three months ended March 31, 2007, compared to $1.8 million for the same period in 2006, primarily due to reduced expenses of $131,743 associated with initial compliance costs with Sarbanes-Oxley Act of 2002, and Financial Accounting Standard 123R implementation costs in 2006. Employee and director non-cash, share-based compensation costs decreased $347,440 because director stock options issued during the first quarter 2006 were fully-vested in 2006 and no stock option awards were granted during the first quarter of 2007 to employees or directors. In addition, salaries and related expenses decreased $9,736 due to an $80,000 severance payment in 2006, off-set by a $70,264 increase attributable to higher salaries and benefits in 2007.

Other Income (Expense), Net

Other income increased 64%, or $80,836, to $207,756 income for the three months ended March 31, 2007, compared to $126,920 income for the comparable period in 2006, primarily due to a $73,731 increase in interest income as a result of higher interest rates and cash balances. In

addition, unrealized loss on fair value of warrants decreased $4,166 because, effective January 1, 2007, we reclassified the fair value of warrants to purchase common stock to Stockholders Equity, due to the adoption of Financial Accounting Standards Board Staff Position 00-19-2, *Accounting for Registration Payment Arrangements* .

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Net Loss

Net loss decreased 39%, or $1.2 million, to $1.9 million for the three months ended March 31, 2007, compared to $3.1 million for the same period in 2006, primarily due to increased revenues from Wyeth.

Liquidity and Capital Resources

As of March 31, 2007, we had $14.7 million of working capital compared to $11.4 million as of March 31, 2006. We have accumulated net losses of approximately $49.1 million from our inception through March 31, 2007. We believe that our cash, cash equivalents and short-term investments, will be sufficient to fund our operations at planned levels through early 2008.

Cash flows from operating activities Net cash used in operating activities for the three months ended March 31, 2007, was approximately $721,695 compared to $2.1 million for the three months ended March 31, 2006. Expenditures remained substantially unchanged during this period because increased research and development expenses, clinical trial costs, contract manufacturing costs, general and administrative expenses in support of our operations and marketing expenses were offset by increases in accounts payable and collections of accounts receivable.

Cash flows from investing activities Cash flows provided by investing activities of $154,549 primarily represent the application of maturing short-term investments during the three months ended March 31, 2007, to fund operating activities. Cash flows from investing activities for the three months ended March 31, 2006, included the receipt of $505,927 as payment in full of the note receivable from the buyer of our probiotics division.

Cash flows from financing activities Cash flows from financing activities of $308,469 for the three months ended March 31, 2007, primarily reflects net proceeds from a $250,00 bank term loan for the purchase of equipment to be used in our research and development activities. We received cash of $61,969 and $413,634 in the first quarters of 2007 and 2006, respectively, from the exercise of outstanding stock options and warrants.

We had approximately $15.4 million in cash, cash equivalents and short-term investments at March 31, 2007. On March 26, 2007, we executed a $250,000 bank term loan agreement for the purchase of equipment to be used in our research and development activities. The stated interest rate and effective interest rate of the loan are 8.25% and 9.34%, respectively, and the loan matures February 2010. Principal and interest payments are to be made in 36 equal monthly payments of $7,877 each. The obligations under the loan are secured by the acquired equipment.

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 continue to develop the infrastructure to support commercialization of our products. We will need to raise additional capital to fund operations, continue research and development projects, and commercialize our products. We may not be able to secure additional financing on favorable terms, or at all. In November 2005, the Securities and Exchange Commission declared effective our registration statement that we filed using a shelf registration process. In addition to the registered direct offering completed on April 21, 2006, for approximately $11.9 million, we may offer from time-to-time, one or more additional offerings of common stock and/or warrants to purchase common stock under this shelf registration up to an aggregate public offering price of $40 million. As of March 31, 2007, approximately $28 million remains available for issuance under this shelf registration statement. The issuance of a large number of additional equity securities could cause substantial dilution to existing stockholders and could cause a decrease in the market price for shares of our common stock, which could impair our ability to raise capital in the future through the issuance of equity securities. 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 development activities or discontinue operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing our risk. We invest excess cash principally in U.S. marketable securities from a diversified portfolio of institutions with strong credit ratings and in U.S. government and agency bills and notes, and by policy, limit the amount of credit exposure at any one institution. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we believe we have no material exposure to interest rate risk arising from our investments.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the first quarter of fiscal 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material litigation.

Item 1A. 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 on Form 10-Q 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 on Form 10-Q.

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 $1.9 million in 2007, $10.7 million in 2006, $8.9 million in 2005, and $5.7 million in 2004. We have accumulated net losses of approximately $49.3 million from our inception through March 31, 2007, 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 during 2007. 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 delay, reduce or eliminate the pursuit of licensing, strategic alliances and development of drug delivery programs.

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 2008. 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 or 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.

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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, including delays of clinical supplies; 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, efficacious, or bioequivalent, 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 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

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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 Corporation, Biovail, Inc., Penwest, Skyepharma PLC, Elan, Flamel, Impax Laboratories, Inc., Labopharm, and KV Pharmaceuticals, Inc.

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 (FTC), and Environmental Protection Agency) and in other countries. For example, our activities, including preclinical studies, clinical trials, 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.

Our ability to commercialize products containing pseudoephedrine may be adversely impacted by retail sales controls, legislation, and other measures designed to counter diversion and misuse of pseudoephedrine in the production of methamphetamine, an illegal drug.

We are engaged in the development of an extended release formulation of pseudoephedrine. On March 10, 2006, Congress enacted the Patriot Act, which included the Combat Methamphetamine Epidemic Act of 2005. Among its various

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provisions, this national legislation placed restrictions on the purchase and sale of all products containing pseudoephedrine and imposed quotas on manufacturers relating to the sale of products containing pseudoephedrine. Many states have also imposed statutory and regulatory restrictions on the manufacture, distribution and sale of pseudoephedrine products. We believe that such quotas and restrictions resulted in delays in obtaining materials necessary for the development of our pseudoephedrine product. While we have obtained sufficient supplies to support the planned submission of our ANDA with the FDA in 2007, our ability to commercialize products containing pseudoephedrine and the market for such products may be adversely impacted by existing or new retail sales controls, legislation and market changes relating to diversion and misuse of pseudoephedrine in the production of methamphetamine.

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.

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.

If our existing or new collaborations are not successful, we will have to establish our own capabilities or discontinue commercialization of the affected product. Developing our own capabilities would be expensive and time consuming and could delay the commercialization of the affected product.

Some of our products are being developed and commercialized in collaboration with corporate partners. Under these collaborations, we may be dependent on our collaborators to fund some portion of development, to conduct clinical trials, to obtain regulatory approvals for, and manufacture, market and sell products using our CDT platform.

We have very limited experience in manufacturing, marketing and selling pharmaceutical products. There can be no assurance that we will be successful in developing these capabilities.

Our existing collaborations may be subject to termination on short notice. If any of our collaborations are terminated, we may be required to devote additional resources to the product covered by the collaboration, seek a new collaborator on short notice or abandon the product. The terms of any additional collaborations or other arrangements that we establish may not be favorable to us.

Our collaborations or other arrangements may not be successful because of factors such as:

- 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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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. Consequently, 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. We currently rely on Cardinal Health PTS, LLC for the production of a number of our product candidates. Cardinal Health PTS, LLC is involved with an ownership transition that could impact its ability to provide services for us. 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.

The manufacture of any of our products is subject to regulation by the FDA and comparable agencies in foreign countries. Any delay in complying or failure to comply with such manufacturing requirements could materially adversely affect the communication of our products and 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 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.

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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. We do not carry key main life insurance on any of our personnel.

In addition, we are dependent upon the continued availability of Dr. Reza Fassihi, a member of our board of directors with whom we have a consulting agreement. The agreement may be terminated by either 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.

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.

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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 May 1, 2007, 38,125,146 shares of our common stock were outstanding, and there were 5,557,457 shares of our common stock issuable upon exercise or conversion of outstanding options and warrants. Sales of a large number of shares 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 during 2007. The issuance of a large number of additional shares of our common stock upon the exercise or 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, or 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.

Item 6. Exhibits

The following exhibits are filed herewith:

		Filed	Incorporated by Reference			
Exhibit No.	**Description**	**Herewith**	**Form**	**Exhibit No.**	**File No.**	**Filing Date**
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of. 2002	X				
31.2	Certification of Chief 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 Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				

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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 Pharma, INC.

Date: May 8, 2007

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

Date: May 8, 2007

By: */s/ Richard M. Levy*
Richard M. Levy
Chief Financial Officer and Vice President - Finance
(Principal Financial Officer)

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EXHIBIT INDEX

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